FEDERAL COURT OF AUSTRALIA

Stanford v DePuy International Ltd (No 6) [2016] FCA 1452

File number(s):	NSD 231 of 2011
Judge(s):	**WIGNEY J**
Date of judgment:	1 December 2016
Catchwords:	**PRACTICE AND PROCEDURE** – representative proceeding – application for court approval of settlement of proceedings under s 33V of the *Federal Court of Australia Act 1976* (Cth) – where settlement has occurred after trial judge reserved judgment – whether the settlement is fair and reasonable and in the interests of the group members as a whole – factors relevant to the reasonableness of the settlement – whether the proposed settlement scheme is fair and reasonable – whether the eligibility criteria for participating in the settlement scheme are fair and reasonable – where exclusion criteria would preclude some group members from participating in the settlement scheme – whether the settlement approval costs and administration costs are reasonable – whether the releases and indemnities that the group members will be bound by are reasonable – whether the reimbursement costs for the lead applicants are reasonable – where the Court has received objections from some group members
Legislation:	*Competition and Consumer Act* 2010 (Cth) *Federal Court of Australia Act 1976* (Cth), s 33V *Manufacturers Warranties Act 1974* (SA) *Trade Practices Act 1974* (Cth), Pt VIB, ss 74B, 74D, 74AC, 74AD
Cases cited:	*Australian Competition and Consumer Commission v Chats House Investments Pty Limited* (1996) 71 FCR 250 *Camilleri v The Trust Company (Nominees) Limited* [2015] FCA 1468 *Courtney v Medtel Pty Ltd (No 5)* [2004] FCA 1406 *Darwalla Milling Co Pty Ltd v F Hoffman-La Roche Ltd & Ors (No 2)* [2006] FCA 1388 *Foley v Gay* [2016] FCA 273 *Kelly v Willmott Forests Ltd (in liquidation) (No 4)* [2016] FCA 323 *Lopez v Star World Enterprises Pty Ltd* [1999] FCA 104

	Mercieca v SPI Electricity Pty Ltd [2012] VSC 204 *Modtech Engineering Pty Ltd v GPT Management Holdings Ltd* [2013] FCA 626 *P Dawson Nominees Pty Ltd v Brookfield Multiplex Limited (No 4)* [2010] FCA 1029 *Pharm-a-Care Laboratories Pty Ltd v Commonwealth of Australia (No 6)* [2011] FCA 277 *Rod Investments (Vic) Pty Ltd v Abeyratne* [2010] VSC 457 *Williams v FAI Home Security Pty Ltd (No 4)* [2000] FCA 1925
Date of hearing:	24 June, 29 June 2016
Registry:	New South Wales
Division:	General Division
National Practice Area:	Commercial and Corporations
Sub-area:	Regulator and Consumer Protection
Category:	Catchwords
Number of paragraphs:	166
Counsel for the Applicants:	Mr J C Sheahan SC with Ms Z M Hillman
Solicitor for the First Applicant:	Maurice Blackburn Lawyers
Solicitor for the Second Applicant:	Shine Lawyers
Counsel for the Respondents:	Mr R A Dick SC with Ms S Mirzabegian
Solicitor for the First Respondent:	Herbert Smith Freehills
Solicitor for the Second Respondent:	Norton Rose Fulbright

ORDERS

NSD 231 of 2011

BETWEEN:	**TAMMY MAREE STANFORD** First Applicant
	JAMIE DUNSMORE Second Applicant
AND:	**DEPUY INTERNATIONAL LTD** First Respondent
	JOHNSON & JOHNSON MEDICAL PTY LIMITED Second Respondent

JUDGE: **WIGNEY J**

DATE OF ORDER: **29 JUNE 2016**

THE COURT ORDERS THAT:

Approval of the Settlement

1. Pursuant to section 33V and 33ZF of the *Federal Court of Australia Act 1976* (Cth) (**Act**), the settlement of the proceeding is approved on the terms set out in:
   (a) the Settlement Deed dated 31 March 2016 (**Deed**) which is Annexure JKS-92 to the affidavit of Julian Klaus Schimmel affirmed on 17 June 2016;
   (b) the Amended Settlement Scheme dated 17 June 2016 (**Amended Settlement Scheme**) which is Annexure JKS-93 to the affidavit of Julian Klaus Schimmel affirmed on 17 June 2016.
2. The proceeding be dismissed:
   (a) on the basis that the dismissal is a defence and absolute bar to any claim or proceeding by any Applicant or Group Member with respect to ASR Claims as defined in the Deed;
   (b) with no order as to costs; and
   (c) without prejudice to the Parties' ability to relist the matter for the purpose of seeking orders consequential to the Deed or Amended Settlement Scheme.
3. Pursuant to section 33ZF of the Act:

(a) The Applicants' Costs (as defined in clause 1.1 of the Deed) are approved in the amount certified as reasonable and recommended for approval in the report of Ross Nicholas dated 15 June 2016 (admitted as exhibit 4 on the hearing of the Amended Interlocutory Application) and are to be paid in accordance with clause 5.1 of the Deed and clause 3.1 of the Amended Settlement Scheme;

(b) The following payments are approved as Reimbursement Payments (as defined in clause 1.1 of the Deed) and are to be paid in accordance with clause 5.1 of the Deed and clause 3.1 of the Amended Settlement Scheme:

(i) Tammy Stanford - $40,000;

(ii) Jamie Dunsmore - $40,000;

(iii) Mary Bentjees - $10,000;

(iv) Robert Webb - $10,000;

(c) Maurice Blackburn Pty Limited (**Maurice Blackburn**) and Shine Lawyers Pty Limited (**Shine Lawyers**) are jointly appointed as Administrators of the Amended Settlement Scheme;

(d) The Applicants are authorised to enter into and give effect to the Deed *nunc pro tunc* for and on behalf of the Group Members as defined in the Third Further Amended Statement of Claim.

Further Notice to Group Members to Group Members

4. The form and content of a Further Notice to Group Members (**Further Notice to Group Members**) which is annexed as Annexure JKS-136 to the affidavit of Julian Klaus Schimmel affirmed on 23 June 2016 (with the date 29 June 2016 inserted in the first sentence of the second paragraph of the Further Notice to Group Members) is approved for the purposes of sections 33X and 33Y of the Act.

5. Pursuant to sections 33Y and 33ZF of the Act, the Further Notice to Group Members is to be given to Group Members according to the following procedure:

(a) By 15 July 2016, the parties are to cause the Further Notice to Group Members to be sent by Crawford & Company (Australia) Pty Ltd (**Crawford**) to all Group Members in the proceeding for whom Crawford has contact details;

(b) By 15 July 2016:

(i) Maurice Blackburn is to cause the Further Notice to Group Members to be displayed on the website www.depuyclassaction.com.au;

(ii) Maurice Blackburn is to display the Further Notice to Group Members on its website;

(iii) Shine Lawyers is to display the Further Notice to Group Members on its website;

(iv) Duncan Basheer Hannon is to display the Further Notice to Group Members on its website;

(v) Lempriere Abbott McLeod is to display the Further Notice to Group Members on its website;

(c) By 15 July 2016, each of Maurice Blackburn, Shine Lawyers, Duncan Basheer Hannon and Lempriere Abbott McLeod are to send the Further Notice to Group Members to the Group Members for whom they (respectively) have postal and/or email addresses.

6. Distribution of the Further Notice to Group Members if done in compliance with order 5 is deemed to be satisfactory notice to all Group Members and the Further Notice to Group Members need not otherwise be given personally to each Group Member in accordance with sub-section 33Y(5) of the Act.

7. Pursuant to section 33ZF of the Act, Crawford's reasonable costs of giving effect to paragraph 5(a) above:

(a) are approved as "Administration Costs" for the purpose of clauses 1.1, 6.5(a) and 9.3(b) of the Deed; and

(b) are to be paid by Maurice Blackburn within 14 days of presentation of an invoice with respect to such costs.

8. Pursuant to section 33ZF of the Act, the reasonable costs of distributing the Further Notice to Group Members in accordance with paragraph 5(b) above are approved as Administration Costs as defined in the Deed.

Note: Entry of orders is dealt with in Rule 39.32 of the *Federal Court Rules 2011*.

REASONS FOR JUDGMENT

WIGNEY J:

1 The task of determining whether to approve a proposed settlement of a representative proceeding is a task which is both important and onerous. That is because the Court must assume a protective role in relation to the interests of all group members. A settlement will not be approved unless the Court is satisfied that the settlement is fair and reasonable having regard to the interests of the group members who will be bound by it. General statements of principle such as these are made so frequently that unfortunately some may consider them trite. Worse still, some disaffected group members who oppose a settlement might regard such statements as being little more than lip service. These reasons for approving the settlement of a representative proceeding between the manufacturer and importer of a particular type of hip prosthesis, and patients who alleged that the prosthesis was defective and unsafe, will hopefully satisfy any disaffected group members that the Court has not merely paid lip service to those statements, but has carefully examined the reasonableness of the settlement and weighed their genuine fears and concerns in the balance.

2 Between about late 2003 and December 2009, Johnson & Johnson Medical Pty Ltd imported into Australia medical devices, referred to generally as "ASR implants", manufactured by DePuy International Ltd for use in hip replacement or resurfacing surgery. Those devices were surgically implanted in about 5000 patients in Australia. Unfortunately, many of those patients had major problems with the ASR implants. Many had to undergo revision surgery to remove or replace the implant or a component of it that was no longer functioning as intended. The consequences for many, if not most, of those patients, have been disastrous. By late August 2010, DePuy had instituted a worldwide recall of the ASR implants.

3 In 2011, Mrs Tammy Stanford and Mr Jamie Dunsmore separately commenced representative proceedings against DePuy and Johnson & Johnson Medical, both in their own right and on behalf of group members, being other persons in Australia who, like them, had ASR implants surgically implanted. In broad terms, they contended that DePuy and Johnson & Johnson Medical contravened the *Trade Practices Act 1974* (Cth) because the ASR implants were not reasonably fit for the purpose for which they were required, were not of merchantable quality, and were not safe, such as persons generally were entitled to expect. They also alleged that DePuy and Johnson & Johnson Medical were negligent in designing, manufacturing and supplying the ASR implants. They sought, amongst other things,

compensation for loss and damage caused by the manufacture and supply of the ASR implants. They claimed that relief both for themselves and for group members.

4 DePuy and Johnson & Johnson Medical did not admit liability. Far from it. They vigorously defended the proceedings. Teams of highly qualified, experienced and no-doubt costly lawyers were assembled. As each side faced off, millions of documents were discovered and parsed over, in particular by the lawyers acting for Mrs Stanford and Mr Dunsmore. A vast array of evidence was amassed, including reports from eminent experts in various specialist medical and other fields. In short, many millions of dollars were expended in pursuit and defence of the proceedings.

5 To be fair, it appears that concerted efforts were made to settle the matter before trial. Those efforts were unsuccessful. The matter proceeded to trial. The trial ran for 17 weeks. It was hard-fought. At the conclusion of the trial, the trial judge, not surprisingly, reserved judgment. Almost nine months later, but before judgment was delivered, the parties conditionally agreed to settle the proceedings. The agreement was conditional because, by reason of s 33V of the *Federal Court of Australia Act 1976* (Cth), a representative proceeding may not be settled or discontinued without the leave of the Court.

6 The application for the approval of the settlement was heard by the Court on 24 June 2016. Detailed evidence in support of the approval of the settlement was led, mainly by the applicants. Equally detailed submissions, both written and oral, were advanced. The Court also heard impassioned pleas from a number of group members who opposed approval of the settlement.

