THE HIGH COURT

[2015 No. 7340 P.]

BETWEEN

JOAN DINEEN

PLAINTIFF

AND

DEPUY INTERNATIONAL LIMITED

DEFENDANT

JUDGMENT of Mr. Justice Cross delivered on the 1st day of December, 2017

1. Introduction

1.1 The plaintiff is a married lady with five surviving children who was born on 9th January, 1936, and lives at her home near Blarney, Co. Cork, with her husband and one of her daughters

1.2 The plaintiff claims damages for alleged personal injury as a result of the alleged failure of a ASR/XL replacement hip manufactured and supplied by the defendant which was inserted on 6th February, 2009, as a replacement for her right hip.

1.3 It is a matter of fact that there are, in excess, one thousand claims in respect of alleged injury allegedly caused by the defendant's ASR hip.

1.4 In respect of these claims, the court has approved of a Alternative Dispute Resolution Scheme whereby certain of these claims can be assessed by a panel of senior counsel and retired members of the judiciary on a without prejudice basis without admission of liability. The ADR Scheme does not allow for any award of aggravated damages.

1.5 Certain potential claimants do not come within the Alternative Dispute Resolution Scheme and, of course, there is ultimately no obligation on any plaintiff to confine themselves to the scheme and any award made therein can be rejected by either party.

1.6 While a significant number of claims against DePuy have come before the courts for a judicial determination, all of these claims, bar one, have up to the present being compromised prior to any judicial decision.

1.7 In the only case that has so far resulted in a determination, *Gillian O'Sullivan v. DePuy International Limited* (judgment of this Court delivered 29th November, 2016), the issues were limited as the defendant by open letter stated:-

> *"Our client's position is that they have no liability to your client in relation to the claims made by her in these proceedings. Nevertheless, in order to avoid the substantial costs likely to arise during a full trial of the action, our client hereby agrees to the trial proceeding on the basis that your client will not be required to establish that the DePuy product supplied to her were defective, leading to the necessity for early revision, which offer is made without admission of liability. The claims can therefore proceed as an assessment of compensatory damages only without any admission of liability.*
>
> *In these circumstances, the only issue required to be dealt with by the court is the issue of the quantification of damages along with any issues of causation in relation to the quantification of damages..."*

1.8 In the instant case, the defendant issued an open letter offering a similar concession as in the *Gillian O'Sullivan* case (above) subject to the plaintiff waiving any claim for aggravated damages. It should be noted that in the *O'Sullivan* case, the plaintiff did maintain a claim for aggravated damages which was unsuccessful.

1.9 The plaintiff in this case is claiming special damages being the future and past care needs of the plaintiff, general damages for pain and suffering and aggravated damages.

1.10 Notwithstanding the fact as pointed out to the parties by the court that it was open to the defendant to make the same concession as in the *Gillian O'Sullivan* case (above) and at the same time to put in issue the claim for aggravated damages, the defendant declined to make that concession unless the plaintiff waived any right to aggravated damages.

1.11 It is, of course, entirely within the rights of the plaintiff to seek to establish her claim in law and to seek aggravated as well as compensatory damages and it is entirely within the rights of the defendant to test the plaintiff's claim to obtain in the circumstances a determination on liability.

1.12 The case commenced hearing on 30th June, 2017, and proceeded until Tuesday, 7th November, 2017, though due to difficulty in securing the attendance of expert witnesses, there were only 20 hearing days in that period.

2 The Pleadings

2.1 By personal injury summons, the plaintiff claimed that the defendants were producers, manufacturers or suppliers of a defective product within the meaning of the Liability for Defective Products Act 1991 which were implanted in the plaintiff causing her personal injury loss and damage.

2.2 The plaintiff underwent a right hip replacement surgery on 6th February, 2009, due to the plaintiff's pain and disability. This procedure was carried out by the well known orthopaedic surgeon Mr. KML at the Bon Secours Hospital, Tralee, Co. Kerry. The implant was the product known as the ASR/XL involving total acetabular implant, a femoral implant and a taper sleeve adaptor. It is agreed that the ASR/XL was inserted by Mr. KML at the ideal angle as recommended by the defendants.

2.3 Section 2(1) of the liability for defective products Act 1991 provides:

> *"The producer should be liable in damages in tort for damage caused wholly or partly by a defect in his product"*

2.4 Section 4 of the 1991 Act provides that the onus is on the injured person, in this case the plaintiff, to prove the damage the defect and the causal relationship between the defect and the damage.

2.5 Section 5 of the 1991 Act provides:

> *"(i) for the purpose of this Act a product is defective if it fails to 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 reasonable be expected that the product would be put, and*
>
> *(c) the time when the product was put into circulation.*
>
> *(ii) a product shall not be considered defective for the sole reason that a better product is subsequently put into circulation".*

2.6 The plaintiff claims that the defendants supplied a defective product within the meaning of s. 2 of the Liability for Defective Products Act 1991.

2.7 The plaintiff claims that as a result of the personal injuries sustained that she is entitled to damages including aggravated damages. The plaintiff also claims in negligence.

2.8 The defence is, in essence, a full defence of all matters, denial of negligence or statutory duty and in particular, a denial of breach of s. 2 of the Liability for Defective Products Act 1991, and a further plea that if the product was defective within the meaning of the 1991 Act, the defendants will rely upon s. 6(e) of the Liability for Defective Products Act 1991. It is further denied that the plaintiff sustained any injuries as a result of the defendant's products. The claim for aggravated damages is also denied.

2.9 Section 6(e) of the 1991 Act provides:

> *"6. A producer shall not be liable under this Act 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 …".*
>
> It is of course incumbent upon the producer (the defendant in this case to establish a s. 6(e) defence).

3 Mrs. Dineen

3.1 The plaintiff is a most pleasant lady who was present only on the first day of the trial to give evidence and sometimes it appeared that the trial proceeded on issues of principal without taking much account of Mrs. Dineen's individual position.

