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

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

Dated: 28/02/2011 **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.

IN THE FEDERAL COURT OF AUSTRALIA
NEW SOUTH WALES DISTRICT REGISTRY
GENERAL DIVISION

No. of 2011

TAMMY MAREE STANFORD
Applicant

DEPUY INTERNATIONAL LIMITED
First Respondent

JOHNSON & JOHNSON MEDICAL PTY LIMITED
ACN 000 160 403
Second Respondent

STATEMENT OF CLAIM

The proceeding

1. The applicant (**Mrs Stanford**) brings this proceeding as a representative proceeding pursuant to Part IVA of the *Federal Court of Australia Act 1976* (Cth) in her own right and on behalf of persons (**Group Members**) in whom one or more components of the DePuy ASR Articular Surface Replacement System, DePuy ASR Hip Resurfacing System or DePuy ASR XL Acetabular System (**Affected Implants**) were surgically implanted within Australia.

The applicant

2. Mrs Stanford was born on 26 February 1971 and resides in Howrah in the State of Tasmania.

The respondents

3. At all material times the first respondent (**DePuy**) was and is:

   (a) a company incorporated pursuant to the laws of the United Kingdom and is capable of being sued;

   (b) a foreign corporation within the meaning of section 4 of the *Trade Practices Act 1974* (Cth) (**TPA**);

   (c) the principal manufacturer and seller of the Affected Implants and was carrying on business in connection with the supply, sale, distribution, promotion,

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marketing and regulatory approval of the Affected Implants in conjunction with the second respondent.

4. At all material times the second respondent (**Johnson & Johnson**) was and is:

   (a) a company registered pursuant to the *Corporations Act 2001* (Cth) and is capable of being sued;

   (b) a trading corporation within the meaning of section 4 of the TPA; and

   (c) in the business of marketing and distributing products in Australia including medical devices such as the Affected Implants.

The Affected Implants

5. The Affected Implants are metal devices that were designed and manufactured for use in hip replacement, hip arthroplasty and hip joint resurfacing surgery where they were intended to be surgically implanted into a patient's hip by and on the advice of orthopaedic surgeons.

6. The Affected Implants are ordinarily acquired for personal use or consumption.

7. The Affected Implants are goods within the meaning of sections 4 and 74A(2)(a) of the TPA.

The manufacture of the Affected Implants and their importation into Australia

8. At all material times the Affected Implants were manufactured outside Australia by or on behalf of DePuy.

9. At all material times the Affected Implants were imported into Australia by or on behalf of Johnson & Johnson, which was not the manufacturer of the Affected Implants.

10. At all material times when the Affected Implants were imported into Australia, DePuy did not have a place of business in Australia.

11. Pursuant to section 74A(4) of the TPA and by reason of the matters pleaded in paragraphs 8 to 10, Johnson & Johnson is deemed to have manufactured the Affected Implants.

12. Johnson & Johnson is the sponsor of the Affected Implants within the meaning of and for the purposes of the *Therapeutic Goods Act 1989* (Cth).

Supply of the Affected Implants in trade or commerce

13. The Affected Implants were supplied by DePuy (as the manufacturer of the Affected Implants) to Johnson & Johnson, which acquired the Affected Implants for re-supply to hospitals and/or doctors, including hospitals and/or doctors that treated Mrs Stanford and Group Members.

14. The Affected Implants were supplied by Johnson & Johnson (as the deemed manufacturer of the Affected Implants as pleaded in paragraph 11) to hospitals and/or doctors that treated Mrs Stanford and Group Members, and which acquired the Affected Implants for re-supply and surgical implantation into persons, including Mrs Stanford and Group Members.

15. The supply as alleged in paragraphs 13 and 14 was in trade or commerce within the meaning of section 4 of the TPA.

Particulars

Johnson & Johnson and DePuy are each part of the same group of companies in that they are each subsidiaries of Johnson & Johnson Inc, a public company incorporated in the United States of America and listed on the New York Stock Exchange.

