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

NOTICE OF FILING

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DETAILS OF FILING

Document Lodged:	Defence - Form 33 - Rule 16.32
File Number:	NSD213/2011
File Title:	Tammy Maree Stanford & Anor v DePuy International Limited & Anor
District Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA

Dated: 31/05/2013 **Registrar**

Note

This Notice forms part of the document and contains information that might otherwise appear elsewhere in the document. The Notice must be included in the document served on each party to the proceeding.

Form 33

Rule 16.32

Defence of the Second Respondent

No. NSD 213 of 2011

Federal Court of Australia

District Registry: New South Wales

Division: General

Tammy Maree Stanford and another

Applicants

DePuy International Limited and another

Respondents

In answer to the Second Further Amended Statement of Claim (**Claim**) dated 16 May 2013~~25 September 2012~~, the Second Respondent pleads as follows:

The Proceeding

1. In answer to paragraph 1, the Second Respondent:

   (a) Admits that the Applicants bring this proceeding as a representative proceeding in their own right and on behalf of the Group Members; and

   (b) Otherwise does not know and cannot admit paragraph 1.

The First Applicant

2. As to paragraph 2, the Second Respondent:

   (a) Admits paragraphs (a) and (b);

   (b) Otherwise does not know and therefore cannot admit the allegations therein.

The Second Applicant

Filed on behalf of:	Johnson & Johnson Medical Pty Ltd
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3. As to paragraph 3, the Second Respondent:

   (a) Admits paragraphs (a) and (b);

   (b) Otherwise does not know and therefore cannot admit the allegations therein.

The Respondents

4. The Second Respondent admits paragraph 4.

5. The Second Respondent admits paragraph 5.

The Implants

6. In answer to paragraph 6, the Second Respondent:

   (a) Admits that the ASR XL Implant was designed and manufactured to be inserted during hip replacement surgery, and admits that the ASR Resurfacing Implant was designed and manufactured to be inserted during hip implant surgery, but denies that the latter constitutes a "hip replacement";

   (b) Admits paragraph 6(b), save that they were also to be used to replace or reconstruct diseased hip joints or hip joints causing pain and disability; and

   (c) Admits paragraph 6(c).

7. The Second Respondent admits paragraph 7, save that:

   (a) The correct names for the ASR Acetabular Component referred to in paragraph 7(a)(ii) are "ASR 100 Acetabular Component" or "ASR 300 Acetabular Component" (the principal difference being that the latter has spikes); and

   (b) The correct name for the ASR Resurfacing Femoral Component referred to in paragraph 7(b)(ii) is "ASR Femoral Implant".

8. The Second Respondent admits paragraph 8, save that the correct name for the ASR XL Femoral Component referred to in paragraph 8(d) is "ASR Uni Femoral Implant".

9. The Second Respondent admits paragraph 9.

Mrs Stanford's Implant

10. The Second Respondent admits paragraph 10.

11. The Second Respondent does not know and cannot admit paragraph 11.

12. The Second Respondent admits that the ASR XL Implant was surgically removed from Mrs Stanford's left hip and replaced on 10 January 2011, but otherwise does not know and cannot admit paragraph 12.

Mr Dunsmore's Implant

13. The Second Respondent admits paragraph 13.

14. The Second Respondent does not know and cannot admit paragraph 14.

15. The Second Respondent admits that Mr Dunsmore had revision surgery and total hip replacement surgery on 23 February 2009, but otherwise does not know and cannot admit paragraph 15.

16. The Second Respondent does not know and cannot admit paragraph 16.

17. The Second Respondent admits paragraph 17.

Supply of Implants to Group Members

18. The Second Respondent admits paragraph 18.

19. The Second Respondent admits paragraph 19.

Purposes for which the Implants were acquired

20. In answer to paragraph 20, the Second Respondent:

    (a) Admits that the Implants were acquired by the Applicants and the Group Members for the purpose of alleviating pain, alleviating disability and/or improving function in a hip joint for as long as reasonably practicable in light of factors affecting implant functioning in individual patients, including but not confined to the surgeon's surgical experience and technique, the patient's age, activity level or underlying medical condition; and