3.2 The plaintiff who is now 81 does, it is agreed, suffer from a wide range of what are described as "*co-morbidities*". Apart from the hip replacement issues, she had a diastolic heart failure with preserved ejection fraction, pulmonary hypertension, atrial fibrillation, permanent pacemaker insertion, venous insufficiency, hypercholesterolaemia, left hydronephrosis with left pelvic-ureteric junction obstruction, choledocholithiasis, lower limb oedema, cellulitis, hypothyroidism, bilateral knee replacement and pre-history of falls.

3.3 When the plaintiff was provided with her hip replacement in 2009, she received a 54mm cup, a 47mm head and size 11 stem. The ASR/XL is a total hip replacement with a stem going down into the femoral bone. The ASR product is what is known as a "*metal on metal"* hip replacement.

3.4 The ASR metal on metal hips were originally designed with a preference for younger and more active recipients but, in any event, no one has criticised Mr. KML for his decision to utilise the defendant's hip replacement product on the plaintiff.

3.5 As stated above, the plaintiff also had a left total knee replacement in March 2011 and a right total knee replacement in June 2013. Her knees have not given any problems since the operations.

3.6 Due to many complaints and failings around the world, the defendants withdrew the ASR product in August, 2010. The product had been withdrawn from Australia in November, 2009, some nine months after Mrs. Dineen's hip replacement operation, as the complaints of failure seemed to have originated there. The difficulty that had arisen in relation to the DePuy ASR hips was that a number of these hips produced excessive ion wear into a recipient's blood which can result in bone or muscular problems and ultimately cause significant pain to the recipient.

3.7 DePuy established "*recall clinics*" for any patients, including the plaintiff, who had been fitted with their product prior to its recall. The plaintiff's initial blood test in December 2010, at the recall clinic indicated a cobalt reading of 4.6 parts per billions and a chromium reading of 3.2 parts per billion which is approximately double the advisable level.

3.8 Over the next few years, her blood ion readings were checked and in particular her cobalt reading rose to 16 parts per billion in January 2014.

3.9 Whereas the plaintiff's complaints are in relation to pain were intermittent, she was complaining of clicking in her right hip and in January 2015, her cobalt had risen to 20.6 parts per billion and her chromium levels to 4.8 parts per billion.

3.10 The plaintiff's case is that this level of metal in her body can cause osteolysis or decay of the bone structure surrounding the device.

3.11 As a result of these readings and the plaintiff's symptoms, Mr. KML undertook a revision in July 2015 and Mr. KML found at the surgery that there was a large periacetabular fluid filled sac (referred to as a pseudo-tumour by the plaintiff's experts) but (as has been indicated in this case and stated in previous cases) the difference between a "*pseudo-tumour*" and a "*fluid filled sac*" can be regarded as mainly one of language, and that the replacement cup was loose and the bone in the acetabulm was eroded.

3.12 Unfortunately, the plaintiff did not make any significant recovery as a result of the July 2015 revision and her mobility was

reduced, she was fearful of falling over (she had some falls prior to the first hip replacement). She had pain and she walked with the aid of a stick, she slept downstairs, she became far less mobile and was somewhat depressed.

3.13 However after the first revision the plaintiff's blood metal ion levels decreased dramatically but the plaintiff continued to complain of pain and x-rays demonstrated a fracture of the plaintiff's right acetabulum (which probably was caused in the revision operation (without any fault being ascribed to the surgeon)) and radiolucency around the cup in her right hip. Accordingly a further revision of the acetabular component was carried out by Mr. KML in November, 2016. After this third operation the plaintiff suffered a very serious infection which resulted in a large blister at the back of her knee.

3.14 It is the plaintiff's case that the initial defective product caused raised blood ion levels and the pain and clicking which resulted in the revision performed by Mr. KML which dealt with the raised ion level problem however the first revision failed to take and required a second revision. It is the plaintiff's case that she will require a third revision in the future.

3.15 It is the plaintiff's case that the increased blood ion levels were caused in particular by wear of the taper and also some wear of the cup and head in the ASR and that the need for the operation to replace the ASR/XL was proved by the findings of Mr. KML at the revision.

3.16 It was initially anticipated that the plaintiff's hip replacement would last for the rest of her life from when she was 73 but she has now had two revisions and the plaintiff's expert indicated to believes that she will require a third one.

4 The plaintiff's case

4.1 The plaintiff gave evidence of pain in her right hip in 2014 and a sensation of clicking. Whereas the defendant pointed out that her symptoms were somewhat intermittent in relation to the pain it is not contended by the defendants that Mr. KML carried out an unnecessary operation and when he carried out the revision Mr. KML found erosion of the posterior and anterior walls of her right acetabulum. He also found "large peri acetabular fluid filled sac". Accordingly, the plaintiff claims that there is clear evidence that the raised blood ion levels which were in the range which would give a surgeon concerns for a revision even without any other symptoms. This problem of raised ion levels was caused by excessive wear of the ASR/XL product and caused damage to the plaintiff which validated the decision to revise the defendant's hip.

4.2 It is important to state that whereas the initial surgery and the angle of implantation by Mr. KML were praised by all experts, there was some implicit criticism of his decision to revise in July 2015 and also of the manner and type of replacement chosen. Mr. KML is not a party to this case and there is no plea that he was, in any sense, a Tortfeasor or that the plaintiff has any liability under the Civil Liability Act 1961, in respect of his actions. I determine, therefore, that any criticism of the surgeon is not any allegation of legal fault or negligence and that what occurred to Mrs. Dineen must be viewed as one of the consequences of her condition.

4.3 It is clear as the defendant's experts accepted that the raised ion levels must have been caused by *something*. In an initial report it was suggested on behalf of the defendant that the raised ion levels may have been caused by the knee replacement however it was accepted by the defendant's expert that as the ion levels decreased dramatically once the hip had been revised that the raised ion levels were caused by the ASR hip.

4.4 The plaintiff's experts submitted that an examination and testing of the ASR indicated significant wear in the taper joint and also to a lesser extent in the cup.

