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Details of Filing

Document Lodged:	Statement of Claim - Form 17 - Rule 8.06(1)(a)
File Number:	NSD35/2018
File Title:	JODIE PHILIPSEN & ANOR v ASTORA WOMEN'S HEALTH LLC
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA

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Important Information

As required by the Court's Rules, this Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

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THIRD FURTHER AMENDED STATEMENT OF CLAIM

Form 17
Rule 8.05(1)(a)

~~Second~~ Third Further Amended Statement of Claim

No. 35 of 2018

Federal Court of Australia

District Registry: New South Wales

Division: General

Jodie Philipsen

First Applicant

Janice Seymour

Second Applicant

~~**American Medical Systems LLC**~~

Astora Women's Health, LLC

Respondent

Part A – Introduction

(i) Group Members

1. The Applicants 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 other persons (**Group Members**) who as at 31 July 2018:

      (i) had surgery performed on them in Australia to implant one or more of the following Implants (**Implants**):

         (A) mesh implants (**Mesh Implants**), consisting of:

            (i) the implants contained in the Perigee Transobturator Anterior Prolapse Repair System being an:

               i. IntePro™ (**the Perigee IntePro™ Implant)** which was made of non-absorbable polypropylene; or

Filed on behalf of (name & role of party) Jodie Philipsen and Janice Seymour, the Applicants
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ii. IntePro™ Lite (**the Perigee IntePro™ Lite Implant)** which was made of lighter weight non-absorbable polypropylene;

(ii) the implants contained in the Apogee Vaginal Vault and Posterior Prolapse Repair System being an:

i. IntePro™ (**the Apogee IntePro™ Implant**) which was made of non-absorbable polypropylene; or

ii. IntePro™ Lite (**the Apogee IntePro™ Lite Implant)** which was made of a lighter weight non-absorbable polypropylene;

(iii) the implants contained in the Elevate Anterior and Apical Prolapse Repair System (**the Elevate Anterior and Apical Implant**) which were made of IntePro™ Lite, non-absorbable polypropylene mesh;

(iv) the implants contained in the Elevate Apical and Posterior Prolapse Repair System (**the Elevate Apical and Posterior Implant**) which were made of IntePro™ Lite, non-absorbable polypropylene mesh;

(Group Members who had surgery to implant one or more of the Mesh Implants being the **Mesh Sub-Group Members);** and/or

(B) sling implants (**Sling Implants**), consisting of:

(i) the implants contained in the SPARC Sling System (**Sparc Implant**) which were made with AMS Polypropylene sling mesh;

(ii) the implants contained in the MONARC Subfascial Hammock System (**Monarc Implant**) which were made with AMS Polypropylene sling mesh;

(iii) the implants contained in the MiniArc Single-Incision Sling System (**MiniArc Single Incision Implant**) which were made with AMS Polypropylene sling mesh;

(iv) the implants contained in the MiniArc Precise Single-Incision Sling System (**MiniArc Precise Implant**) which were made with AMS Polypropylene sling mesh;

(v) the implants contained in the MiniArc Pro Single-Incision Sling System (**MiniArc Pro Implant**) which were made with AMS Polypropylene sling mesh;

(vi) the implants contained in the RetroArc Retropubic Sling System (**RetroArc Implant**) which were made with polypropylene mesh;

(Group Members who had surgery to implant one or more of the Sling Implants being the **Sling Sub-Group Members)**; and

(ii) have suffered from one or more of the Implant Complications and/or Implant Removal Complications pleaded in paragraphs 9 and 10 below;

(ii) The Applicants

2. The First Applicant (Ms Philipsen):

(a) was born on 18 February 1969;

(b) is married with two children; and

(c) is a Mesh Sub-Group Member by reason of the matters pleaded at paragraphs 16 to 27 below.

3. The Second Applicant (Ms Seymour):

(a) was born on 17 January 1961;

(b) has given birth to four children; and

(c) is a Sling Sub-Group Member by reason of the matters pleaded at 48 to 59 below.

(iii) <u>American Medical Systems LLC</u>~~The Respondent~~

4. At all material times <u>until, at the latest, 28 June 2018</u>, American Medical Systems LLC ("**AMS LLC**"):

(a) was ~~and is a~~ a company incorporated under the laws of the United States of America;

(b) was formerly known as American Medical Systems, Inc.;

(c) was ~~and is~~ a foreign corporation within the meaning of section 4 of the *Trade Practices Act 1974* (Cth) (**the TPA**) and section 4 of the *Competition and Consumer Act 2010* (Cth) (**the CCA**);

(d) carried on the business of:

(i) supplying the Implants in trade or commerce, either directly or through a related entity (AMS Sales LLC (**AMS Sales**)), to another related entity (American Medical Systems Australia Pty Limited (**AMS Australia**)) so as to be distributed to hospitals or alternatively to doctors in Australia for resupply to patients including the Applicants and Group Members; and, or in the alternative

(ii) marketing and promoting the Implants;

in Australia;

PARTICULARS

Conduct of business in Australia by supply the Implants

AMS LLC supplied the Implants, directly or through AMS Sales, to AMS Australia during the following periods of time:

A. the Monarc Implants from about January 2003 until about 19 January 2016;

B. the Apogee IntePro Implants and the Apogee IntePro Lite Implants from about July 2004 until about 19 January 2016;

C. the Perigee IntePro Implants and the Perigee IntePro Lite Implants from about July 2004 until about 19 January 2016;

D. the Sparc Implants from about May 2001 until about 19 January 2016;

E. the MiniArc Precise Implants from about July 2010 until about 19 January 2016;

F. the MiniArc Single Incision Implants from about September 2007 until about 19 January 2016;

G. the MiniArc Pro Implants from about September 2007 until about August 2016;

H. the Elevate Anterior and Apical Implants from about July 2009 until about 19 January 2016;

I. the Elevate Apical and Posterior Implants from about December 2008 until about 19 January 2016;

J. the RetroArc Implant from about 2013 until about 19 January 2016.

Conduct of business in Australia by marketing and promotion of the Implants

AMS LLC marketed and promoted the Implants in Australia by, amongst other things, causing the distribution of its product brochures to doctors, including for re-distribution to patients, including:

A. a product brochure for the Apogee and Perigee Implants titled "*Restore your body, Pelvic Organ Prolapse, AMS Solutions for Life"*;

B. a product brochure for the Apogee Implant titled "*Apogee: Vaginal Vault and Posterior Repair System*";

C. a product brochure for the Perigee Implants titled "*The Comprehensive System and Standardized Approach for Anterior Prolapse Repair: Transobturator Anterior Prolapse Repair System*";

D. a product brochure for the Elevate implants titled "*Elevate Apical and Prolapse Repair System – A Total Transvaginal Approach to Prolapse Repair requiring just a Single Incision*";

E. a product brochure for the Elevate Implants titled "*Elevate Prolapse Repair System, a Guide to Prolapse Repair*";

F. a product brochure for the Elevate Implants titled "*Elevate Prolapse Repair System, a Guide to Correcting Pelvic Organ Prolapse – AMS Solutions for Life*";

G. a product brochure for the Monarc Implant titled "*Continence Restored with Confidence: A Proven Transobturator System for Female Stress Urinary Incontinence*";

H. a product brochure for the Monarc Implant titled "*Loss of Bladder Control is Treatable: Take Control and Restore Your Lifestyle*";

I. a product brochure for the Monarc Implant titled "*The confident cure for incontinence: Regain Control and Restore Your Lifestyle*"; and

J. a product brochure for the Monarc Implant and Sparc Implant titled "*Take Control of Stress Urinary Incontinence, AMS Solutions for Life*".

Further particulars may be provided following discovery.

4A. Further:

(a) in the period from:

(i) about January 2003 to 31 May 2012, AMS LLC produced or assembled the Monarc Implants;

(ii) about July 2004 to 31 May 2012, AMS LLC produced or assembled the Apogee IntePro Implants and the Apogee IntePro Lite Implants;

(iii) about July 2004 to 31 May 2012, AMS LLC produced or assembled the Perigee IntePro Implants and the Perigee IntePro Lite Implants;

(iv) about May 2001 to 31 May 2012, produced or assembled the Sparc Implants;

(v) about July 2010 to 31 May 2012, produced or assembled the ~~the~~ MiniArc Precise Implants;

(vi) about September 2007 to January 2011, AMS LLC produced or assembled the MiniArc Single Incision Implants;

(vii) about September 2007 to 31 May 2012, AMS LLC produced or assembled the MiniArc Pro Implants;

(viii) about July 2009 to 31 May 2012, AMS LLC produced or assembled the Elevate Anterior and Apical Implants;

(ix) about December 2008 to 31 May 2012, AMS LLC produced or assembled the Elevate Apical and Posterior Implants; and, or alternatively;

(b) at all material times AMS LLC held itself out to the public as the manufacturer of the Implants; and, or alternatively

PARTICULARS

A. The technical file concerning the Elevate Implants held out American Medical Systems, Inc. (being the predecessor name of AMS LLC) as the legal manufacturer of those implants.

B. The technical file concerning the Sparc and Monarc Implants held out American Medical Systems, Inc. (being the predecessor name of AMS LLC) as the legal manufacturer of those implants.

C. The technical file concerning the Perigee Implants held out American Medical Systems, Inc. (being the predecessor name of AMS LLC) as the legal manufacturer of those implants.

D. The technical file concerning the Apogee Implants held out American Medical Systems, Inc. (being the predecessor name of AMS LLC) as the legal manufacturer of those implants.

E. The technical file concerning the MiniArc Implants held out American Medical Systems, Inc. (being the predecessor name of AMS LLC) as the legal manufacturer of those implants.

Further particulars may be provided following discovery.

(c) at all material times AMS LLC caused or permitted its name to be applied to each of the Implants; and

PARTICULARS

A. The name “American Medical Systems, Inc.”, being the name by which AMS LLC was then known, was applied to the packaging in which the Implants were supplied.

B. Further, the name “American Medical Systems, Inc.” was applied to the Instructions for Use labels which accompanied the Implants.

Further particulars may be supplied following discovery.

(d) ~~By~~ by reason of the matters set out at subparagraphs (a), (b) and, or alternatively, (c) above, was at all material times the manufacturer of each of the Implants for the purposes of the TPA and ACL.

PARTICULARS

A. The applicants refer to ss.74A(1) and ss74A(3)(a) and (b) of the TPA and ss.7(1)(a), (b) and (c) of the ACL.

Part B – The Conditions, Implants and Complications

(i) The Conditions

5. Pelvic organ prolapse (**POP**):

(a) can occur when pelvic support structures are damaged, weakened or otherwise compromised;

(aa) is an anatomical change in which there is a downward displacement of a pelvic organ;

(b) involves one or more of the following organs descending into the vagina or past the vaginal opening:

(i) the bladder (being the cystocele form of POP);

(ii) the uterus (being the procidentia form of POP);

(iii) the rectum (being the rectocele form of POP);

(iv) pre-hysterectomy, the apex of the vagina (being apical prolapse);

(v) post-hysterectomy, the apex of the vagina (being vaginal vault prolapse); and

(vi) the bowel (being the enterocele form of POP);

(bb) is not a life-threatening condition;

(c) may result in one or more of the following symptoms (**the POP Symptoms**):

(i) problems with bowel movement;

(ii) problems with voiding;

(iii) problems during sexual intercourse;

(iii) vaginal bulge; and

(iv) feelings of pelvic and in addition, or alternatively, vaginal fullness, heaviness, discomfort and/or pain; and

(cc) may be treated, surgically or non-surgically, at the election of the patient.