    (b) Otherwise does not know and cannot admit the paragraph; in particular, it is not admitted that the Applicants or the Group Members acquired the Implants for a purpose of avoiding or ~~of not giving rise to~~eliminating any risk of, any susceptibility to, or any increased risk of or susceptibility to~~that~~ the adverse events described in paragraphs 23 and 24 of the Claim ~~would occur~~;

    (c) Further says that:

(i) no hip implant device is as effective as a healthy natural hip joint or guaranteed not to require revision at some point;

(ii) every hip implant device and hip implant surgery is susceptible to or carries an inherent risk that:

(A) one or more adverse events will occur; and/or

~~(ii)~~(B) the device may wear out earlier than anticipated, cause pain and/or disability and/or require early revision; and

(iii) each type of hip implant device carries its own set of benefits and risks, and the surgeon determines which device will offer the most benefit and the least risk for an individual patient, given that patient's characteristics.

21. In answer to paragraph 21, the Second Respondent:

(a) Admits that it knew that the Implants were acquired for the purpose of alleviating pain, alleviating disability and/or improving function in a hip joint for as long as reasonably practicable in light of factors affecting implant functioning in individual patients, including but not confined to the surgeon's surgical experience and technique, the patient's age, activity level or underlying medical condition;

(b) Otherwise denies paragraph 21; in particular, the Second Respondent denies knowing that the Applicants or the Group Members acquired the Implants for a purpose of avoiding or ~~of not giving rise to~~eliminating any risk of, any susceptibility to, or any increased risk of or susceptibility to~~that~~ the adverse events described in paragraphs 23 and 24 of the Claim ~~would occur~~; and

(c) Repeats paragraph 20(c) above and paragraphs 30(e), (f) and (g) below.

The design of the Implants

22. In answer to paragraph 22, the Second Respondent:

(a) Admits that the ASR Acetabular Component had a sub-hemispherical geometry or shape, but otherwise denies paragraph 22(a), and says further that it was designed and manufactured to have an outer diameter with a geometry of approximately 165 degrees;

(b) Admits that the ASR Acetabular Component had a sub-hemispherical geometry or shape, whereas the acetabular components in some other Metal-on-Metal Devices had a hemispherical geometry or shape, but otherwise does not admit

paragraph 22(b) because (if and to the extent it refers to something besides the sub-hemispherical geometry of the ASR Acetabular Component) its meaning is unclear;

(c) Admits paragraph 22(c);

(d) Admits paragraph 22(d), save that the average pore size was in the range of 250-350 µm;

(e) Admits paragraph 22(e);

(f) Admits paragraph 22(f);

(g) Admits that the ASR Acetabular Component was designed and manufactured to have a diametric clearance of between 80 and 120 µm between it and either the ASR Resurfacing Femoral Component or the ASR XL Femoral Component, but otherwise denies paragraph 22(g);

(h) Does not admit that the internal groove leaves a sharp edge, as "sharp" is an imprecise term which is undefined in the pleadings, but admits that the internal groove reduces the internal functional bearing surface of the sub-hemispherical surface of the ASR Acetabular Component;

(i) Does not admit paragraph 22(i) because the way in which different Metal-on-Metal Devices are designed makes it difficult or inutile to compare the "rim chamfer" of the Implants with other products;

(j) Admits paragraph 22(j) in the sense that the ASR Acetabular Component has a larger dimension at its core than at its outer edge;

(k) Admits that it had a smaller functional bearing surface and arc of cover than some other Metal-on-Metal Devices, but otherwise does not admit paragraph 22(k) because it does not know that to be the case in respect of all other Metal-on-Metal Devices;

(l) Further says that:

(i) the First Respondent deployed an international and interdisciplinary team to design the Implants, which used up-to-date scientific and technical knowledge, and subjected the Implants to an extensive testing programme over several years;

(ii) the First Respondent designed the Implants based on clinical evidence available at the time as to the advantages of metal-on-metal, large diameter bearings in terms of bone conservation, range of motion, reduced likelihood of dislocation, lower risk of device fracture, and lower wear rates relative to other types of bearings;