7 As already indicated, in broad terms, the approval application required the Court to address two related questions: *first*, was the proposed settlement was fair and reasonable having regard to the claims made by group members who would be bound by the settlement; and *second*, and had the proposed settlement been undertaken in the interests of the group members as a whole, rather than just in the interests of the applicants and the respondents? The answer to both those questions, having regard to the detailed evidence and submissions, including the group members' objections, was and is "yes".

8 On 29 June 2016, the Court approved the settlement and made a number of consequential and ancillary orders. In all the circumstances it was considered to be in the best interests of the

parties, group members and the administration of justice generally, for the orders to be pronounced immediately with detailed reasons to follow.

9 These are the Court's reasons for approving the settlement.

FACTUAL BACKGROUND

10 It is unnecessary to spell out the facts in great details. Following is a simplified summary of the facts that were material to the question whether the settlement should be approved.

11 The ASR implants the subject of the representative proceedings were manufactured by DePuy, a company based in Leeds in the United Kingdom. They were imported into Australia and distributed by the Australian based company Johnson & Johnson Medical. Both DePuy and Johnson & Johnson Medical were subsidiaries of Johnson & Johnson Inc, a company based in the United States of America. The ASR implants were imported into Australia for use in hip surgery between about late 2003 and late 2009. They were the subject of a worldwide recall by DePuy in late August 2010.

12 Detailed records of surgery involving hip prostheses, including ASR implants, were maintained by the Australian Orthopaedic Association. From those records, it was ascertained that approximately 5,500 ASR implants were implanted in approximately 5,000 patients. Some patients were surgically implanted with an ASR implant in both of their hips. In some instances, patients who had received an ASR implant had that implant surgically removed or "revised" and replaced by another ASR implant.

Commencement of the representative proceeding

13 Mrs Stanford commenced representative proceedings in this Court against DePuy and Johnson & Johnson Medical on 28 February 2011. Mrs Stanford was one of the many patients who had an ASR implant surgically implanted and later revised. She claimed that DePuy and Johnson & Johnson Medical had been negligent and were liable pursuant various provisions of the Trade Practices Act. The allegations that formed the basis of those causes of action will be considered in some more detail later. Mrs Stanford sought damages, both on her own behalf and on behalf of group members comprising other persons who had undergone hip replacement surgery involving ASR implants.

14 Mr Dunsmore, who was represented by different lawyers, also commenced representative proceedings in this Court against DePuy and Johnson & Johnson Medical. Mr Dunsmore's

action, which he commenced in September 2011, was based on essentially the same causes of action as those alleged by Mrs Stanford. The group members were also relevantly the same. In April 2012, Mr Dunsmore's proceeding was consolidated with Mrs Stanford's proceeding.

15 To complicate matters further, in October 2011 Ms Mary Beentjes and Mr Robert Webb each commenced separate representative proceedings against DePuy and Johnson & Johnson Medical in the Supreme Court of South Australia. Their cases were commenced on behalf of South Australian patients who had received ASR implants. Ms Beentjes' case concerned patients who had received an ASR implant system in hip resurfacing surgery, while Mr Webb's case concerned patients who had received an ASR implant system in an operation involving total hip replacement. Their claims alleged causes of action in negligence and under the Trade Practices Act, as well as under South Australian legislation: the *Manufacturers Warranties Act 1974* (SA). Those proceedings were in due course transferred to this Court and consolidated with Mrs Stanford's and Mr Dunsmore's proceedings. The Court ordered that the South Australian patients who were group members in Ms Beentjes' and Mr Webb's action were to be sub-group members in respect of their claims under the South Australian Act.

The causes of action and defences

16 The applicants' case that both DePuy and Johnson & Johnson Medical were liable for damages suffered by them as a result of the ASR implants was based on both statutory causes of action under the Trade Practices Act and the common law cause of action for negligence.

17 Insofar as the statutory causes of action were concerned, the applicants relied on three sections of the Trade Practices Act.

18 First, it was alleged that the ASR implants were not reasonably fit for the purpose for which they were acquired, and the applicants therefore had an action for damages against both DePuy and Johnson & Johnson Medical under s 74B of the Trade Practices Act. Second, it was alleged that DePuy and Johnson & Johnson Medical were liable for damages under s 74D of the Trade Practices Act because the ASR implants were not of merchantable quality. Third, it was alleged that DePuy and Johnson & Johnson Medical were liable under s 74AD of the Trade Practices Act because the ASR implants had a defect within the meaning of s 74AC; in simple terms, it was said that the safety of the ASR implants was not such as persons generally were entitled to expect.

19 DePuy and Johnson & Johnson Medical denied that the ASR implants were not reasonably fit for purpose and were not of merchantable quality. They also denied that the safety of the ASR implants was not such as persons generally were entitled to expect. The issues raised by the defences to the statutory causes of action are addressed later. Suffice it to say that the defences raised not only a number of complex factual and evidentiary issues, but also some potentially difficult questions of law, including the proper construction of the relevant provisions of the Trade Practices Act, as well as questions concerning causation and damages.

20 In relation to their common law cause of action in negligence, the applicants claimed that DePuy and Johnson & Johnson Medical acted negligently in relation to the design, manufacture and supply of the ASR implants. They contended that DePuy and Johnson & Johnson Medical breached the duty of care that they owed to persons in their position by releasing ASR implants onto the market in circumstances where they knew, or ought to have known, that the implants would have an increased risk of wear and premature failure in patients. It was also alleged that that DePuy and Johnson & Johnson Medical breached their continuing duty to monitor and test the performance and wear of the ASR implants and take steps to suspend or withdraw the implants if concerns about their performance arose.

21 DePuy and Johnson & Johnson Medical admitted that they owed a duty of care to the applicants and group members in respect of the design and manufacture of the implants, however they denied breaching that duty. In simple terms, they contended that that the ASR implants accorded with the state of scientific knowledge at the time of supply. Thus, it was said that any risks associated with the supply of the ASR implants were not reasonably foreseeable.

The course of the proceeding

22 As indicated earlier, the various proceedings were commenced in 2011 and consolidated in 2012. During 2013, DePuy and Johnson & Johnson Medical discovered somewhere in excess of 1.8 million documents. By late 2013, the applicants had served their lay witness affidavits and expert reports. During early 2014, the parties were working towards a trial that was listed to commence on 6 June 2014. When DePuy and Johnson & Johnson Medical served their evidence in April 2014, however, it became clear that a 2014 trial date was not feasible. The evidence served by DePuy and Johnson & Johnson Medical was voluminous

and included highly technical expert evidence across a range of specialist disciplines. The June 2014 trial date was vacated.

23 In June 2014, the applicants served their evidence in reply. Further expert reports and other material were exchanged by the parties in the latter part of 2014 and early 2015. The trial was listed to commence on 2 March 2015.

24 The parties commenced settlement negotiations in mid-2014. Needless to say, the task of coming up with an appropriate settlement figure was by no means straightforward. For the purpose of settlement negotiations, the applicants' lawyers engaged actuaries and conducted a group member sampling or survey process in order to gather information concerning the demographics and experiences of group members. The survey and actuarial advice and data obtained as a result of those processes is summarised later in the context of the evidence led in support of approval of the settlement.

25 It is also worth noting, in the context of the settlement negotiations, that in November 2013, lawyers in the United States announced that they had settled a class action concerning the ASR implants which involved some 8,000 claimants. The settlement was for $2.47 billion. More will be said about the terms of this settlement later in the context of the reasonableness of the settlement reached in this matter. Many of the group members who opposed the terms of the settlement pointed to the amount of the settlement that had been reached in the United States as an indication that the settlement sum here was inadequate. Suffice it to say at this stage that, for reasons that will be explained, the settlement in the United States does not provide a reliable benchmark or guide for the reasonableness of the settlement of these proceedings.

26 Despite the attempts to settle the matter, the trial commenced before the trial judge on 2 March 2015. In broad terms, the trial concerned the determination of the issues of fact and law that were common to the applicants and group members; primarily those issues that would determine whether DePuy and Johnson & Johnson Medical were liable, under the Trade Practices Act or in negligence, in respect of any loss or damage suffered by the applicants and group members. The quantum of any award of damages, in respect of Mrs Stanford and Mr Dunsmore, was also to be determined.

27 The trial ran for 17 weeks. Both parties were represented by large legal teams. For the applicants, three senior counsel and four junior counsel were involved at various stages, as

well as a large team of senior and junior solicitors from one of Australia's preeminent plaintiff class action firms. The representation at trial of DePuy and Johnson & Johnson Medical involved two senior counsel and three junior counsel, as well as teams of lawyers from two large law firms.

28 The trial was complex, hard-fought and difficult. There was little common ground. Over 6,500 documents were tendered by the parties. Many of the documents concerned highly technical matters. The applicants alone tendered 52 expert reports across a range of specialist disciplines. They also read 21 affidavits from lay witnesses, though many those affidavits also concerned highly technical matters. Ultimately 19 of the applicants' witnesses gave oral evidence and were cross examined. For its part, DePuy and Johnson & Johnson Medical tendered 23 expert reports and read seven affidavits from lay witnesses. Of the respondents' witnesses, 13 gave oral evidence and were cross examined. The transcript of the oral evidence at trial exceeded 5,000 pages. The parties' closing submissions ran to over 2,000 pages.

Evidence and issues in the proceeding

29 It is plainly neither necessary nor desirable to discuss the evidence and issues that emerged at trial in any great detail. That said, it is important to address that topic, if only to emphasise that the litigation involved considerable complexity and risk for the applicants and group members, both in relation to liability and the quantum of damages. While at an intuitive level the case against DePuy and Johnson & Johnson Medical may have appeared to be fairly straightforward and strong, it in fact gave rise to a number of complex factual and legal issues. The applicants were by no means assured of success, or complete success.

30 The applicants' case relied fairly heavily on data recorded by the Australian Orthopaedic Association in relation to the outcome of all hip replacements performed in Australia. That data revealed that ASR implants required earlier and more frequent revision than other hip replacement prostheses in their class. For example, in relation to complete hip replacements, the ASR implants had a revision rate at 7 years of 37.1 percent, whereas other comparable implants had a revision rate of 14 percent. There was also evidence of a similar high revision rate for ASR implants found in comparable registries overseas, in particular in the United Kingdom. The applicants also relied on evidence that revealed that DePuy's own internal health hazard evaluation led to its decision to initiate a worldwide recall of ASR implants in August 2010 because they were defective and could cause health problems.

31 The applicants contended that the grossly increased rate of revision in relation to the ASR implants, together with DePuy's decision to recall the ASR implants in 2010, was enough to demonstrate that the ASR implants were not fit for purpose and were not of merchantable quality. The applicants led evidence from a number of epidemiologists, biostatisticians and other witnesses in relation to the reliability of the revision data and the conclusions that could properly be drawn from it. Those witnesses included: Professor Ross Crawford, an orthopaedic surgeon and Professor of Orthopaedic Research and Queensland University of Technology; Professor Lyn March, Professor of Rheumatology and Musculoskeletal Epidemiology at the University of Sydney; Professor Kerrie Mengerson, Professor in the Science and Engineering Faculty at the Queensland University of Technology; and Professor Stephen Graves, a trained orthopaedic surgeon and director of the relevant registry at the Australian Orthopaedic Association.