4.5 The plaintiff's experts claimed that the ASR product as manufactured by the defendant which was a "*Metal on Metal*" type which utilised large heads measuring at least 44 millimetres and placed these large heads on a similar size stems as other standard (smaller) metal on metal hips and they gave evidence that the malfunction which could occur involving excessive metal wear was entirely foreseeable on the basis that if you increased the head size and keep the stem size the same you are at risk of generating excessive metal debris from the taper junction.

4.6 The plaintiff relied upon the evidence of Dr. L, Mr. N, Prof B to the effect that the analysis as carried out on the cup also demonstrated excessive wear at the edge.

4.7 The plaintiff claims that while any replacement hip might fail, that the ASR hips failed at a significantly greater degree. A competitor of the defendant's metal on plastic hip had a failure rate of 1.91% at seven years and the plaintiff's expert referred to defendants figures which indicated a failure of over 40% at six years post replacement. Other studies indicated a failure rate of over 40% after ten years compared to what was stated to be the acceptable failure rate of the bench marker 5% at ten years.

4.8 Mr. N was initially one of the orthopaedic surgeons chosen by DePuy in England to use and advocate their hips which he did extensively and with enthusiasm but he found that the failure rate and increase ion levels was such that when he brought this to the attention of the defendants they indicated that the problem was that of surgeons inserting the ASR at an incorrect angle. This was also the explanation given to various surgeons around the world and in particular in Australia who complained about the ASR product. Each complainant was initially advised that the problems were those of the surgeons in failing to properly align the hips at the required angles and that other surgeons were managing very well without difficulty.

4.9 In time however when the failures became widespread, (and the failures occurred what ever the angle of placement of the hips) the defendants withdrew their product first in Australia and then worldwide in August 2010. When the product was withdrawn in the United States of America it was formally stated by DePuy that it was a defective product when they are applied to the FDR to withdraw the ASR.

4.10 The plaintiff maintains that the defendants created a cup which required an unacceptable degree of accuracy on the surgeons when positioning it and which would deflect excessively on insertion it was too thin and was deformable had a reduced arc of coverage that would lead to edge loading and create a head and cup combination which had a dangerously small clearance resulting in excessive wear. In particular the plaintiff relies upon the evidence of Prof B that "*the frictional moment increases with head size so that it gets worse (with) bigger and bigger heads so that, combined with having to be resisted by a small surface area, places high stress on the taper – there is too much movement trying to be resisted by a small connection area and gives, it looses the battle so to speak, to a certain extent to varying amount from patient to patient …*".

4.11 The plaintiff further contends that the defendants were negligent in that they did not properly test the product prior to its launch and also in relation to their manufacturer of what is allegedly a defective product.

5 The defendants case

5.1 The defendants submit that there is no credible evidence that Mrs. Dineen's initial ASR showed excessive wear or any defect the defendants point out that the plaintiff's expert Mr. N identified the largest wear was in relation to the taper and the second and less significant cause was from the bearings which was only "*a little more*" than it should have been. The defendants contends that all metal on metal hip implants devices are susceptible to wear and that the on going development of hip replacements involving from time to time metal on metal, metal on plastic, plastic on plastic and again metal on metal indicate that with advances over the years in medical and technical thinking different replacements were considered to be optimal. The defendants' expert Dr. C was that the taper wear was "*nominal and by no means extreme*" and that the volumetric wear from the bearing surface was below the threshold that Dr. L had opined as being typical of a failed implant.

5.2 The defendants contested the plaintiff's readings as to wear obtained from a CMM machine. The defendants claims that the revision was carried out solely on the basis of ion readings and that she should not have had a revision but should have been monitored and the defendants dispute that there was erosion in the anterior and posterior portion of the acetabulum was not recorded by the surgeon Mr. KML as being severe and as there was no historically they are disputed it amounted to osteolysis.

5.3 The defendants submit that every Metal on Metal implant wears and shreds metal debris which is not a defect and there is no evidence that the metal debris were excessive. The defendants maintain that the product was adequately tested and indeed the results of their testing were submitted to appear review examination in learned publications.

5.4 The defendants accept that the product was withdrawn and say that it was stated to be "*defective*" because the form in the United States of America required a particular boxes to be ticked so that the product could be withdrawn and that it could call the product defective had no more meaning than that.

6 Was the ASR a defective product, and if so did this product cause injury to the plaintiff?
6.1 In general let me state that I accepted the expertise and independence of all of the witnesses. In the defendant's submissions an attack is made upon the independence of the plaintiff's expert witnesses and in particular of Dr. L and Mr. N who have a personal involvement in certain litigation against the defendants in the United States. There was no criticism of the independence of these witnesses as they gave evidence by way of cross examination or otherwise. In *Gillian O'Sullivan v. DePuy International Limited* (Cross J., 29th November, 2016), a sustained criticism of Mr. N's independence as an expert was made and was formally rejected by this Court. In *Kineely v. DePuy International Limited* [2012 No. 13047 P.], a similar attack on the independence of Dr. L was made and was rejected by Barton J.

6.2 It is not acceptable that an attack be made on the independence of a expert witness or on the weight to be given to their evidence by way of legal submissions which have not been ventilated in court so that the witness can deal with these allegations. Neither did the defendant in this case merely make a "*pro forma*" reliance upon this point so that it could be further ventilated in a higher court. Accordingly, the submissions in relation to the independence of these experts should not be entertained but to avoid any doubt, I repeat the acceptance I gave in *O'Sullivan* of the independence and expertise of Mr. N and adopt the similar acceptance by Barton J. of the independence and expertise of Dr. L. As stated above, I also accept in this case, the independence and expertise of the defendant's expert witnesses especially Dr. C and Dr. E.

6.3 I accept the submissions and evidence on behalf of the defendant that any replacement hip might fail and any replacement hip in particular may produce excessive ion levels and possible damage to bones or to muscles.

6.4 I also note and sympathise with the quotation from a paper delivered by Mr. I of DePuy, that a hip replacement will often involve a race between the mortality of the recipient and the debasement of the product.

