IN THE FEDERAL COURT OF AUSTRALIA (FCA)
NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA
GENERAL DIVISION **No: NSD213/2011**

NOTICE OF FILING

This document was filed electronically in the FEDERAL COURT OF AUSTRALIA (FCA) on 16/05/2014.

DETAILS OF FILING

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File Title:	Tammy Maree Stanford & Anor v DePuy International Limited & Anor
District Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA

Dated: 16/05/2014 **Registrar**

Note

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Form 17
Rule 8.05(1)(a)

Third ~~Second~~ Further Amended Statement of Claim

Amended on 16 May 2014 and filed pursuant to an order made on 16 May 2014

No. NSD 213 of 2011

Federal Court of Australia

District Registry: New South Wales

Division: General

Tammy Stanford and Another

Applicants

DePuy International Limited and Another

Respondents

A. THE PROCEEDING

1. The First Applicant (**Mrs Stanford**) and the Second Applicant (**Mr Dunsmore**) bring this proceeding as a representative proceeding pursuant to Part IVA of the *Federal Court of Australia Act 1976* (Cth):

   (a) in their own right; and

   (b) on behalf of persons (**Group Members**) who had surgery performed on them in Australia to implant one or both of the following implants (**Implants**):

      (i) DePuy ASR Hip Resurfacing System (**ASR Resurfacing Implant**); and/or

      (ii) DePuy ASR XL Acetabular System (**ASR XL Implant**).

Filed on behalf of	Tammy Stanford (First Applicant); Jamie Dunsmore (Second Applicant)		
Prepared by	Ben Slade and Rebecca Jancauskas		
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B. CLAIMS BY THE APPLICANTS IN THEIR OWN RIGHT AND ON BEHALF OF ALL GROUP MEMBERS

The First Applicant

2. Mrs Stanford:

   (a) was born on 26 February 1971;

   (b) at all material times resided in Tasmania;

   (c) is married;

   (d) has two dependant children; and

   (e) is a school teacher.

The Second Applicant

3. Mr Dunsmore:

   (a) was born on 25 August 1964;

   (b) at all material times resided in New South Wales;

   (c) is married;

   (d) has two dependent children; and

   (e) is a house painter.

The Respondents

4. The First Respondent (**DePuy**):

   (a) at all material times:

      (i) was and is a company incorporated under the laws of the United Kingdom;

      (ii) was and is a foreign corporation within the meaning of section 4 of the *Trade Practices Act 1974* (Cth) (***Trade Practices Act***);

   (b) between July 2003 and a date on or about December 2009:

      (i) manufactured the Implants within the meaning of sections 74A(1) and 75AA of the *Trade Practices Act*;

      (ii) did not have a place of business in Australia;

(iii) supplied the Implants in trade or commerce to the Second Respondent (**Johnson & Johnson**).

5. Johnson & Johnson:

(a) at all material times:

(i) was and is a company;

(ii) was and is a trading corporation within the meaning of section 4 of the *Trade Practices Act*;

(iii) did not manufacture the Implants;

(b) between sometime in 2004, when the Therapeutic Goods Administration approved the ASR Resurfacing Implant for use in Australia, and a date on or about December 2009:

(i) imported, or had its agent import, the ASR Resurfacing Implant into Australia;

(ii) is deemed to be the manufacturer of the ASR Resurfacing Implant for the purposes of sections 74A(4) and 75AB of the *Trade Practices Act*, by reason of the matters pleaded at paragraphs 4(b)(ii), 5(a)(iii) and 5(b)(i) of this Third ~~Second~~ Further Amended Statement of Claim;

(iii) acquired the ASR Resurfacing Implant from DePuy for re-supply in trade or commerce to hospitals, including hospitals that treated Mr Dunsmore and Group Members, which acquired the ASR Resurfacing Implant for re-supply to Mr Dunsmore and Group Members;

(iv) in trade or commerce supplied the ASR Resurfacing Implant to hospitals;

(v) marketed and distributed the ASR Resurfacing Implant in Australia;

(c) between sometime in 2005, when the Therapeutic Goods Administration approved the ASR XL Implant for use in Australia, and a date on or about December 2009:

(i) imported, or had its agent import, the ASR XL Implant into Australia;

(ii) is deemed to be the manufacturer of the ASR XL Implant for the purposes of sections 74A(4) and 75AB of the *Trade Practices Act*, by reason of the matters pleaded at paragraphs 4(b)(ii), 5(a)(iii) and 5(b)(i) of this Third ~~Second~~ Further Amended Statement of Claim;

(iii) acquired the ASR XL Implant from DePuy for re-supply in trade or commerce to hospitals, including hospitals that treated Mrs Stanford, Mr Dunsmore and Group Members, which acquired the ASR XL Implant for re-supply to Mrs Stanford, Mr Dunsmore and Group Members;

(iv) in trade or commerce supplied the ASR Resurfacing Implant to hospitals;

(v) marketed and distributed the ASR XL Implant in Australia.

The Implants

6. The Implants were designed and manufactured:

(a) to be implanted during hip replacement surgery;

(b) to be used to replace damaged hip joints causing pain and disability;

(c) in such a way that their articulating surfaces were both made of a high-carbon cobalt chromium metal alloy (**Metal**) and, as such, were "metal-on-metal" hip replacement devices (**Metal-on-Metal Devices**).

7. The ASR Resurfacing Implant is a device in which:

(a) the acetabulum is:

(i) reamed;

(ii) has implanted into it an acetabular component variously known as a "Total ASR Acetabular Implant" or an "ASR Acetabular Implant" or an acetabular component known as an "ASR 300 Acetabular Component" (**ASR Acetabular Component**);

(b) the femoral head is:

(i) reamed;

(ii) resurfaced with a Metal cap variously known as a "Total ASR Femoral Implant" or an "ASR Femoral Implant" (**ASR Resurfacing Femoral Component**).

8. The ASR XL Implant is a device in which:

(a) the acetabulum is:

(i) reamed;

(ii) has implanted into it an ASR Acetabular Component;

(b) the femoral head is removed;

(c) a femoral stem is inserted into the femur; and

(d) a Metal femoral implant variously known as an "ASR Unipolar Femoral Implant", "ASR XL Femoral Implant" or an "ASR Uni Femoral Implant" or a Metal femoral implant known as an "ASR XL Anatomic Head" (**ASR XL Femoral Component**) is attached by means of a taper sleeve adapter (**ASR Taper Sleeve**) to the femoral stem.

9. The ASR Resurfacing Femoral Component and the ASR XL Femoral Component have the same:

(a) bearing surface geometry;

(b) bearing surface finish; and

(c) material specifications.

Mrs Stanford's Implant

10. On 17 November 2005, an ASR XL Implant was surgically implanted into Mrs Stanford's left hip during total hip replacement surgery.

Particulars

Mrs Stanford's ASR XL Implant:

(i) *was surgically implanted by Dr John Mills at the Lenah Valley Campus of Calvary Health Care in Tasmania;*

(ii) *comprised the following components:*

(A) *ASR Total Acetabular Implant (Size 48, Standard Duofix);*

(B) *ASR Unipolar Femoral Implant (Size 43); and*

(C) *ASR Taper Sleeve Adaptor (12/14 Taper +2).*

Mrs Stanford was also surgically implanted with a Corail cementless femoral stem without collar.

11. On 17 December 2010 and 22 December 2010, Mrs Stanford was advised that her ASR XL Implant would need to be revised.

Particulars

On 17 December 2010, Mrs Stanford had a consultation with her treating surgeon, Dr John Mills.

In a letter dated 17 December 2010 from Dr Mills to Mrs Stanford's general practitioner, Dr Doris Ng, Dr Mills noted that:

(i) *the ASR acetabular component that had been used in Mrs Stanford's left hip had subsequently been shown to have a higher than expected revision rate;*

(ii) *patients most at risk of problems were those with a small cup size and an inclination angle greater than 45 degrees, and that Mrs Stanford met both of these criteria;*

(iii) *over the past six months Mrs Stanford had had increasing pain and discomfort with clicking and occasional grating in the joint;*

(iv) *clinically Mrs Stanford had grating in the joint with hip movements and her x-rays showed no sign of lysis or other problems with fixation.*

Dr Mills concluded that Mrs Stanford was having signs of impending failure of her prosthesis and was likely to require revision surgery.