32 The applicants also argued that if the evidence of the increased revision rates was not sufficient alone to establish liability under the Trade Practices Act, they were able to point to certain design defects which meant that the ASR implants had a susceptibility to wear and other processes which in turn increased the risk of revision. They led evidence from several bioengineering experts and orthopaedic surgeons to demonstrate that the particular design of the acetabular cup of the ASR implants increased the susceptibility of the implants to "edge loading", which in turn increased the risk of wear and poor clinical performance. The applicants led evidence from the following witnesses in relation to that aspect of their case: Professor Dennis Bobyn, an Emeritus Professor in the Departments of Surgery and Biomedical Engineering at McGill University; Professor John Medley, Professor in the Department of Mechanical and Mechatronics at the University of Waterloo; Dr Gregory Roger, Adjunct Associate Professor of Bioengineering at the University of Sydney; Dr Hugh English, an orthopaedic surgeon based in Brisbane; Dr John Ireland, an orthopaedic surgeon based in Sydney; Dr David Langton, an orthopaedic researcher who had carried out extensive research in relation to the performance of the ASR implants; and Dr Antoni Nargol, an orthopaedic surgeon. Professor Nicholas Athanous, Professor of Musculoskeletal Pathology at the University of Oxford gave evidence about the resulting increase in adverse tissue reactions as a result of increased wear in the metal on metal implants.

33 The applicants also relied on clinical evidence to support the statistical and engineering evidence. A number of the orthopaedic surgeons referred to earlier in the context of the epidemiological and statistical evidence expressed opinions which supported the use of

registry data to demonstrate the increased rate of revision associated with the ASR implants. They noted, in particular, that it was unlikely that patient and surgical factors adversely affected the utility of the data. They also referred to various potentially problematic design features of the ASR implants. The clinical evidence included evidence from Dr John Mills, Mrs Stanford's treating surgeon, and Dr Bernard Zicat, Mr Dunsmore's treating surgeon.

34 In relation to causation and the quantum of damages, Mrs Stanford and Mr Dunsmore relied on their treating surgeons, as well as expert evidence from two physiotherapists, a rheumatologist, two neurosurgeons, a neurologist, two physicians in rehabilitation medicine, three occupational therapists, a psychiatrist, a forensic accountant and an architect. Both Mrs Stanford and Mr Dunsmore and their spouses also gave evidence concerning the way in which the surgery had impacted upon their quality of life.

35 Each aspect of the applicants' case on both liability and quantum was challenged by DePuy and Johnson & Johnson Medical. Detailed expert and other evidence which challenged, contradicted or otherwise impugned the applicants' case, was adduced.

36 In relation to the increased revision rates reported in registry data, DePuy and Johnson & Johnson Medical contested the utility of the registry data and argued that the increased revision rates reported in the data did not demonstrate that the ASR implants had any material defects. They contended, among other things, that the data was inconclusive; that there were limitations in the registry's methodology and other flaws in the data; that the reported revision rate for the ASR implants was inflated by a "learning curve" that affected surgeons implanting the devices; and that the revision rate for the ASR implants was affected by a "recall effect", whereby the revision decisions of patients and their surgeons were influenced by DePuy's recall of the ASR implants in August 2010. The evidence adduced by the respondents in relation to this aspect of the case included evidence from the following witnesses: Dr Michael Bailey, a biostatistician at Monash University; and Professor Val Gebski, Professor of Biostatistics and Research Methodology at the University of Sydney.

37 DePuy and Johnson and Johnson Medical also called evidence from several clinical experts that suggested that surgeons were influenced by the so-called "recall effect" and that this inflated the revision rates for the ASR implants. The witnesses relied on in respect of this issue included: Dr Michael Dixon, an orthopaedic surgeon based in Sydney; and Professor Keith Petrie, Professor of Health Psychology at the Faculty of Medicine and Health Sciences at the University of Auckland. DePuy also relied on evidence from Dr Cuckler, who

maintained that the ASR implants did not perform any worse than comparable implants in the same class.

38 DePuy and Johnson & Johnson Medical also challenged the applicants' evidence concerning the design features of the ASR implants, in particular the alleged susceptibility to edge loading. They contended that the ASR implants were no more susceptible to edge loading than other implants in their class and that, in any event, there was no demonstrated correlation between edge loading and poor clinical performance. They also pointed to evidence that they contended established that the design of the ASR implants accorded with scientific knowledge at the time of supply, including the known risks with these types of implants. In relation to this aspect of their defence, DePuy and Johnson & Johnson Medical relied on evidence from the following experts: Dr John Cuckler, an orthopaedic surgeon based in the United States with particular expertise in hip and knee replacement, biomaterials research and implant design and development; Dr Avram Edidin, a biomedical engineer; Professor David Williams, an expert in biocompatibility; Mr Christopher Hunt, a bioengineer employed by DePuy; and Dr Graham Isaac, a Distinguished Engineering Fellow employed by DePuy.

39 In response to the applicants' negligence case, DePuy and Johnson & Johnson Medical called evidence from Ms Sally Hunter, the director of regulatory affairs at DePuy's Leeds office, in support of DePuy's case that it followed all relevant regulatory processes in relation to the supply of the ASR implants; and Dr Aran Maree, the Medical Director for Johnson & Johnson Medical in Australia at the time, in relation to the company's claimed adherence to regulatory and complaints investigation processes. DePuy and Johnson & Johnson Medical argued that the evidence showed that the ASR implants were extensively tested according to accepted testing standards at the time of supply.

40 In relation to quantum, DePuy and Johnson & Johnson Medical relied on evidence from a rehabilitation physician, a toxicologist, a vocational psychologist, a psychiatrist, and a quantity surveyor.

41 Aside from the difficult factual and evidential issues the subject of the evidence called by the parties, the litigation raised several legal issues, in particular in relation to the proper construction of s 74B and 74D of the Trade Practices Act. The main issue in relation to those sections was whether the question of merchantability and fitness for purpose should be

approached on the basis of the state of scientific knowledge at the time of supply, or the knowledge at the time of trial.

42 The applicants argued that a product's fitness for purpose must be determined by reference to the actual performance of the product and the current state of knowledge, as opposed to a hypothetical inquiry into whether any defect was within the state of scientific knowledge at the time of supply. DePuy and Johnson & Johnson Medical contended, however, that it was necessary for the applicants to demonstrate that the ASR implants were not fit for purpose by reference to the state of knowledge at the time of supply. They argued that, for them to be liable, any identified defect must have been within the state of scientific knowledge at the time of supply. DePuy and Johnson & Johnson Medical claimed that the evidence showed that the design of the ASR implants accorded with the scientific knowledge at the time of supply, including the known risks associated with those types of implants.

43 There were also questions of law concerning causation. Those questions arose in the context of the applicants' case based on the registry data and the elevated revision rate in respect of the ASR implants. In simple terms, there was an issue about which party bore the evidentiary onus: did the applicants have the onus of proving that the increased revision rates were caused by a design feature or defect in the ASR implants; or in the circumstances, did DePuy and Johnson & Johnson Medical effectively bear the onus of showing that the statistically high revision rates were the result of "confounders", such as the recall effect, or patient and surgical factors unrelated to any design features of the ASR implants.

44 The divergent position of the parties was not limited to the question of liability. Difficult questions of fact and law also arose in relation to the assessment of damages. To give but one example, the assessment of general or non-economic damages in respect of the causes of action under the Trade Practices Act was governed by provisions in Div 3 Pt VIB of that Act (now the *Competition and Consumer Act* 2010 (Cth)). In the cases of the cause of action in negligence, however, each of the states and territories had different statutory regimes for the calculation of non-economic loss. A question arose as to which regime or regimes should be used to assess damages. As discussed later, the settlement scheme has in effect adopted the Commonwealth statutory regime for the purposes of the assessment of compensation payable under the scheme.

45 Needless to say, the parties were well apart on the quantum of damages. In closing submissions, Mrs Stanford submitted that her damages in respect of the Trade Practices Act

causes of action should be assessed at $1,223,586, whereas DePuy and Johnson & Johnson Medical submitted that the damages were properly assessed as being $111,130. Mr Dunsmore submitted that his damages in respect of the Trade Practices Act causes of action were properly assessed at $886,138, whereas DePuy and Johnson & Johnson Medical contended that Mr Dunsmore was only entitled to damages assessed in the amount of $63,005. The parties were equally divided in respect of the assessment of damages in respect of the cause of action for negligence, though the amounts claimed for damages in respect of negligence were generally higher.

46 This short and highly simplified summary of the evidence and issues in the litigation serves to illustrate that the applicants and group members faced a number of factual and legal hurdles at the trial. They were by no means assured of success in respect of the common issues concerning liability. Nor could it confidently be asserted that, even if liability was established, damages would necessarily be assessed in the amounts contended by Mrs Stanford and Mr Dunsmore. The reasonableness of the proposed settlement must be considered in the context of the significant litigation risk faced by the applicants and group members in this difficult case.

47 The trial concluded on 26 June 2015. The trial judge reserved his judgment. In early October 2015 the legal representatives of the parties attended a mediation. It would appear that an agreement in principle to settle the proceedings was reached between the parties in late 2015 or early 2016. On 31 March 2016, the parties executed a Settlement Deed.

THE SETTLEMENT

48 The terms of the settlement in respect of which approval was sought were set out in two documents: the Settlement Deed dated 31 March 2016 and the Settlement Scheme – ASR Class Action, the amended version of which was dated 17 June 2016.

49 The key terms of the Settlement Deed are as follows.

50 First, the settlement is conditional upon final approval by the Court (clause 2.1).

51 Second, the settlement is on a “no admissions” basis: it is made with a specific denial of liability and is not to be represented as an admission of liability by DePuy or Johnson & Johnson Medical (clause 3.2).

52 Third, subject to final Court approval being obtained, DePuy and Johnson & Johnson Medical will pay the settlement sum, being the amount of $250 million plus interest, into a nominated bank account (clause 3.1).

53 Fourth, a regime is established whereby DePuy and Johnson & Johnson Medical are to be responsible for the negotiation and resolution of certain "assumed liens", being liens asserted by third parties such as Medicare and private health insurers in respect of reimbursement for expenses advanced for the benefit of group members (clause 4). Other "residual liens" referable to group members are to be paid from the settlement sum in addition to the compensation amounts assessed in accordance with the Settlement Scheme.

54 Fifth, the settlement sum is to be applied and distributed as follows (clause 5): *first*, to meet such of the applicants' costs of the proceedings as have been verified as reasonable by an independent costs expert and subsequently approved by the Court; *second*, to make certain payments to Mrs Stanford, Mr Dunsmore, Ms Beentjes and Mr Webb for reimbursement of time and expenses expended by them in prosecuting the proceeding; *third*, to meet the costs of administering the settlement scheme as approved by the Court; and *fourth*, to eligible claimants, being those of the applicants and group members who are or become eligible to receive payments pursuant to the settlement.

55 It should be noted in the context of the payments to be made out of the settlement fund that the applicants' legal costs and disbursements at the time of settlement were estimated to be in the order of $36 million. An independent costs expert has since verified the total amount of $36,856,243.95 as being reasonable. That evidence, and the question of the reasonableness of the legal costs, will be considered later.

56 Sixth, upon payment of the settlement sum, the applicants in their own right and on behalf of group members, will grant releases to DePuy, Johnson & Johnson Medical and various related and third parties in respect of all claims arising from or related to the proceedings (clause 7.1). The related and third parties to whom the releases are granted include: companies related to DePuy and Johnson & Johnson Medical; the directors, officers, employees and legal and other professional advisers of DePuy, Johnson & Johnson Medical and their related companies; persons involved in the design, development, manufacture, marketing, sale and distribution of the ASR implants; physicians and hospitals connected with the prescription, implantation, use or removal of the ASR implants; and insurers of those persons and entities. The release is supported by an obligation on the part of the applicants

and group members to indemnify DePuy, Johnson & Johnson Medical and the specified related or third parties in respect of any cross claim that may be filed against them in any proceedings instituted by the applicants or group members against other parties (clause 7.2).