(iii) following the process detailed in (i) and (ii) above, the First Respondent designed the Implants with the following features:

(A) the sub-hemispherical geometry or shape of the ASR Acetabular Component was designed to preserve more of the patient's bone, require less medialization and acetabular reaming, and allow for a greater range of impingement-free motion;

(B) the ASR Acetabular Component was designed and manufactured to have a diametric clearance of between 80 and 120 μm between it and the ASR Resurfacing Femoral Component or ASR XL Femoral Component so as to allow the patient's body to create a thin film of synovial fluid, enabling lubrication and smoother motion, and reducing wear and ion release;

(C) the ASR Acetabular Component was designed with a larger dimension at its core than at its outer edge to minimise deformation during impaction, maintain cup shape and minimise equatorial deflection to help maintain bearing function;

(D) the ASR Acetabular Component was designed with a cup impactor that enabled surgeons to have a relatively unobstructed view and thereby assist (inter alia) in avoiding soft-tissue damage, as well as a trigger-release mechanism to detach the impactor without moving the cup;

(E) the ASR Resurfacing Femoral Component was designed with a tapered pin to maximise bone preservation in the femoral head and to aid as a guide for implantation and full seating of the femoral component rather than acting as a load carrying feature, the aim of which was to limit incidence of femoral neck fractures; and

(F) the surface, porous coating and hydroxyapatite layer of the ASR Acetabular Component were designed to improve stability, fixation

and osteointegration, particularly by aiding fast, deep biological bony in-growth.

23. The Second Respondent denies paragraph 23, but admits that use of the Implants carried a risk that one or more of the adverse events described in paragraphs 23(a), 23(b) and 23(c) could occur and says that:

(a) These potential adverse events were identified in the instructions for use that accompanied all Implants and/or in medical literature that was publicly available in Australia from 2004 onwards; and

(b) Use of alternative hip replacement or hip resurfacing prostheses likewise carried risks of adverse events, which varied in degree from patient to patient~~Potential adverse events could likewise occur if alternative hip replacement or hip resurfacing prostheses were used~~.

24. The Second Respondent denies paragraph 24.

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

25. The Second Respondent denies paragraph 25, but admits that, as with all of their products, the Respondents reviewed and evaluated data concerning the Implants from a variety of sources, including national joint registries, peer reviewed published literature, company-sponsored clinical trials, internal complaints data, and external clinical research reports. In particular:

(a) It was aware of the revision rates and other data relating to the Implants that was published in the 2006, 2007, 2008, 2009, 2010 and 2011 Annual Reports of the National Joint Replacement Registry of Australia at least by about the date each of those reports was published;

(b) It was aware of the revision rates and other data relating to the Implants that was published in the 2007, 2008, 2009, 2010 and 2011 Annual Reports of the National Joint Registry for England & Wales (NJREW) at least by about the date each of those reports was published;

(c) It was aware, as and when it became available, of information relating to the Implants that was generated by various post-market clinical follow-up studies conducted or sponsored by the First Respondent;

(d) It also became aware, as and when it was published or provided to them, of certain other post-market clinical data relating to the Implants, including that contained in published articles and internal complaints;

(e) It was aware, by September 2007, of the matters set out in the document entitled "Internal Review – September 2007 Discussion with the TGA";

(f) It was aware by 3 October 2007 of the facts set out in the "Dear Doctor" letter that it issued on or about that date;

(f)(A) It was aware by 2008 of the revision rates and other data that was referred to by T.P. Vail MD in "Interpretation of DePuy ASR Data in International Joint Registries";

(f)(B) It was aware by about 26 March 2008 of the data referred to in its internal "Health Hazard/Risk Evaluation" Report (**HHE**) of that date;

(f)(C) It was aware by about 25 September 2009 of the data referred to in its internal HHE of that date;

(f)(D) By about 31 December 2009, it had withdrawn the Implants from the Therapeutic Goods Register and ceased to supply the Implants in Australia (save that some stock remained available for the purpose of revision until August 2010);