Johnson & Johnson supplied the Affected Implants to treating hospitals and/or doctors in Australia for monetary reward. This supply was in trade or commerce within Australia.

DePuy supplied the Affected Implants to Johnson & Johnson for the purpose of sale to treating hospitals and/or doctors for monetary reward. This supply was in trade or commerce between Australia and places outside Australia.

Further particulars may be provided after discovery if necessary.

Acquisition of the Affected Implants by Mrs Stanford and Group Members

16. On 31 August 2005, Mrs Stanford's treating doctor recommended that she consider hip replacement surgery on her left hip.

Particulars

On 31 August 2005, Mrs Stanford had a consultation with Dr John Mills, who noted that Mrs Stanford was having increasing disability associated with a severely arthritic left hip as a result of developmental dysplasia of the hip. Dr Mills noted that Mrs Stanford's symptoms clearly interfered with her quality of life, that she was very disabled and walks with a shuffling gait, that she has with a marked limp and a positive Trendelendberg sign and restricted range of motion. In view of these findings, Dr Mills recommended that Mrs Stanford consider hip replacement surgery.

17. On 17 November 2005, on the advice of Mrs Stanford's treating doctor, an Affected Implant was surgically implanted into Mrs Stanford's left hip during a total hip replacement.

Particulars

Mrs Stanford's Affected Implant was surgically implanted by Dr John Mills on 17 November 2005 at the Lenah Valley Campus of Calvary Health Care in Tasmania.

Mrs Stanford's Affected Implant comprised the following components:

(a) DePuy ASR Total Acetabular Implant (Size 48, Standard Duofix);

(b) DePuy ASR Unipolar Femoral Implant (Size 43);

(c) DePuy ASR Taper Sleeve Adaptor (12/14 Taper +2); and

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

18. Mrs Stanford and each Group Member was supplied with an Affected Implant by her or his treating hospital or doctor on the advice of her or his treating doctor.

Particulars

Mrs Stanford's Affected Implant were supplied by the Lenah Valley Campus of Calvary Health Care in Tasmania.

Mrs Stanford also repeats the particulars to paragraph 17.

19. The price for which Mrs Stanford and Group Members acquired the Affected Implants did not, respectively, exceed $40,000.

20. Mrs Stanford and each Group Member acquired an Affected Implant for personal use and not for any of the following purposes:

(a) re-supplying the Affected Implant; or

(b) using up or transforming an Affected Implant, in trade or commerce, in the course of a process of production or manufacture; or

(c) repairing or treating other goods or fixtures on land.

21. By reason of the matters in paragraphs 19 and 20, the supply of the Affected Implants to Mrs Stanford and each Group Member as pleaded in paragraph 18 was to them as consumers within the meaning of section 4B of the TPA.

22. On or about 25 November 2005, Mrs Stanford was discharged from hospital following her hip replacement surgery.

Recall of the Affected Implants

23. In about December 2009, DePuy and/or Johnson & Johnson withdrew supply of the Affected Implants in Australia.

Particulars

Further particulars will be provided after discovery.

24. On or about 8 March 2010, DePuy published an Urgent Field Safety Notice in the United Kingdom in which it noted that its analysis of data from a variety of sources suggested a higher than expected revision rate for the Affected Implants which was linked to the use of head sizes of less than 50 millimetres.

Particulars

Urgent Field Safety Notice dated 8 March 2010.

25. In about March 2010, Johnson & Johnson published a Safety Alert Notice in Australia in relation to the Affected Implants after receiving new data from the United Kingdom that demonstrated that the Affected Implants had a higher than expected revision rate after three years when used with head sizes of less than 50 millimetres.

Particulars

Further particulars will be provided after discovery.

26. On or about 24 August 2010, DePuy ceased the supply of the Affected Implants in the United Kingdom and conducted a voluntary recall of the Affected Implants in the United Kingdom.