57 The key terms and provisions of the Settlement Scheme are as follows.

58 First, the two law firms who acted for Mrs Stanford and Mr Dunsmore will jointly perform the role of Court appointed scheme administrators (clause 2). Importantly, upon being so appointed, those firms are to cease to act for the applicants and any group members.

59 Second, consistently with the Settlement Deed, the administrators will apply the settlement sum to payment of the reimbursement expenses of Mrs Stanford, Mr Dunsmore, Ms Beentjes and Mr Webb and the applicants' legal costs. The balance is then to be paid to group members and administration costs in accordance with the provisions of the Settlement Scheme (clause 3).

60 Third, group members are required to register their compensation claims with the administrators within certain specified timeframes (clause 4).

61 Fourth, upon the registration of a claim by a group member, the administrators will assess the group member's eligibility for compensation (clause 5).

62 The eligibility criteria are critical to the settlement scheme and are a critical consideration in respect of the reasonableness of the settlement. The main point is that not all group members will be eligible for compensation. Group members will only be eligible to claim compensation if they satisfy the following criteria: *first*, they were implanted with an ASR implant in Australia; *second*, they have undergone either an actual or a "deemed ASR revision" within 13 years of their primary surgery; *third*, the ASR revision was not an "ineligible revision"; and *fourth*, the group member has not opted out of the proceeding. A deemed ASR revision occurs where a revision was reasonably necessary, but the group member did not undergo the revision surgery due to the group member's comorbidities. In other words, the group member was too ill for the revision surgery to take place. An ineligible revision is a revision that was performed in certain circumstances set out in the Settlement Scheme (clause 5.3), being circumstances which could not be said to have been caused by or attributable to the ASR implant.

63 The rationale for having the administrators determine the eligibility of group members was to avoid the additional costs associated with retaining external persons to assess eligibility. The

expert evidence led by the applicants to support the eligibility criteria is considered later. Suffice it to say at this stage that the reasonableness of the eligibility criteria was supported by expert evidence from Professor Ross Crawford, a highly qualified and experienced orthopaedic surgeon and Professor of Orthopaedic Research at the Queensland University of Technology.

64 Fifth, eligible group members may elect to accept a "fast track resolution" of their claim, which entitles them to a single $55,000 lump sum payment (clause 6). Members who had ASR implants for both hips are able to claim a fast track payment in respect of each hip. The estates of deceased group members are required to elect to receive a fast track resolution discounted to $40,000.

65 Sixth, those eligible group members who do not take up a fast track resolution will then proceed to have their claim assessed (clause 7). The claims assessment process involves the administrators preparing claims books which comprise information and materials to enable an assessment to be made of the group member's compensable loss or damage. The information and materials will consist of instructions and information from the group member; information from other persons such as family members and friends; contemporaneous medical records, financial information such as tax returns, employment records and invoices for expenses; information concerning payments already made by the respondents; and, subject to certain restrictions designed to minimise costs, reports from treating documents, health experts and accountants. The claims books will then be submitted to an assessor chosen from a panel of senior lawyers who will assess claims according to the *Competition and Consumer Act 2010* (Cth) and on the basis that the eligible group member is only entitled to compensation for loss or damage that was caused by their ASR revision or the circumstances requiring the ASR revision. Non-economic loss must be assessed at no less than $40,000. Provision is also made for eligible group members to apply for a review of their compensation award if they are not satisfied with their assessment.

EVIDENCE IN SUPPORT OF APPROVAL OF THE SETTLEMENT

66 Mrs Stanford and Mr Dunsmore adduced substantial and compelling evidence from a number of sources in relation to the reasonableness of the settlement reached with DePuy and Johnson & Johnson Medical. As detailed later, a number of group members lodged written objections to the settlement and a number more made oral submissions at the hearing in

opposition. There was, however, no direct challenge to the evidence adduced in support of the settlement.

67 The evidential material relied on by Mrs Stanford and Mr Dunsmore on the approval application was:

(a) two affidavits of Mr Julian Schimmel, an experienced solicitor employed by the firm representing Mrs Stanford, affirmed 17 June 2016 and 23 June 2016;

(b) confidential affidavit of Mr Ben Slade, principal of the firm representing Mrs Stanford, affirmed 17 June 2016;

(c) two confidential opinions of Dr Duncan Graham SC, one of the trial counsel for Mrs Stanford and Mr Dunsmore, dated 17 June and 22 June 2016;

(d) affidavit of Rebecca Jancauskas, partner of the law firm representing Mr Dunsmore, affirmed 17 June 2016;

(e) expert report of Professor Crawford;

(f) expert report of Dr Sarah Whitehouse, Senior Research Fellow and Biostatistician in Orthopaedics at Queensland University of Technology;

(g) expert report of Mr Geoff Atkins, Fellow of the Institute of Actuaries;

(h) expert report of Mr Ross Nicholas, legal costs expert and solicitor;

68 Mr Schimmel's affidavit evidence addressed the factual background to the proceedings; gave a detailed summary of the evidence led and the issues that arose at the trial; explained and gave a rationale for various key aspects of the settlement; provided a response to a number points made in written objections lodged by certain group members; and explained the basis and calculation of the reimbursement payment which, if approved, will be made to Mrs Stanford. Much of what has already been said concerning the factual background and the issues and evidence at the trial is based on Mr Schimmel's evidence. Mr Schimmel's responses to some of the group member objections are addressed later.

69 Mr Slade is a highly experienced class action lawyer. A confidentiality order has been made in respect of his affidavit because much of it concerns settlement negotiations that were and are confidential as between the parties. It also contained Mr Slade's views and opinions relating to the reasons for settlement and his understanding of the potential outcomes if settlement is not approved. Given the confidentiality order, it is not possible to say anything more concerning Mr Slade's evidence. It is sufficient to note that the Court gave careful

attention to his evidence. His views and opinions, which were expressed with obvious care, clarity and candour, were afforded significant weight insofar as they bore on the reasonableness of the settlement.

70 The same can be said about the opinions of Dr Graham SC. Dr Graham was one of the trial counsel who appeared for Mrs Stanford and Mr Dunsmore. His opinions are the subject of a confidentiality order. They are not only the subject of legal professional privilege, but they contain confidential information concerning the settlement negotiations and the prospects of success of the applicants and group members. The Court ordinarily expects applicants for the approval of a settlement to fully apprise the Court of the factors that have been taken into account in negotiating and entering into the settlement, including the opinions of counsel concerning the prospects of success and the likely assessment of damages. Applicants should plainly be able to tender the opinions of their counsel in such circumstances without being required to publicly disclose that information to their potential prejudice.

71 Dr Graham's opinions were, with respect, detailed, candid, thorough, well-reasoned and compelling. They were deserving of, and were given, considerable weight in assessing the reasonableness and fairness of the proposed settlement.

72 The affidavit of Ms Jancauskas addressed, amongst other things, the reactions of some group members who had contacted her firm in relation to the settlement, as well as the nature of some of the objections to the settlement that her firm had received. She also explained and quantified the reimbursement payments which, if approved, will be made to Mr Dunsmore, Ms Beentjes and Mr Webb. Ms Jancauskas' evidence was that to her knowledge the settlement had generally been widely supported by group members.

73 The expert opinion evidence of Professor Crawford was primarily directed to the reasonableness of the eligibility criteria. In his opinion, the requirement that, to be eligible to receive compensation, group members must have undergone an ASR revision (which, as explained earlier, includes deemed ASR revisions, but excludes ineligible revisions) within 13 years is both reasonable and fair. It should be noted, in this context, that the original settlement scheme involved a "cut off" point of ten years. Group members who underwent ASR revisions after that time would not have been eligible. Professor Crawford's opinion, however, was that 13 years was a more appropriate cut off point. Revisions up to that time could reasonably be considered to have been related to the ASR implant, whereas revisions

after that time could not reasonably be regarded as device related. The scheme was amended to reflect that opinion. Professor Crawford expressed his conclusion as follows:

> Ultimately, a very small number of revisions in both the ASR XL and ASR Resurfacing may transpire to have been device related, but once an implant has functioned well for 13 years the probability is that the device has performed successfully and that any revision beyond that date would be considered as a revision as for any other conventional hip replacement.

74 Similarly, the original settlement scheme did not include the notion of a deemed ASR revision in the eligibility criteria. Professor Crawford's opinion, however, was that the inclusion of a deemed ASR revision in the eligibility criteria would be fair and reasonable. The scheme was amended accordingly. Professor Crawford's opinion relevant to the inclusion of a deemed ASR revision in the eligibility criteria was as follows:

> Very occasionally a patient may be medically unwell and a revision operation cannot be performed because of the patient being considered unfit to undergo a revision hip replacement. I consider that this is a possible circumstance but very rarely is a patient unwell enough to not undergo a revision operation. Having said that I think it is reasonable to accept a deemed ASR revision if a patient has comorbidities that are so significant that there is an unacceptable risk of death or substantial deterioration of a group members health were they to undergo a revision operation.

75 Finally, Professor Crawford expressed the opinion that it was fair and reasonable to exclude certain "ineligible" revisions from the scheme on the basis that they were not likely to be "device related" revisions. Revisions that fall into that category include revisions related to a fractured femoral neck within certain time periods and revisions related to or arising from post-operative infection and unrelated trauma.

76 The evidence of Ms Whitehouse concerned the conduct of a survey which gathered data from a relatively small group of ASR implant patients that could then be extrapolated and generalised to a larger group of approximately 1800 to 2000 patients. The purpose of the survey was to assess the incidence of post-operative complications after ASR revision surgery, and more broadly, to evaluate outcomes after revision surgery. Ms Whitehouse's survey involved a group of 330 patients, though completed surveys were ultimately only returned by 311 patients. It is unnecessary to consider further the results of Ms Whitehouse's survey. The real significance of her survey was that ultimately the profile of claimants

revealed by the survey was one of the important inputs used in Mr Atkins' actuarial assessment of compensation amounts under the settlement scheme.

77 Mr Atkins expressed three opinions that were important in considering the reasonableness of the settlement sum and settlement scheme. First, Mr Atkins expressed the opinion that his best actuarial assessment of the ultimate number of eligible claimants under the settlement scheme was 2,018 (2,350 people, less 332 people who had opted out of the proceedings). Second, Mr Atkins' preliminary assessment of the compensation amounts likely to be assessed as payable to eligible claimants according to the terms of the scheme was $276 million. Mr Atkins noted, however, that the preliminary estimate was not sufficiently reliable to determine the pro rata amounts that would ultimately become payable to eligible group members who elected to have their compensation assessed (as opposed to opting for a fast track payment). Third, and subject to the qualification just referred to, if the preliminary estimate was accurate, Mr Atkins calculated that the settlement sum of $250 million would suffice to pay assessed compensation at a rate of 69 cents in the dollar. In simple terms, Mr Atkins' actuarial assessment was that eligible claimants would ultimately receive almost 70 percent of the compensation assessed as payable to them under the scheme. Mr Atkins also prepared a financial model of the distribution of the settlement fund that provided a forecast of future cash flows into and out of the fund. He indicated his willingness to continue to provide actuarial advice and assistance in relation to the administration of the settlement scheme going forward if it was approved by the Court.