6. Stress urinary incontinence (**SUI**):

(a) can occur when pelvic support structures to the bladder and urethra are damaged, weakened or otherwise compromised; and

(b) involves urine involuntarily leaking from the urethra during moments of increased abdominal pressure such as with physical activity, coughing, sneezing or laughing (**the SUI Symptoms)**; and

(c) may be treated, surgically or non-surgically, at the election of the patient.

(ii) The Implants

7. The Implants are surgical implants that were:

(a) made, at least partly, from polypropylene;

(b) implanted transvaginally; and

(c) implanted in such a way that they:

(i) passed through;

(ii) attached to; and in addition or alternatively,

(iii) were brought into proximity with

the vagina and, in the case of the Sling Implants, the urethra;

(d) intended to, and did, elicit a chronic inflammatory reaction of the tissues and, or alternatively, the surrounding tissues in which they are implanted; and

(e) remain, for so long as they are implanted, catalysts for the continuous regeneration of scar tissue within and surrounding the Implant, which can cause the Implant (separately or in conjunction with surrounding tissue) to contract.

8. The price of the Implants acquired by each of the Group Members did not, respectively, exceed forty thousand dollars ($40,000) per Implant.

(iii) The Implant Risks and Complications

9. By reason of one or more of the matters pleaded at paragraph 7, or in any event, the Implants had a risk of and in addition, or alternatively were susceptible to causing the following complications (**Implant Complications**):

~~(a) causing a chronic inflammatory reaction of the tissues in which the Implants were implanted, attached and in addition, or alternatively, the surrounding tissues;~~

~~(b) the chronic inflammatory reaction resulting in the continuous regeneration of scar tissue within and surrounding the Implant for so long as it remained in the body, causing the Implant (separately or in conjunction with surrounding tissue) to contract;~~

~~(c) causing further complications, the likelihood of which could not be predicted for any patient, including:~~

~~(i) chronic pain with potentially life altering consequences with or without psychiatric injury;~~

~~(ii) damage to entrapment of nerves in the scar tissue surrounding the Implant resulting in chronic pain with potentially life altering consequences with or without psychiatric injury;~~

~~(iii) de novo dyspareunia including severe chronic dyspareunia, worsened dyspareunia and in addition, or alternatively, apareunia;~~

~~(iv) erosion or extrusion of the Implant into the vaginal canal resulting in infection of the tissue surrounding the non-exposed part of the Implant which may be difficult to treat resulting in offensive vaginal discharge;~~

~~(v) erosion or extrusion of the Implant into the vaginal canal resulting in pain suffered by the patient, her partner or both during sexual intercourse;~~

~~(vi) erosion or extrusion of the Implant into surrounding organs such as the bladder, urethra or rectum with the risk of damage to those organs and pain;~~

~~(vii) difficulty voiding or defecating;~~

~~(viii) de novo urge incontinence and/or urge incontinence;~~

~~(ix) de novo stress urinary incontinence in the case of the Mesh Implants; and~~

~~(x) infection~~

~~(the complications referred to at subparagraphs (a) to (c) being the **Implant Complications**)~~

~~(d) requiring reoperation or revision surgery associated with Implant Complications;~~

~~(e) not fulfilling, in the case of the Mesh Implants, the Mesh Purpose (as defined at paragraph 11) or, in the case of the Sling Implants, the Sling Purpose (as defined at paragraph 43).~~

(a) pain, which may be chronic and, or, severe and may be refractory to treatment;

(b) entrapment of nerves in the scar tissue surrounding the Implant resulting in pain which may be chronic and, or, severe and may not remain localised and may be refractory to treatment;

(c) de novo dyspareunia which may be severe, worsened dyspareunia and in addition, or alternatively, apareunia;

(d) erosion or extrusion of the Implant into the vaginal canal resulting in:

(i) infection of the tissue surrounding the non-exposed part of the Implant which may be difficult to treat effectively and may result in offensive discharge;

(ii) pain including during sexual intercourse;

(e) erosion or extrusion of the Implant into surrounding organs such as the bladder, urethra or rectum with the risk of damage to those organs, infection and, or, pain;

(f) difficulty voiding or defecating;

(g) urge incontinence;

(h) de novo stress urinary incontinence in the case of the POP Implants; and

(i) psychiatric injury as a consequence of the development of one or more of the complications referred to at (a) to (h) above.

9A The risk that a patient may suffer an Implant Complication is a lifelong risk.

9B The likelihood of occurrence of an Implant Complication cannot be accurately predicted for a patient, although certain patients may be particularly susceptible (**Particularly Susceptible Patients**) to Implant Complications, including if they:

(a) suffer an autoimmune condition or connective tissue disorder;

(b) have used or are using immuno-suppressant medication;

(c) are of an advance age;

(d) are obese;

(e) suffer uncontrolled diabetes; and, or

(f) are anaemic.

10. Further, at all material times:

(a) the Implants were designed to be permanent implants and were difficult or impossible safely to remove from patients suffering from one or more of the Implant Complications;

(b) treatment of the Implant Complications was difficult or impossible, or alternatively carried with it the risk of new or aggravated complications; ~~and in addition or alternatively~~

(c) treatment of the Implant Complications may require one or more surgical procedures for the purpose of removing the Implants or parts thereof that were reasonably capable of being removed; and

(d) patients may suffer psychiatric injury as a consequence of the matters referred to at paragraphs (a) to (c) above

(**the Implant Removal Complications**)

Part C – The Mesh Implants

(i) Purpose of the Mesh Implants

11. The Mesh Implants were designed and manufactured to:

    (a) be used during pelvic surgery for the safe and effective treatment of pelvic organ prolapse;

    (b) restore safely and effectively pelvic anatomy and pelvic function; and

    (c) thereby alleviate the symptoms of pelvic organ prolapse.