Particulars

Urgent Field Safety Notice dated 24 August 2010.

27. On or about 30 August 2010, Johnson & Johnson in consultation with the Therapeutic Goods Administration circulated an Urgent Medical Device Hazard Alert in Australia in which it issued additional information regarding the Affected Implants and:

    (a) recommended that patients who received an Affected Implant should be informed of the Urgent Medical Device Hazard Alert and instructed to return for a follow up visit;

(b) recommended that patients who were symptomatic or implanted with a cup angle greater than 45 degrees, particularly where a small component had been implanted, should be considered for testing of metal ion levels and that if testing revealed soft tissue reactions, fluid collections or tissue masses then revision surgery should be considered;

(c) noted that a small number of 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; and

(d) stated that the early revision of poorly performing hip replacements that generate metal debris should give a better revision outcome.

Particulars

Urgent Medical Device Hazard Alert dated 30 August 2010.

The Fault

28. The Affected Implants acquired by Mrs Stanford and Group Members were designed, manufactured or recommended for use in such a way that, after being surgically implanted in persons during hip replacement, hip arthroplasty or hip resurfacing surgery, they:

(a) carried a superadded risk of the person requiring revision hip replacement, hip arthroplasty or hip resurfacing surgery; and/or

(b) carried a superadded risk of the person developing subsequent pain, swelling or decreased range of movement in the hip on the same side that the Affected Implant was surgically implanted; and/or

(c) carried a superadded risk of producing metal wear debris in the hip joint in which the Affected Implant was surgically implanted,

(the **Fault**).

Particulars

Particulars will be provided after discovery.

Failure and revision of Mrs Stanford's Affected Implant

29. On 17 December 2010, Mrs Stanford had a consultation with her treating doctor, who concluded that Mrs Stanford was having signs of impending failure of her Affected Implant and that she was likely to require revision surgery.

Particulars

Letter dated 17 December 2010 from Dr John Mills to Dr Doris Ng in which Dr Mills noted that:

(a) 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;

(b) 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;

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

(d) 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.

30. On 22 December 2010, Mrs Stanford had a consultation with her treating doctor, who informed her that it was inevitable that she would require revision surgery for the removal of the Affected Implant from her left hip.

Particulars

Letter dated 22 December 2010 from Dr John Mills to Dr Doris Ng in which Dr Mills noted that an 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.

31. On 10 January 2011, on the advice of Mrs Stanford's treating doctor, the Affected Implant was surgically removed from Mrs Stanford's left hip and replaced by another prosthetic device.

Particulars

The Affected Implant was removed from Mrs Stanford's left hip by Dr John Mills at the Lenah Valley Campus of Calvary Health Care in Tasmania on 10 January 2011.

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 Affected 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.

32. On or about 22 January 2011, Mrs Stanford was discharged from hospital following the revision of her Affected Implant in her left hip.

Unsuitable goods – section 74B of the TPA

33. By reason of the matters pleaded in paragraphs 3(b), 4(b), 7-11 and 13-21 above:

    (a) DePuy, a foreign corporation, in trade or commerce, supplied Affected Implants manufactured by it to Johnson & Johnson, which acquired the Affected Implants for re-supply, and treating hospitals and/or treating doctors supplied the Affected Implants to Mrs Stanford and Group Members as consumers; and/or

    (b) Johnson & Johnson, a trading corporation, in trade or commerce, supplied Affected Implants manufactured by it to treating hospitals and/or doctors, which acquired the Affected Implants for re-supply, and treating hospitals and/or doctors then supplied the Affected Implants to Mrs Stanford and Group Members as consumers.

34. The Affected Implants were acquired by Mrs Stanford and Group Members for the purpose of having the Affected Implants surgically implanted into their bodies in order to facilitate or restore hip joint function including for the purposes of relieving pain and increasing mobility (**Particular Purpose**).