On 22 December 2010, after having had an ultrasound, Mrs Stanford had another consultation with Dr Mills. In a letter dated 22 December 2010 from Dr Mills to Dr Ng, Dr Mills noted that the ultrasound showed an increased effusion. Dr Mills stated that given her marked and audible crepitus with abduction of the hip and the effusion, it was highly likely that she was having failure of the metal-on-metal prosthesis.

Dr Mills concluded that he thought it was inevitable that Mrs Stanford will come to revision surgery, and he noted that given Mrs Stanford's level of symptoms she has elected to proceed with the revision surgery sooner rather than later.

12. On 10 January 2011, on the advice of Mrs Stanford's treating orthopaedic surgeon, the ASR XL Implant was surgically removed from Mrs Stanford's left hip and replaced.

Particulars

The ASR XL Implant was removed from Mrs Stanford's left hip by Dr Mills at the Lenah Valley Campus of Calvary Health Care in Tasmania.

A histopathology report in relation to a piece of synovial tissue taken during revision surgery revealed necrotic connective tissue and fibrin with collections of histiocytes.

The operation record in relation to Mrs Stanford's revision surgery notes synovial hypertrophy with metallosis, synovial effusion and lysis behind the acetabular cup, and that Dr Mills performed debridement and a synovectomy before replacing Mrs Stanford's Implant with a DePuy Pinnacle Multihole Acetabular Cup, Biolox Delta Ceramax Ceramic Insert, Biolox Delta TS Rev Articul/eze Ceramic Femoral Head and Pinnacle Cannelous Bone Screw.

On or about 22 January 2011, Mrs Stanford was discharged from hospital following the revision of her ASR XL Implant that had been implanted in her left hip.

Mr Dunsmore's Implants

13. On 14 December 2004, an ASR Resurfacing Implant was surgically implanted into Mr Dunsmore's left hip.

Particulars

Mr Dunsmore's ASR Resurfacing Implant:

(i) *was surgically implanted by Dr Bernard Zicat at Ryde Hospital in Eastwood in New South Wales;*

(ii) *comprised:*

(A) *a DePuy ASR Total Acetabular Implant (size 58mm); and*

(B) *a DePuy ASR Femoral Implant (size 51mm).*

14. In about early February 2009, Mr Dunsmore was advised that he should have revision of his ASR Resurfacing Implant.

Particulars

Sometime after the ASR Resurfacing Implant was implanted into Mr Dunsmore, he experienced:

(i) *pain in his lower back and left groin that intensified over time;*

(ii) *a frequent clicking noise in his left hip whenever he walked or bent down;*

(iii) *frequent headaches for the first time.*

In early February 2009, Mr Dunsmore attended an appointment with Dr Zicat at which:

(i) *Mr Dunsmore informed Dr Zicat of the pain he had been experiencing;*

(ii) *Dr Zicat performed x-rays on the Mr Dunsmore's left hip;*

Dr Zicat subsequently informed Mr Dunsmore (and it was the case) that:

(i) *the ASR Resurfacing Implant was loose;*

(ii) *the ASR Resurfacing Implant had not taken to the bone; and*

(iii) *accordingly, that Mr Dunsmore should have revision surgery as soon as possible.*

15. On 23 February 2009, Mr Dunsmore had revision surgery and total hip replacement surgery during which:

(a) the ASR Acetabular Component was left in place;

(b) the ASR Resurfacing Femoral Component was removed; and

(c) an ASR XL Femoral Component and ASR Taper Sleeve were implanted into his left hip together with a femoral stem, such that Mr Dunsmore now had an ASR XL Implant.

Particulars

Mr Dunsmore's surgery was performed by Dr Bernard Zicat at Concord Hospital in Concord in New South Wales.

16. On 22 December 2010, Mr Dunsmore was advised that his ASR XL Implant would require revision.

Particulars

Immediately after Mr Dunsmore's ASR XL Implant was implanted, Mr Dunsmore experienced pain in his lower back, left hip and left thigh that was similar to, but slightly more intense than, the pain he had experienced in relation to his ASR Resurfacing Implant but which intensified over time.

Some time after the ASR XL Implant was implanted into Mr Dunsmore, he experienced:

(i) *a frequent clicking noise in his left hip;*

(ii) *frequent headaches;*

(iii) *daily bouts of lethargy; and*

(iv) *a deterioration in his eye sight.*

In about late 2010, Dr Zicat:

(i) *informed Mr Dunsmore that the ASR XL Implant had been recalled; and*

(ii) *advised Mr Dunsmore to have a blood test.*

On 22 December 2010, Mr Dunsmore attended an appointment with Dr Zicat at which Dr Zicat:

(i) *informed Mr Dunsmore that the cobalt and chromium levels in his blood were elevated;*

(ii) *informed Mr Dunsmore that his cobalt reading was 94nmol/L and his chromium reading was 113 nmol/L;*

(iii) *advised Mr Dunsmore to have revision surgery on his left hip.*

17. On 19 January 2011, the ASR XL Implant was removed from Mr Dunsmore's left hip and replaced.

Particulars

The ASR XL Implant was removed from Mr Dunsmore's left hip by Dr Bernard Zicat at the Mater Hospital in New South Wales. All of the components of the ASR XL Implant were removed and replaced with a ceramic hip prosthesis.

Supply of the Implants to Group Members

18. Each Group Member was supplied with an Implant by her or his treating hospital or doctor.

Particulars

Particulars may be provided after the trial of common issues.

19. The price of the Implants acquired by Mrs Stanford, Mr Dunsmore and Group Members did not, respectively, exceed $40,000.

Purposes for which the Implants were acquired

20. The Implants were acquired by Mrs Stanford, Mr Dunsmore and Group Members for the purpose (**Purpose**) of:

(a) alleviating pain and disability in a hip joint; and/or

(b) alleviating pain and disability in a hip joint for as long as possible <u>without the need for revision surgery</u>.

Particulars

Mrs Stanford acquired an ASR XL Implant on 17 November 2005 for the purpose of alleviating pain and disability in her hip joint that had been caused by developmental dysplasia and she did so in order to alleviate that pain and disability for as long as possible.

Mr Dunsmore acquired an ASR Resurfacing Implant on 14 December 2004 for the purpose of alleviating pain and disability in his hip joint that had been caused by osteoarthritis secondary to dysplasia in his hip.

Mr Dunsmore acquired an ASR XL Implant on 23 February 2009 for the purpose of alleviating pain and disability caused by the implantation of his ASR Resurfacing Implant.

Particulars of Group Members' acquisitions of their Implants may be provided after the trial of common issues.

21. The Purpose was made known to DePuy and Johnson & Johnson by implication.

Particulars

DePuy and Johnson & Johnson marketed the Implants as being devices that were fit for the purpose of alleviating pain in a hip joint:

- *In the surgical technique manuals published by DePuy in 2004, 2006 and 2008, it was noted that the DePuy ASR system is indicated for total joint replacement in patients with pain and disability secondary to structural damage in the hip joint.*
- *According to its instructions for use, the ASR XL Implant was said to be indicated for patients suffering severe pain and disability due to structural damage in the hip joint.*
- *In an publication entitled 'hole in one' published in 2005, DePuy stated at page 24: "Many patients have enjoyed relief from pain and improved function, compared to their status before surgery".*
- *At page 26, DePuy stated: "You may expect your new joint and wound to be quite painful for up to 12 weeks after your surgery. … The pain will steadily decrease over time as your body heals. Most people find that the pain is negligible by 3 months and some report a continual improvement of their pain up to one year after… In terms of reducing pain and increasing function significantly without complications, many studies have reported that almost all joint replacements have been successful".*

DePuy and Johnson & Johnson marketed the Implants as being devices that were fit for the purpose of enabling increased patient mobility and function in a hip joint:

- *In an undated publication entitled 'High Performance Hip Replacement' DePuy stated in relation to the ASR XL Implant at page 4: "While traditional hip replacement utilized relatively small bearing diameters, it*

is now recognized that a larger ball offers greater range of motion and stability because it is more like the natural hip".