(f)(E) It was aware by about 8 January 2010 of the data referred to in its internal HHE of that date;

(g) It was aware by 8 March 2010 of the facts set out in the Urgent Field Safety Notice issued by the First Respondent on that date;

(h) It was aware by 25 May 2010 of the revision rate data set out in the Medical Device Alert issued by the Medical and Healthcare products Regulatory Agency on that date;

(h)(A) It was aware by about 9 August 2010 of the data referred to in its internal HHE of that date; and

(i) It was aware by 24 August 2010 of the facts set out in the Urgent Field Safety Notice and in the Recall Notice issued by the First Respondent on that date, including the data from the NJREW referred to therein.

25A. In further answer to paragraph 25, the Second Respondent says that Mrs Stanford and Mr Dunsmore were each implanted with an Implant, in November 2005 and December

2004 respectively, before the Respondents allegedly knew or ought to have known the matters pleaded in paragraphs 24 and 25.

Discontinuance of supply of the Implants

26. The Second Respondent admits paragraph 26, save that some stock remained available for the purposes of revision until about August 2010.

27. The Second Respondent admits paragraph 27.

Trade Practices Act

28. The Second Respondent admits paragraph 28.

29. The Second Respondent admits paragraph 29.

30. The Second Respondent denies paragraph 30, repeats paragraphs 20(a) to 20(c) above, and further says:

    (a) No artificial hip replacement or hip resurfacing prosthesis is as effective as a healthy natural hip joint;

    (b) No artificial hip replacement or hip resurfacing prosthesis is guaranteed to last for a patient's remaining lifetime, or to be without risk of or susceptibility to adverse complications, and it is an inherent or obvious risk of any artificial hip replacement or hip resurfacing prosthesis that revision surgery may be necessary, notwithstanding that the prosthesis used is fit for purpose and/or of merchantable quality;

    (c) The risk that use of the Implants would result in one or more of the adverse events described in paragraphs 23(a), 23(b) and 23(c) of the Claim varied in degree from patient to patient (for example, the presence of hip dysplasia reduces the bone stock available to support the acetabular cup, which tends to adversely affect fixation and increase the risk that a prosthesis will loosen);

    (d) Use of alternative hip replacement or hip resurfacing prostheses likewise carried risks of or susceptibility to adverse events, which varied in degree from patient to patient;

    (e) The Respondents advised surgeons in Australia of the risks associated with using the Implants;

Particulars

Surgical technique manuals and instructions for use which were distributed to surgeons in Australia, including:

(i) DePuy ASR Articular Surface Replacement – Surgical Technique (Versions 1, 2 & 3);

(ii) DePuy ASR XL Anatomic Head System – Surgical Technique (Version 1);

(iii) DePuy ASR 300 Acetabular Cup System – Instructions for Use; and

(iv) Hip prostheses and hemi-hip prostheses – Instructions for Use.

(f) Individual surgeons chose to use the Implants (rather than alternative hip replacement prostheses) when operating on the Applicants and the Group Members;

(g) The Second Respondent's expectation was that, prior to using the Implants, the Applicants and Group Members would be informed, by their respective surgeons, to the degree their surgeons judged appropriate, that such use carried risks, including the risk that the Implants may not alleviate a patient's pain or disability and/or may require early revision;

Particulars

The usual practice for a patient considering a hip replacement surgery is to consult with a surgeon to determine the best implant option for his or her health condition. There is no one bearing surface combination that meets the medical needs of all patients. Metal-on-metal remains a hip replacement option for surgeons and patients, and, as with all hip replacement options, metal-on-metal implants have benefits and risks.

(h) Further or alternatively, the state of scientific or technical knowledge at the time the Implants were supplied was not such as to enable the Defects (as defined, the existence of which is denied) to be discovered; and

Particulars

Prior to launching the Implants, the First Respondent conducted extensive laboratory testing on the Implants, including tests on simulators that evaluated how the Implants would wear over time, the materials used in the Implants,

and the strength of the Implants. These laboratory tests were conducted by the First Respondent and by independent internationally renowned academic research institutions.