    (the Mesh Purpose).

12. The Mesh Purpose was the purpose for which implants of a kind such as the Mesh Implants were commonly supplied.

(ii) Alternative treatments for POP

13. At all material times:

    (a) reconstructive surgery for the treatment for POP could be undertaken without the use of Mesh Implants (**Native Tissue Repair**);

    (b) Native Tissue Repair was as effective in treating POP, or in the alternative was not materially less effective in treating POP, as reconstructive surgery for the treatment for POP undertaken using Mesh Implants;

    (c) in addition to sub-paragraph (b) above, Native Tissue Repair was as effective in achieving the Mesh Purpose, or in the alternative was not materially less effective in achieving the Mesh Purpose, as reconstructive surgery for the treatment for POP undertaken using Mesh Implants;

    (d) Native Tissue Repair did not have the risks of, and in addition, or alternatively, was not susceptible to causing, the Mesh Complications and the Mesh Removal Complications;

    (e) in addition to sub-paragraph (d) above, Native Tissue Repair:

        (i) did not have the risk of, and in addition, or alternatively, was not susceptible to causing, the Implant Complications; or in the alternative

        (ii) did not have as great a risk of, and in addition, or alternatively, was not materially more susceptible to causing, the Implant Complications; and

    (f) Native Tissue Repair was an accepted method of reconstructive surgery for the treatment for POP;

(g) In addition, or alternatively Native Tissue Repair was as safe in treating POP, or the alternative was not materially less safe in treating POP, as reconstructive surgery for the treatment of POP undertaking using Mesh Implants;

(h) In addition, or alternatively Native Tissue Repair was as safe in achieving the Mesh Purpose, or in the alternative was not materially less safe in achieving the Mesh Purpose, as reconstructive surgery for the treatment of POP undertaken using Mesh Implants.

(iii) Evaluation and warnings in respect of the Mesh Implants

14. Prior to the release in Australia of the Mesh Implants and the supply, distribution, marketing or promotion in Australia of the Mesh Implants, AMS LLC did not undertake adequate clinical or other evaluation of the risks associated with the effectiveness, including long-term risks and long-term effectiveness, associated with the use of the Mesh Implants, including:

(a) the risk of the occurrence of the Implant Complications;

(b) the risk of occurrence of the Implant Removal Complications;

(c) whether reconstructive surgery for the treatment of POP undertaken using Mesh Implants was more effective, or in the alternative was not materially less effective than Native Tissue Repair in treating POP; and

(d) whether reconstructive surgery for the treatment of POP undertaken using Mesh Implants was safer, or in the alternative was not materially less safe than Native Tissue Repair in treating POP~~;~~

~~(e) whether the technique by which the Mesh Implants were designed to be inserted was reliable and reproducible~~

(**the Mesh Evaluation Matters**).

15. At all material times, AMS LLC failed to give sufficient information or warning to the Mesh Sub-Group Members (directly or by providing sufficient information or warning to their treating hospital and/or treating doctors)

(a) of:

(i) the risk or susceptibility of the Mesh Implants to cause one or more of the Implant Complications;

(i)(A) the heightened risks for Particularly Susceptible Patients associated with the use of the Implants;

(ii) the Implant Removal Complications; and in addition, or alternatively

(iii) the Mesh Evaluation Matters;

(b) of the matters pleaded in paragraph 14 above

(**the Mesh Warning Matters**).

(iv) Ms Philipsen's Mesh Implants

16. On or around 18 April 2006 Ms Philipsen was suffering from POP in the form of:

    (a) a symptomatic, grade 2 utero-vaginal prolapse; and

    (b) a cystocele.

17. On 18 April 2006, Ms Philipsen consulted obstetrician and gynaecologist, and Mrs Philipsen's Treating Doctor, Dr Serag Youssif, who diagnosed her as suffering from POP and advised her of the option to treat her POP by undergoing pelvic surgery using Mesh Implants.

18. On 5 July 2006, on the advice of Dr Serag Youssif, Ms Philipsen had pelvic surgery, during the course of which she was implanted with a Perigee IntePro™ Implant and an Apogee IntePro™ Implant.

PARTICULARS

Ms Philipsen was implanted with a Perigee IntePro™ Implant and an Apogee IntePro™ Implant by Dr Serag Youssif at Epworth Eastern, 1 Arnold Street, Box Hill, Victoria. The implants were supplied to Ms Philipsen by Dr Youssif and in addition, or alternatively, by Epworth Eastern.

19. At no time before 5 July 2006 was Ms Philipsen informed of the Mesh Warning Matters.

20. Following the implantation of the Perigee IntePro™ and Apogee IntePro™ implants and prior to 25 June 2008, Ms Philipsen experienced Implant Complications, namely:

    (a) pain;

    (b) dyspareunia;

    (c) mesh extrusion through her posterior vaginal wall.

21. On 25 June 2008, Ms Philipsen underwent surgery in order to excise eroded mesh from the posterior vaginal wall.

PARTICULARS

The surgery was performed by Dr Serag Youssif at Epworth Eastern in Box Hill, Victoria.

22. Following the surgery on 25 June 2008 and prior to 25 August 2011, Ms Philipsen experienced Implant Complications and/or Implant Removal Complications, namely:

    (a) pain;

    (b) dyspareunia;

(c) recurrent uterine prolapse;

(d) mesh exposure through her posterior vaginal wall;

(e) slight stress incontinence with a full bladder.