- *In an undated publication entitled 'High Performance Hip Replacement' DePuy stated in relation to the ASR XL Implant at page 4: "for many patients, the DePuy ASR XL Metal-on-Metal Hip System offers significant benefits over a traditional hip replacement. The DePuy ASR XL System uses a larger diameter, high performance metal bearing developed using today's advanced technology. The DePuy ASR XL System allows your surgeon to use a larger replacement ball, more like your natural thigh bone."*

- *In a publication entitled 'DePuy ASR XL Head System' and stated to be issued on 04/05, DePuy stated at page 7: "The DePuy ASR XL Head System can generate excellent range of motion (141° – 156°) across the size range. This increased range of motion, minimises the risk of dislocation significantly, increasing joint stability and allowing the patient to enjoy a more active and fulfilling life after their operation".*

- *In a publication entitled 'Intelligent Hip Surgery' and stated to be issued in 2005, DePuy stated at page 2: "patients approaching hip replacement surgery want to feel confident that their implant … will allow them to live a full and active life and that they will recover from the operation quickly. That's why we believe that today's Intelligent Hip Surgery should place equal importance on maximising survivorship, optimising function and accelerating recovery".*

- *In a publication entitled 'Intelligent Hip Surgery' and stated to be issued in 2005, DePuy stated at page 4: "Improved joint stability. Natural head size improves joint stability, minimises the risk of dislocation and produces a 154° range of motion for the DePuy ASR XL Head System".*

DePuy and Johnson & Johnson marketed the Implants as having features that would promoted their longevity and reduce the risk of requiring revision surgery:

- *In a publication entitled 'Intelligent Hip Surgery' and stated to be issued in 2005, DePuy stated at page 2: "patients approaching hip replacement surgery want to feel confident that their implant will last as long as possible, will allow them to live a full and active life and that they will recover from the operation quickly. That's why we believe that today's Intelligent Hip Surgery should place equal importance on maximising survivorship, optimising function and accelerating recovery".*

- *In an undated publication entitled 'Intelligent Hip Surgery' and stated to be issued in 2005, DePuy stated at page 4: "Optimised bearing clearance and measure deflection assures fluid film lubrication and lower wear. Large component diameter and optimised radial clearance*

accounts for cup deflection and assures fluid film lubrication. This leads to a significant reduction in wear compared to third generation resurfacing systems".

- *In an undated publication entitled 'High Performance Hip Replacement' DePuy stated in relation to the ASR Resurfacing Implant at page 5: "The metal caps, placed over reshaped bone, create a metal-on-metal joint. As a result, the joint may experience less friction and less wear than some traditional hip replacement options such as metal-on-plastic".*

- *In an undated publication entitled 'High Performance Hip Replacement' DePuy stated in relation to a picture of the ASR Resurfacing Implant at page 6: "Metal bearing surface reduces wear".*

- *In an undated publication entitled 'High Performance Hip Replacement' DePuy stated in relation to a picture of the ASR XL Implant at page 6: "Large diameter metal ball closely matches natural anatomy and reduces wear".*

- *In a publication entitled 'DePuy ASR XL Head System' and stated to be issued on 04/05, DePuy at page 10 stated: "A DePuy ASR XL Head System head coupled with Corail AMT stem, for example, combines unsurpassed long-term survivorship with lower component wear, improved function and less chance of dislocation".*

- *In the surgical technique manuals published by DePuy in 2004, 2006 and 2008, DePuy stated in each case at page 2:*

  "Advanced implant Performance for enhanced function restoration.

  - Optimised implant tribology and maximised fluid film thickness result in a high performance low wear bearing proven in vitro.

  - Optimised femoral cementing techniques with clinically proven acetabular fixation provide long-term implant stability.

  - The unique tapered internal geometry combined with slim central guide pin reduces the risk of stress shielding.

  The success of the contemporary Surface Replacement procedure means it is predicted to account for a significant part of all primary procedures in the future and it is now considered an appropriate management option for the following groups of patients:

  - Aged less than 65 years.

  - Aged 65 years and over who participate in activities predicted to shorten the life of a traditional total hip replacement."

- *In a publication entitled 'Articular Surface Replacement' and stated to be issued on 01/05, DePuy stated at page 4 in relation to a picture of the ASR Acetabular Component: "'Optimised bearing clearance and deflection for fluid film lubrication and lower wear".*

- *In a publication entitled 'Articular Surface Replacement' and stated to be issued on 01/05, DePuy stated at page 7: "The DePuy ASR System is engineered to achieve optimum clearance, for fluid film lubrication and significantly improved wear performance".*

- *In a publication entitled 'DePuy ASR XL Head System' and stated to be issued on 04/05, DePuy at page 3 promoted the ASR XL Implant as "maximising survivorship".*

- *In a publication entitled 'DePuy ASR XL Head System' and stated to be issued on 04/05, DePuy stated at page 5: "The DePuy ASR XL Head System is designed and manufactured to ensure optimal clearance to allow a film of joint fluid to flow across, and lubricate, the entire bearing surface – measurably lowering wear rates".*

- *In a publication entitled 'DePuy ASR XL Head System' and stated to be issued on 04/05, DePuy stated at page 11: "A DePuy ASR XL Head System coupled with Corail AMT stem, for example, combines unsurpassed long-term survivorship with lower component wear, improve function and less chance of dislocation".*

The design of the Implants

22. The ASR Acetabular Component was designed or manufactured in such a way that it had, among other things, the following features (**ASR Acetabular Component Features**):

    (a) it had a subhemispherical geometry~~, which was approximately seven-eights of a full hemisphere~~;

    (b) it was shallower than the acetabular components in some other Metal-on-Metal Devices;

Particulars

Other Metal-on-Metal Devices include the Birmingham Hip Resurfacing prosthesis manufactured by Smith & Nephew and the Conserve Plus prosthesis manufactured by Wright Medical.

(c) it was made from:

(i) a cast high-carbon cobalt-chromium alloy;

(ii) with a beaded surface that is created by a high-temperature sintering process;

(d) the surface onto which the acetabular bone fixates had a porous ("Porocoat") surface with an average pore size of 250µm and a hydroxyapatite layer that is 30-50µm thick;

(e) the porous coating did not extend to the rim of its surface;

(f) it consisted of a single piece of hardware and in that sense was a "monoblock" cup;

(g) it had a diametral clearance ~~of 110µm~~ prior to insertion of between 100µm and 170µm for the various bearing sizes, each of which was subject to a variance of 20µm between the ASR Acetabular Component and either the ASR Resurfacing Femoral Component or the ASR XL Femoral Component;

(h) it had an internal groove in the bearing surface below the rim to which the instrumentation used by the orthopaedic surgeon for impaction attaches and which:

(i) leaves a sharp edge;

(ii) reduces the functional bearing surface of the subhemispherical surface of the ASR Acetabular Component;

(i) it had a rim chamfer with a radius smaller than other Metal-on-Metal Devices;

(j) it was thinner at the equator than at the pole;

(k) it had a smaller functional bearing surface and arc of cover than other Metal-on-Metal Devices.

Particulars

The arc of cover is given by the product of the component radius and angle in radians subtended between the vertical and the lateral acetabular component edge.

The ASR Acetabular Component has an arc of cover of between 144-160°, depending on the diameter of the cup of the component.

The ASR Acetabular Component has a smaller arc of cover than the acetabular component of the Birmingham Hip Replacement manufactured by

Smith & Nephew that has an arc of cover of between 158-165°, depending on the diameter of the cup of the component.

The ASR Acetabular Component has a smaller arc of cover than the acetabular component of the Conserve Plus prosthesis manufactured by Wright Medical Technology that has an arc of cover of between 162-165°, depending on the diameter of the cup of the component.

The diametral clearance between the ASR Acetabular Component and either the ASR Resurfacing Femoral Component or the ASR XL Femoral Component prior to insertion varies across the Implants' size range. The clearance remains constant at 100µm for femoral head sizes from 39mm to 53mm and increases thereafter up to 170µm for the 63mm head size. The diametral clearances were subject to a variation of 20µm.

