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Details of Filing

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Important Information

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Form 33
Rule 16.32

Defence to the Second 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

Respondent

Part A – Introduction

(i) Group Members

1. In answer to the allegations in paragraph 1 of the Second Further Amended Statement of Claim (**SFASOC**), the Respondent:

   (a) says that the First Applicant does not have an alleged claim in respect of, or arising out of, the same, similar or related circumstances as those alleged by all Mesh Sub-Group Members and Sling Sub-Group Members, and does not have claims that give rise to substantial common issues of law or fact for all Mesh Sub-Group Members and Sling Sub-Group Members;

   (b) says that the Second Applicant does not have an alleged claim in respect of, or arising out of, the same, similar or related circumstances as those alleged by all Sling Sub-Group Members and Mesh Sub-Group Members, and does not have claims that give rise to substantial common issues of law or fact for all Sling Sub-Group Members and Mesh Sub-Group Members;

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(c) refers to paragraphs 4(c) and (e) to (ie) of this Defence and says that not all Group Members have claims as alleged against the same person as each of the Applicants; and

(d) otherwise does not know and cannot admit the allegations in paragraph 1.

(ii) The Applicants

2. The Respondent does not know and cannot admit the allegations in paragraph 2 of the SFASOC.

3. The Respondent does not know and cannot admit the allegations in paragraph 3 of the SFASOC.

(iii) The Respondent

4. In answer to the allegations in paragraph 4 of the SFASOC, the Respondent:

(a) admits the allegations in paragraphs 4(a) and 4(c);

(b) admits that it was known as American Medical Systems, Inc until on or about 17 December 2014, since when it has been known as American Medical Systems, LLC;

(c) admits that it manufactured the following medical devices during the following periods (the **AMS LLC Devices**):

(i) the Perigee Transobturator Anterior Prolapse Repair System with IntePro (**Perigee with IntePro**), from about July 2004 until about May 2008~~31 May 2012~~;

(ii) the Perigee Transobturator Anterior Prolapse Repair System with IntePro Lite (**Perigee with IntePro Lite**), from about October 2007 until 31 May 2012;

(iii) the Apogee Vaginal Vault and Posterior Prolapse Repair System with IntePro (**Apogee with IntePro**), from about July 2004 until about May 2008~~31 May 2012~~;

(iv) the Apogee Vaginal Vault and Posterior Prolapse Repair System with IntePro Lite (**Apogee with IntePro Lite**), from about October 2007 until 31 May 2012;

(v) the Elevate Anterior and Apical Prolapse Repair System (**Elevate Anterior**), from about July 2009 until 31 May 2012;

(vi) the Elevate Apical and Posterior Prolapse Repair System (**Elevate Posterior**), from about December 2008 until 31 May 2012 (subparagraphs (i)-(vi), the **AMS LLC Mesh Devices**);

(vii) the SPARC Sling System (**SPARC**), from about May 2001 until 31 May 2012;

(viii) the MONARC Subfascial Hammock System (**MONARC**), from about January 2003 until 31 May 2012;

(ix) the MiniArc Single-Incision Sling System (**MiniArc**), from about September 2007 until about January 2011;

(x) the MiniArc Precise Single-Incision Sling System (**MiniArc Precise**), from about July 2010 until 31 May 2012 (subparagraphs (vii)-(x), the **AMS LLC Sling Devices**);

(d) says that it supplied the AMS LLC Devices to AMS Sales LLC (**AMS Sales**), a United States corporation;

(e) denies that it manufactured or supplied the MiniArc Pro Single-Incision Sling System (**MiniArc Pro**) at any time;

~~(d)~~(f) denies that it manufactured or supplied the RetroArc Retropubic Sling System (**RetroArc**) at any time;

(g) denies that it manufactured or supplied any of the AMS LLC Devices after 31 May 2012;

(h) ~~, and~~ says that ~~at all material times from 1 June 2012 the AMS Devices were manufactured by~~ AMS Medical Systems Ireland Limited (**AMS Ireland**) manufactured, and supplied to AMS Sales, the following medical devices manufactured during the following periods (the **AMS Ireland Devices**);

(i) the Perigee with IntePro Lite from about November 2012 until about June 2015;

(ii) the Apogee with IntePro Lite from about November 2012 until about January 2015;

(iii) the Elevate Anterior from about March 2013 until about December 2015;

(iv) the Elevate Posterior from about February 2013 until about December 2015 (subparagraphs (i)-(iv), the **AMS Ireland Mesh Devices**);

(v) the SPARC from about August 2012 until about November 2015;

(vi) the MONARC from about May 2013 until about February 2016;

(vii) the MiniArc Precise from about June 2012 until about November 2015;

(viii) the MiniArc Pro from about July 2012 until about December 2015;

(ix) the RetroArc from about October 2013 until about January 2016 (subparagraphs (v)-(ix), the **AMS Ireland Sling Devices**);