23. On 25 August 2011, Ms Philipsen underwent further surgery in order to excise the eroded mesh from the posterior vaginal wall and undergo a vaginal hysterectomy.

PARTICULARS

The surgery was performed by Dr Yik Lim at the Mitcham Private Hospital in Mitcham, Victoria.

24. Following the surgery on 25 August 2011 and prior to 1 October 2013, Ms Philipsen experienced further Implant Complications and/or Implant Removal Complications, namely:

(a) pain;

(b) dyspareunia;

(c) a pricking sensation in the vagina;

(d) mild urinary urgency;

(e) vaginal discomfort;

(f) mesh exposure through her anterior vaginal wall.

25. On 1 October 2013, Ms Philipsen underwent further surgery in order to excise the exposed mesh from the anterior vaginal wall.

PARTICULARS

The surgery was performed by Dr Yik Lim at Mitcham Private Hospital in Mitcham, Victoria.

26. Following the surgery on 1 October 2013, Ms Philipsen has suffered further Implant Complications and/or Implant Removal Complications, namely:

(a) chronic pain; and

(b) dyspareunia.

27. By reason of the matters pleaded at paragraphs 16 to 26 above, Ms Philipsen has suffered loss and damage for which AMS, LLC was liable until (at the latest) 28 June 2018.

PARTICULARS

(A) Personal injury including one or more of the Implant Complications and Implant Removal Complications including, in respect of the

surgeries undergone on 5 July 2006, 25 June 2008, 25 August 2011 and 1 October 2013, the complications pleaded at paragraphs ~~18~~ 20 to 26 above and psychiatric injury including depression;

(B) Health care expenses;

(C) Additional out of pocket expenses;

(D) Economic loss;

(E) The need for gratuitous and in addition, or alternatively, commercial care; and

(F) Non-economic loss.

Additional particulars may be provided following the service of evidence.

(v) Claims under the *Trade Practices Act* and the *Competition and Consumer Act*

28. The Mesh Implants were goods within the meaning of sections 4 and 74A (2) (a) of the TPA, and sections 2 and 271 of Schedule 2 of the CCA.

29. The Mesh Implants were supplied to each of the Mesh Sub-Group Members as consumers within the meaning of section 4B of the TPA and section 3 of Schedule 2 of the CCA.

30. By reason of:

(a) the fact that prior to the release in Australia of the Mesh Implants and the supply, distribution, marketing or promotion in Australia of the Mesh Implants, AMS LLC did not undertake adequate clinical or other evaluation of the Mesh Evaluation Matters; and

(b) the matters pleaded in paragraphs 9, 9A, 9B, 10 and in addition, or alternatively, 13 above;

(c) the fact that neither the packaging of the Mesh Implants, their Instructions For Use, nor any other document or any other source of information disseminated by AMS LLC gave sufficient warning, advice or information as to some or all of the Mesh Warning Matters; and in addition, or alternatively,

(d) the fact that, by reason of the matters set out in paragraphs (a) to (c) above the Mesh Implants were not fit for the Mesh Purpose

the safety of the Mesh Implants was not such as persons generally were entitled to expect and the Mesh Implants had a defect for the purposes of section 75AC(1) and 75AD(1) of the TPA and, or alternatively, a safety defect for the purposes of sections 9 and 138 of Schedule 2 of the CCA.

31. By reason of the matters pleaded at paragraph 30 (a) to (d) above, the Mesh Implants acquired by each of the Mesh Sub-Group Members were not of merchantable quality

within the meaning of section 74D(3) of the TPA, or acceptable quality within the meaning of section 54 of Schedule 2 of the CCA.

32. In the premises, each of the Mesh Sub-Group Members has suffered loss and damage, by reason of the fact that:

(a) the safety of the Mesh Implants was not such as persons generally were entitled to expect and the Mesh Implants had a defect or a safety defect as pleaded at paragraph 30 (a) to (d) above; and in addition, or in the alternative,

(b) the Mesh Implants were not of merchantable or acceptable quality as pleaded in paragraph 31 above.

PARTICULARS

(A) In respect of Ms Philipsen, the particulars to paragraph 27 above are repeated.

(B) Particulars of each of the other Group Members' loss and damage may be provided after the trial of common issues but is expected to include:

(i) personal injury including one or more of the Implant Complications and Implant Removal Complications;

(ii) health care expenses;

(iii) other out of pocket expenses;

(iv) economic loss;

(v) the need for gratuitous and in addition, or alternatively, commercial care; and

(vi) non-economic loss.

33. In the premises, AMS LLC ~~is~~ was, until 28 June 2018, liable to compensate each of the Mesh Sub-Group Members for their loss and damage pursuant to:

(a) section 75AD of the TPA, or section 138 of Schedule 2 of the CCA, as the case may be; and in addition, or alternatively

(b) section 74D(1) of the TPA, or sections 54, 271 and 272 of Schedule 2 of the CCA, as the case may be.

(vi) Claims in Negligence

34. AMS LLC owed each of the Mesh Sub-Group Members a duty to exercise reasonable care and skill in the design, manufacture, marketing and supply of the Mesh Implants.

35. AMS LLC:

(a) knew or ought to have known that the purpose for which the Mesh Implants were commonly supplied was the Mesh Purpose; and

(b) did not undertake adequate clinical or other evaluation of the Mesh Evaluation Matters prior to the release in Australia of the Mesh Implants and the supply, distribution, marketing or promotion in Australia of the Mesh Implants.

36. In the circumstances pleaded at paragraph 35 above, AMS LLC designed, manufactured, marketed and in addition, or alternatively, supplied the Mesh Implants containing:

(a) the characteristics pleaded at paragraph ~~9~~ 7 above; and in addition, or alternatively;

(b) a risk of, and in addition, or alternatively, a susceptibility to causing the Implant Complications and in addition, or alternatively, the Implant Removal Complications.