6.5 I note the fact that DePuy when they withdrew their product in the United States of America, formally admitted that the product was defective. I do not find that they are thereby estopped from denying a defective product as the plaintiff must prove that the product is defective within the meaning of the 1991 Act. However, neither do I accept the explanation tendered for this admission on behalf of the defendants to the effect that the defendants were merely filling in a form and ticking a box, describing their own product as being defective. Such a large and clearly well advised organisation as the defendant and their parent companies cannot place themselves or their corporate actions in the position of a consumer who alleges they did not know what they were signing.

6.6 The admission by DePuy that their product was "*defective*" is an important strong piece of evidence but it is not necessarily decisive in relation to the breach of the statutory duty in this jurisdiction. However, while the plaintiff must satisfy the definition of a defective product in the 1991 Act, there is nothing in the definition other than the ordinary and usual meaning of language. I note that the defendants withdrew, an employed engineer Mr. I as a witness. Mr. I had, it seems, given evidence in other jurisdictions and was central to the development and marketing of the ASR and ASR/XL. I infer from his withdrawal that his evidence would not have been of assistance to the defendants in denying the defective nature of the ASR or in explaining the admission by DePuy to the FDR in the United States of America that the product was "*defective*".

6.7 I accept that the fashion for various replacements metal on plastic, plastic on plastic or metal on metal changed over the years and the desirability of manufacturing a particular system will and has changed over the years. I accept that each of the systems have advantages and that at present, metal on metal hips are no longer favoured.

6.8 Accordingly, the fact that manufacturers, including the defendant, may have in previous years stressed the dangers of a metal on metal type hip replacement and subsequently manufactured a product such as the ASR is not indicative of a defective product or indeed that the metal on metal concept is necessarily defective.

6.9 Shortly after the production of the ASR, it was subject to detailed criticism from the principal proponent of what is known as the "*Birmingham*" hip which was an early Metal on Metal hip replacement. These criticisms might be regarded from a commercial point of view as the criticisms of a rival manufacturer but the critic pointed to specific factors in the ASR which would make it more likely to cause erosion and raise metal ion levels. These criticisms ultimately prove to be perceptive and accurate.

6.10 In the case of *A. v. National Blood Authority* [2001] 3 AER 289, Burton J. held at pp. 341 to 342:-

> *"If there is a known risk, i.e., the existence of the defect is known or should have been known in the light of [reasonably] accessible information, then the producer continues to produce and supply at his own risk. It would, in my judgment, be inconsistent with the purpose of the Directive if a producer, in the case of a known risk, continues to supply products simply because, and despite the fact that, he is unable to identify in which if any of his products that defect will occur or recur…"*

6.11 However, in *Wilkes v. DePuy International Limited* [2016] EWHC 3096 (QB), the High Court of England and Wales departed somewhat from the decision in *A. v. National Blood Authority* dealing with the English Consumer Protection Act 1987 which is similar to the Irish Liability for Defective Products Act 1991. The High Court in *Wilkes* found that the approach to defect under the English Act is objective and the focus must be on whether the product suffered from a defect and that the Act requires all consideration of "*all relevant circumstances*" including producer's risk/benefit balance and indeed the extent to which a risk might be eliminated.

6.12 The defendants submit that the state of scientific knowledge and belief even today does not prove a defect or causation in that ion levels can be patient specific and all Metal on Metal hip replacements can produce raised ion levels.

6.13 While accepting the validity of the propositions in *Wilkes* (above) I reject any suggestion that a balancing of the risks or advantages to the producer can make a defective product into a safe or non-defective product. The test under the Act is an objective one.

6.14 I find that the DePuy ASR and in particular the DePuy ASR/XL is a defective product within the meaning of s. 5 of the 1991 Act in that it *"failed to provide for the safety which a person is entitled to expect taking all the circumstances into account".*

6.15 In particular, I accept the evidence that the defendant's ASR was manufactured in a manner so that unless the surgeon inserted the hip at the particular correct angle, the likelihood of failure was high and I accept the evidence that the determination of what was the actual angle of insertion was a difficult procedure for the surgeon. I also accept that the cup was thin compared to others in the market and was thus, easily deformable in its insertion and had a reduced arc of coverage that easily led to what is known as edge loading and therefore would wear. I further accept that the head and cup combination had a very small clearance which small clearance produced greater wear that other Metal on Metal devices. Accordingly, the design of the ASR with the larger head component inserted on the same or shorter heads was likely to produce excessive debris.

6.16 I accept the evidence of Prof B that because of the high friction between the metal on metal bearing whereby the movement increases with head size, it gets worse with bigger and larger heads and in combination with a small surface area, this places high stress on the taper and produces too much movement to be resisted by the small connection area.

6.17 The results of these defects was that the ASR failed to an alarming degree. These failures rate were unacceptable and significantly higher than what might be anticipated to be a "*normal*" or "*acceptable*" failure rate. This failure resulted in excessive ion levels and damage to the user's bones or muscles and necessitated revisions.

6.18 I also find that the plaintiff herself suffered injury as a result of this defective product that she noticed some pain and clicking and that when Mr. KML performed the first revision, he found evidence of bony damage and also of the large sac or pseudo-tumour.

6.19 Where as I accept the evidence from the defendant that a sac or pseudo-tumour can exist without any damage to the individual or the artificial hip, the presence of the sac together with the damage to the bony structure and the high ion levels all are evidence of injury to Mrs. Dineen which necessitated and validated the revision.

6.20 Once the revision took place, the plaintiff's blood ion levels decreased dramatically. It is just not credible to accept as the defendant's experts do that the blood ion level high increase came from the hips but to dispute that this was indicative of wear. I accept the evidence of excessive wear on the plaintiff's ASR/XL which was caused in essence by the defective design.

6.21 I do not find any additional findings of negligence over and above the particulars breach of statutory duty as outlined above.