(i) denies that it manufactured or supplied the AMS Ireland Devices at any time;

~~(e)~~(j) denies that it supplied the AMS LLC Devices (or the Implants) to American Medical Systems Australia Pty Limited (**AMS Australia**)~~, and says that it supplied the AMS Devices to AMS Sales LLC, a United States corporation~~;

~~(f)~~(k) denies that it supplied the AMS LLC Devices (or the Implants) in "trade or commerce" as defined in section 4 of the ~~*TPA*~~ *Trade Practices Act 1974* (Cth) (the **TPA**) or section 2 of Schedule 2 to the ~~CCA~~ *Competition and Consumer Act 2010* (Cth) (the **CCA**);

~~(g)~~(l) denies that it manufactured, supplied, marketed or promoted the AMS LLC Devices or the AMS Ireland Devices (collectively, the **AMS Devices**) (or the Implants) in Australia;

~~(h)~~(m) denies that it carried on business in Australia; and

(n) otherwise denies the allegations in paragraph 4.

4A. In answer to the allegations in paragraph 4A of the SFASOC, the Respondent:

(a) admits that it produced or assembled the AMS LLC Devices;

(b) denies the allegations in subparagraph 4A(b);

(c) in answer to the allegations in subparagraph 4A(c):

(i) says that it caused or permitted the name "American Medical Systems, Inc" to be applied to the packaging in which the AMS LLC Devices were supplied;

(ii) says that it did not supply the AMS Ireland Devices; and

(iii) otherwise denies the allegations in subparagraph 4A(c);

(d) repeats paragraphs 4(a), (d) and (j) to (m) above;

(e) says that by reason of the matters pleaded in paragraphs 4(a), (d) and (j) to (m) above the provisions of the TPA and Schedule 2 to the CCA referred to in the particulars under paragraph 4A(d) of the SFASOC can have no applicability to the Respondent; and

(f) otherwise denies the allegations in paragraph 4A.

Part B - The Conditions, Implants and Complications

(i) The Conditions

5. The Respondent admits the allegations in paragraph 5 of the SFASOC, and:

   (a) further says that pelvic organ prolapse (**POP**) occurs when the tissues in the pelvic floor weaken and internal organs, commonly the bladder, uterus, bowel, vaginal cuff or rectum move from their usual alignment and prolapse into or protrude from the vagina;

   (b) further says that there are various types of POP which can occur singly or in combination:

      (i) anterior prolapse of the bladder (cystocele) occurs when the bladder prolapses into the anterior wall of the vagina;

      (ii) apical or vault prolapse occurs when the uterus or vaginal cuff prolapses or when a prolapse of the small intestine (enterocele) occurs;

      (iii) posterior prolapse of the rectum (rectocele) occurs when the bowel prolapses forward into the back wall of the vagina;

      (iv) uterine prolapse occurs with the descent of the uterus into the top, or apex, of the vagina;

   (c) further says that:

      (i) POP is a life-altering condition;

      (ii) symptoms of POP include bulging, pelvic heaviness, pelvic pressure, pelvic pain, dyspareunia (painful sexual intercourse), loss of bladder or bowel control, recurrent bladder infections, excessive vaginal discharge, apareunia and infection.

6. The Respondent admits the allegations in paragraph 6 of the SFASOC, and:

   (a) further says that stress urinary incontinence (**SUI**) is the involuntary leakage of urine during activities in which there is intra-abdominal pressure, such as coughing, sneezing, jumping, jogging, laughing or sexual intercourse;

   (b) further says that SUI is caused by the weakening of tissue supporting the urethra, through depletion of tissue integrity (caused by factors such as aging and decreased circulating estrogen levels) and/or tissue trauma (such as in the case of vaginal childbirth or prior pelvic surgeries);

   (c) further says that:

(i) SUI is a life-altering condition; and

(ii) the symptoms of SUI can also include loss of urine when running, jumping, walking or standing from sitting, loss with sexual intercourse, loss with rolling over while asleep, constant drip of urine and infection.

(ii) The Implants

7. In answer to the allegations in paragraph 7 of the SFASOC, the Respondent:

(a) admits the allegations in paragraph 7(a);

(b) says that the Implants differ in materials, quantities of material, shape and implantation technique;

(c) says that the Perigee ~~Transobturator Anterior Prolapse Repair System~~ with IntePro:

(i) consists of four helical-shaped needle passers and a polypropylene mesh assembly. The mesh assembly consists of a mesh graft, mesh arms, a tensioning suture, sheaths and needle tip connectors. A transobturator surgical approach is used for this device;

(ii) was designed for the placement of a graft material in the anterior vaginal wall via the obturator foramen, for the treatment of anterior vaginal prolapse only and not for any other type of prolapse;