23. The Implants functioned in such a way that they had, among other things, the following characteristics (**ASR Characteristics**):

(a) by reason of some or all of the ASR Acetabular Component Features, the Implants were susceptible to:

(i) suboptimal positioning of the ASR Acetabular Component by orthopaedic surgeons;

(ii) deformation of the ASR Acetabular Component during the impaction into the acetabulum;

(iii) disruption of the process of fluid film lubrication;

(iv) the ASR Acetabular Component functioning as if it had been implanted at a higher angle of inclination;

(v) "edge loading" whereby contact between the ASR Acetabular Component and either the ASR Resurfacing Femoral Component or the ASR XL Femoral Component would occur close to the edge of the ASR Acetabular Component;

(vi) excessive wear of the Metal articulating surfaces of the ASR Acetabular Component and either the ASR Resurfacing Femoral Component or the ASR XL Femoral Component;

(vii) ions of cobalt and chromium being released ~~from the metal wear debris~~ from the Implants into the blood and synovial fluid of the patient;

(viii) damaging the soft tissues surrounding the hip joint as a result of wear debris;

(ix) osteolysis or damage to the hip bones as a result of wear debris;

(x) failure of bony ingrowth into the porous surface of the ASR Acetabular Component;

(xi) loosening of the ASR Acetabular Component;

(xii) inadequate fixation of the ASR Acetabular Component into the acetabulum.

(b) in the case of the ASR Resurfacing Implant,

(i) it was susceptible to fracture of the patient's femoral neck; and

(ii) it was susceptible to loosening of the femoral component.

(c) in the case of the ASR XL Implant:

(i) it was susceptible to fretting, corrosion or wear at the junction between the ASR Taper Sleeve and the ASR XL Femoral Component; and

(ii) it was susceptible to impingement of soft tissue against the ASR Acetabular Component.

24. As a result of any or all of the ASR Acetabular Component Features or the ASR Characteristics or in any event, the Implants had an increased risk of:

(a) ~~wearing out~~ requiring revision earlier and/or at a higher rate; and/or

(b) causing pain and/or disability.~~; and/or~~

~~(c) requiring early revision,~~

compared overall to other hip replacement prostheses used in the period between July 2003 and December 2009 (**Defects**).

Particulars

Wear of the Implants

The rate and volume of wear may vary from patient to patient.

The following wear rates were calculated and reported during 2011 for a series of patients who had been implanted with the ASR Resurfacing Implant and who had suffered an adverse reaction to metal debris:

- *the ASR Resurfacing Femoral Component exhibited a mean wear at a rate of 8.30mm^3/year and a mean wear volume of 19.22mm^3/year;*
- *the ASR Acetabular Component exhibited a mean wear at a rate of 9.26mm^3/year and a mean wear volume of 19.30mm^3/year;*

- *the combined mean wear rate for the ASR Resurfacing Femoral Component and the ASR Acetabular Component was 17.64mm^3/year and the combined mean wear volume was 38.69mm^3/year.*

The following wear rates were calculated and reported during 2011 for a series of patients who had been implanted with the ASR Resurfacing Implant and who had suffered fracture of the femoral neck following an adverse reaction to metal debris:

- *the ASR Resurfacing Femoral Component exhibited a mean wear at a rate of 14.53mm^3/year and a mean wear volume of 56.49m^3/year;*

- *the ASR Acetabular Component exhibited a mean wear at a rate of 36.75mm^3/year and a mean wear volume of 142.94mm^3/year;*

- *the combined mean wear rate for the ASR Resurfacing Femoral Component and the ASR Acetabular Component was 68.50mm^3/year and the combined mean wear volume was 271.21mm^3/year*

In a different series of patients who had been implanted with the ASR Resurfacing Implant and who had suffered an adverse reaction to metal debris, the volumetric wear rate has been calculated and reported during 2011 to be between 2.30mm^3/year and 95.5mm^3/year.

In a series of patients who had been implanted with the ASR XL Implant and who had suffered an adverse reaction to metal debris, the volumetric wear rate has been calculated and reported during 2011 to be between 1.27mm^3/year and 24.08mm^3/year.

The following wear rates were calculated and reported for a series of patients who had been implanted with the ASR Resurfacing Implant in comparison to a major competitor, namely the Birmingham Hip Resurfacing manufactured prosthesis:

- *the ASR Acetabular Component exhibited a mean linear wear rate of 9.2µm/year and a mean linear wear depth of 21.992µm compared to a mean linear wear rate of 4.2µm/year and a mean linear wear depth of 14.9µm for the acetabular component of the Birmingham Hip Resurfacing prosthesis;*

- *the ASR Resurfacing Femoral Component exhibited a mean linear wear rate of 6.0µm/year and a mean linear wear depth of 13.14µm compared to a mean linear wear rate of 3.5µm/year and a mean linear wear depth of 15.07µm for the femoral component of the Birmingham Hip Resurfacing prosthesis.*

The out-of-roundness values of the ASR Acetabular Components among a series of patients who had suffered pain and effusion following implantation of

an ASR Resurfacing Implant were reported during 2011 to have ranged from 17.7µm to 91.8µm compared to out-of-roundness values of 1.7µm to 3.1µm for patients who had suffered an early fracture within eight months of implantation.

The wear of the ASR Resurfacing Implant is greater than the Birmingham Hip Resurfacing manufactured prosthesis.

Causing pain and disability

Increased metal wear from metal-on-metal hip resurfacing prostheses is associated with an increased probability of adverse clinical outcomes, including severe destruction of soft tissues and bony necrosis.

High ion levels in the blood of patients are associated with effusion and pain in patients who had been implanted with the ASR Resurfacing Implant.

Soft tissue reaction to particulate metal debris can cause fluid or mass formation with subsequent destruction of soft tissues and bone resorption leading to loosening of the implant or fracture of the femoral neck.

There is a correlation between metal wear and delayed fracture of the femoral neck among patients with extremely high levels of metal ions or wear from the bearing surfaces of the ASR Resurfacing Implant.

If the failure of a patient's Implant requires its revision, the surgery is ordinarily performed under general anaesthetic. During the post-operative recovery period the patient ordinarily suffers pain and a degree of disability and also experiences limited hip joint function, often for a period of several months.

Early revision of the Implants

Revision that occurred within ten years of implantation of a hip replacement is widely accepted to be early revision.

*In 2007, the Australian National Joint Replacement Registry (**NJRR**) reported that the ASR Resurfacing Implant had a revision rate of 5.16% compared to the revision rate for other resurfacing hip replacements of 2.35%.*

In 2008, the NJRR reported that:

- *the ASR Resurfacing Implant had a three year cumulative percentage revision rate of 4.5% compared to the revision rate for other resurfacing hip replacements of 2.5%; and*
- *the ASR XL Implant had a three year revision rate of 6% when used with the Corail femoral stem compared to the revision rate for other total hip replacements of 2.9%.*

In 2009, the NJRR reported that:

- *the ASR Resurfacing Implant had a five year revision rate of 8.7% compared to the revision rate for other total resurfacing hip replacements of 4.1%; and*

- *the ASR XL Implant had a three year revision rate of 5.4% (regardless of the femoral stem with which it was used) compared to the revision rate for other total hip replacements of 2.6%.*

In an Urgent Field Safety Notice dated 8 March 2010, DePuy reported that:

- *the ASR Resurfacing Implant and the ASR XL Implant had a higher than expected revision rate linked to the usage of the ASR Acetabular Component with corresponding femoral head sizes less than 50mm in diameter;*

- *the NJRR had reported a cumulative percentage revision rate of 5.4% at three years for the ASR XL Implant; and*

- *recent published and unpublished data suggested that the revision rate for the ASR XL Implant may be higher in cohorts where a large proportion is female or has small acetabula and that femoral components less than 50mm are associated with a revision rate of 8-9% at three years.*

In a Safety Alert Notice issued in about March or April 2010, Johnson & Johnson reported that:

- *the ASR Resurfacing Implant and the ASR XL Implant had a higher than expected revision rate linked to the usage of the ASR Acetabular Component with corresponding femoral head sizes less than 50mm in diameter;*

- *the NJRR had reported a cumulative percentage revision rate of 5.4% at three years for the ASR XL Implant; and*

- *recent published and unpublished data suggested that the revision rate for the ASR XL Implant may be higher in cohorts where a large proportion is female or has small acetabula and that femoral components less than 50mm are associated with a revision rate of 8-9% at three years.*

*In a Medical Device Alert dated 25 May 2010, the Medicines and Healthcare products Regulatory Agency (**MHRA**) reported that the ASR Acetabular Component used with both the ASR Resurfacing Implant and the ASR XL Implant had a higher than anticipated revision rate.*

In an Urgent Field Safety Notice dated 24 August 2010, DePuy reported that the five year revision rate across the entire size was:

- *12% for the ASR XL Implant; and*
- *13% for the ASR Resurfacing Implant.*

In an Urgent Medical Device Hazard Alert dated 30 August 2010, Johnson & Johnson reported that the five year revision rate across the entire size was:

- *12% for the ASR XL Implant; and*
- *13% for the ASR Resurfacing Implant.*

In a Medical Device Alert dated 7 September 2010, the MHRA reported that DePuy had determined that the Implants had a five year revision rate that was higher than expected across the entire size range.

In 2010, the NJRR reported that:

- *the ASR Resurfacing Implant had a five year revision rate of 10.9% compared to the revision rate for other resurfacing hip replacements of 4%; and*
- *the ASR XL Implant had a five year revision rate of 9.3% compared to the revision rate for other total hip replacements of 3.4%.*

In a study published in about February 2011, the following revision rates were reported:

- *9.8% at five years for the ASR Resurfacing Implant;*
- *1.5% at ten years for the Birmingham Hip Resurfacing Implant;*
- *less than 1% at five years for the Conserve Plus hip resurfacing implant.*

In March 2011, the British Orthopaedic Association and the British Hip Society reported that the ASR XL Implant had a six year revision rate of 49% in certain hospitals in the United Kingdom.

In a study published in 2011, the ASR XL Implant was found to have a 40 month revision rate of 11%.

In 2011, the NJRR reported that:

- *the ASR Resurfacing Implant had a seven year revision rate of 13% compared to the revision rate for other resurfacing hip replacements of 5.8%; and*

- *the ASR XL Implant had a five year revision rate of 10.2% compared to the revision rate for other total hip replacements of 3.5%.*

In 2011, the National Joint Registry for England and Wales reported that "the ASR results are noticeably worse than other groups by two years post-surgery".

DePuy's and Johnson & Johnson's knowledge of the Defects

25. DePuy and Johnson & Johnson knew or ought to have known:

(a) from 2006 that the Implants had an increased risk of wearing ~~out earlier and~~ at a higher rate~~ as pleaded in paragraph 24(a)~~;

Particulars

By September 2006, DePuy had received feedback that the design of the ASR Acetabular Component was flawed because it was too thin and the diametral clearance was too small, resulting in the risk of wear.

During 2007, an engineer employed by DePuy or one of its related companies gave a presentation at a medical conference in Dallas in the United States of America in which he reported that, two years after one of the Implants had been implanted, approximately 30% of women and 7.5% of men had markedly raised metal ion concentrations in their blood. Metal ion concentrations were known or should have been known by DePuy to be a surrogate indicator of wear of Metal-on-Metal Devices.

In about June 2008 in response to increasing clinical concern about adverse reactions caused by metal ions and metal debris, DePuy initiated the development of the "ASR Alpha" acetabular component (also known as the "ASR II"), which was a modified and redesigned version of the ASR Acetabular Component. The ASR Alpha was intended to be compatible with the existing ASR XL Femoral Component and the ASR Resurfacing Femoral Component. The development of the ASR Alpha involved removal of the internal groove (identified as an ASR Acetabular Component Feature in paragraph 22(h) above) so that the functional bearing surface (identified as an ASR Acetabular Component Feature in paragraph 22(k) above) was increased. The development of the ASR Alpha also involved reconsideration of the geometry of the rim of the ASR Acetabular Component so as to reduce ion release from the bearing surface and reduce contact stress during microseparation and therefore to reduce wear. Despite laboratory experiments indicating that a prototype ASR Alpha acetabular component had improved wear resistance compared to the existing ASR Acetabular Component at three and four million cycles, the ASR Alpha project was abandoned in about November 2008.

In September 2008, Dr David Langton and colleagues published an article in the Journal of Bone and Joint Surgery *to the effect that higher concentrations of metal ions, which are a surrogate indicator of volumetric wear, had been found among patients who had an ASR Resurfacing Implant smaller than 53mm.*

Members of DePuy's surgical design team acknowledged in 2006 that the true test of the Implants would be in the clinical environment and that the performance of the Implants would take many years to understand fully.

(b) from 2006 that the Implants had an increased risk of causing pain and/or disability as pleaded in paragraph 24(b);

Particulars

DePuy designed and manufactured the ASR Acetabular Components so that they had the ASR Acetabular Component Features. As the importer and distributor of the Implants, Johnson & Johnson knew or ought to have known of the ASR Acetabular Component Features.

DePuy and Johnson & Johnson knew or ought to have known that the Implants had the ASR Characteristics.

DePuy and Johnson & Johnson knew or ought to have known that the early wear of the Implants carried an increased risk of causing pain and/or disability in the patient.

In an Urgent Medical Device Hazard Alert dated 30 August 2010 published by Johnson & Johnson in Australia, it was acknowledged at the time of publication that some patients may develop progressive soft tissue reactions to metal wear debris, which could cause soft tissue damage and may compromise the results of revision surgery.

Members of DePuy's surgical design team acknowledged in 2006 that the true test of the Implants would be in the clinical environment and that the performance of the Implants would take many years to understand fully.

(c) from 2007 that the Implants had an increased risk of requiring ~~early~~ revision earlier and/or at a higher rate as pleaded in paragraph 24(a)~~(c)~~.

Particulars

DePuy and Johnson & Johnson knew or ought to have known about the increased risk of early revision as a result of:

- *a meeting between representatives of Johnson & Johnson and the Therapeutic Goods Administration sometime in September 2007;*

- *the Safety Alert issued by Johnson & Johnson to surgeons in Australia in about October 2007;*
- *17 notices that were issued by the NJRR to DePuy or one of its related companies between sometime in 2007 and sometime in 2009;*
- *the NJRR Annual Report released in October 2007;*
- *the NJRR Annual Report for 2008;*
- *the NJRR Annual Report for 2009;*
- *Urgent Field Safety Notice published by DePuy dated 8 March 2010;*
- *Medical Device Alert issued by the MHRA 25 May 2010.*

Members of DePuy's surgical design team acknowledged in 2006 that the true test of the Implants would be in the clinical environment and that the performance of the Implants would take many years to understand fully.

Discontinuance of supply of the Implants

26. In about December 2009, Johnson & Johnson discontinued supply of the Implants in Australia.

27. In about August 2010, a worldwide recall of the Implants was carried out by or on behalf of DePuy.

Particulars

On or about 24 August 2010, DePuy issued an Urgent Field Safety Notice and conducted a recall of the Implants in the United Kingdom.

On or about 30 August 2010, Johnson & Johnson, in consultation with the Therapeutic Goods Administration, issued an Urgent Medical Device Hazard Alert in Australia concerning the Implants.

The Implants were also recalled in other countries, including Austria, the United States of America, Canada, India, Malaysia, New Zealand, Singapore, South Korea, Thailand, China, Denmark, Germany, Croatia, France, Netherlands, Norway, Poland, Czech Republic, Finland, Sweden, Russia and Turkey.

Trade Practices Act

28. By reason of the matters pleaded in paragraph 6(b) and 20, the Implants were ordinarily acquired for personal use and, as such, are goods within the meaning of sections 4 and 74A(2)(a) of the *Trade Practices Act*.

29. By reason of the matters pleaded in paragraph 19, the Implants were supplied to Mrs Stanford, Mr Dunsmore and Group Members as consumers within the meaning of section 4B of the *Trade Practices Act*.