7 Does Section 6 of the 1991 Act provide a Defence?
7.1 As is stated above, s. 6 of the 1991 Act provides, inter alia, that:-

> *"A producer shall not be liable under this Act 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…"*

7.2 Also as stated above, the onus is upon the defendant to establish this defence as stated by Finlay Geoghegan J. in *Murphy v. DePuy Orthopaedics Inc & Ors* [2016] IECA 15:-

> *"the onus will be on the defendants to establish, firstly, what was the state of scientific and technical knowledge at the time and, secondly, that such knowledge was not such as to enable the defect in question to be discovered."*

7.3 The plaintiff relies upon the case of *European Commission v. United Kingdom* [1997] AER (EC) 481 to the effect that the test is not the subjective state of knowledge of the producer but the objective is scientific and technical knowledge of which the producers presumed to have been informed.

7.4 I accept the learned authors of McMahon and Binchy *Law of Torts* (4th Ed.) p. 417 to the effect that the defence must establish not the standards in the sector where the product was operating but at the state of scientist and technical knowledge "*including the most advanced level of such knowledge*" at the time when the product was put into circulation. This interpretation is in accord with the opinion of Advocate General Tesauro in *European Commission v. United Kingdom* (above) (which I accept) when he stated:-

> *"the progress of scientific culture does not develop linearly insofar as new studies new discoveries may initially be criticised and regarded as unreliable by most of the scientific discovery yet subsequently after the passage of time undergo an opposite process … It is therefore quite possible that at the time when a given product is marketed there will be isolated opinions to the effect that it is defective whilst most academics do not take that view … The state of scientific knowledge cannot be identified with the views expressed by the majority of learned opinion, but the most advanced level of research which has been carried out at a given time … More generally the "state of knowledge" must be construed so as to include all data in the information circuit of the scientific community as a whole, bearing in mind however on the basis of reasonableness test the actual opportunities for the information to circulate".*

7.5 I also accept the submission of the defendant that the time for making the assessment as to the state of knowledge is the time when the product was put into circulation. This does not of course excuse a producer who puts a product into circulation on the basis of the state of knowledge at the time but keeps it in circulation when that state of knowledge changes. To do so would be negligent as well as defeating defence under section 6. The "*state of knowledge*" relevant to the plaintiff is the defendant's state of

knowledge not when the ASR was first produced but when the ASR which Mrs. Dineen used was manufactured.

7.6 The "*state of knowledge*" at the time the ASR was produced was that it was a new and indeed revolutionary design of Metal on Metal hips all of which were prone to wear but the ASR contained particular features not in other artificial hips that had the potential to cause harm. This fact was pointed out to the defendants and the public by the proprietor of the "*Birmingham hip*" product at a public meeting and accordingly, was part of the "*state of knowledge*" that was available at the time of production.

7.7 I do not believe that the defendants produced their product in the subjective knowledge that it was a defective one. However, as the metal on metal hip concept involved known risks of ion debris and failure, rigorous testing was required including testing of all possible combinations of taper and cup. I accept the evidence of Prof B that the defendants did not test the actabular cup at higher levels and only tested one head size in a simulation machine at one angle i.e. 45º and never tested the ASR in circumstances in which micro separation was simulated and never tested the revised thickened cup design in a simulation machine. The testing was insufficient for a new and revolutionary design that the defendants ought to have known carried with it particular possible risks. I conclude that had rigorous testing being undertaking by the defendants that that testing would have uncovered the problems with the ASR which were subsequently discovered and accepted by DePuy when they analysed revised hips which had failed.

7.8 I fully accept the evidence of SH on behalf of DePuy that the defendants did indeed test in accordance with general international guidelines and I also accept the evidence that the testing was subject unusually to Peer Review and in particular the United States of America FDA raise no issues with the testing that was done on the product. The fact that the defendants testing regime satisfied the regulatory authorities is not an answer to the fact that the state of knowledge at the time of production does not offer the defendants a defence under s. 6 of the 1991 Act.

7.9 I find that the defendants ought to have been aware due to the scientific and technical knowledge of possible problems with metal on metal hips and in particular they ought to have been aware at the time of the initial manufacture of the ASR that they were designing what was at the time a revolutionary or new product and that accordingly even if the regulatory bodies do not complain about the level of the testing, the defendants ought to have rigorously tested all combinations of the stem and the ASR femoral sleeve component to a level which would have demonstrated the amount of wear after prolonged use. I note, as stated above that Mr. I who was the lead designer it seems of the ASR did not give evidence as to the state of knowledge of DePuy or which would have been available to DePuy at the time and given the existence of evidence as to the state of knowledge at the time, I infer that Mr. I, had he been called on behalf of the defendant would not have been able to counter such evidence.

7.10 Initially when the complaints were made by surgeons the defendants contended that the problems were of the surgeons own making but subsequently the defendants realised that this was not the case. The defendants realising that there was a problem with the ASR commenced designing what was known as the "*Alpha*" project to remedy the defects with a new ASR model. This "*Alpha*" project was discontinued for what I accept were commercial reasons in that in August, 2008 the sale of the ASR while it was dropping and the defendants decided to develop different products.

7.11 It is a fact that while the defendants were attempting to develop the "*Alpha*" they maintained production of the ASR and the plaintiff was fitted with the ASR in 2009 after the abandonment of the alpha project.

7.12 This is a fact that will be considered subsequently under the heading of "aggravated damages".

7.13 I am satisfied however that the defendants have failed to establish a defence under s. 6(e) of 1991 Act and find that even at the time the ASR was brought into production in 2004 there was a significant body of scientific and technical evidence as to its dangers which of itself would defeat such a defence. I also find that the defendants did not given the knowledge of the possible difficulties adequately test the implant.

7.14 I further find that by the time the plaintiff's ASR was inserted in the plaintiff the state of scientific and technical knowledge was such that it ought to have given serious concern to the defendants and leads me to the conclusion that this scientific and technical knowledge was indeed such to enable the defendants to discover the defects. The defendants were, by the time Mrs. Dineen's ASR was produced, aware of serious problems and alarming failures of the ASR. They sought to remedy these problems by developing an alternative model (Alpha). The development of "*Alpha*" was suspended for commercial reasons before Mrs. Dineen got her ASR so clearly, even if I am incorrect in my view that at the time of initial manufacture, the state of knowledge was not such to enable the existence of the defect to be discovered, the existence of the defect had been discovered by the time Mrs. Dineen got her ASR/XL and the defence must fail in her case.