(iii) was indicated on the Australian Register for Therapeutic Goods (**ARTG**) for the placement of graft material in the anterior vaginal wall via the obturator foramen for the treatment of anterior vaginal wall prolapse; and

(iv) was not designed, manufactured or intended for use in the treatment of SUI;

(d) says that the Perigee ~~Transobturator Anterior Prolapse Repair System~~ with IntePro Lite:

(i) consists of four helical-shaped needle passers and a polypropylene mesh assembly. The mesh assembly consists of a mesh graft, mesh arms, a tensioning suture, sheaths and needle tip connectors. A transobturator surgical approach is used for this device;

(ii) was designed for the placement of a graft material in the anterior vaginal wall via the obturator foramen, for the treatment of anterior vaginal prolapse only and not for any other type of prolapse;

(iii) was indicated on the ARTG for the placement of graft material in the anterior vaginal wall via the obturator foramen for the treatment of anterior vaginal wall prolapse; and

(iv) was not designed, manufactured or intended for use in the treatment of SUI;

(e) says that the Apogee ~~Vaginal Vault and Posterior Prolapse Repair System~~ with IntePro:

(i) consists of two curved needle passers and a polypropylene mesh assembly. The mesh assembly consists of a mesh graft, mesh arms, a tensioning suture, sheaths and needle tip connectors. A trans-gluteal surgical approach is used for this device;

(ii) was designed for use in vaginal vault suspension to treat vault and posterior pelvic organ prolapse only and not any other type of prolapse;

(iii) was indicated on the ARTG for use in vaginal vault suspension to treat pelvic organ prolapse; and

(iv) was not designed, manufactured or intended for use in the treatment of SUI;

(f) says that the Apogee ~~Vaginal Vault and Posterior Prolapse Repair System~~ with IntePro Lite:

(i) consists of two curved needle passers and a polypropylene mesh assembly. The mesh assembly consists of a mesh graft, mesh arms, a tensioning suture, sheaths and needle tip connectors. A trans-gluteal surgical approach is used for this device;

(ii) was designed for use in vaginal vault suspension to treat vault and posterior vaginal prolapse only and not any other type of prolapse;

(iii) was indicated on the ARTG for use in vaginal vault suspension to treat pelvic organ prolapse; and

(iv) was not designed, manufactured or intended for use in the treatment of SUI;

(g) says that the Elevate Anterior ~~and Apical Prolapse Repair System~~:

(i) consists of a mesh assembly and non-implantable surgical instruments that can be used as aids to place the mesh assembly in the pelvic floor. The mesh assembly is made from knitted polymeric mesh;

(ii) was designed for transvaginal surgical treatment to correct anterior vaginal wall prolapse and vaginal apical prolapse only and not any other type of prolapse;

(iii) was indicated on the ARTG for transvaginal surgical treatment to correct anterior vaginal wall prolapse and vaginal apical prolapse; and

(iv) was not designed, manufactured or intended for use in the treatment of SUI;

(h) says that the Elevate Posterior ~~and Apical Prolapse Repair System~~:

(i) consists of a mesh assembly and non-implantable surgical instruments that can be used as aids to place the mesh assembly in the pelvic floor. The mesh assemblies are made from polymeric mesh, or a combination of polymeric mesh and surgical mesh derived from non-viable porcine dermis;

(ii) was designed for transvaginal surgical treatment to correct posterior vaginal wall prolapse and vaginal apical prolapse only and not any other type of prolapse;

(iii) was indicated on the ARTG for transvaginal surgical treatment to correct posterior vaginal wall prolapse and vaginal apical prolapse; and

(iv) was not designed, manufactured or intended for use in the treatment of SUI;

(i) says that the SPARC ~~Sling System~~:

(i) consists of one sling mesh assembly and two identical curved stainless steel needle passers designed to place the sling mesh using a suprapubic surgical approach;

(ii) was designed for the placement of a pubourethral sling for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency;

(iii) was indicated on the ARTG for the placement of a pubourethral sling for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency; and

(iv) was not designed, manufactured or intended for use in the treatment of POP;

(j) says that the MONARC ~~Subfascial Hammock System~~:

(i) consists of one polypropolene sling mesh assembly and two helical-shaped needle passers designed to place the sling mesh through the obturator foramen;

(ii) was designed for the placement of a pubourethral sling for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency;

(iii) was indicated on the ARTG for the placement of a pubourethral sling for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency; and

(iv) was not designed, manufactured or intended for use in the treatment of POP;

(k) says that the MiniArc ~~Single Incision Sling System~~:

(i) consists of one sling mesh assembly and one delivery tool for suburethral placement, which includes a stainless steel curved needle passer with attached plastic handle;

(ii) was designed for the placement of a suburethral mesh for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency;

(iii) was indicated on the ARTG for the placement of a suburethral sling for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency; and

(iv) was not designed, manufactured or intended for use in the treatment of POP;