All orthopaedic implants, no matter what materials are used, experience wear over time and generate what is called "wear debris". Laboratory testing has demonstrated that metal-on-metal articulation generates a lower volume of wear debris than either metal-on-polyethylene or ceramic-on-polyethylene.

After the Implants were approved for use by the Therapeutic Goods Administration (**TGA**) and made available on the Australian Register of Therapeutic Goods, the Second Respondent continued to review and evaluate data concerning the Implants from a variety of sources as described in paragraph 25.

(i) By reason of s 74B(2)(a) and (b) of the *Trade Practices Act* and paragraphs 30(e), (f) and (g), s74B(1) does not apply insofar as the Implants carried or gave rise to the risk that the Implants would wear out, cause pain or disability and/or require early revision.

31. The Second Respondent denies paragraph 31 and further says:

(a) Paragraphs 20(a) to 20(c) and 30(a) through 30(h) above are repeated;

(b) By reason of s 74D(2)(a) and (b) of the *Trade Practices Act* and paragraphs 30(e), (f) and (g) above, s 74D(1) does not apply insofar as the Implants carried or gave rise to the risk that the Implants would wear out, cause pain or disability and/or require early revision; and

(c) Further or alternatively, the relevant circumstances referred to in s 74D(3)(c), to which the Court must have regard in determining whether the Implants were of merchantable quality, include the state of scientific or technical knowledge at the time of their supply, which was not such as to enable the Defects (as defined, the existence of which is denied) to be discovered, and the matters pleaded in paragraphs 20(a) to 20(c), 22(l), 23(a) to 23(b) and 30(a) to 30(h) above.

32. The Second Respondent denies paragraph 32 and says, in the alternative:

(a) The First Respondent has established a programme to make certain payments, on a without admissions basis, to and on behalf of patients who acquired the Implants (**the Reimbursement Programme**);

(b) Payments to and on behalf of patients under the Reimbursement Programme are available to the Applicants and all Group Members for the following:

(i) Reasonable and customary costs of monitoring and testing incurred due to the recall of the Implants (including monitoring and testing to ascertain whether revision surgery is necessary);

(ii) Reasonable and customary costs of medical treatment incurred due to the recall of the Implants (including the costs of revision surgery); and

(iii) Reasonable out-of-pocket expenses incurred due to the recall of the Implants (including payment for revision surgery and other types of surgery, payments for health care expenses and medical monitoring, payment for other out-of-pocket expenses, payment for economic loss incurred due to treatment and recovery from treatment, and payment for gratuitous care and commercial care incurred during treatment and recovery from treatment);

(c) Payments under the Reimbursement Programme have been made to and on behalf of the Applicants and many of the Group Members;

Particulars

As at 30 April 2013~~24 October 2012~~, 4,127~~3887~~ patients (including the Applicants and many of the Group Members) have registered under the Reimbursement Programme.

(d) Insofar as the Applicants and the Group Members seek damages or compensation which includes any costs or other amounts which have been paid to them under the Reimbursement Programme, the Second Respondent will seek to have such damages or compensation reduced by the amounts paid to the Applicants or the Group Members under the Reimbursement Programme; and

(e) To the extent that the Applicants and the Group Members have failed or refused to participate in the Reimbursement Programme, and have suffered loss or damage which would have been avoided by so participating, the Applicants and the Group Members have failed to take reasonable steps to mitigate their loss.

32A. The Second Respondent denies paragraph 32A and says that:

(a) For the purposes of s 75AC(2) of the *Trade Practices Act*, the relevant circumstances include those pleaded in paragraphs 20(a) to 20(c), 22(l), 23(a) to 23(b) and 30(a) to 30(h) above; and

(b) Even if the Implants had the Defects (as defined, the existence of which is denied), the state of scientific and technical knowledge at the time when the Implants were supplied was not such as to enable that defect to be discovered, such that s 75AK(1)(c) affords a complete defence to the claim under s 75AC of the *Trade Practices Act*.

32B. The Second Respondent denies paragraph 32B and, in the alternative, repeats paragraphs 32(a) to 32(e) above.