37. In addition to paragraph 36 above, AMS LLC continued to design, manufacture, market and in addition, or alternatively, supply the Mesh Implants notwithstanding the matters pleaded in paragraph 35 above.

38. In addition, or alternatively, to paragraphs 35 and 36 above AMS LLC failed to conduct adequate evaluation of the safety and effectiveness of the Mesh Implants in treating POP after releasing them in Australia.

39. AMS LLC:

(a) failed to inform any of the Mesh Sub-Group Members of:

(i) the matters pleaded in paragraphs 35 and 36 (a) and (b) above; and in addition, or alternatively

(ii) the Mesh Warning Matters; and

(b) further or in the alternative, failed to inform:

(i) AMS Australia;

(ii) treating hospitals; and in addition, or alternatively

(iii) treating doctors

of the matters pleaded in paragraph 36 (a) and (b) above; and in addition, or alternatively the Mesh Warning Matters.

40. By reason of the matters pleaded at paragraphs 35 to 39 above, AMS LLC breached its duty of care to each of the Mesh Sub-Group Members pleaded at paragraph 34 above.

41. By reason of the matters pleaded at paragraphs 35 to 40 above, each of the Mesh Sub-Group Members has suffered loss or damage for which ~~each claims damages from~~ AMS LLC was liable until (at the latest) 28 June 2018.

PARTICULARS

The particulars to paragraph 32 above are repeated.

42. ~~In the premises, AMS LLC is liable for the loss or damage suffered by each of the Mesh Sub-Group Members.~~[Not used.]

Part D – The Sling Implants

(i) Purpose of the Sling Implants

43. AMS LLC marketed the Sling Implants as being designed to:

(a) be implanted in women for the safe and effective surgical treatment of pure or predominant stress urinary incontinence;

(b) provide urethral support safely and effectively in patients; and

(c) alleviate safely and effectively involuntary urine leakage caused by stress urinary incontinence.

(**the Sling Purpose**).

44. The Sling Purpose was the purpose for which implants of a kind such as the Sling Implants were commonly marketed.

(ii) Availability of alternative treatments

45. At all material times:

(a) there were alternative treatments available for the treatment of SUI (**Alternative Treatments**) which could be undertaken without the use of Sling Implants;

PARTICULARS

The Alternative Treatments included:

(A) open colposuspension (Burch procedure);
(B) laparoscopic colposuspension;
(C) fascial (or native tissue or autologous) sling repair; and
(D) non-surgical treatments including but not limited to pelvic floor exercises.

(b) the Alternative Treatments were accepted methods of treating SUI;

(c) the Alternative Treatments were as effective in treating SUI, or alternatively were not materially less effective in treating SUI as surgery for the treatment of SUI undertaken using Sling Implants;

(d) the Alternative Treatments did not have the risks of causing, and were not susceptible to cause, some or all of the Implant Complications or the Implant Removal Complications; and

(e) in addition to sub-paragraph 45 (d) above, or alternatively, the Alternative Treatments:

(i) did not have the risks of, and in addition or alternatively, were not susceptible to causing, the Implant Complications or the Implant Removal Complications; and

(ii) did not have a greater risk of, and in addition, or alternatively, were not materially more susceptible to causing, the Implant Complications.

(f) In addition, or alternatively, the Alternative Treatments were as safe in treating SUI, or in the alternative, were not materially less safe in treating SUI, as surgery for the treatment of SUI undertaking using Sling Implants;

(g) In addition, or alternatively, the Alternative Treatments were as safe in achieving the Sling Purpose, or in the alternative, were not materially less safe in achieving the Sling Purpose, as surgery for the treatment of SUI undertaken using Sling Implants.

(iii) Evaluation and warnings in respect of the Sling Implants

46. Prior to the release in Australia of the Sling Implants and the supply, distribution, marketing or promotion in Australia of the Sling Implants, AMS LLC did not undertake adequate clinical or other evaluation of the risks associated with the effectiveness of, including long-term risks and long-term effectiveness associated with the use of the Sling Implants, including:

(a) the risk of occurrence of the Implant Complications;

(b) the risk of occurrence of the Implant Removal Complications;

(c) whether surgery for the treatment of SUI undertaken using Sling Implants was more effective, or in the alternative was not materially less effective than the Alternative Treatments in treating SUI;

(d) whether surgery for the treatment of SUI undertaken using Sling Implants was safer, or in the alternative was not materially less safe than the Alternative Treatments in treating SUI;

(e) whether the technique by which the Sling Implants were designed to be inserted was reliable and reproducible

(**the Sling Evaluation Matters**).

47. AMS LLC failed to give any, or any sufficient, information or warning to the Sling Sub-Group Members, their treating hospitals and/or their treating doctors:

(a) of:

(i) the risk or susceptibility of the Sling Implants to cause one or more of the Implant Complications;

(i)(A) the heightened risks for Particularly Susceptible Patients associated with the use of the Implants;

(ii) the Implant Removal Complications;

(iii) the Sling Evaluation Matters; and in addition, or alternatively

(b) of the matters pleaded in paragraph 45 above

(the **Sling Warning Matters**).

(iv) Ms Seymour's Tape Implant

48. Prior to 9 October 2007, Ms Seymour was suffering from SUI.

49. On 9 October 2007, on the advice of Dr Satish Prasad, Ms Seymour underwent the implantation of a Monarc Implant.

PARTICULARS

Ms Seymour was implanted with a Monarc Implant by Dr Prasad at the Mater Hospital, Ward Street, Rockhampton. The Monarc Implant was supplied to Ms Seymour by Dr Prasad and in addition, or alternatively, the Mater Hospital, Rockhampton.