78 The expert report of Mr Nicholas addressed the following questions in relation to the costs and disbursements charged or claimed by each of the law firms retained by the representative applicants: the reasonableness or otherwise of the terms of the respective fee and retainer agreements; whether the fees and disbursements charged had been calculated in accordance with the fee and retainer agreements; whether any significant portion of the fees and disbursements charged were inappropriately or unnecessarily charged or incurred in conducting the representative proceeding; whether the fees and disbursements were of an unreasonable amount having regard to the nature of the work performed, the time taken to perform the work, the seniority of the persons undertaking that work and the appropriateness of the charge out rates; and whether, if any work was unreasonable in the circumstances, the group members could be considered to have approved (explicitly or impliedly) the costs claimed.

79 It is unnecessary to detail Mr Nicholas' answers to those questions. It is sufficient to note that Mr Nicholas effectively certified total costs and disbursements of $36,856,243.95 as being reasonable for work that had been performed by the four law firms and persons (including counsel) retained by them. This was slightly less than the amount that had been claimed by the law firms; together they had lodged claims totalling approximately $40 million. The main difference was the disallowance of a claim for interest by two of the law firms.

GROUP MEMBER OBJECTIONS

80 Group members were notified of the proposed settlement by way of a Court approved settlement notice. That notice was sent by post and email to group members who had registered with the four firms of solicitors who acted for Mrs Stanford, Mr Dunsmore, Ms Beentjes and Mr Webb. The notice was also published on a number of websites. In response, the firms received many hundreds of queries concerning the registration process in respect of the proposed settlement, the eligibility criteria and the process by which compensation would be assessed, including the fast track option.

81 The evidence of Mr Schimmel and Ms Jancauskas was that many group members who contacted their firms expressed relief and gratitude in respect of the proposed settlement. As at 17 June 2016, 1,175 group members had registered to participate in the settlement.

82 There were, however, a number of group members who opposed the settlement. Thirty six written notices of objection to the proposed settlement were received by the applicants' solicitors. The written objections were annexed to Mr Schimmel's affidavits. The common themes of the objections will be addressed shortly.

83 At the hearing of the approval application, 14 group members, or persons speaking on their behalf, appeared and addressed the Court orally in relation to their opposition to the settlement. Some of these group members had previously provided written objections. Others had not. Their speeches were, almost without exception, poignant, impassioned and forceful. It was impossible not to be moved by some of the heart-rending stories of loss and suffering, and impressed by the courage shown by some of the group members who spoke against the settlement. The group members who spoke succeeded in putting a human face to the subject-matter of the proceeding and the approval application. They also raised some valid and important points about the settlement from their perspective. Their participation in the process was welcome and appreciated.

84 Two points should be made before considering some of the specific arguments advanced by these group members.

85 First, the group members who objected to the settlement, both orally and in writing, ultimately represented a relatively small minority of the group members. As has already been noted, the majority of group holders either expressed no opposition to the settlement, or expressed satisfaction with the settlement, either directly to the solicitors or implicitly by registering to participate in the settlement. Just as it was important to listen and have regard to the views of the vocal opponents of the settlement, it was equally important to have regard to the apparent views or wishes of the mostly silent majority.

86 Second, the impression that one gained was that the group members who did appear in opposition to the settlement were not fairly representative of the cohort of group members as a whole. Rather, they tended to be the group members who had endured the most pain, suffering and loss arising from (in their case) the ASR implant and subsequent revision surgery and other complications. As was observed during the hearing, they were, in many respects, the "worst of the worst". Their descriptions of how their lives had been changed following the ASR implants suggested that no amount of money could adequately compensate them for the catastrophic pain and suffering they have endured, and continue to endure.

87 Third, in some respects, the opposition to the settlement expressed by some of these group members appeared to be driven as much by emotion and anger, if not hostility, towards DePuy and Johnson & Johnson Medical, and the approach that those companies and their representatives had taken to the litigation and settlement. That is not intended to be a criticism of the group members who spoke so powerfully about their anger and frustration concerning the process. It is perfectly understandable that some of the group members felt that way. At the end of the day, however, approval of the settlement must be approached calmly, rationally, without undue emotion, and with the interests of the group members as a whole firmly in mind.

88 Following is a brief summary of some of the main points of objection raised by some of the group members, balanced, where appropriate, against any available response or explanation that was the subject of evidence or explanation by the applicants' lawyers. Further consideration will also be given to some of these points in the context of the consideration of the overall reasonableness of the settlement.

The eligibility criteria

89 Many of the objections related in one way or another to the eligibility criteria. As has already been noted, the eligibility criteria were an important consideration in relation to the reasonableness of the settlement. On the one hand, group members who do not meet the eligibility criteria will not be able to claim compensation under the settlement scheme, but will nonetheless be bound by the settlement, including the releases. On the other hand, if the eligibility criteria are loosened and more group members become eligible to claim compensation, the percentage of the assessed compensation amounts that eligible group members will actually receive from the available settlement funds will most likely be reduced. That is apparent from the analysis conducted by Mr Atkins.

90 Some of the objections related to the requirement in the original settlement scheme that to be eligible for compensation a group member had to have undergone actual revision surgery. At least nine group members objected on the basis that, although their surgeons had recommended that they undergo revision surgery, they were unable to undergo the surgery because of medical complications. Other objections related to the original ten year cut-off date. One group member also raised an objection concerning the original settlement scheme definition of an ASR revision, which referred to the surgical removal of the "acetabular cup". The settlement scheme was subsequently amended to address each of those issues in line with the expert opinion of Professor Crawford. Group members who were unable to undergo revision surgery for medical reasons were eligible on the basis they had undergone deemed ASR surgery. The initial ten year cut-off period was also increased to 13 years, a period that was reasonable in Professor Crawford's opinion. The definition of ASR revision was expanded to include the removal of any one or more components of an ASR implant.

91 Some group members who had not yet undergone revision surgery objected on the basis that eligibility should not be based on the group member having had revision surgery, be it actual or deemed. Some of these objectors complained that they had suffered stress arising from their uncertainty about whether their prosthesis would fail or not. Others claimed that despite the fact that they had not had revision surgery, they nonetheless had been exposed to unknown dangers, including exposure to elevated metal ion concentrations and associated complications said to arise from the ASR implants.

92 The applicants made a number of points in relation to those objections. Each of those points supported the inclusion of eligibility criteria based on the group member having undergone an ASR revision as defined within 13 years of the original ASR implant surgery.

93 First, the essence of the case pleaded against DePuy and Johnson & Johnson Medical was that design defects in the ASR implants gave rise to an increased risk of premature revision. The purpose of the settlement should, in those circumstances, be to compensate group members who have suffered compensable injury arising from premature revision.

94 Second, the expert evidence of Professor Crawford was that the requirement that eligible group members must have undergone an ASR revision, as defined in the settlement scheme, was reasonable. The ASR implants appeared to continue to function in a satisfactory way in some patients, meaning that there was no need for revision. In those circumstances, the applicants suggested that it was difficult to see why patients who had not had to undergo revision surgery should be entitled to compensation under the settlement scheme.

95 Third, insofar as the complaints concerning elevated metal ion concentrations were concerned, it would appear that the question whether elevated metal ion complications caused systematic complications was highly contested at trial and far from clear. Professor Crawford's evidence was that systemic toxicity may be a reason for revision, however it is rare. If a group member requires a revision within 13 years because of elevated metal ion concentrations, he or she will be eligible under the settlement scheme, but that is because of the need for revision, not because of the toxicity itself.

Adequacy of the settlement sum

96 A number of group members objected to the settlement on the basis that the settlement sum of $250 million was inadequate. There were a number of elements to those objections. Some group members simply asserted that the settlement amount was manifestly inadequate, particularly having regard to the number of group members who are likely to be entitled to claim compensation. Others pointed out that the settlement sum compared unfavourably with the settlement that was reached in the United States. The objections based on the settlement of the class action in the United States will be dealt with separately. Other group members referred to the inadequacy of the settlement sum when compared to the amount of the legal costs payable to the lawyers who acted for the representative applicants and the administration costs. The reasonableness of the legal costs will also be dealt with separately.

97 A related and, with respect, pertinent and powerful objection referred to by a number of group members concerned the inherent uncertainty of the settlement insofar as actual recoveries by group members was concerned. On the one hand, the settlement sum was fixed at $250 million. On the other hand, there was no certainty concerning the number of group members who are, or will be, eligible and who will register under the settlement scheme. Nor is there any certainty concerning the amounts that may be assessed as payable to eligible group members under the scheme. The greater the number of eligible group members who register, and the larger the assessed claims of those group members, the more likely it is that the settlement sum will be insufficient to meet the aggregate assessed compensation claims of eligible group members under the scheme. Group members will then ultimately only receive a percentage of their assessed compensation claims.

98 There could be no doubt that this was a legitimate concern for the group members. It was perfectly understandable that group members would be concerned about the uncertainty inherent in the settlement as far as they were concerned. The inherent uncertainty in the settlement in this regard was apparent from the evidence of Mr Atkins. As some group members pointed out, the settlement gave certainty to DePuy and Johnson & Johnson Medical, who are simply required to pay a fixed amount. It does not, however, provide any certainty to the group members. Those concerns will be addressed later in the context of the overall reasonableness of the settlement.

The United States settlement

99 It is necessary to say something briefly concerning the settlement of the United States class action in the context of the objections based on the adequacy of the settlement sum.

100 It is not at all difficult to see why some group members felt a profound sense of injustice and discontent when they compared the settlement of these proceedings with the settlement that had been reached in the class action in the United States concerning the ASR implants. At first blush at least, members of the class of persons affected by ASR implants in the United States appeared to obtain a much better result than they did in Australia. Why did DePuy settle the proceedings before trial in the United States, but vigorously defend the proceedings almost to the bitter end in Australia? Why did DePuy take a different approach to the litigation in the United States? Why was DePuy apparently willing to pay so much more to litigants in the United States?

101 Despite the superficial attraction of comparing the settlement of this matter with the settlement achieved in the United States, it was necessary to approach this issue with considerable caution. That was so for a number of reasons.

102 First, a comparison of the settlement in this proceeding with settlements reached in other jurisdictions was, strictly speaking, not relevant to the Court's consideration of whether the settlement should be approved. The question for the Court in this approval application was, in simple terms, whether the settlement of this particular representative proceeding was, in all the circumstances, fair and reasonable to the group members as a whole as a matter of Australian law. That necessarily involved a consideration of the laws in this jurisdiction that bore upon the potential liability of the respondents, the assessment of damages, and the conduct and settlement of representative proceedings generally. There could be little doubt that that there were material differences between the laws in Australia and the laws in the United States that governed the respective proceedings and their settlement. There may well also have been significant differences between the facts, circumstances and allegations in the proceedings that were settled in the United States and the specific facts, circumstances and allegations in these proceedings. At a more general level, there are also obvious and fundamental differences between important aspects of the systems of justice in the United States and Australia. To give but one example, actions such as this are, for the most part, tried before juries in the United States. They are invariably tried by judge alone in Australia.

103 Second, what at first may have appeared to be a huge gulf between the settlement sum in the United States class action ($2,475,000,000) and the proposed settlement in Australia ($250,000,000), upon close analysis turned out to be not so significant, at least insofar as the amounts ultimately received by claimants was concerned. It was necessary to have regard to a number of apparent differences between the two settlement schemes. Those differences were a product not only of the different class action regimes in Australia and the United States, but also different terms and conditions in the settlement schemes themselves.