8 The Consequences for Mrs. Dineen

8.1 The plaintiff is entitled to succeed against the defendant in damages in tort pursuant to the provisions of s. 5 of the Liability for Defective Products Act 1991.

8.2 Prior to the hip replacement in 2009, the plaintiff was suffering from considerable arthritic symptoms which necessitated the replacement.

8.3 Subsequent to the replacement, the plaintiff's right hip commenced to cause her pain in 2014 and she had a sensation of clicking. This pain was intermittent and from time to time, the plaintiff herself gave different accounts of it. She was, as has been stated, also suffering from considerable "*co-morbidities*" and the revision of her hip in 2015, Mr. KML discovered erosion of the posterior and anterior walls of her right acetabulum and also a sac or pseudo-tumour. The blood ion levels reduced considerably but the first revision did not take. She was in severe pain and a second revision was required. All of these matters are matters which resulted in considerable pain and suffering to the plaintiff, in addition she suffered loss of amenity to life and the quality of her life has been severely diminished due to multiple operations.

8.4 The plaintiff has a claim for considerable care into the future and also the need to reconfigure her dwelling. She is residing on the ground floor. This is seems commenced prior to the initial revision but the need for same was undoubtedly continued by the fact that the revision was not successful. She is much less independent that she was and though her husband is older than she is, he drives the plaintiff. She does some limited shopping but has the support of a very caring and supportive family. The plaintiff's family have cared for the plaintiff as a result of the indexed events certainly since July 2015.

8.5 The plaintiff did not call any geriatrician but the defendant called one, Dr. R and also a cardiologist, Dr. K who essentially gave the only evidence as to the plaintiff's longevity. The evidence of Dr. R was that the average life expectancy of an 81 year old Irish female was 8.7 years but that due to her co-morbidities, he estimated the plaintiff had a life expectancy between four and five years. Dr. K was a very impressive witness and though not a geriatrician brought the expertise of a cardiologist to bear on the issue and he

calculated, given the plaintiff's heart and various co-morbidities which she endured, that her expectancy would be no more than three to four years.

8.6 The plaintiff submitted that any deficit in the life expectancy of the plaintiff was due to the indexed events and its consequences but there was no evidence to support this submission, the plaintiff's actuary did give evidence as to the average life expectancy of someone the plaintiff's age but the only evidence of life expectancy, specific to the plaintiff, was given on behalf of the defendants by Dr. R and Dr. K.

8.7 Though Dr. K was looking forward in his analysis, one difficulty of geriatricians or other experts using base rates to calculate future life expectancy is that there is always a historic element in their figures. If the average life expectancy of a 50 year old is say 40 years and the average expectancy of a 50 year old with diabetes is say 20 years, what that means is that 50% of persons in that cohort twenty years ago are dead by now. Medical advances in the past 20 years which would have possibly affected the past death rate are ignored in establishing the baseline for the future, therefore, the figures are potentially too low as some people would have died 20 years ago but their equivalents would survive today if looking into the future.

8.8 Accordingly, though I was impressed by Dr. K in his evidence and its fairness, and whereas there must be a significant reduction in the plaintiff's life expectancy and no evidence was adduced that the plaintiff's hip problems are any significant causal factor to her diminished life expectancy, I will assess the plaintiff as having an expectancy of four further years to take into account Dr. R and Dr. K's evidence.

9 Aggravated or Exemplary Damages

9.1 In *Conway v. Irish National Teacher's Organisation* [1991] 2 I.R. 305, Finlay C.J. awarded exemplary damages against a trade union that had breached the constitutional rights of a plaintiff by rendering her unable to access primary education for a number of months and stated that the case was:-

> *"an appropriate case in which the court should feel obliged to mark its disapproval of the conduct of the defendants to the extent of awarding exemplary damages against them for the following reasons:—*
>
> > *(a) the right which was breached on this occasion was one expressly vested in a child by the Constitution;*
> >
> > *(b) the right which was breached was one which, having regard to the education and training of a child was of supreme and fundamental importance;*
> >
> > *(c) it must be presumed that the defendants were aware of that importance;*
> >
> > *(d) the breach of the constitutional right involved was an intended, as distinct from an inadvertent, consequence of the defendants' conduct."*

9.2 In that case, Finlay C.J. defined aggravated damages as being damages which are

> *"…compensatory damages increased by reason of:-*
>
> > *(i) the manner in which the wrong was committed, involving such elements as oppressiveness, arrogance or outrage, or*
> >
> > *(ii) the conduct of the wrongdoer after the commission of the wrong, such as a refusal to apologise or to ameliorate the harm done or the making of threats to repeat the wrong, or*
> >
> > *(iii) conduct of the wrongdoer and/or his representatives in the defence of the claim of the wronged plaintiff up to and including the trial of the action."*

9.3 In *Swaine v. Commissioner of Public Works* [2003] I.R. 521, the plaintiff had been exposed to asbestos during his employment as a plumber and was suffering from a chronic reactive anxiety neurosis and Keane C.J. referring to *Conway* (above) stated that the circumstances in which aggravated damages may be awarded:-

> *"is not intended to be exhaustive, these circumstances which he has identified do not typically arise in case of negligence and if they do are not a ground for increasing the amount of compensatory damages."*

9.4 For example, a reckless driver who is intoxicated and drives at speed on the wrong side of the road but causes only minimal injury will not be visited with any extra damages but someone who through momentary inadvertence causes catastrophic injury will be obliged to pay the full consequences of their actions. Whereas the inner nature of the tort action may frequently involve moral culpability, that moral culpability is not generally reflected in damages. However, if a Tortfeasor were, post accident to disappear and render his ascertainment very difficult then the manner in which the wrong was committed might well be invoked to result in a successful claim for aggravated damages. Also, the actions of a Tortfeasor who deliberately sought to run down a pedestrian or crash a vehicle would be distinguished fro someone whose driving was negligent, or indeed even reckless.