(l) says that the MiniArc Precise ~~Single Incision Sling System~~:

(i) consists of one sling mesh assembly (with self-fixating tips and knitted with reinforcement fibres) and one delivery tool for subu~~e~~r<u>e</u>thral placement, which includes a stainless steel curved needle passer with attached plastic handle;

(ii) was designed for the placement of a suburethral mesh for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency;

(iii) was indicated on the ARTG for the placement of a suburethral sling for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency; and

(iv) was not designed, manufactured or intended for use in the treatment of POP;

<u>(m) says that the RetroArc:</u>

(i) consists of one sling mesh assembly, two delivery needles for suburethral placement and one handle;

(ii) was designed for the placement of a suburethral sling for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency; and

(iii) was not designed, manufactured or intended for use in the treatment of POP;

(n) says that the MiniArc Pro:

(i) consists of one sling mesh assembly, one feedback system and one delivery tool for suburethral placement, which includes a stainless steel needle passer with attached plastic handle;

(ii) was designed for the placement of a suburethral mesh for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency; and

(iii) was not designed, manufactured or intended for use in the treatment of POP;

~~(m)~~(o) repeats paragraphs 4(~~c~~d) and (f) above;

~~(n)~~(p) says that before any implant surgery, the doctor or doctors with whom each Applicant and each Group Member decided to have the implant surgery (**treating surgeon**) would, as a matter of course, have:

(i) undertaken training, or otherwise been familiar with the surgical procedures and techniques involving meshes, prior to using an AMS Device, in accordance with the Instructions for Use of the device;

(ii) consulted with that Applicant or Group Member about, and obtained, understood and assessed all relevant information about, the Applicant's or Group Member's clinical needs, presenting symptoms, relevant medical and surgical history and their surgical preferences and goals;

(iii) considered, in light of the matters in subparagraph (ii) above, whether implant surgery (including with an AMS Device) was an appropriate treatment option for that Applicant or Group Member given the benefits and risks involved and the benefits and risks of other treatment options available, and would only have discussed with that Applicant or Group Member implant surgery with an AMS Device as an available treatment option for that Applicant or Group Member if, in

the judgement of the treating surgeon, implant surgery with an AMS Device was a treatment option that did not involve unacceptable risk;

(iv) informed the Applicant or Group Member of the risks associated with implant surgery with an AMS Device, including the risks that a surgical implant may not restore pelvic anatomy or pelvic function, or provide urethral support (as the case may be), may not alleviate their symptoms, may not improve their quality of life, may erode, or may require revision surgery (which itself carried risk);

(v) informed the Applicant or Group Member of the benefits and risks associated with other surgical and non-surgical treatment options, and the benefits and risks associated with no treatment; and

(vi) determined, in conjunction with the patient and having discussed all available treatment options and their benefits and risks, an appropriate course or method of treatment, including implantation with one or more of the AMS Devices, alternative treatments with or without another implant, alternative surgeries or no surgery, depending on the matters in subparagraphs (ii)-(v) above, as well as the treating surgeon's surgical training, skills, preferences and experience; and

(vii) obtained the informed consent of the Applicant or Group Member to the implant surgery;

~~(o)~~(q) says that the Instructions for Use for each AMS Device recommended that the user undertake training, or otherwise be familiar with the surgical procedures and techniques involving meshes, prior to using the device, and it was reasonable for the Respondent to expect that users, including the treating surgeon, would do so;

~~(p)~~(r) says that it was reasonable for the Respondent to expect that the treating surgeon would not undertake the implant surgery with an AMS Device if the treating surgeon was not adequately trained or experienced and had not taken the steps referred to in paragraphs 7(p~~n~~)(i) to (vii) above;

~~(q)~~(s) says that it was reasonable for the Respondent to expect that if the treating surgeon did not understand the risks of the implant surgery or did not understand the Instructions for Use for the device, the treating surgeon would not have undertaken the implant surgery; and

~~(r)~~(t) otherwise does not know and cannot admit the allegations in paragraph 7.

8. The Respondent admits the allegations in paragraph 8.

(iii) The Implant Risks and Complications

9. In answer to the allegations in paragraph 9 of the SFASOC, the Respondent:

   (a) repeats paragraphs 7(c) to (nl) above;

   (b) repeats paragraphs 4(ed) and (f) above;

   (c) repeats paragraphs 7(pn) to (sq) above;

   (d) says that the expected inflammatory response generated by the non-absorbable polypropylene mesh, which formed a component of each of the AMS Devices, was necessary for tissue ingrowth;

   (e) says that all surgical procedures present risks; and

   (f) otherwise denies the allegations in paragraph 9.