104 The parties adduced some, albeit fairly limited, evidence concerning the United States settlement. There were some apparent differences between that settlement, and the settlement scheme in this matter. They included the following:

(a) The class action in the United States related to about 8,000 claimants who had their ASR implants in place for 8 years or less. Claimants who had their ASR implants in place for more than 8 years were not eligible to participate in the

settlement. The settlement of this matter was likely to involve just over 2,000 eligible group members who had a revision within 13 years.

(b) The settlement in this matter required DePuy and Johnson & Johnson Medical to pay not only the settlement sum of $250 million, but also pre-settlement interest. Pre-settlement interest had been estimated to amount to $781,370. The settlement fund will also earn interest during the course of the settlement administration. Mr Atkins calculated that almost $10 million will be earned in interest during the course of the settlement. That amount can be applied to pay assessed compensation. In contrast, the defendants in the United States settlement retain the settlement funds until individual claimants have been assessed. Payments are made on a rolling basis. It would appear, therefore, that the settlement sum in the United States settlement does not earn interest that can be applied for the benefit of the claimants.

(c) The United States settlement involved a "base payment" of $250,000 per hip. Various amounts were, however, to be deducted from that amount, including administration costs and attorneys' contingency fees, which vary by jurisdiction but can be as high as 50 percent of the amount of compensation payable. The base payment was also subject to certain other pre-set negotiated reductions, including an amount based on the time that the ASR device was "in situ". The in situ deductions revert to the defendants and can be as high as 40 percent, in the case where the ASR implant was revised between 7 and 8 years after implantation. Other deductions from the base payment include amounts based on the claimants' age, body mass index, smoking status and other factors. The minimum base payment where the length of implantation was more than 5 years was $150,000 per hip for represented claimants and $177,000 per hip for unrepresented claimants, subject to the pre-set negotiated deductions. Settlement claimants also have the ability to claim "Part B" compensation for certain specified events associated with their revision surgery.

105 In his affidavit evidence, Mr Schimmel estimated that the average payment to a claimant in the US settlement would be $176,426, whereas the average compensation payable to an eligible group member in the settlement scheme in this matter, if approved, would be $101,477. The reliability of Mr Schimmel's estimate of the average payments under the

United States settlement must be said to be somewhat doubtful. A letter from a United States attorney who was involved in the United States settlement, which was tendered by the respondents, tended to cast doubt on at least some aspects or components of Mr Schimmel's estimate. The utility of comparing estimates of average payment per claimant under the respective settlement schemes is also somewhat doubtful. The United States scheme involved a "grid" style payment scheme involving base amounts with pre-set negotiated deductions, as well as deductions for legal and administrative fees, whereas the settlement scheme in this matter involved a settlement fund and at the group members' discretion, either a fast track payment or an assessment process. The eligibility criteria for the respective schemes were also materially different. Nevertheless, the point remained that the ultimate outcome for claimants under the US settlement was unlikely to be nearly as good as what first appeared to be the case. Indeed, the lawyers seemed to be the biggest winners in the United States: the total contingency fees payable to the lawyers was estimated to be somewhere in the vicinity of $775 million. Given that contingency fees payable to attorneys in some states in the United States may be as high as 50 percent, that may have been an underestimate.

106 Third, it would seem that there has been other litigation in the United States concerning ASR implants. The settlement of the class action must be considered in the context of that other litigation. According to the attorney who was responsible for managing the ASR implant litigation in the United States, there have been four trials in the United States concerning ASR implants. Three of those trials proceeded to verdict. The first trial was in a Maryland state court. It did not proceed to verdict as the plaintiff accepted a voluntary dismissal. The second was in a California state court. In that case, there was a verdict for the plaintiff for non-punitive damages of approximately US$8 million, though that verdict was under appeal. The third trial was in a state court in Chicago. That case resulted in a verdict for the defendant. The fourth case post-dated the class action settlement. It resulted in a verdict for the plaintiff for non-punitive damages of approximately US$2 million. That case was also on appeal.

107 If nothing else, the other cases in the United States tended to show why it was dangerous to draw any relevant inferences or conclusions from what has happened in the United States. Class action litigation in the United States is, in short and colloquial terms, an entirely different ballgame. The size of the two awards of damages tends to reveal that the assessment of damages in the United States, at least by juries at first instance, is not subject to the same rigour and constraints as it is in Australia. As Mr Schimmel pointed out in his

affidavit, an award of damages of $8 million for an individual claimant in a product liability case like this matter simply could not happen in Australia. Those awards, and the somewhat inconsistent and unpredictable results in the four trials, also suggest that the litigation risks for a defendant such as DePuy in the United States may be significantly greater than the litigation risk in Australia. That may explain why DePuy may have been willing to settle the class action in the United States before trial and on possibly more favourable terms for the claimants.

108 What flowed from all this was that ultimately there was very little to be gained from undertaking any sort comparison between the two settlements. It was rather like comparing apples with oranges. At a superficial level it may well be the case that the United States settlement appeared to be far more generous, at least for some claimants. There may, however, have been all manner of reasons why that was so. It could also perhaps be said that the United States settlement provided at least some more certainty, or at least less uncertainty, for claimants. By the same token, although the grid style payment system tended to provide some degree of certainty, it may ultimately have been to the disadvantage of certain claimants who, for whatever reason, may have suffered loss or damage that may not be fully compensated by an amount that was not the result of an assessment process, but rather was the product a general formula involving a base payment and pre-set deductions.

109 In any event, for the reasons already given, even if the United States settlement scheme could have been said to be more generous and to provide more certainty, it did not necessarily follow that the settlement arrived at in this matter was not fair and reasonable in all the circumstances.

Adequacy of the fast track payment

110 A number of group members raised objections to the adequacy of the fast track payment of $55,000. The only point that need be made in relation to such objections is that, with the exception of claims by the estates of deceased group members, fast track resolution is entirely optional and at the discretion of individual group members. Any group member not content with the fast track payment can elect to have their claim for compensation assessed through the settlement scheme.

Other objections

111 Other objections to the settlement included that the settlement was on a "no admission" basis; that the fees payable to the lawyers from the settlement sum were unreasonable; that the assessment process under the scheme may take many years; and that the settlement scheme does not involve court appointed assessors.

APPROVAL OF SETTLEMENTS – RELEVANT PRINCIPLES

112 The principles that apply in relation to the approval of the settlement of a representative proceeding under s 33V of the Federal Court Act are now well-settled. Another excursus with detailed reference to the authorities is not required. Following is a brief summary of the key principles which were of relevance to the approval of the settlement in question in this matter.

113 First, in approving a settlement the central question is whether the proposed settlement is fair and reasonable and in the interests of group members considered as a whole: *Australian Competition and Consumer Commission v Chats House Investments Pty Limited* (1996) 71 FCR 250 at 258 C; *Williams v FAI Home Security Pty Ltd (No 4)* [2000] FCA 1925; (2000) 180 ALR 459 at [19]-[23]; *Lopez v Star World Enterprises Pty Ltd* [1999] FCA 104 at [15]; *Camilleri v The Trust Company (Nominees) Limited* [2015] FCA 1468 at [5].

114 Second, there is no definitive or exhaustive list of factors that must or may be taken into account in approving a settlement. The merits of each settlement must be considered having regard to the particular facts and circumstances of the case. Approval should not be approached in a formulaic way, as if there is a "check-list" of factors that need to be ticked-off: *Darwalla Milling Co Pty Ltd v F Hoffman-La Roche Ltd & Ors (No 2)* [2006] FCA 1388; (2006) 236 ALR 322 at 333-335 [33]-[35]. Nevertheless, the factors that are likely to be relevant include: the complexity and duration of the litigation; the stage of the proceedings; the risks and prospects of success of establishing liability and damages; the risks of an appeal; and the reasonableness of the settlement in light of the "best case" recovery and the attendant risks of litigation: see generally *Williams* at [19]; *Modtech Engineering Pty Ltd v GPT Management Holdings Ltd* [2013] FCA 626 at [11] and [13].

115 Third, in relation to the risks and prospects of success of establishing liability and damages, some weight, and perhaps considerable weight, should be given to the judgment and tactical and other decisions made by the parties and their legal representatives. The task of the Court

is not to "second-guess" or go behind those judgments and decisions. Rather, it is to assess the reasonableness of those decisions having regard to the known and knowable facts and circumstances: *Pharm-a-Care Laboratories Pty Ltd v Commonwealth of Australia (No 6)* [2011] FCA 277 at [22], quoting *Darwalla Milling* at 339 [50]; *Modtech* at [12].

116 Where settlement is reached prior to judicial determination, the assessment of the proposed settlement must be undertaken mindful of the unpredictability of the applicant's and group members' fate. In those circumstances, the settlement must be viewed as a pragmatic compromise to the relevant claims. In that regard, the Court should be mindful of the fact that the parties and their legal representatives are often in a better position to appreciate the risks, and also mindful of the fact that different parties and their lawyers will have different appetites for risk: *Kelly v Willmott Forests Ltd (in liquidation) (No 4)* [2016] FCA 323 at [74].

117 Fourth, approval of a settlement should not be approached as if there is a single outcome that may be seen to be fair and reasonable. Reasonableness is a range, and the question is whether the proposed settlement falls within that range having regard to the known facts and circumstances, not whether it is the best outcome which the Court considers might have been achieved: *Darwalla* at 339 [50]; *Kelly v Willmott Forests* at [74].

118 Fifth, that principle applies both to the reasonableness of any settlement sum and the reasonableness of the structure and workings of any settlement scheme by which a settlement sum is proposed to be distributed among group members. In relation to schemes for the distribution of a settlement sum among group members, a particular concern of the Court is to ensure that the interests of one group member, or one class of group members (in particular the representative applicant or applicants) is not preferred over the interests of other group members: *Chats House* at 258 C; *Rod Investments (Vic) Pty Ltd v Abeyratne* [2010] VSC 457 at [19]. The scheme should operate to achieve a broadly fair division of the settlement sum, treating like group members alike; it should also operate as cost-effectively as possible: *Mercieca v SPI Electricity Pty Ltd* [2012] VSC 204 at [37]-[39].

119 Sixth, there is no definitive or exhaustive list of the factors that may lead the Court to refuse to approve a proposed settlement. The types of factors that may lead the Court to conclude that a proposed settlement is not fair and reasonable and in the interests of group members as a whole include: where the settlement involves group members being bound to terms that may have an adverse effect on them that go beyond the claims and defences in the

representative proceedings, or where the adverse effect is not balanced by any proposed benefit under the settlement; where preparation of the proceedings has been adversely affected by funding or other difficulties not disclosed to group members; where potential conflicts of interest are not properly recognised and addressed in the course of the settlement application; where less than the whole of the costs of the proceeding have been scrutinised and are proposed to be the subject of reimbursement through the settlement fund; and where the prospects of success of the claim are not properly laid before the Court: see *Kelly v Willmott Forests* at [6]-[12].

120 Seventh, in assessing the fairness and reasonableness of the costs component of a proposed settlement, the Court takes a pragmatic approach, seeking some independent verification of the reasonableness of the costs claimed, but not imposing an onerous or exhaustive task upon an applicant: *Courtney v Medtel Pty Ltd (No 5)* [2004] FCA 1406; 212 ALR 311. The Court's task is not to perform a taxation of the fees. Rather, the Court considers whether the fees and disbursements are unreasonable in any respect having regard to, amongst other things, the nature of the work performed, the time taken to perform the work, the seniority of the persons undertaking the work and the appropriateness of the charge out rates of those persons: *Modtech* at [32]. The Court should not approve an amount that is disproportionate, but such an assessment cannot be made on the simplistic basis that the costs claimed are high in absolute terms, or high as a percentage of the total recovery: *Foley v Gay* [2016] FCA 273 at [23]-[24].