9.5 This is not, however, to say that *Swaine* (above) is authority for the proposition that aggravated damages cannot be awarded in tort actions for negligence.

9.6 In the case of *Phillip v. Ryan* [2004] 4 I.R. 241, the defendants failed to diagnose the plaintiff's condition of prostate cancer in circumstances where the judge found that they had deliberately knowingly altered a clinical record to suggest that he had advised the plaintiff to undergo further tests both this fact and the apparent failure of the defendant's solicitors to inform the plaintiff's solicitors that the record had been falsified was:-

> *"behaviour…calculated to deceive the plaintiff, his advisers and the court in a material matter. Regrettably the defendants made a deliberate decision not to correct the false impression they had earlier conveyed to the plaintiff that there would be evidence supported by a genuine contemporaneous note that the plaintiff had been advised to have a further test carried out."*

9.7 Accordingly, whereas a higher degree of damages is not appropriate in cases of greater negligence e.g. reckless driving as opposed to careless driving clearly aggravated damages are available in tort actions for negligence as to how a defendant has

conducted its defence rather than for the actual negligence itself.

9.8 In *Daly v. Mulhern & Ors* [2008] 2 I.R. 1, O'Sullivan J. awarded aggravated damages in circumstances in which a defendant personally admitted liability, told the plaintiff there was no need to call the police and that he would compensate her and then subsequent the defendants denied the fact of the accident and liability in the pleadings. As O'Sullivan J. stated the Supreme Court in Swaine:-

> *"…has not decided that there are no circumstances in actions for negligence where aggravated damages may be awarded."*

9.9 Though Conway (above) was a "*constitutional*" tort, very many tort actions could be framed by competent Pleaders invoking loss of constitutional rights including the right to bodily integrity. I do not see any real distinction between so called "*constitutional*" torts and "*ordinary*" torts. In each case, the claim for aggravated damages must be examined on its merits in accordance with the principles outlined in Conway and subject to the caveats expressed in Swaine.

9.10 Clearly, therefore, even if the first of the three headings that can result in aggravated damages as identified by Finlay C.J. in *Conway* (the manner in which the wrong was committed), is not likely to result in an award of aggravated damages in a tort action as the damages are dictated by the level of injury, (and I am not deciding that that is the case) then the two further categories as identified by Finlay C.J. i.e. the conduct of the wrongdoer after the commission of the wrong and the conduct of the wrongdoer or his representatives in the defence of a claim up to including the trial may give rise to a claim for aggravated damages. Indeed, if a producer fraudulently and deliberately manufactured a known dangerous and defective product then a strong case might be made in a tort action under the first heading of *Conway*. I will discuss whether this applies in the plaintiff's case subsequently.

9.11 I have previously indicated in *Gillian O'Sullivan v. DePuy International Limited* [2016] IEHC 684, and in other cases that specially in the light of the statutory provisions which enable a plaintiff who has sustained very significant injuries to have their case dismissed entirely in the event of exaggeration being found, and given the entirely disproportionate and unreal "*balance*" imposed by the statute against a dishonest defendant (for example, denying the existence of an accident or pleading that a plaintiff drove on the wrong side of the road, when the defendant and its advisers know full well that that is not the case) dishonesty by a defendant in the defence of the case might well give rise to a claim for aggravated damages. A defendant is, of course, always entitled to put a plaintiff to the proof of their case and indeed to robustly challenge and cross examine a plaintiff's witness. Putting a plaintiff to the proof is entirely different from a defendant asserting what he knows or ought to know is untrue.

9.12 The supposed statutory "*balance*" against a dishonest defendant is that the defence can be struck out. It is virtually impossible to image any case in which a defendant is found to be dishonest in denying the existence of an accident or, for example, maintaining that a plaintiff drove on the wrong side of the road in which the defendant is not going to be unsuccessful in any event and accordingly, the supposed deterrent of having its defence struck out is no deterrent at all. The only way in which any fairness or balance in the arena can be ensured is if courts are prepared to award aggravated damages in suitable cases.

10 Aggravated Damages in Mrs. Dineen's Case

10.1 An award of aggravated damages to Mrs. Dineen might come under the third heading as identified by Finlay C.J. in *Conway* (above). The plaintiff claims that the denial of liability by the plaintiff under the pre-conditions placed on their purported offer of an assessment has caused the plaintiff additional hurt.

10.2 The plaintiff relies upon statements of this Court in *O'Sullivan v. DePuy International* [2016] IEHC 684, which referred to a defendant swearing an affidavit of verification where there is no real defence.

10.3 I have already indicated that the defendants made an admission of a defective product when they withdrew the ASR in the United States of America. A distinction can be made between admitting a product is defective and denying that in litigation that a plaintiff can avail of the 1991 Act.

10.4 I have been made aware that decisions against DePuy in respect of the ASR have been made in courts and other jurisdictions but I have come to the conclusion that the defendants were entitled to put the plaintiff to the proof and to have the law in relation to the ASR product tested within this jurisdiction.

10.5 As stated at the beginning of this decision there are over a thousand such cases and it is clearly of some benefit even though they may have suspected the result that the defendants and their advisers will be able to have some legal certainty in this jurisdiction.

10.6 Were the defendants, however, to continue to deny liability, as opposed to for example denying causation, and put plaintiffs to the proof in further cases after the law is settled, then I see little possible argument against an award of aggravated damages.

10.7 In relation to the other headings for aggravated damages under *Conway* and I am also of the view that in this case the plaintiff has not demonstrated a case for aggravated damages.