35. The Particular Purpose was either expressly or by implication made known to DePuy and Johnson & Johnson.

Particulars

This knowledge is to be inferred from the purpose for which the Affected Implants were designed, manufactured, promoted and distributed and from the fact that Johnson & Johnson was the sponsor of the Affected Implants within the meaning of the Therapeutic Goods Act 1989 *(Cth).*

In the Surgical Technique manual published by DePuy in 2006 in relation to the DePuy ASR Articular Surface Replacement System, it was

noted that the DePuy ASR system is indicated for total joint replacement in patients with severe pain and disability secondary to structural damage in the hip joint.

In a brochure published by DePuy in 2005 in relation to the DePuy ASR XL Head System, it was said that the system was designed to provide high function for all patients. Under the heading "Restoring the patient's normal range of motion and minimising the risk of dislocation", it was said that the system generated an excellent range of motion (141° to 156°) across the size range and that 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.

Further particulars will be provided after discovery.

36. By virtue of the Fault, the Affected Implants acquired by Mrs Stanford and Group Members were not reasonably fit for the Particular Purpose within the meaning of section 74B of the TPA.

37. Mrs Stanford and Group Members suffered injury, loss or damage by reason that the Affected Implants were not reasonably fit for the Particular Purpose.

Particulars

The loss or damage suffered by Mrs Stanford 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;*
- *economic loss;*
- *health care expenses;*
- *other out of pocket expenses;*
- *the need for gratuitous and/or commercial care and assistance;*
- *non-economic loss.*

Goods of unmerchantable quality – section 74D of the TPA

38. By reason of the matters pleaded in paragraphs 3(b), 4(b), 7-11 and 13-21 above:

(a) DePuy, a foreign corporation, in trade or commerce, supplied Affected Implants manufactured by it to Johnson & Johnson, which acquired the Affected Implants for re-supply, and treating hospitals supplied the Affected Implants to Mrs Stanford and Group Members as consumers; and/or

(b) Johnson & Johnson, a trading corporation, in trade or commerce, supplied Affected Implants manufactured by it to treating hospitals, which acquired the Affected Implants for re-supply, and treating hospitals then supplied the Affected Implants to Mrs Stanford and Group Members as consumers.

39. By virtue of the Fault, the Affected Implants acquired by Mrs Stanford and Group Members were not of merchantable quality within the meaning of section 74D(1)(c) of the TPA in that they were not as fit for the purpose or purposes for which components of total hip replacement, hip arthroplasty and hip resurfacing systems are commonly bought as it is reasonable to expect.

Particulars

The purposes for which components of total hip replacement, hip arthroplasty and hip resurfacing systems are commonly bought include the facilitation or restoration of hip joint function and the relief of pain and disability as a result of structural damage caused to a person's hip joint as a result of 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.

The Affected Implants were described in the surgical technique manuals and marketing brochures published by DePuy as goods specifically designed and manufactured for these purposes. They were surgically implanted Mrs Stanford's and Group Members' treating orthopaedic surgeons on the expectation that they would fulfil these purposes.

40. Mrs Stanford and Group Members suffered injury, loss or damage by reason that the Affected Implants were not of merchantable quality.

Particulars

The loss or damage suffered by Mrs Stanford 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;*

- *economic loss;*
- *health care expenses;*
- *other out of pocket expenses;*
- *the need for gratuitous and/or commercial care and assistance;*
- *non-economic loss.*

Negligence

41. As the manufacturer of the Affected Implants, DePuy owed Mrs Stanford and Group Members a duty to exercise reasonable care so as to avoid injuries occurring as a result of their use.