30. By reason of all or any of the Defects, and the failure to provide surgeons with adequate instructions as to how to position the Implants so as to avoid the Implants' susceptibility to the increased risks pleaded in paragraph 24 above, the Implants acquired by Mrs Stanford, Mr Dunsmore and Group Members were not, within the meaning of section 74B of the *Trade Practices Act*, reasonably fit for the Purpose.

31. By reason of all or any of the Defects, and the failure to provide surgeons with adequate instructions as to how to position the Implants so as to avoid the Implants' susceptibility to the increased risks pleaded in paragraph 24 above, the Implants acquired by Mrs Stanford, Mr Dunsmore and Group Members were not of merchantable quality within the meaning of sections 74D(1) and 74D(3) of the *Trade Practices Act*.

Particulars

The Implants were not of merchantable quality because they were not as fit for the purpose or purposes for which hip replacement prostheses are commonly bought as it is reasonable to expect.

The purposes for which hip replacement prostheses are commonly bought include the alleviation of pain and/or disability as a result of structural damage in a hip joint due to certain conditions including rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, congenital hip dysplasia, protrusion acetabuli, slipped upper femoral epiphytis and disability due to previous fusion and for the relief of pain and disability associated with those conditions and/or the alleviation of pain and/or disability in a hip joint for as long as possible.

Mrs Stanford and Mr Dunsmore refer to and repeat the descriptions applied to the Implants as particularised for paragraph 21 above.

32. Mrs Stanford, Mr Dunsmore and Group Members suffered loss or damage by reason that the Implants were:

(a) not fit for the Purpose as pleaded in paragraph 30; and

(b) further or in the alternative, not of merchantable quality as pleaded in paragraph 31.

Particulars

The loss or damage suffered by Mrs Stanford, Mr Dunsmore and Group Members includes but is not limited to:

- *personal injury, including revision hip replacement, hip arthroplasty or hip resurfacing surgery, soft tissue injury to the hip, metallosis of the hip joint, synovitis of the hip joint and psychiatric injury;*
- *health care expenses and medical monitoring;*
- *other out of pocket expenses;*
- *economic loss;*
- *the need for gratuitous and/or commercial care;*
- *non-economic loss.*

32A. By reason of all or any of the Defects, and the failure to provide surgeons with adequate instructions as to how to position the Implants so as to avoid the Implants' susceptibility to the increased risks pleaded in paragraph 24 above, the safety of the Implants acquired by Mrs Stanford, Mr Dunsmore and Group Members was not such as persons generally were entitled to expect and had a defect within the meaning of sections 75AC(1) and 75AD of the *Trade Practices Act*.

Particulars

Mrs Stanford and Mr Dunsmore refer to and repeat the particulars subjoined to paragraph 24 above.

32B. Mrs Stanford, Mr Dunsmore and Group Members suffered injuries because the Implants had the defect as pleaded in paragraph 32A and suffered loss as a result of those injuries.

Particulars

The injuries and loss suffered by Mrs Stanford, Mr Dunsmore and Group Members includes but is not limited to:

- *personal injury, including revision hip replacement, hip arthroplasty or hip resurfacing surgery, soft tissue injury to the hip, metallosis of the hip joint, synovitis of the hip joint and psychiatric injury;*
- *health care expenses and medical monitoring;*
- *other out of pocket expenses;*
- *economic loss;*
- *the need for gratuitous and/or commercial care;*
- *non-economic loss.*

33. In the premises, DePuy and/or Johnson & Johnson are liable to compensate Mrs Stanford, Mr Dunsmore and Group Members for their loss and/or damage pursuant to:

    (a) section 74B(1) of the *Trade Practices Act*;

    (b) further or in the alternative, section 74D(1) of the *Trade Practices Act*;

    (c) further or in the alternative, section 75AD of the *Trade Practices Act.*

Negligence

34. DePuy owed Mrs Stanford, Mr Dunsmore and Group Members a duty to exercise reasonable care and skill in the design, manufacture and supply of the Implants.

35. In breach of its duty of care to Mrs Stanford, Mr Dunsmore and Group Members, DePuy:

    (a) designed and manufactured the Implants in such a way that they had the Defects;

    (b) designed and manufactured the Implants in such a way that it knew or ought to have known that they would have the Defects;

    (c) supplied and continued to supply the Implants when it knew or ought to have known that they had the Defects;

    (d) failed to test the Implants adequately before making them available to Johnson & Johnson for supply in Australia;

Particulars

Mrs Stanford and Mr Dunsmore refer to paragraphs 22 and 23 and the particulars to paragraph 24.

DePuy did not conduct any adequate clinical or other experimental studies of the Implants before making them available for supply in Australia.

Further particulars will be provided after the completion of discovery and other interlocutory processes and the service of expert evidence.

    (e) failed promptly to warn Johnson & Johnson, hospitals and orthopaedic surgeons, Mrs Stanford, Mr Dunsmore and Group Members that the Implants had the Defects;

    (f) failed to warn Johnson & Johnson, hospitals and orthopaedic surgeons, Mrs Stanford, Mr Dunsmore and Group Members adequately or at all that the Implants had the Defects;

(g) failed adequately to inform Johnson & Johnson, hospitals and orthopaedic surgeons, Mrs Stanford, Mr Dunsmore and Group Members that the long term safety and efficacy of the Implants were not fully understood;

(h) failed to inform orthopaedic surgeons that, in order to avoid excessive wear, the ASR Acetabular Component should not be inserted at angles of inclination outside of the range of 40 to 45 degrees and/or angles of anteversion outside of the range of 15 to 20 degrees.

36. As a result of DePuy's negligence, Mrs Stanford, Mr Dunsmore and Group Members suffered loss or damage.

Particulars

The loss or damage suffered by Mrs Stanford, Mr Dunsmore and Group Members includes but is not limited to:

- *personal injury, including revision hip replacement, hip arthroplasty or hip resurfacing surgery, soft tissue injury to the hip, metallosis of the hip joint, synovitis of the hip joint and psychiatric injury;*
- *health care expenses and medical monitoring;*
- *other out of pocket expenses;*
- *economic loss;*
- *the need for gratuitous and/or commercial care;*
- *non-economic loss.*

37. Further, as a result of DePuy's negligence, each of Mrs Stanford, Mr Dunsmore and Group Members is entitled to exemplary and/or aggravated damages.

Particulars

The Implants were supplied by DePuy in contumelious and contumacious disregard for the welfare of Mrs Stanford, Mr Dunsmore and Group Members.

Members of DePuy's surgical design team acknowledged that the true test of the Implants would be in the clinical environment and that the performance of the Implants would take many years to understand fully. One of the members of DePuy's design team, Dr Thomas Schmalzried, has acknowledged that "There is considerable danger in extrapolating data from one design to a modified design even when the modifications are small and logical. It is prudent to regard any modified design as a new implant and to consider its clinical introduction with similar scrutiny, even when modifications are minor".

Despite knowing that the long term safety and efficacy of the Implants were not understood and had not been adequately tested, DePuy supplied the Implants to Mrs Stanford, Mr Dunsmore and Group Members in order to generate financial gain and profits from their sale at the expense and risk of injury to patients.

Mrs Stanford, Mr Dunsmore and Group Members were unwitting participants in a large unofficial trial being conducted by DePuy and its agents and affiliates, involving more than 5,000 participants in Australia and more than 90,000 participants globally.

When DePuy became aware of the Defects, DePuy failed to discontinue supply of the Implants and it failed to warn hospitals and orthopaedic surgeons in Australia not to use the Implants and instead DePuy continued to supply the Implants in order to generate financial gain and profit despite knowing or having a reckless disregard for the fact that the Implants would cause injury.

Mrs Stanford and Mr Dunsmore repeat paragraphs 22 and 23, the particulars to paragraph 24 and paragraph 25.

39. Johnson & Johnson owed Mrs Stanford, Mr Dunsmore and Group Members a duty to exercise reasonable care and skill in the supply of the Implants.