121 Eighth, the absence of any objection or opposition to the settlement by any group member or group members is a highly relevant consideration, at least where the Court is satisfied that all group members have been given timely notice of the critical elements of the settlement: *P Dawson Nominees Pty Ltd v Brookfield Multiplex Limited (No 4)* [2010] FCA 1029 at [23]; *Camilleri* at [5(f)]. The same reasoning would most likely apply where only a very small proportion of the group members have objected.

THE SETTLEMENT SHOULD BE APPROVED

122 Applying those principles to the facts and circumstances of this proceeding and the proposed settlement, and having regard to the detailed expert and other evidence laid before the Court by the applicants, the Court concluded that the settlement should be approved. The material before the Court, on balance, demonstrated that the settlement that had been reached was fair and reasonable and was in the interests of group members as a whole. It was in all the

circumstances a reasonable compromise. It did not unfairly or arbitrarily discriminate against or prefer the interests of one class of group members over the interests of others.

123 That is not to say that this conclusion was arrived at easily and without some solicitude. The fears and concerns that were expressed by some group members were real and understandable; no more so than in relation to the element of uncertainty that was inherent in the settlement from their perspective. Anxious consideration was given to that concern, as well as all of the other criticisms of the settlement made by the objecting group members. At the end of the day, however, the whole of the evidence and other material before the Court, including the confidential evidence, supported approval of the settlement.

124 This was undoubtedly a unique and somewhat unusual settlement. It was reached some months after a long, hard-fought and complex trial had been concluded and tens of millions of dollars had been expended in legal costs. Intuitively, it could perhaps be said that the applicants' case appeared to be very strong. It was objectively supported by statistics and supported by expert witnesses of the highest calibre. It is, however, equally fair to say that every element of the applicants' case – every aspect of the chain of logic that would have led to the applicants' success – was the subject of extensive and vigorous challenge. Virtually nothing was conceded. That is not intended to be a criticism. DePuy and Johnson & Johnson Medical were well represented and were entitled to take any, indeed every, reasonable point, both legal and factual, that was available to them in their defence. The points that they took appeared to be far from weak, spurious or unsupportable. For the most part, their factual defences were supported by expert witnesses of equal calibre to the applicants' expert witnesses. And even putting liability to one side, there was a vast chasm between the parties' submissions in relation to the assessment or quantum of damages.

125 The point is that, despite a 17 week trial, and despite the applicants' intuitively strong case, there remained considerable uncertainty and risk for the applicants and group members in terms of the outcome of the trial. And the stakes were very high indeed. To put it bluntly, the risk of the applicants failing completely could not be excluded. That would have meant no recovery by the applicants and group members at all, and the likelihood of an adverse costs order against the applicants for potentially many millions of dollars. Nor was it possible to exclude the risk that, even if successful on liability, the applicants might have obtained a materially lower award of damages than they contended for. That too may have had implications for the group members as a whole.

126 Even if they succeeded in respect of some or all of the common issues in respect of liability and quantum, the applicants faced an almost inevitable appeal. And even if successful on any appeal, if the matter was to be litigated to finality it would have been necessary for a further trial, or most a series of further trials, to be conducted in relation to the assessment of damages for the group members other than the applicants. Those group members would have been required to marshal their own suite of lay and expert witnesses in relation to the assessment of their damages claims. That would most likely have been time consuming, expensive and stressful, particularly if the respondents continued to adopt the approach they had taken at the trial in respect of the common issues.

127 In those circumstances, it was perhaps not surprising that the applicants and their legal advisers continued to pursue the option of settling the matter after the conclusion of the trial and while the trial judge's judgment was reserved. It should be noted again, in this regard, that the solicitors who were primarily responsible for the conduct of the proceedings and the settlement negotiations on behalf of the applicants were highly experienced and qualified in the conduct of complex representative proceedings on behalf of applicants.

128 In considering the reasonableness and fairness of the settlement, the following matters needed to be considered: the reasonableness of the settlement sum; the fairness and reasonableness of the distribution of the settlement sum (the settlement scheme); the reasonableness of the releases; the reasonableness of the legal fees and other costs and expenses; the reasonableness of the reimbursement payments; and the reasonableness of other terms of the settlement, including the fact that it was on a "no admission of liability" basis.

The reasonableness of the settlement sum

129 Was the global settlement of sum of $250 million a reasonable compromise of the group members' claims, having regard to all the known facts and circumstances?

130 This was, in many respects, the most difficult issue. That was so for a number of reasons. First, as already discussed, complex questions of fact and law were involved in the assessment of the applicants' damages; second, the precise number of group members who had suffered compensable loss and damage was unknown; third, there was no "one size fits all" formula that could be applied to ascertain the loss and damage suffered by individual group members, so even if the precise number of group members was known, it would still not have been possible to come up with an amount reflecting aggregate or global damages;

and fourth, it was necessary to apply to any estimate of the global damages a discount to reflect the compromise in all the circumstances.

131 The applicants approached the reasonableness of the settlement sum in two ways. First, they adduced confidential evidence from Mr Slade and tendered the confidential opinions of Dr Graham SC. Confidential submissions addressing the evidence of Mr Slade and the opinions of Dr Graham were also advanced. Second, they adduced survey and actuarial evidence that sought to deal with some of the uncertainties.

132 It is obviously not possible to say anything further about the evidence of Mr Slade and the opinion of Dr Graham. To do so would risk revealing the substance of what they have said and thereby defeat the confidentiality order. It is, however, possible to say that, in the particular circumstances of this case, the views and opinions of Mr Slade and Dr Graham were deserving of considerable attention and weight. Both were and are highly qualified and experienced in this sort of litigation. Both were intimately involved in the preparation for and conduct of the trial. Both were in a considerably better position than the Court to assess the strengths and weaknesses of the applicants' case, the risks faced by the applicants and group members, the range of possible outcomes and the reasonableness of the settlement. While it must be acknowledged that their opinions were not (and because of the confidentiality orders, realistically could not be) tested or challenged, upon careful and detailed analysis there was no reason to doubt what they said. This was a case where, perhaps more than many others, the Court would not have been justified in second guessing the judgment and opinions of the applicants' lawyers.

133 The reasonableness of the settlement sum was also supported by the survey evidence of Ms Whitehouse which, in turn, informed the expert actuarial assessment of Mr Atkins. The evidence of Ms Whitehouse and Mr Atkins was considered earlier. While Mr Atkins' estimates were highly sensitive to various assumptions (including those derived from Ms Whitehouse's survey) and were therefore heavily qualified, they supported the proposition that the settlement sum, if distributed according to the settlement scheme, would be sufficient to pay about 70 percent of the compensation assessed as payable to every group member in accordance with the scheme.

134 It is important to emphasise again, at this juncture, that the question was not whether the settlement sum was sufficient to ensure that each group member would receive a fair and reasonable estimate of their total damages. That would assume that group members had no

risk in the litigation. The question was whether the compromise embodied in the settlement was a fair and reasonable compromise in all the circumstances. It was necessary to have regard to the litigation risk which, as already discussed, in this matter was, to say the very least, not insignificant. If it was accepted that the process for assessing compensation under the settlement scheme was fair and reasonable (an issue that will be specifically addressed later), and that Mr Atkins' estimate of the global compensation amount under the scheme was a reasonably accurate estimate, the relevant question, put in admittedly simplistic terms, was whether a compromise which involved a discount of approximately 30 percent from the likely global compensation amount was a fair and reasonable compromise, or was at least within the range of fair and reasonable compromises. In all the circumstances, and taking into account the confidential views of Mr Slade and Dr Graham, the answer to that question was in the affirmative: the settlement sum was, in short, a reasonable compromise.

135 Two final matters should be noted in the context of the reasonableness of the settlement sum. First, under the terms of the settlement, DePuy and Johnson & Johnson Medical are also obliged to meet certain categories of health care liens (defined in the settlement scheme as "assumed liens"). No estimate was given of the potential amount or value of those liens. Second, DePuy has already paid approximately $136 million to group members, or third parties on behalf of group members, pursuant to a voluntary reimbursement programme. That programme generally covered the costs of revision operations, at least in the case of patients who underwent revision surgery after August 2010. Those payments were relevant to the question of the adequacy of the settlement. The fact that those amounts had already been paid or reimbursed meant that they will not have to be claimed again by the relevant group members under the settlement scheme.

136 In all the circumstances, the settlement sum, as a key component in the overall settlement, was fair and reasonable. As noted earlier, reasonableness is a range. The settlement sum was within that range.

Reasonableness of key elements of the settlement scheme

137 Was the process for distributing the settlement sum between group members established by the settlement scheme fair and reasonable? The answer to that question involved a number of key elements.

138 The first element was whether the eligibility criteria in the settlement scheme were fair and reasonable. Group members were broadly defined in the proceeding. They were not limited

to those who had revision surgery in respect of an ASR implant. As explained in detail earlier, however, to be eligible for compensation under the settlement scheme, a group member must have undergone an ASR revision (not including an ineligible revision) or a deemed ASR revision (as defined) within 13 years of the initial ASR implant surgery. It followed that some group members will not be eligible to receive any compensation under the settlement, but will nonetheless be bound by its terms, including the releases. Was that an unfair or arbitrary result?

139 There was nothing arbitrary or unfair about the eligibility criteria. They were based on and supported by the expert opinion of Professor Crawford. His opinion, in short, was that the criteria were fair and reasonable. The fairness of the criteria was also supported, to an extent, by common sense and reason. It would be somewhat unfair to group members who had undergone significant surgery to replace a non-performing ASR implant if group members who had not had, and did not need, revision surgery within 13 years were nevertheless able to obtain an award of compensation. The introduction of the eligibility criteria into the scheme distinguished appropriately, and not arbitrarily, between group members who had a reasonable hope and expectation of establishing compensable damages in these proceedings, as against those who did not.

140 The second element concerned the means by which eligible group members could access the amount of compensation payable to them under the settlement scheme. Eligible group members are able to elect to receive a fast track settlement of $55,000, or have their compensation determined through an assessment process. The mechanics of the assessment process under the settlement scheme were discussed in detail earlier. The assessment process involves the preparation of claims books and an assessment of a group members' claim by an experienced independent assessor in accordance with the provisions in Part VIB of the Competition and Consumer Act. Was this process fair and reasonable?

141 A number of points may be made concerning the assessment process under the settlement scheme. First, the assessment process is not the only option available to group members. The fast track settlement gives eligible group members the option of taking, at their absolute discretion, a course which avoids the necessity of any assessment process and will result in a prompt payment of a fixed amount. The fast track settlement option may suit group members who have not suffered significant loss or damage, or who would simply prefer an option that

would allow for a more expedient payment of their entitlements under the settlement scheme, without further complications.

142 Second, the assessment process, established for those who do not take the fast track option, appears to be reasonably streamlined, non-adversarial and cost-effective. There are also safeguards built into the scheme in the form of review procedures. The scheme appropriately caters for the differentiated needs and circumstances of eligible group members. It would appear to have been eminently sensible and reasonable for the scheme to adopt the damages provisions of the Competition and Consumer Act, as opposed to state based legislation that might otherwise have been applicable, at least in respect of the cause of action in negligence. It would perhaps be fair to say that the statutory causes of action were the stronger and more substantial causes of action. The adoption of the non-economic damages regime in the Commonwealth statute also resulted in a uniform basis of assessment that avoided potentially arbitrary and disparate results based on the state in which a particular group member may have been supplied with the ASR implant.