10. The Respondent denies the allegations in paragraph 10 of the SFASOC and repeats paragraphs 9(a) to (e) above.

Part C - The Mesh Implants

(i) Purpose of the Mesh Implants

11. In answer to the allegations in paragraph 11 of the SFASOC, the Respondent:

   (a) denies that it marketed the Mesh Implants in Australia;

   (b) repeats paragraphs 7(c) to (h) and 7(pn) to (sq) above; and

   (c) otherwise does not know and cannot admit the allegations in paragraph 11.

12. In answer to the allegations in paragraph 12 of the SFASOC, the Respondent:

   (a) repeats paragraphs 7(c) to (h) above; and

   (b) otherwise does not know and cannot admit the allegations in paragraph 12.

(ii) Alternative treatments for POP

13. The Respondent denies the allegations in paragraph 13 of the SFASOC, and:

   (a) repeats paragraphs 7(c) to (hl) and 7(pn) to (sq) above;

   (b) says that reconstructive surgery for the treatment of POP may be undertaken, depending on the specific patient's history, presenting symptoms, preference and the treating

surgeon's judgement, experience and preferences, with or without the use of mesh implants; and

(c) says that all surgical procedures present risks.

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

14. The Respondent denies the allegations in paragraph 14 of the SFASOC and repeats paragraphs 9, 10 and 13 above.

15. The Respondent denies the allegations in paragraph 15 of the SFASOC and repeats paragraphs 7(c) to (hi) and 7(pn) to (sq) above.

(iv) Ms Philipsen's Mesh Implant

16. The Respondent does not know and cannot admit the allegations in paragraph 16.

17. The Respondent does not know and cannot admit the allegations in paragraph 17.

18. The Respondent does not know and cannot admit the allegations in paragraph 18.

19. In answer to the allegations in paragraph 19 of the SFASOC, the Respondent:

(a) repeats paragraph 15 above;

(b) denies that, if Ms Philipsen was implanted with a Perigee with IntePro ~~Implant~~ and an Apogee with IntePro ~~Implant~~ as alleged in paragraph 18 of the SFASOC, it failed to give adequate warning of any matters of which it was obliged to warn; and

(c) otherwise does not know and cannot admit the allegations in paragraph 19.

20. The Respondent does not know and cannot admit the allegations in paragraph 20.

21. The Respondent does not know and cannot admit the allegations in paragraph 21.

22. The Respondent does not know and cannot admit the allegations in paragraph 22.

23. The Respondent does not know and cannot admit the allegations in paragraph 23.

24. The Respondent does not know and cannot admit the allegations in paragraph 24.

25. The Respondent does not know and cannot admit the allegations in paragraph 25.

26. The Respondent does not know and cannot admit the allegations in paragraph 26.

27. In answer to the allegations in paragraph 27 of the SFASOC, the Respondent:

(a) does not know and cannot admit whether Ms Philipsen has suffered loss and damage; and

(b) if (which is not admitted) Ms Philipsen has suffered loss and damage, denies that it is liable for that loss and damage.

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

28. In answer to the allegations in paragraph 28 of the SFASOC, the Respondent:

(a) admits that the AMS LLC Mesh Devices and the AMS Ireland Mesh Devices (collectively, the **AMS Mesh Devices**) were goods as that term is defined in sections 4 and 74A(2)(a) of the TPA and sections 2 and 271 of Schedule 2 to the CCA; and

(b) otherwise does not admit the allegations in paragraph 28.

29. In answer to the allegations in paragraph 29 of the SFASOC, the Respondent:

(a) admits that any AMS Mesh Devices that were supplied to Mesh Sub-Group Members were supplied to those Mesh Sub-Group Members as consumers as that term is defined in section 4B of the TPA and section 3 of Schedule 2 to the CCA; and

(b) otherwise does not know and cannot admit the allegations in paragraph 29.

30. The Respondent denies the allegations in paragraph 30 of the SFASOC and repeats paragraphs 7 and 9 to 15 above.

31. The Respondent denies the allegations in paragraph 31 of the SFASOC, and:

(a) repeats paragraphs 7 to 15 above; ~~and~~

(b) says further that by reason of the matters pleaded in paragraphs 4(d), (j) ~~(f)~~ and 4(k~~g~~) above, the Respondent did not supply the AMS LLC Mesh Devices in trade or commerce and accordingly section 74D of the TPA can have no applicability to the AMS LLC Mesh Devices (or the Mesh Implants); and

~~(b)~~(c) says further that the Respondent did not supply the AMS Ireland Mesh Devices and accordingly section 74D of the TPA can have no applicability to the AMS Ireland Mesh Devices (or the Mesh Implants).

32. The Respondent denies the allegations in paragraph 32 of the SFASOC.

33. The Respondent denies the allegations in paragraph 33 of the SFASOC, and:

(a) repeats paragraphs 4(a), (d) and (j) to (m) ~~(f) to (h)~~ and paragraph 4A above; ~~denies that the Respondent carried on business in Australia;~~

(b) says that accordingly the provisions of the TPA and of Schedule 2 to the CCA pleaded in paragraph 33 of the SFASOC have no applicability to the Respondent; and

(c) denies that the Respondent is liable to compensate any of the Mesh Sub-Group Members pursuant to those provisions.