42. DePuy was negligent.

Particulars

DePuy:

(a) designed the Affected Implants in such a way that, when implanted, they carried a superadded risk of revision hip replacement, hip arthroplasty or hip resurfacing surgery being required;

(b) designed the Affected Implants in such a way that, when implanted, they carried a superadded risk of the person developing subsequent pain, swelling, or a decreased range of movement in the hip on the same side surgery was performed;

(c) designed the Affected Implants in such a way that, when implanted, they carried a superadded risk of producing metal wear debris in the hip joint in which they were implanted;

(d) prior to supplying the Affected Implants to Johnson & Johnson for re-supply and use in hip replacement, hip arthroplasty or resurfacing surgery, failed to test them either adequately or at all for any superadded risk, when implanted, of:

- *revision hip replacement, hip arthroplasty or hip resurfacing surgery being required;*
- *the person developing subsequent pain, swelling, or a decreased range of movement in the hip on the same side surgery was performed;*

- *producing metal wear debris in the hip joint in which they were implanted;*

(e) *failed promptly to warn Johnson & Johnson, hospitals, orthopaedic surgeons, Mrs Stanford and Group Members that the Affected Implants when implanted carried superadded risks of:*

- *revision hip replacement, hip arthroplasty or hip resurfacing surgery being required;*

- *the person developing subsequent pain, swelling, or a decreased range of movement in the hip on the same side surgery was performed;*

- *producing metal wear debris in the hip joint in which they were implanted.*

43. As the distributor and supplier of the Affected Implants within Australia and as the sponsor of the Affected Implants as pleaded in paragraph 12 above, Johnson & Johnson owed Mrs Stanford and Group Members a duty to exercise reasonable care so as to avoid injuries occurring as a result of the use of the Affected Implants.

44. Johnson & Johnson was negligent.

Particulars

Johnson & Johnson failed promptly to warn hospitals, orthopaedic surgeons, Mrs Stanford and Group Members that the Affected Implants when implanted carried superadded risks of:

- *revision hip replacement, hip arthroplasty or hip resurfacing surgery being required;*

- *the person developing subsequent pain, swelling, or a decreased range of movement in the hip on the same side surgery was performed;*

- *producing metal wear debris in the hip joint in which they were implanted.*

45. As a result of the negligence of DePuy, Mrs Stanford and Group Members suffered loss or damage.

Particulars

The loss or damage suffered by Mrs Stanford 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;

- *economic loss;*
- *health care expenses;*
- *other out of pocket expenses;*
- *the need for gratuitous and/or commercial care and assistance;*
- *non-economic loss.*

46. As a result of the negligence of Johnson & Johnson, Mrs Stanford and Group Members suffered loss or damage.

Particulars

The loss or damage suffered by Mrs Stanford 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;*
- *economic loss;*
- *health care expenses;*
- *other out of pocket expenses;*
- *the need for gratuitous and/or commercial care and assistance;*
- *non-economic loss.*

Liability of DePuy and Johnson & Johnson

47. By reason of:

(a) the matters in paragraph 37; and/or

(b) the matters in paragraph 40; and/or

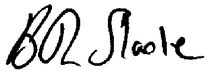
(c) the matters in paragraph 45; and/or

(d) the matters in paragraph 46,

DePuy and/or Johnson & Johnson are liable to compensate Mrs Stanford and Group Members who have suffered injury, loss and damage.

The applicant claims, in her own right and on behalf of Group Members, the relief specified in the application.

Date: 28 February 2011



Ben Slade
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Solicitor for the applicant

This pleading was prepared by Julian Schimmel, solicitor and Duncan Graham of counsel.

IN THE FEDERAL COURT OF AUSTRALIA
NEW SOUTH WALES DISTRICT REGISTRY
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No. of 2011

TAMMY MAREE STANFORD
Applicant

DEPUY INTERNATIONAL LIMITED
First Respondent

JOHNSON & JOHNSON MEDICAL PTY LIMITED
ACN 000 160 403
Second Respondent

CERTIFICATE OF LEGAL PRACTITIONER

(Order 11, rule 1B)

I, **BEN SLADE**, legal practitioner, certify to the Court that, in relation to the pleading dated 28 February 2011 filed on behalf of the applicant the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 28 February 2011

BD Slade

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Ben Slade
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