143 Overall, while some of the objecting group members criticised aspects of the fast track settlement and the assessment process, there was, with respect, no proper or reasonable basis for concluding that it was arbitrary, unfair or unreasonable in the way it allocated or distributed the settlement sum between eligible group members.

144 The third element concerned uncertainty. It has already been acknowledged that there was a degree of uncertainty and risk associated with a settlement scheme where the total amount of compensation available was fixed, but the number and size of the claims that may ultimately be made under the scheme was not known and not fixed. The applicants adduced expert actuarial evidence which went some way to alleviating that uncertainty, and allowed some assessment of the risk. As already indicated, however, the actuarial estimates were highly sensitive to the assumptions upon which they were based. The uncertainty and risk remained. Was the risk and uncertainty involved unsatisfactory such that the settlement scheme as a whole was unfair or unreasonable?

145 It was, of course, possible to envisage different ways in which the settlement could have been structured. A grid payment system, like the one established as part of the settlement of the class action in the United States, was one example. A number of the objecting group members indicated their preference for a settlement structured in that way. For the reasons already given, however, the Court's task in considering whether to approve a settlement does

not require it to speculate about whether the settlement could have been structured differently, or whether a different or better outcome for the group members may have been achieved if it had been structured differently. The question was whether the structure and likely outcome of the settlement as a whole was fair and reasonable.

146 In all the circumstances, there was nothing inherently unfair or unreasonable in the structure of this settlement. While the settlement scheme involved some uncertainty because the amount available for distribution was capped, but the precise number and profile of eligible group members between whom the settlement sum must be divided was not known, it did not necessarily follow that the settlement scheme was unfair or unreasonable.

147 While the settlement scheme involved risks and uncertainty, so too did the alternative to settlement. It could not be said with any degree of certainty that the applicants (and group members) would necessarily have succeeded if the matter proceeded to judgment (and appeal), or that the award of damages would be for the full amount that the applicants claimed. For the reasons already given, although it could perhaps be said that the applicants' case was intuitively strong, the hard-fought trial nevertheless raised complex and difficult issues of fact and law. There remained a risk that the applicants might have failed altogether in establishing their case, or failed to obtain an award of damages as large as they sought. The uncertainty of the settlement scheme had to be balanced against that risk and uncertainty.

148 The question whether the degree of risk or uncertainty involved in the settlement was unreasonable ultimately overlapped, to a large extent, with the question whether the settlement sum was fair and reasonable. It hinged on the evidence and other material considered earlier in that context, including the cogency and reliability of the survey and actuarial evidence of Ms Whitehouse and Mr Atkins, as well the matters addressed in detail in the confidential evidence of Mr Slade and the confidential opinions of Dr Graham, including the prospects of success and litigation risk. That evidence and material supported the conclusion that the risk and uncertainty involved in the settlement scheme was not such that the settlement as a whole could be said to be unfair or unreasonable.

Reasonableness of the releases

149 No group member objected to the settlement on the basis that the releases were unreasonable. It was nevertheless important to consider this aspect of the settlement.

150 There was no doubt that the releases and the supporting indemnities were broad. Once DePuy and Johnson & Johnson Medical paid the settlement sum, group members released and indemnified not only DePuy and Johnson & Johnson Medical, but also certain specified related and third parties, from any liability arising from or related to the settled representative proceeding, or any matter or allegation that could have been the subject of the proceeding. Were the releases fair and reasonable? Were they are fair price to pay for the compensation received under the terms of the settlement?

151 Two aspects of the releases and indemnities stood out. The first was that the releases and indemnities bound all group members, not just eligible group members who were able to claim compensation under the settlement scheme. Was this arbitrary or unfair to the non-eligible group members? The answer to that question essentially hinged on the reasonableness of the eligibility criteria. That issue has already been addressed in considerable detail. For the reasons given earlier, the eligibility criteria fairly and reasonably limited the group members who were eligible to claim compensation under the settlement scheme to those who had a reasonable hope and expectation of establishing compensable damages in the proceedings, as against those who did not. In the circumstances, it was neither arbitrary nor unfair for ineligible group members to be bound by the releases and indemnities.

152 The second aspect of the releases and indemnities that needed to be considered was that the releases were provided not just to DePuy and Johnson & Johnson Medical, but extended to related and third parties. The releases and indemnities were also not limited to the matters that were the subject of the proceeding, but extended to matters, circumstances or allegations that "could have" been the subject of the proceeding. Were the releases and indemnities so broad as to be unfair or unreasonable?

153 The releases and indemnities were not, in the circumstances, too broad. They were no broader than was necessary to bring finality to this complex litigation. The extent to which they extended beyond the parties and beyond the matters that were the subject of the proceeding was not unreasonable. For example, they were not so broad as to preclude a group member from pursuing a claim for damages against a surgeon or hospital in respect of hip replacement surgery involving an ASR implant if that claim did not involve an allegation that the ASR implant itself was defective or not fit for purpose.

154 In all the circumstances the releases and indemnities represented a fair and reasonable price to pay for the receipt of the settlement sum and to bring finality to litigation concerning ASR implants as far as group members were concerned. The releases and indemnities did not provide a reason for refusing to approve the settlement.

Reasonableness of the legal costs

155 There was no denying that the legal costs and disbursements payable out of the settlement funds were significant. Indeed, "significant" is perhaps an understatement. It was perhaps not surprising that a number of the objecting group members felt aggrieved by the amount of money that was to be paid to the lawyers from the settlement fund. It must be recalled, however, that the proceeding was difficult and complex and called for highly experienced and qualified solicitors and counsel. The trial ran for 17 weeks. No doubt the work involved in preparing the matter for trial was substantial.

156 Of perhaps more significance was the fact that an independent legal costs expert had verified that the retainer agreements and the work performed pursuant to them was reasonable. But for some minor matters (including a claim for interest by two of the firms), the amounts claimed by the firms had been verified as reasonable. As noted earlier, the total amount verified as reasonable was $36,856,243.95.

157 As discussed earlier in the context of the relevant principles, the Court's role in approving a settlement does not include performing an assessment or taxation of legal costs. Careful attention was given to Mr Nicholas' report. The questions asked of Mr Nicholas were reasonable and apposite, the materials provided to him were sufficient and the methodology adopted and applied by him was commercial and reasonable. While various group members complained about the size of the legal fees, there was no direct challenge to, or criticism of, Mr Nicholas' report. There was no reason to reject his opinions and conclusions. Nor was there any basis to substitute the Court's own subjective assessment of a reasonable amount for legal costs for the amounts verified as reasonable by Mr Nicholas. Finally, there was no basis for concluding that the legal fees charged were disproportionate. The fees and disbursements incurred, inclusive of the cost of a 17 week trial, represented only approximately 14.8 percent of the settlement sum. That was not disproportionate in all the circumstances, particularly having regard to the nature of the proceedings.

The reimbursement payments

158 The reimbursement payments sought by the representative applicants were $40,000 each in the case of Mrs Stanford and Mr Dunsmore and $10,000 each in the case of Ms Beentjes and Mr Webb. Those payments were to reflect the time expended and the personal expense incurred by the applicants in prosecuting the proceeding for the benefit of the group members as a whole. The amounts sought were supported by the affidavit evidence of Mr Schimmel (in the case of Mrs Stanford) and Ms Jancauskas (in the case of Mr Dunsmore, Ms Beentjes and Mr Webb). The time spent by the applicants included numerous medical appointments for the purposes of preparation of experts' reports, as well as attendance at conferences with solicitors and otherwise providing information and instructions. The amounts involved represented a miniscule proportion of the settlement sum. No group member objected to the reimbursement payments. They were reasonable and in line with similar payments approved in other representative proceedings.

Objections by group members

159 As has already been noted, 36 group members submitted written objections to the settlement. A number of those group members attended the approval hearing and addressed the Court in powerful and moving terms. Some group members who had not lodged written objections also attended the hearing and addressed the Court, either personally or through a friend or member of their family. Many of the objecting group members raised specific issues or made specific complaints about the terms of the settlement. Others, understandably, simply wanted to tell the Court how profoundly their lives had been adversely affected by complications and surgery arising from ASR implant surgery. That simple message was not lost on the Court.

160 The fact that a number of group members objected to the settlement was undoubtedly a matter that was required to be taken into account. That said, it was perhaps equally significant that only a relatively small proportion of group members objected. There was also evidence that the applicants' solicitors were contacted by many group members who supported the settlement. The evidence was that 1,175 group members had already registered under the settlement scheme by the time the approval application was heard. The available inference was that the vast majority of group members either actively supported, or at least did not oppose, the settlement.

161 It was perhaps not surprising that some group members objected to the settlement, but many others did not. That may simply have been a reflection of the fact that different group

members had different "appetites for risk", to use an expression coined by Murphy J in *Kelly v Willmott Forests* (at [74]). While a number of the objecting group members said that they were prepared to assume the risk associated with holding out for the final judgment (and the almost inevitable appeal), it also appeared that many others did not want to take that risk. It may also have been the case that many group members had simply been worn down by the lengthy and stressful litigation, and wanted to avoid the inevitable further delay if the case was to be fully litigated. The likelihood of further significant delay if the matter was not settled would most likely have been a highly relevant consideration for many of the elderly group members. Still other group members may simply not have had the wherewithal to object to the settlement, in which case it might equally be doubted that they would ultimately have had the wherewithal to press their individual claims in relation to compensation if it came to that.

162 Whatever may have been their precise reason for not objecting, the point remained that it was open to infer that a majority of group members, perhaps the vast majority, saw the settlement as a reasonable compromise that they were prepared to accept. While the vocal minority who did object could not be ignored, nor could the silent majority.

163 Most of the specific points raised by the objecting group members have already been addressed. It remains only to address a few miscellaneous issues.

164 First, a number of the objecting group members were aggrieved by the fact that the settlement was on a "no admissions" basis. They wanted DePuy and Johnson & Johnson Medical to acknowledge and take responsibility for the pain and suffering that they had endured. Such an emotional response was perfectly understandable. It was not, however, a proper or reasonable basis to find that the settlement was not fair and reasonable. Experience suggests that representative proceedings of this type rarely settle on anything other than a no admissions basis. Settlement of proceedings on a no admissions basis is commonplace.

165 Second, many objecting group members pointed to the United States settlement as evidence that this settlement was unreasonable. It was again perfectly understandable that group members would see the United States settlement as setting some sort of benchmark against which the reasonableness of this settlement should have been measured. For the reasons already given, however, the Court was required to consider the fairness and reasonableness of the settlement having regard to the particular facts and circumstances of this matter, not having regard to a case in a foreign jurisdiction involving different laws, a different justice

system, and most likely different facts and circumstances. In any event, it was difficult to compare the settlement in the United States with the settlement reached in this proceeding. On the limited facts available, it seemed that the settlement achieved in the United States may not have been significantly more generous to the settlement reached in this matter, other than perhaps insofar as the United States class action attorneys were concerned. The United States settlement did not provide a proper or reasonable reason for not approving the settlement reached in this proceeding.

CONCLUSION AND ORDERS

166 For all the above reasons, the Court decided to approve the settlement. The approval orders proposed by the applicants were accordingly made, along with a number of uncontentious ancillary orders, including confidentiality orders in respect of some of the evidence.

I certify that the preceding one hundred and sixty-six (166) numbered paragraphs are a true copy of the Reasons for Judgment herein of the Honourable Justice Wigney.

Associate: 

Dated: 1 December 2016