(vi) Claims in Negligence

34. The Respondent denies the allegations in paragraph 34 of the SFASOC, and:

(a) says that each of the AMS Devices was:

(i) assessed by the Therapeutic Goods Administration before its use in Australia and then included on the ARTG until about August 2016;

(ii) available only to surgeons, or to hospitals for use by surgeons;

(b) says that the Respondent caused to be made available information about each of those devices for surgeons who would use the devices;

(c) repeats paragraphs 7(pn) to (sq) above;

(d) denies that the Respondent owed any Mesh Sub-Group Member the duty of care alleged in paragraph 34 of the SFASOC; and

(e) further and in the alternative to subparagraph (d) above, says that the Respondent satisfied any duty it had to exercise reasonable care and skill in the design and manufacture of the AMS LLC Mesh Devices.

35. The Respondent denies the allegations in paragraph 35 of the SFASOC and repeats paragraphs 9 to 14 above.

36. The Respondent denies the allegations in paragraph 36 of the SFASOC, and:

(a) repeats paragraphs 9 to 14, 34 and 35 above; and

(b) says that the Respondent caused to be made available information about each of the AMS Mesh Devices for surgeons who would use the devices.

37. The Respondent denies the allegations in paragraph 37 of the SFASOC and repeats paragraphs 4(ge) to (i) above.

38. The Respondent denies the allegations in paragraph 38 of theSFASOC and repeats paragraph 36 above.

39. The Respondent denies the allegations in paragraph 39 of the SFASOC and repeats paragraphs 9 to 14 and 36 above.

40. The Respondent denies the allegations in paragraph 40 of the SFASOC and repeats paragraphs 34 to 39 above.

41. In answer to the allegations in paragraph 41 of the SFASOC, the Respondent:

    (a) repeats paragraphs 34 to 40 above;

    (b) denies that it was negligent; and

    (c) does not know and cannot admit that any Mesh Sub-Group Member has suffered loss or damage.

42. The Respondent denies the allegations in paragraph 42 of the SFASOC and repeats paragraphs 34 to 41 above.

Part D - The Sling Implants

(i) Purpose of the Sling Implants

43. The Respondent denies the allegations in paragraph 43 of the SFASOC, and:

    (a) repeats paragraphs 7(i) to (nl) and 9(b), (d) and (e) above; and

    (b) denies that it marketed the Sling Implants in Australia.

44. In answer to the allegations in paragraph 44 of the SFASOC, the Respondent:

    (a) repeats paragraph 43(a) above;

    (b) denies that it marketed the Sling Implants in Australia; and

    (c) otherwise does not know and cannot admit the allegations in paragraph 44.

(ii) Availability of alternative treatments

45. The Respondent denies the allegations in paragraph 45 of the SFASOC, and:

    (a) repeats paragraph 43(a) above;

    (b) says that surgery for the treatment of SUI may be undertaken, depending on the matters in paragraph 7(pn) above, with or without the use of sling implants; and

    (c) says that all surgical procedures present risks.

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

46. The Respondent denies the allegations in paragraph 46 of the SFASOC, and:

    (a) denies (if it is alleged) that it supplied, distributed, marketed or promoted the Sling Implants in Australia; and

    (b) repeats paragraphs 43 and 45 above.

47. The Respondent denies the allegations in paragraph 47 of the SFASOC and repeats paragraph 43(a) above.

(iv) Ms Seymour's Sling Implant

48. The Respondent does not know and cannot admit the allegations in paragraph 48.

49. The Respondent does not know and cannot admit the allegations in paragraph 49.

50. In answer to the allegations in paragraph 50 of the SFASOC, the Respondent:

    (a) repeats paragraph 47 above;

    (b) denies that, if Ms Philipsen was implanted with a MONARC ~~"Monarc Implant"~~ as alleged in paragraph 49 of the SFASOC (or any implant manufactured by the Respondent), it failed to give adequate warning of any matters of which it was obliged to warn; and

    (c) otherwise does not know and cannot admit the allegations in paragraph 50.

51. The Respondent does not know and cannot admit the allegations in paragraph 51.

52. The Respondent does not know and cannot admit the allegations in paragraph 52.

53. The Respondent does not know and cannot admit the allegations in paragraph 53.

54. The Respondent does not know and cannot admit the allegations in paragraph 54.

55. The Respondent does not know and cannot admit the allegations in paragraph 55.

56. The Respondent does not know and cannot admit the allegations in paragraph 56.

56A. The Respondent does not know and cannot admit the allegations in paragraph 56A.

56B. The Respondent does not know and cannot admit the allegations in paragraph 56B.