40. In breach of its duty of care to Mrs Stanford, Mr Dunsmore and Group Members, Johnson & Johnson:

    (a) supplied and continued to supply the Implants that had the Defects;

    (b) supplied and continued to supply the Implants when it knew or ought to have known that they had the Defects;

    (c) failed to investigate or inquire of DePuy, adequately or at all, as to the safety and efficacy of the Implants;

    (d) failed to satisfy itself that the Implants had been adequately tested by DePuy before supplying the Implants in Australia;

    (e) failed promptly to warn hospitals and surgeons, Mrs Stanford, Mr Dunsmore and Group Members that the Implants had the Defects.

Particulars

Mrs Stanford and Mr Dunsmore repeat paragraphs 22 and 23 and the particulars to paragraph 24.

The Implants had not been subject to any adequate clinical or other experimental studies.

Further particulars will be provided after the completion of discovery and other interlocutory processes and the service of expert evidence.

41. As a result of Johnson & Johnson's negligence, Mrs Stanford, Mr Dunsmore and Group Members suffered loss or damage.

Particulars

The loss or damage suffered by Mrs Stanford, Mr Dunsmore and Group Members includes but is not limited to:

- *personal injury, including revision hip replacement, hip arthroplasty or hip resurfacing surgery, soft tissue injury to the hip, metallosis of the hip joint, synovitis of the hip joint and psychiatric injury;*
- *health care expenses and medical monitoring;*
- *other out of pocket expenses;*
- *economic loss;*
- *the need for gratuitous and/or commercial care;*
- *non-economic loss.*

42. Further, as a result of Johnson & Johnson's negligence, each of Mrs Stanford, Mr Dunsmore and Group Members is entitled to exemplary and/or aggravated damages.

Particulars

The Implants were supplied by Johnson & Johnson in contumelious and contumacious disregard for the welfare of Mrs Stanford, Mr Dunsmore and Group Members.

When Johnson & Johnson became aware of the Defects, Johnson & Johnson failed to discontinue supply of the Implants and it failed to warn hospitals and orthopaedic surgeons in Australia not to use the Implants and instead Johnson & Johnson continued to supply the Implants in order to generate financial gain and profit despite knowing or having a reckless disregard for the fact that the Implants would cause injury.

Mrs Stanford and Mr Dunsmore repeat paragraphs 22 and 23, the particulars to paragraph 24 and paragraph 25.

44. In the premises, DePuy and Johnson are liable:

(a) for the loss or damage suffered by Mrs Stanford, Mr Dunsmore and Group Members;

(b) for exemplary damages to Mrs Stanford, Mr Dunsmore and Group Members.

C. CLAIM BY THE SUB-GROUP REPRESENTATIVE PARTIES ON BEHALF OF SUB-GROUP MEMBERS

45. On 21 September 2012, the Court made orders pursuant to section 33Q of the *Federal Court of Australia Act 1976* (Cth):

    (a) establishing a sub-group consisting of those Group Members (**Sub-Group Members**) who were surgically implanted with an ASR Resurfacing Implant and/or an ASR XL Implant in the State of South Australia; and

    (b) appointing Mary Beentjes and Robert Harry James Webb to be the sub-group representative parties on behalf of Sub-Group Members.

Mary Beentjes

46. Ms Beentjes:

    (a) was born on 29 March 1981

    (b) at all material times resided in South Australia; and

    (c) is a Station Assistant Manager.

47. On 13 August 2008, an ASR Resurfacing Implant was surgically implanted into Ms Beentjes' left hip during hip resurfacing surgery at the SportsMed SA Hospital, Stepney in the State of South Australia.

Particulars

Ms Beentjes' left ASR Resurfacing Implant:

(i) *was surgically implanted by Dr Roger Oakeshott;*

(ii) *comprised the following components:*

(A) *ASR Total Acetabular Implant (Size 56mm) and*

(B) *ASR Total Femoral Implant (Size 49mm).*

48. On 20 August 2008, an ASR Resurfacing Implant was surgically implanted into Ms Beentjes' right hip during hip resurfacing surgery at the SportsMed SA Hospital, Stepney in the State of South Australia.

Particulars

Ms Beentjes' right ASR Resurfacing Implant:

(i) *was surgically implanted by Dr Roger Oakeshott;*

(ii) *comprised the following components:*

(A) *ASR Total Acetabular Implant (Size 56mm) and*

(B) *ASR Total Femoral Implant (Size 49mm).*

49. Between 23 November 2010 and 17 May 2011, Ms Beentjes was advised that both of her ASR Resurfacing Implants would need to be revised.

Particulars

Between 23 November 2010 and 17 May 2011:

(i) *examinations of Ms Beentjes by Dr Robert Wallace on 23 November 2010, 14 December 2010 and 17 May 2011 showed ongoing and worsening pain and deteriorating function in both hips;*

(ii) *serial MRI scans showed;*

(A) *increasing fluid within both hips joints, likely to represent inflammatory reaction to metal wear particulae, and*

(B) *an effusion on the right side within the iliopsoas tendon sheath.*

(iii) *serial investigations showed elevations of the metal ions Cobalt and Chromium.*

As a result of the above findings and the risks of progressive soft tissue damage, bone damage in her hips and systemic toxicity, Ms Beentjes' ASR Resurfacing Implants were surgically removed and replaced.

50. On 2 November 2011, on the advice of her treating orthopaedic surgeon, Ms Beentjes' right ASR Resurfacing Implant surgically removed from Ms Beentjes and replaced.

Particulars

The ASR Resurfacing Implant was removed from Ms Beentjes' right hip on 2 November 2011 at SportsMed SA Hospital.

The operative diagnosis was metallosis as a result of the failure of the right ASR hip resurfacing system.

Post operative histopathology in relation to the right hip acetabulum membrane and right hip synovial biopsies taken during revision surgery revealed mild chronic synovitis with metallosis.

Ms Beentjes' Implant was replaced with a DePuy Pinnacle Gription acetabular shell sectors, Biolox Delta Ceramax ceramic inserts, Summit femoral stems and Biolox Delta Articul/Eze ceramic femoral heads.

On or about 7 November 2011, Ms Beentjes' was discharged from hospital following the revision of her ASR Resurfacing Implant that had been implanted into her right hip.

51. On 9 November 2011, on the advice of her treating orthopaedic surgeon, Ms Beentjes' left ASR Resurfacing Implant was surgically removed from Ms Beentjes and replaced.

Particulars

The ASR Resurfacing Implant was removed from Ms Beentjes' left hip on 9 November 2011 at SportsMed SA Hospital.

The operative diagnosis was metallosis as a result of the failure of the left ASR hip resurfacing system.

Post operative histopathology in relation to the left hip synovial and left hip psoas biopsies taken during revision surgery revealed moderate chronic synovitis with metallosis and left hip acetabular membrane taken during revision surgery revealed degenerate bone marrow.

Ms Beentjes' Implant was replaced with a DePuy Pinnacle Griptionacetabular shell sector, Biolox Delta Ceramax ceramic insert, Summit femoral stem and Biolox Delta Articul/Eze ceramic femoral head.

On or about 17 November 2011, Ms Beentjes was discharged from hospital following the revision of her ASR Resurfacing Implant that had been implanted into her left hip.

Robert Webb

52. Mr Webb:

(a) was born on 5 November 1954;

(b) at all material times resided in South Australia;

(c) is married; and

(d) holds the rank of Major and is an Operations Officer in the Army Reserves.

53. On 23 May 2007, an ASR XL Implant was surgically implanted into Mr Webb's right hip during total hip replacement surgery at the Calvary Wakefield Hospital, Adelaide in the State of South Australia.