50. At no time before 9 October 2007 was Ms Seymour informed of the Sling Warning Matters in respect of the Sling Implants.

51. The purpose for which Ms Seymour received the Monarc Implant was the Sling Purpose.

52. Following the implantation of the Monarc Implant and prior to 20 November 2007, Ms Seymour experienced an Implant Complication, namely, erosion.

53. On 20 November 2007, Ms Seymour underwent surgery in order to perform an examination under anaesthetic, a cystoscopy and vaginal suturing. During this procedure, mesh exposure was noted and the exposed mesh was excised.

PARTICULARS

The surgery was performed by Dr Satish Prasad at the Mater Hospital, Ward Street, Rockhampton.

54. Following the surgery on 20 November 2007 and prior to 7 February 2008, Ms Seymour experienced a further Implant Complication, namely, extrusion.

55. On 7 February 2008, Ms Seymour underwent further surgery in order to undergo a partial excision of her Monarc Sling, an examination under anaesthetic and a cystoscopy.

PARTICULARS

The surgery was performed by Dr Satish Prasad at the Mater Hospital, Ward Street, Rockhampton.

56. Following the surgery on 7 February 2008 and prior to 15 August 2008, Ms Seymour experienced further Implant Complications and, or alternatively, Implant Removal Complications, namely:

a. pain;

b. erosion;

c. infection.

56A. On 15 August 2008, Ms Seymour underwent the excision of two strands of the eroded Monarc Sling.

PARTICULARS

The excision was performed by Dr Satish Prasad at the Mater Medical Centre, Jessie Street, Rockhampton.

56B. Following the excision on 15 August 2008 and prior to 1 February 2017, Ms Seymour experienced Implant Complications and, or alternatively, Implant Removal Complications, namely:

a. pain;

b. erosion;

c. infection.

57. On 1 February 2017, Ms Seymour underwent further surgery in order to excise the eroded Monarc Sling.

PARTICULARS

The surgery was performed by Dr David Shaker at the Mater Hospital, Ward Street, Rockhampton.

58. Following the surgery on 1 February 2017, Ms Seymour has suffered further Implant Complications and, or alternatively, Implant Removal Complications, namely:

a. dyspareunia;

b. pain; and

c. incontinence.

59. By reason of the matters pleaded at paragraphs 49 to 58 above, Ms Seymour has suffered loss and damage for which ~~she claims damages from~~ AMS LLC was liable until (at the latest) 28 June 2018.

PARTICULARS

(A) Personal injury including one or more of the Implant Complications and the Implant Removal Complications including, in respect of the surgeries undergone on 20 November 2007, 7 February 2008, and 1 February 2017, the complications pleaded at paragraphs 52 to 58 above;

(B) Health care expenses;

(C) Additional out of pocket expenses;

(D) Economic loss;

(E) The need for gratuitous and in addition, or alternatively, commercial care; and

(F) Non-economic loss.

Additional particulars may be provided following the service of evidence.

(v) Claims under the *Trade Practices Act* and the *Competition and Consumer Act*

60. The Sling Implants were goods within the meaning of sections 4 and 74A(2)(a) of the TPA, and sections 2 and 271 of Schedule 2 of the CCA.

61. The Sling Implants were supplied to each of the Sling Sub-Group Members as consumers within the meaning of section 4B of the TPA and section 3 of Schedule 2 of the CCA.

62. By reason of:

(a) the matters pleaded in paragraphs 9, 9A, 9B, 10, 46 and, or alternatively, 47 above; and, or alternatively

(b) the fact that neither the packaging of the Sling Implants, their Instructions For Use, nor any other document or any other source of information disseminated by AMS LLC gave sufficient warning, advice or information as to some or all of the Sling Warning Matters; and, or alternatively

(c) The Sling Implants not being fit for the purpose for which implants of that kind were commonly acquired

the safety of the Sling Implants was not such as persons generally were entitled to expect and the Sling Implants had a defect for the purposes of sections 75AC(1) and 75AD(1) of the TPA and, or alternatively, a safety defect for the purposes of sections 9 and 138 of Schedule 2 of the CCA.

63. By reason of the matters pleaded at paragraph 62 (a) to (c) above, the Sling Implants acquired by each of the Sling Sub-Group Members were not of merchantable quality within the meaning of section 74D(3) of the TPA, or acceptable quality within the meaning of section 54 of Schedule 2 of the CCA.

64. In the premises, each of the Sling Sub-Group Members has suffered loss and damage, by reason of the fact that:

(a) the safety of any of the Sling Implants was not such as persons generally were entitled to expect as pleaded at paragraph 62 above; and in addition, or alternatively

(b) the Sling Implants were not of merchantable or acceptable quality as pleaded in paragraph 63 above.

PARTICULARS

(A) In respect of Ms Seymour the particulars to paragraph 48 to 59 above are repeated.

(B) Particulars of each of the other Sling Sub-Group Members' loss and damage may be provided after the trial of common issues but is expected to include:

(i) personal injury including one or more of the Sling Complications or Removal Complications;

(ii) health care expenses;

(iii) other out of pocket expenses;

(iv) economic loss;

(v) the need for gratuitous and in addition, or alternatively, commercial care; and

(vi) non-economic loss.

65. In the premises, AMS LLC ~~is~~ was, until (at the latest) 28 June 2018, liable to compensate each of the Sling Sub-Group Members for their loss and damage pursuant to:

(a) section 75AD of the TPA, or section 138 of Schedule 2 of the CCA, as the case may be; and, or alternatively,

(b) section 74D(1) of the TPA, or sections 54, 271 and 272 of Schedule 2 of the CCA, as the case may be.