33. The Second Respondent denies paragraph 33 and, in the alternative, repeats paragraphs 32(a) through 32(e) above.

Negligence

34. In answer to paragraph 34, the Second Respondent:

(a) Says the common law does not relevantly operate to impose obligations that are more onerous or extensive than those imposed on the First Respondent by ss 74B, 74D, 75AC and 75AD of the *Trade Practices Act*;

(b) Subject to paragraph 34(a) above, admits that the First Respondent owed the Applicants and the Group Members a duty to take reasonable care that they would not be injured by using the Implants as intended; and

(c) Otherwise denies paragraph 34.

35. The Second Respondent denies paragraph 35 and repeats paragraphs 20(a) to 20(c), 22(l), 23(a) to 23(b) and 30(a) through 30(h) above.

36. The Second Respondent denies paragraph 36 and, in the alternative, repeats paragraphs 32(a) through 32(e) above.

~~37. The Second Respondent denies paragraph 37.~~

~~38.~~37. The Second Respondent denies paragraph 3~~7~~8 and further says:

(a) By reason of s 87E of the *Trade Practices Act*, Part VIB of that Act applies to these proceedings and s 87ZB precludes the Court from awarding exemplary or aggravated damages in respect of personal injury in these proceedings; or

(b) ~~(b)~~ By reason of s 21 of the *Civil Liability Act 2002* (NSW) and s 52 of the *Civil Liability Act 2003* (Qld), the Court is precluded from awarding exemplary or aggravated damages in respect of the Applicants' and the Group Members' claims in negligence (insofar as the latter arise under the laws of NSW or Queensland).

38. Paragraph 38 of the Claim has been deleted.

39. In answer to paragraph 39, the Second Respondent:

(a) Says the common law does not relevantly operate to impose obligations that are more onerous or extensive than those imposed on it by ss 74B, 74D, 75AC and 75AD of the *Trade Practices Act*;

(b) Subject to paragraph 39(a) above, admits that it owed the Applicants and the Group Members a duty to take reasonable care that they would not be injured by using the Implants as intended; and

(c) Otherwise denies paragraph 39.

40. The Second Respondent denies paragraph 40 and repeats paragraphs 20(a) to 20(c), 22(l), 23(a) to 23(b) and 30(a) through 30(h) above.

41. The Second Respondent denies paragraph 41 and, in the alternative, repeats paragraphs 32(a) through 32(e) above.

~~42. The Second Respondent denies paragraph 42.~~

42. The Second Respondent denies paragraph 4~~2~~3 and repeats paragraphs 3~~7~~8(a) and 3~~7~~8(b) above.

43. Paragraph 43 of the Claim has been deleted.

44. The Second Respondent denies paragraph 44.

Claim by the Sub-Group Representatives on behalf of the Sub-Group Members

45. The Second Respondent admits paragraph 45.

Mary Beentjes

46. As to paragraph 46, the Second Respondent:

(a) Admits paragraphs (a) and (b);

(b) Otherwise does not know and therefore cannot admit the allegations therein.

47. As to paragraph 47, the Second Respondent:

(a) Does not know and therefore cannot admit the date of surgery as alleged;

(b) Admits Ms Beentjes received an ASR Acetabular Implant (Size 56mm) and ASR Femoral Implant (Size 49mm);

(c) Otherwise admits the allegations therein.

48. As to paragraph 48, the Second Respondent:

(a) Does not know and therefore cannot admit the date of surgery as alleged;

(b) Admits Ms Beentjes received an ASR Acetabular Implant (Size 56mm) and ASR Femoral Implant (Size 49mm);

(c) Otherwise admits the allegations therein.

49. The Second Respondent does not know and therefore cannot admit paragraph 49.

50. As to paragraph 50, the Second Respondent :

(a) Admits that on 2 November 2011, Ms Beentjes' right implant was surgically removed at the SportsMed SA Hospital and was replaced with a DePuy Pinnacle Gription Acetabular Sector Shell, Biolox Delta Ceramic Insert, Summit femoral stem and a Biolox Delta Articul/eze ceramic head;

(b) Otherwise does not know and therefore cannot admit the allegations therein.