57. The Respondent does not know and cannot admit the allegations in paragraph 57.

58. The Respondent does not know and cannot admit the allegations in paragraph 58.

59. In answer to the allegations in paragraph 59 of the SFASOC, the Respondent:

(a) does not know and cannot admit whether Ms Seymour has suffered loss and damage; and

(b) if (which is not admitted) Ms Seymour has suffered loss or damage, denies that it is liable for that loss or damage.

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

60. In answer to the allegations in paragraph 60 of the SFASOC, the Respondent:

(a) admits that the AMS LLC Sling Devices and the AMS Ireland Sling Devices (collectively, the **AMS Sling Devices**) were goods as that term is defined in sections 4 and 74A(2)(a) of the TPA and sections 2 and 271 of Schedule 2 to the CCA; and

(b) otherwise does not admit the allegations in paragraph 60.

61. In answer to the allegations in paragraph 61 of the SFASOC, the Respondent:

(a) admits that any AMS Sling Devices that were supplied to Sling Sub-Group Members were supplied to those Sling Sub-Group Members as consumers as that term is defined in section 4B of the TPA and section 3 of Schedule 2 to the CCA; and

(b) otherwise does not know and cannot admit the allegations in paragraph 61.

62. The Respondent denies the allegations in paragraph 62 of the SFASOC and repeats paragraphs 4(ed) and (f), 7(a), (b) and (i) to (sq), 10 and 43 to 47 above.

63. The Respondent denies the allegations in paragraph 63 of the SFASOC, and:

(a) repeats paragraphs 4(ed) and (f), 7(a), (b) and (i) to (sq), 10 and 43 to 47 above; and

(b) says further that by reason of the matters pleaded in paragraphs 4(df), (j) and 4(kg) above, the Respondent did not supply the AMS LLC Sling Devices in trade or commerce and accordingly section 74D of the TPA can have no applicability to the AMS LLC Sling Devices (or the Sling Implants); and

~~(b)~~(c) says further that the Respondent did not supply the AMS Ireland Sling Devices and accordingly section 74D of the TPA can have no applicability to the AMS Ireland Sling Devices (or the Sling Implants).

64. The Respondent denies the allegations in paragraph 64 of the SFASOC.

65. The Respondent denies the allegations in paragraph 65 of the SFASOC, and:

(a) repeats paragraphs 4(a), (d) and (j) to (m) ~~(f) to (h)~~ and paragraph 4A above;

~~(b) denies that the Respondent carried on business in Australia;~~

~~(c)~~(b) says that accordingly the provisions of the TPA and of Schedule 2 to the CCA pleaded in paragraph 65 of the SFASOC have no applicability to the Respondent; and

~~(d)~~(c) denies that the Respondent is liable to compensate any of the Sling Sub-Group Members pursuant to those provisions.

(vi) Claims in Negligence

66. The Respondent denies the allegations in paragraph 66 of the SFASOC, and:

(a) repeats paragraphs 34(a) to (c) above;

(b) denies that the Respondent owed any Sling Sub-Group Member the duty of care alleged in paragraph 66 of the SFASOC; and

(c) further and in the alternative to subparagraph (b) above, says that the Respondent satisfied any duty it had to exercise reasonable care and skill in the design and manufacture of the AMS LLC Sling Devices.

67. The Respondent denies the allegations in paragraph 67 of the SFASOC and repeats paragraphs 43 to 46 above.

68. The Respondent denies the allegations in paragraph 68 of the SFASOC, and:

(a) repeats paragraphs 43 to 46, 66 and 67 above; and

(b) says that the Respondent caused to be made available information about each of the AMS Sling Devices for surgeons who would use the devices.

69. The Respondent denies the allegations in paragraph 69 of the SFASOC.

70. The Respondent denies the allegations in paragraph 70 of the SFASOC and repeats paragraph 68 above.

71. The Respondent denies the allegations in paragraph 71 of the SFASOC and repeats paragraph 70 above.

72. The Respondent denies the allegations in paragraph 72 of the SFASOC and repeats paragraphs 43 to 46 and 68 above.

73. The Respondent denies the allegations in paragraph 73 of the SFASOC and repeats paragraphs 63 to 72 above.

74. In answer to the allegations in paragraph 74 of the SFASOC, the Respondent:

(a) repeats paragraphs 66 to 73 above;

(b) denies that it was negligent; and

(c) does not know and cannot admit that any Sling Sub-Group Member has suffered loss or damage.