(vi) Claims in Negligence

66. AMS LLC owed each of the Sling Sub-Group Members a duty to exercise reasonable care and skill in the design, manufacture, marketing and supply of the Sling Implants.

67. AMS LLC:

(a) designed and manufactured the Sling Implants for the Sling Purpose;

(b) did not undertake adequate clinical or other evaluation of the Sling Implants prior to the release in Australia or the Sling Implants and the supply, distribution, marketing or promotion in Australia of the Sling Implants, as pleaded at paragraph 46 above.

68. In the circumstances pleaded at paragraph 67 above, AMS LLC designed, manufactured, marketed and in addition, or alternatively, supplied the Sling Implants containing:

(a) the characteristics pleaded at paragraph ~~9~~ 7 above; and in addition, or alternatively;

(b) a risk of, and in addition, or alternatively, a susceptibility to causing the Implant Complications and, or alternatively, the Implant Removal Complications.

69. In addition to paragraph 68 above, AMS LLC continued to design, manufacture, market and in addition, or alternatively, supply the Sling Implants notwithstanding the matters pleaded at 68 above.

70. In addition, or alternatively, to paragraph 69 above, AMS LLC failed to conduct adequate evaluation of the safety and effectiveness of the Sling Implants in treating SUI after releasing them in Australia.

71. Further, or alternatively, AMS LLC failed to conduct adequate evaluation of the long-term safety and effectiveness of the Sling Implants in treating SUI after releasing them in Australia.

72. AMS LLC:

(a) failed to inform any of the Sling Sub-Group Members of:

(i) the matters pleaded in paragraphs 67 and 68 (a) and (b) above; and, or alternatively;

(ii) the Sling Warning Matters

(b) further or in the alternative, failed to inform:

(i) AMS Australia;

(ii) treating hospitals; and in addition, or alternatively

(iv) treating doctors,

of the matters pleaded in paragraph 68 (a) and (b) above.

73. By reason of the matters pleaded at paragraphs 67 to 72 above, AMS LLC breached its duty of care to each of the Sling Sub-Group Members.

74. By reason of the matters pleaded at paragraphs 67 to 72 above, each of the Sling Sub-Group Members has suffered loss or damage for which AMS LLC was liable until (at the latest) 28 June 2018.

Part E – Succession of the Respondent to the liabilities of AMS LLC

75. By, at the latest, 28 June 2018, the Respondent succeeded to the debts, duties and liabilities of AMS LLC including those debts, duties and liabilities owed to the Applicants with the effect such debts, duties and liabilities may be enforced by the Applicants and Group Members against the Respondent as if they had been incurred by the Respondent.

PARTICULARS

(A) On 27 July 2015, AMS LLC and American Medical Systems Holdings Inc entered into a Liability Assignment and Assumption Agreement the terms of which provided that the liabilities of AMS LLC relating to, resulting from or arising out of litigation relating to the Women's Health Devices, including the items listed on Schedule 3.03 of the Disclosure Schedules to the Preferred Stock Purchase Agreement were thereby distributed, transferred and assigned to American Medical Systems Holdings Inc (**AMS Holdings Inc**).

(B) On 29 September 2015, AMS Holdings Inc was renamed Astora Women's Health Inc (**AWH Inc**).

(C) On 31 December 2015, AWH Inc was converted from a Delaware Corporation to a Delaware Limited Liability Company named Astora Womens Health Holdings LLC (**AWHH LLC**).

(D) On 21 June 2017:

(I) AWHH LLC and Astora Holdings LLC (**AH LLC**) entered into an Agreement and Plan of Merger pursuant to which they agreed that, as at 4.00pm on 21 June 2017:

i. AWHH LLC would be merged into and with AH LLC;

ii. the separate existence of AWHH LLC would cease;

iii. AH LLC would be the surviving entity in the merger; and

iv. the merger would have the effects specified in the Delaware Limited Liability Company Act (**DLLCA**), including (without limitation) section 18-209(g) thereof; and

(II) AH LLC and the Respondent entered into an Agreement and Plan of Merger pursuant to which they agreed that, as at 4.10pm on 21 June 2017:

i. AH LLC would be merged into and with the Respondent;

ii. the separate existence of AH LLC would cease;

iii. the Respondent would be the surviving entity in the merger; and

iv. the merger would have the effects specified in the DLLCA, including (without limitation) section 18-209(g) thereof.

(E) In the circumstances particularised in paragraph (D) above, from 4.10pm on 21 June 2017, by operation of section 18-209(g) of the DLLCA, all debts, liabilities and duties of AWHH LC, AH LC and the Respondent attached to the Respondent and may be enforced against the Respondent to the same extent as if they had been incurred by it.

(F) On 28 June 2018, AMS LLC and the Respondent entered into an Agreement and Plan of Merger pursuant to which they agreed that, as at that day:

(I) AMS LLC would be merged into and with the Respondent;

(II) the separate existence of AMS LLC would cease;

(III) the Respondent would be the surviving entity in the merger; and

(IV) the merger would have the effects specified in the DLLCA.

(G) In the circumstances particularised in paragraphs (E) and (F) above, from (at the latest) 28 June 2018, by operation of section 18-209(g) of the DLLCA, all debts, liabilities and duties of AMS LLC, including the liabilities and duties to the Applicants and the Group Members pleaded above, attached to the Respondent and may be enforced against the Respondent to the same extent as if they had been incurred by the Respondent.

Date: ~~16 April 2019~~ 14 April 2021

Signed by Rebecca Jancauskas

Lawyer for the Applicants

Certificate of lawyer

I, Rebecca Jancauskas, certify to the Court that, in relation to the statement of claim 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: ~~16 April 2019~~ 14 April 2021

Signed by Rebecca Jancauskas
Lawyer for the Applicants