10.8 I have held that the product was defective. I have held that the defendant has failed to establish a defence on the basis of the state of knowledge. I note that Discovery, a number of doctors have been shown to have made complaints to the defendants about the product and that these doctors were advised that the problem was their technique not the product. I do not accept that the defendants in attempt to produce a remodelled ASR under "*Alpha*" is in any sense to be condemned or viewed as a "*cloak and dagger*" operation. I accept that any producers such as DePuy will want secrecy as to what they are doing. I accept the evidence of Mr. A, an employee of the defendants that:-

> *"a number of technologies that we were investigating in our front end research and development team resulting to the metal ion release and improving the scratch fit of the coating on the back of the cups and changing the way that we applied the hydroxyapatite coating on the back of the cups as well. In addition to that we were maintaining the aspiration to have a coated produced on the market in the future."*

10.9 I accept that in August 2008 as the sales of the ASR metal on metal products were dropping, due no small part I believe to doubts about its safety, a commercial decision was made to stop investing in the ASR brand and discontinue the "*Alpha*" project.

10.10 Though Mrs. Dineen's ASR was fitted after "*Alpha*" had been discontinued and though DePuy at that stage knew that there were serious problems with the product, I am not satisfied that the plaintiff has made the case under either the first or second

categories as identified by Finlay C.J. in *Conway* that she should be entitled to aggravated damages. The fact of a finding of a defective product and the failure to establish the "*state of the art*" defence of themselves is not sufficient evidence of *mala fides* or the deliberate production of a product which they knew to be defective, such to trigger an award under any of the categories as outlined in *Conway* (above).

10.11 I do not believe that the defendants deliberately set out to manufacture or sell a product that would cause injury. The state of knowledge at the time was that defects and failures occurred in all hip replacements but that the ASR failure rate proved significantly excessive. Had the defendants robustly tested the ASR product, the defects which subsequently came to light would have been noticed prior to production. However, the threshold for aggravated damages has not been met and accordingly, the plaintiff is entitled to compensatory damages.

11 Special Damages
11.1 The claim for special damages consists of nursing care retrospectively and into the future and aids and appliances including adjustments to the plaintiff's dwelling. The approach I take in relation to the special damages as outlined in my decision in *Gill Russell v. HSE* (18th December, 2014) and in other cases. In this case, two overriding factors must also be taken into account. The first is the life expectancy of the plaintiff though under this heading any special damages that would be reasonably necessary and/or referable to the indexed event will not be disallowed by virtue of the plaintiff's shortened life expectancy. The second factor to take into account is the considerable number of "*co-morbidities*" that the plaintiff is suffering from which the defendant urges are the real cause for the need for much of the items claimed.

11.2 I also, however, take into account the fact that prior to the indexed event, the plaintiff despite many co-morbidities was a reasonably active lady for her age and as a result of the indexed events had to be cared for by members of her family.

11.3 I do not believe that the plaintiff will, given the evidence of the geriatricians which I have essentially accepted, require or have a third revision surgery. The possible disastrous effects of a total failure of a third revision surgery which if it occurred would leave the plaintiff grossly incapacitated can be ignored. I believe that the plaintiff will, however, for the rest of her life be considerably disabled as a result of the indexed events. I believe that the plaintiff will require further orthopaedic treatment but note that the plaintiff's figures are based upon nine further reviews and I will allow the sum of €1,000 under this heading. In relation to the claim for retrospective care, I believe that this claim is well founded. The plaintiff's experts cost this care at €20,521, the defendants at €10,477.39 and I will accept the plaintiff's analysis in this regard having been impressed by the evidence of the plaintiff and her family member. However, due to the fact that I believe the indexed event only caused the necessity for care from the family for a shorter period than allowed, I will reduce the damages under this heading to €15,000.

11.4 In relation to future care, I believe that were it not for the indexed events, the plaintiff would have been likely to have progressed for the substantial remainder of her life without the need for any care. The plaintiff is entitled to have the care in future provided by outside professional agencies. The plaintiff's expert N.R. has quantified the annual care expenditure as €124,830.12. This figure is calculated based upon a claim by N.R. that care is needed ten hours daily and a carer on call by night time. In the alternative, N.R. posited a significantly larger care claim based on a carer full time. The defendant's expert, N.T., cost the future care based upon two hours per day totalling €19,148.50 per annum. I do not believe that the plaintiff will require the level of care for the foreseeable future as suggested by N.R. but I also believe that she will require more than two hours per day and believe that some €40,000 per annum, being double that suggested by N.T., is reasonable and given the relatively short number of years involved I will place the cost of future care in the sum of €150,000. I believe that sum to be fair and reasonable. The fact that I am allowing for only approximately four further years means that the actuarial figures are of little assistance.

11.5 In relation to the assessments for aids and appliances and adaption to the house, the defendants correctly point out that many of these matters as claimed are referable to the "*co-morbidities*" of the plaintiff. However, due to the indexed events I believe the plaintiff is entitled to a grab rail and wall mounted shower seat and costs of her medication after the loss of the medical card, a bed lever, pick up stick and also a stair lift, perching stool for cooking, occupational therapy and similar sundry matters. I do not believe that the expenses for extending the house are reasonably related to the indexed events other than the step to the back door and being fair to both parties, I will assess the costs of occupational therapy and other special damages in the round at €35,000.

11.6 In summary, special damages I allow:

Orthopaedic review €1,000

Past care €15,000

Future Care €150,000

Aids and Appliances €35,000

Total €201,000

12 General Damages
12.1 I have previously outlined the effects of the indexed events on the plaintiff in general terms in my decision. The plaintiff was entitled to expect that the defendant's replacement hip would have afforded her with a good degree of comfort for the remainder of her life. As a result of the breach of duty of the defendants, the plaintiff has had to have two revisions of the replaced hip which have not themselves proved satisfactory and she is now in a significantly worse position than she would have been had the indexed event not occurred. Whereas the plaintiff is not in as serious a position to the plaintiff in *Gillian O'Sullivan v. DePuy International Limited* but Mrs. Dineen's injuries are severe and indeed permanent and this has caused a major disruption to her life.

12.2 The Book of Quantum is not of any assistance as I stated in *O'Sullivan* (above) and bearing in mind my findings, I will assess general damages as follows:-

General damages to date €85,000

General damages into the future €35,000

Summary

Special damages €201,000

General damages €120,000

Total €321,000

12.3 I believe that the sum of €321,000 is fair and reasonable in all the circumstances and the plaintiff is entitled to award in that amount.