Particulars

Mr Webb's ASR XL Implant was:

(i) *surgically implanted by Dr Scott Brumby;*

(ii) *comprised the following components:*

(A) *ASR Total Acetabular Implant (Size 56mm);*

(B) *ASR Unipolar Femoral Implant (Size 49mm); and*

(C) *ASR Taper Sleeve Adaptor (12/14 Taper +5]).*

54. On 31 May 2011, Mr Webb was advised that his ASR XL Implant would need to be revised.

Particulars

After the ASR XL Implant was implanted into Mr Webb, Dr Brumby noted:

(i) *a CT scan of Mr Webb's right hip on 30 September 2010 showed effusion in the greater trochanter;*

(ii) *at an examination on 17 November 2010 Mr Webb had thigh and groin pain;*

(iii) *serum/plasma cobalt levels tested on 17 November 2010 indicated toxicity;*

(iv) *an MRI scan of the right hip on 19 November 2010 showed prominent effusion tracking to the trochanteric bursa through a capsular defect;*

(v) *an MRI scan of the right hip on 14 April 2011 showed larged iliopsoas bursal effusion and small trochanteric bursal effusion;*

(vi) *at an examination by Mr Brumby on 18 May 2011 there was iliopsoas bursa swelling;*

(vii) *ultrasound aspiration of the right hip on 25 May 2011 showed extensive synovial thickening and a large amount of fluid within the iliopsoas bursa;*

(viii) *very high chromium level in synovial fluid from the iliopsoas bursa on 31 May 2011.*

55. On 16 June 2011, on the advice of Mr Webb's treating orthopaedic surgeon, the ASR XL Implant was surgically removed from Mr Webb's right hip and replaced.

Particulars

The ASR XL Implant was removed from Mr Webb's right hip on 16 June 2011 at the Calvary Wakefield Hospital.

The operative diagnosis was metallosis as a result of the right ASR XL head total hip replacement.

A post operative histopathology report in relation to the right hip bursa, right hip capsule and right psoas bursa biopsies taken during revision surgery revealed fibrous membrane with chronic inflammation, surface fibroid necrosis and evidence of metallosis.

The operation record in relation to Mr Webb's revision surgery notes that Dr Brumby replaced Mr Webb's Implant with a DePuy Pinnacle Multihole Acetabular Cup, Biolox Delta Ceramax Ceramic Insert, Biolox Delta TS Rev Articul/eze Ceramic Femoral Head and Pinnacle Cannelous Bone Screw.

On or about 21 June 2011, Mr Webb was discharged from hospital following the revision of his ASR XL Implant that had been implanted into his right hip.

Manufacturers Warranties Act

56. Between July 2003 and a date on or about December 2009, DePuy was the manufacturer of the Implants within the meaning of section 3 of the *Manufacturers Warranties Act.*

57. Between sometime in 2004, when the Therapeutic Goods Administration approved the ASR Resurfacing Implant for use in Australia, and a date on or about December 2009, Johnson & Johnson was the manufacturer of the ASR Resurfacing Implant within the meaning of section 3 of the *Manufacturers Warranties Act,* by reason of the matters pleaded at paragraphs 4(b)(ii), 5(a)(iii) and 5(b)(i) of this Third ~~Second~~ Further Amended Statement of Claim.

58. Between sometime in 2005, when the Therapeutic Goods Administration approved the ASR XL Implant for use in Australia, and a date on or about December 2009, Johnson & Johnson was the manufacturer of the ASR XL Implant within the meaning of section 3 of the *Manufacturers Warranties Act,* by reason of the matters pleaded at paragraphs 4(b)(ii), 5(a)(iii) and 5(b)(i) of this Third ~~Second~~ Further Amended Statement of Claim.

59. The ASR Resurfacing Implants that were sold to Ms Beentjes and Sub-Group Members:

    (a) were goods manufactured for sale or disposal by retail;

    (b) were not normally offered for sale at a genuine retail price in excess of ten thousand dollars; and

    as such were manufactured goods within the meaning of section 3 of the *Manufacturers Warranties Act.*

60. The ASR XL Implants that were sold to Mr Webb and Sub-Group Members:

    (a) were goods manufactured for sale or disposal by retail;

(b) were not normally offered for sale at a genuine retail price in excess of ten thousand dollars; and

as such were manufactured goods within the meaning of section 3 of the *Manufacturers Warranties Act.*

61. The Implants were sold by retail in the State of South Australia or, in the alternative, were delivered, upon being sold by retail, to a purchaser in the State of South Australia.

62. By reason of the matters pleaded in paragraphs 56 to 61:

(a) DePuy warranted that the ASR Resurfacing Implants were of merchantable quality within the meaning of sections 4(1)(c) and 4(2) of the *Manufacturers Warranties Act*;

(b) DePuy warranted that the ASR XL Implants were of merchantable quality within the meaning of sections 4(1)(c) and 4(2) of the *Manufacturers Warranties Act*;

(c) Johnson & Johnson warranted that the ASR Resurfacing Implants were of merchantable quality within the meaning of sections 4(1)(c) and 4(2) of the *Manufacturers Warranties Act*; and

(d) Johnson & Johnson warranted that the ASR XL Implants were of merchantable quality within the meaning of sections 4(1)(c) and 4(2) of the *Manufacturers Warranties Act*

(in each case, the **Statutory Warranty**).

63. By reason of all or any of the Defects as pleaded in paragraph 24 above, the Implants were not of merchantable quality within the meaning of sections 4(1) and 4(2) of the *Manufacturers Warranties Act.*

Particulars

Ms Beentjes and Mr Webb refer to and repeat the particulars to paragraph 31 above.

64. By reason of the matter pleaded in paragraph 63:

(a) DePuy did not comply with the Statutory Warranty in relation to the ASR Resurfacing Implant;

(b) DePuy did not comply with the Statutory Warranty in relation to the ASR XL Implant;

(c) Johnson & Johnson did not comply with the Statutory Warranty in relation to the ASR Resurfacing Implant; and

(d) Johnson & Johnson did not comply with the Statutory Warranty in relation to the ASR XL Implant.

65. Ms Beentjes, Mr Webb and the Sub-Group Members:

(a) purchased the ASR Resurfacing Implants and/or the ASR XL Implants when offered for sale by retail; or

(b) in the alternative, derived title to the ASR Resurfacing Implants and/or the ASR XL Implants though or under a person who purchased them when offered for sale by retail, and

as such, purchased the Implants as consumers within the meaning of section 3 of the *Manufacturers Warranties Act.*

Particulars

Mr Webb purchased his ASR XL Implant from, or derived title to it through or under the Calvary Wakefield Hospital.

Mrs Beentjes purchased his ASR XL Implant from, or derived title to it through or under the SportsMed SA Hospital.

66. Ms Beentjes, Mr Webb and the Sub-Group Members have or had lawful possession of their Implants.

67. In the premises and further to the remedies sought by Sub-Group Members as Group Members in paragraphs 33 and 44, DePuy and/or Johnson & Johnson are liable to pay damages to Ms Beentjes, Mr Webb and the Sub-Group Members pursuant to section 5(1) of the *Manufacturers Warranties Act.*

Particulars

The claim for damages by Ms Beentjes, Mr Webb and the Sub-Group Members includes but is not limited to damages for:

- *personal injury, including revision hip replacement, hip arthroplasty or hip resurfacing surgery, soft tissue injury to the hip, metallosis of the hip joint, synovitis of the hip joint and psychiatric injury;*
- *health care expenses and medical monitoring;*
- *other out of pocket expenses;*
- *economic loss;*
- *the need for gratuitous and/or commercial care;*
- *non-economic loss.*

Date: 16 May 2014

Signed by Ben Slade	Signed by Rebecca Jancauskas
Lawyer for the First Applicant	Lawyer for the Second Applicant

This pleading was prepared by Ben Slade and Rebecca Jancauskas

Schedule

No. 213 of 2011

Federal Court of Australia
District Registry: New South Wales
Division: General

Applicants

First Applicant:	Tammy Stanford
Second Applicant:	Jamie Dunsmore

Respondents

First Respondent:	DePuy International Limited
Second Respondent:	Johnson & Johnson Medical Pty Limited (ACN 000 160 403)

Certificate of lawyer

I Ben Slade certify to the Court that, in relation to the third ~~second~~ further amended statement of claim filed on behalf of the First Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 16 May 2014

Signed by Ben Slade

Lawyer for the First Applicant

Certificate of lawyer

I Rebecca Jancauskas certify to the Court that, in relation to the third ~~second~~ further amended statement of claim filed on behalf of the Second Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 16 May 2014

Signed by Rebecca Jancauskas

Lawyer for the Second Applicant