51. As to paragraph 51, the Second Respondent :

(a) Admits that on 9 November 2011, Ms Beentjes' left implant was surgically removed at SportsMed SA Hospital and was replaced with a DePuy Pinnacle Gription Acetabular Sector Shell, Biolox Delta Ceramic Insert, Summit femoral stem and a Biolox Delta Articul/eze ceramic head, and that Ms Beentjes was discharged on or about 17 November 2011;

(b) Otherwise does not know and therefore cannot admit the allegations therein.

Robert Webb

52. As to paragraph 52, the Second Respondent:

(a) Admits paragraphs (a) and (d);

(b) Otherwise does not know and therefore cannot admit the allegations therein.

53. As to paragraph 53, the Second Respondent:

(a) Admits that on 23 May 2007 an ASR XL Implant was surgically implanted into Mr Webb's right hip during surgery at the Calvary Wakefield Hospital, Adelaide in the State of South Australia by Dr Scott Brumby and comprised an ASR Acetabular Implant (size 56mm) and an ASR Unipolar Femoral Implant (size 49mm);

(b) Otherwise does not know and therefore cannot admit the allegations therein.

54. As to paragraph 54, the Second Respondent:

(a) Admits that on 25 May 2011 an ultrasound of Mr Webb's right hip was undertaken;

(b) Otherwise does not know and therefore cannot admit the allegations therein.

55. As to paragraph 55, the Second Respondent:

(a) Admits that on 16 June 2011, the implant and a bursa were surgically removed from the Mr Webb's right hip at the Calvary Wakefield Hospital;

(b) Otherwise does not know and therefore cannot admit the allegations therein.

Manufacturers Warranties Act

56. In answer to paragraph 56, the Second Respondent:

(a) Denies the paragraph; and

(b) Further says the First Respondent was not the "manufacturer" of the Implants within the meaning of s 3 of the *Manufacturers Warranties Act 1974* (SA) (repealed) (MWA) because the Implants were not "manufactured for sale or disposal by retail" and were not, therefore, "manufactured goods" or "goods" within the meaning of s 3 of the MWA.

57. In answer to paragraph 57, the Second Respondent:

(a) Denies the paragraph; and

(b) Further says that it was not the "manufacturer" of the Implants within the meaning of s 3 of the MWA because the Implants were not "manufactured for sale or

disposal by retail" and were not, therefore, "manufactured goods" or "goods" within the meaning of s 3 of the MWA.

58. The Second Respondent denies paragraph 58 and repeats paragraph 57(b) above.

59. The Second Respondent denies paragraph 59.

60. The Second Respondent denies paragraph 60.

61. The Second Respondent denies paragraph 61.

62. The Second Respondent denies paragraph 62, repeats paragraphs 56(b) and 57(b) above and says that, accordingly, the MWA does not apply to the Implants.

63. In answer to paragraph 63, the Second Respondent:

(a) Denies the paragraph;

(b) Repeats paragraphs 56(b) and 57(b) above and says that, accordingly, the MWA does not apply to the Implants;

(c) Further or alternatively, repeats paragraphs 20(a) to 20(c), 22(l), 23(a) to 23(b) and 30(a) to 30(h) above;

(d) Further or alternatively, by reason of s 4(3)(a) of the MWA and paragraph 30(e), (f) and (g) above, ss 4(1) and 4(2) do not give rise to a liability insofar as the Implants carried or gave rise to the risk that they would wear out, cause pain or disability and/or require early revision.

64. The Second Respondent denies paragraph 64 and repeats paragraphs 63(b) to 63(d) above.

65. The Second Respondent denies paragraph 65.

66. The Second Respondent does not know and therefore cannot admit paragraph 66.

67. The Second Respondent denies paragraph 67, repeats paragraphs 32(a) to 32(e) above, and further says that any amounts recovered by the Sub-Group Members in respect of the damages claimed in paragraphs 33 and 44 will reduce the amount recoverable by them pursuant to the MWA, and vice-versa.

68. The Second Respondent denies that the Applicants and the Group Members are entitled to the relief sought in the Amended Application or any other relief.