State of scientific or technical knowledge

75. Further, or in the alternative, in answer to the allegations in paragraphs 30, 31, 62 and 63 of the SFASOC, the Respondent says that, at all material times, the state of scientific or technical knowledge was not such as to enable it to discover the matters alleged in paragraphs 30 and 62 of the SFASOC, if found to exist (which is denied), such that:

(a) section 75AK(1)(c) of the TPA affords a complete defence to the claim under section 75AD of the TPA;

(b) section 142 of the *Australian Consumer Law* (the **ACL**), being Schedule 2 to the CCA, affords a complete defence to the claim under section 138 of the ACL;

(c) the state of scientific or technical knowledge is one of the relevant circumstances for the purpose of sections 75AC and 75AD of the TPA to which the Court must have regard in determining whether the Implants were defective;

(d) the state of scientific or technical knowledge is one of the relevant circumstances for the purpose of sections 9 and 138 of the ACL to which the Court must have regard in determining whether the Implants were defective;

(e) the state of scientific or technical knowledge is one of the relevant circumstances for the purpose of section 74D(3) of the TPA to which the Court must have regard in determining whether the Implants were of merchantable quality;

(f) the state of scientific or technical knowledge is one of the relevant circumstances for the purpose of section 54(3) of the ACL to which the Court must have regard in determining whether the Implants were of acceptable quality; and

(g) the Respondent did not breach any duty of care owed under the general law.

Limitations

76. Further, pending receipt of further particulars of the Group Members' claims, in answer to the allegations in paragraphs 28 to 42 and 60 to 74 of the SFASOC, the Respondent says that the Group Members' causes of action will be subject to, and the Respondent is relying upon, the limitation periods prescribed by the:

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

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

(c) *Limitation of Actions Act* 1974 (QLD);

(d) *Limitation Act* 2005 (WA);

(e) *Limitation Act* 1935 (WA);

(f) *Limitation Act* 1985 (ACT);

(g) *Limitation Act* 1974 (TAS);

(h) *Limitation of Actions Act* 1936 (SA);

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

(j) the TPA, including sections 74J(1) and (3), 75AO(l) and (2), 82(2), 87F, 87G and 87H;

(k) the CCA, including sections 87F, 87G and 87H of the CCA and sections 143(1) and (2), 236(2) and 273 of the ACL;

(l) the limitation statute applicable for the relevant place of the cause of action for negligent design and/or negligent manufacture, including but not limited to Minnesota.

77. Further, and in answer to Ms Philipsen's claim for common law damages (which is not admitted), the Respondent says that:

(a) Ms Philipsen's alleged cause of action accrued more than 3 years before the commencement of these proceedings;

(b) pursuant to subsection 27D(1) of the *Limitation of Actions Act 1958* (Vic), her cause of action can not be maintained, subject to the Court extending time in accordance with sections 23A and 27K of the *Limitation of Actions Act 1958* (Vic); and

(c) Ms Philipsen's alleged cause of action for negligent design and/or negligent manufacture is further statute barred by the statute identified in paragraph 76(l) above.

78. Further, and in answer to Ms Philipsen's claim for compensation under the TPA and CCA (which is not admitted), the Respondent says that:

(a) Ms Philipsen's alleged cause of action accrued more than 3 years before the commencement of these proceedings;

(b) these proceedings were commenced:

(i) more than 10 years after the time of the first supply to a consumer of the goods to which Ms Philipsen's claim relates; and

(ii) more than 10 years after the supply by the manufacturer of the goods to which Ms Philipsen's claim relates;

(c) pursuant to the provisions pleaded at paragraph 76(j) and (k) above, her cause of action is statute barred.

79. Further, and in answer to Ms Seymour's claim for common law damages (which is not admitted), the Respondent says that:

(a) Ms Seymour's alleged cause of action accrued more than 3 years before the commencement of these proceedings;

(b) pursuant to subsection 11(1) of the *Limitation of Actions Act 1974* (Qld), her cause of action can not be maintained, subject to the Court extending time in accordance with section 31 of the *Limitation of Actions Act 1974* (Qld); and

(c) Ms Seymour's alleged cause of action for negligent design and/or negligent manufacture is further statute barred by the statute identified in paragraph 76(l) above.

80. Further, and in answer to Ms Seymour's claim for compensation under the TPA and CCA (which is not admitted), the Respondent says that:

(a) Ms Seymour's alleged cause of action accrued more than 3 years before the commencement of these proceedings;

(b) these proceedings were commenced:

(i) more than 10 years after the time of the first supply to a consumer of the goods to which Ms Seymour's claim relates; and

(ii) more than 10 years after the supply by the manufacturer of the goods to which Ms Seymour's claim relates;

(c) pursuant to the provisions pleaded at paragraph 76(j) and (k) above, her cause of action is statute barred.

Date: ~~30 October 2018~~ 2 25 June 2019

Signed by David Cameron McCredie
Lawyer for the Respondent

This pleading was prepared by David Cameron McCredie, lawyer for the Respondent, and Kate Morgan SC and Derek Wong of Counsel.

Certificate of lawyer

I David Cameron McCredie certify to the Court that, in relation to the defence filed on behalf of the 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: ~~30 October 2018~~25 June 2019

Signed by David Cameron McCredie
Lawyer for the Respondent