69. In further or alternative answer to the whole of the Claim, the Second Respondent says:

(a) By reason of s 87E of the *Trade Practices Act*, Part VIB of that Act applies to these proceedings, such that:

(i) The Court must not award personal injury damages if the proceedings were commenced more than 3 years after the date of discoverability for the injury to which an Applicant or Group Member's personal injury damages would relate (s 87F);

(ii) The Court must not award as personal injury damages for non-economic loss an amount that exceeds the amount permitted under Division 3 of Part VIB, and if the non-economic loss suffered is less than 15% of a most extreme case, the Court must not award personal injury damages for non-economic loss (ss 87L & 87S);

(iii) The Court must assess personal injury damages for economic loss due to loss of earnings or the deprivation or impairment of earning capacity, or due to the loss of an expectation of financial support, in accordance with Division 4 of Part VIB (s 87U);

(iv) The Court must not award personal injury damages for gratuitous attendant care services, or for loss of the capacity to provide gratuitous attendant care services to others, except in accordance with s 87W and s 87X respectively;

(v) The Court must assess the present value of any future economic loss that is included in an award of personal injury damages in accordance with s 87Y;

(vi) The Court must not award personal injury damages for economic loss due to the loss of employer superannuation contributions, except in accordance with s 87Z; and

(vii) The Court must not order the payment of interest on personal injury damages, except in accordance with s 87ZA.

(b) Alternatively, the Second Respondent says that one of the following Acts applies to each of the claims made in these proceedings by the Applicants and the Group Members, and in each case, the Second Respondent will rely on the material provisions of the applicable Act, as if those provisions were set out herein:

(i) *Civil Liability Act 2002* (NSW), including but not limited to Part 1A (Divisions 1 to 4) and Part 2 (Divisions 1 to 4 and 6);

(ii) *Wrongs Act 1958* (Vic), including but not limited to Part VB, Part VBA and Part X;

(iii) *Civil Liability Act 2003* (Qld), including but not limited to Chapter 2 (Part 1, divisions 1 to 3) and Chapter 3 (Parts 1 to 3);

(iv) *Civil Liability Act 2002* (WA), including but not limited to Part 1A (Divisions 1 to 3 and 6) and Part 2 (Divisions 1 to 3);

(v) *Personal Injuries (Liabilities and Damages) Act 2002* (NT), including but not limited to Part 4 (Divisions 1 to 5);

(vi) *Civil Law (Wrongs) Act 2002* (ACT), including but not limited to Chapter 4 (Parts 4.1 to 4.3) and Chapter 7 (Parts 7.1 and 7.2)

(vii) *Civil Liability Act 2002* (Tas), including but not limited to Part 6 (Divisions 1 to 4) and Part 7; and

(viii) *Civil Liability Act 1936* (SA), including but not limited to Part 6 (Divisions 1 to 3) and Part 8.

(c) Further or alternatively, that one of the following Acts applies to each of the claims made in these proceedings by the Applicants and the Group Members, and in each case, the Second Respondent will rely on the material provisions of the applicable Act, as if those provisions were set out herein:

(i) *Limitation Act 1969* (NSW);

(ii) *Limitation of Actions Act 1958* (Vic);

(iii) *Limitations of Actions Act 1974* (Qld);

(iv) *Limitation Act 2005* (WA)

(v) *Limitation Act 1981* (NT);

(vi) *Limitation Act 1985* (ACT)

(vii) *Limitation Act 1974* (Tas); and

(viii) *Limitation of Actions Act 1936* (SA).

Date: 31 May 2013~~24 October 2012~~

Signed by Barry Richardson

Solicitor for the Second Respondent

This pleading was prepared by Garry Rich, of Counsel

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 Barry Richardson certify to the Court that, in relation to the defence filed on behalf of the Second Respondent, the factual and legal material available to me at present provides a proper basis for:

(a) each allegation in the pleading; and

(b) each denial in the pleading; and

(c) each non admission in the pleading.

Date: 31 May 2013~~24 October 2012~~

Signed by Barry Richardson
Lawyer for the Second Respondent