NOTICE OF FILING AND HEARING

This document was lodged electronically in the FEDERAL COURT OF AUSTRALIA (FCA) on 14/04/2021 5:08:46 PM AEST and has been accepted for filing under the Court's Rules. Filing and hearing details follow and important additional information about these are set out below.

Filing and Hearing Details

Document Lodged:	Originating Application Starting a Representative Proceeding under Part IVA Federal Court of Australia Act 1976 - Form 19 - Rule 9.32
File Number:	NSD35/2018
File Title:	JODIE PHILIPSEN & ANOR v ASTORA WOMEN'S HEALTH LLC
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA
Reason for Listing:	Case Management Hearing
Time and date for hearing:	07/05/2021, 10:15 AM
Place:	Court Room Not Assigned, Level 17, Law Courts Building 184 Phillip Street Queens Square, Sydney; By Web Conference, Level 17, Law Courts Building 184 Phillip Street Queens Square, Sydney

Dated: 15/04/2021 9:06:54 AM AEST Registrar

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.

The Reason for Listing shown above is descriptive and does not limit the issues that might be dealt with, or the orders that might be made, at the hearing.

The date and time of lodgment also shown above are the date and time that the document was received by the Court. Under the Court's Rules the date of filing of the document is the day it was lodged (if that is a business day for the Registry which accepts it and the document was received by 4.30 pm local time at that Registry) or otherwise the next working day for that Registry.

FOURTH FURTHER AMENDED ORIGINATING APPLICATION

Form 19
Rule 9.32

Fourth ~~Third~~ further amended originating application starting a representative proceeding under Part IVA of the Federal Court of Australia Act 1976

No. 35 of 2018

Federal Court of Australia

District Registry: New South Wales

Division: General

Jodie Philipsen

First Applicant

Janice Seymour

Second Applicant

Astora Women's Health LLC

Respondent

To the Respondent

The Applicants apply for the relief set out in this application.

The Court will hear this application, or make orders for the conduct of the proceeding, at the time and place stated below. If you or your lawyer do not attend, then the Court may make orders in your absence.

You must file a notice of address for service (Form 10) in the Registry before attending Court or taking any other steps in the proceeding.

Time and date for hearing:

Place:

The Court ordered that the time for serving this application be abridged to

Filed on behalf of (name & role of party) Jodie Philipsen and Janice Seymour (the Applicants)
Prepared by (name of person/lawyer) Rebecca Jancauskas
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Date: ~~1 March 2021~~ 14 April 2021

Signed by an officer acting with the authority
of the District Registrar

Details of claim

The Mesh Implants

On the grounds stated in the accompanying ~~Second~~ Third Further Amended Statement of Claim, the Applicants claim that the Respondent is liable for contraventions by American Medical Systems LLC (**AMS LLC**) of sections 75AD and 74D of the *Trade Practices Act 1974* (Cth) (**Trade Practices Act**) and additionally, or alternatively, sections 54 and 138 of Schedule 2 of the *Competition and Consumer Act 2010* (Cth) (**Competition and Consumer Act**), and for negligence by AMS LLC in the manufacture, marketing and supply of certain pelvic mesh systems intended to treat pelvic organ prolapse, and the Applicants claim relief as follows:

1. Declarations that:
   (a) The safety of the **Mesh Implants** (as defined in the ~~Second~~ Third Further Amended Statement of Claim) acquired by the First Applicant and each of the **Mesh Sub-Group Members** (as defined in the ~~Second~~ Third Further Amended Statement of Claim) was not such as persons generally were entitled to expect and had a defect for the purposes of section 75AC(1) and 75AD(1) of the Trade Practices Act and a safety defect for the purposes of sections 9 and 138 of Schedule 2 of the Competition and Consumer Act;
   (b) The Mesh Implants acquired by the First Applicant and each of the Mesh Sub-Group Members were not of merchantable quality, or acceptable quality, within the meaning of section 74D of the Trade Practices Act and section 54 of Schedule 2 of the Competition and Consumer Act;
   (c) ~~American Medical Systems LLC~~ ("AMS LLC") breached its duty of care to the First Applicant and each of the Mesh Sub-Group Members by designing and manufacturing each of the Mesh Implants in such a way that they had:
      (i) The characteristics pleaded at paragraph ~~9~~7 of the ~~Second~~ Third Further Amended Statement of Claim; and in addition, or alternatively,
      (ii) a risk of and in addition, or alternatively, were susceptible to, causing the **Implant Complications** (as defined in the ~~Second~~ Third Further Amended Statement of Claim) and in addition, or alternatively, the **Implant Removal Complications** (as defined in the ~~Second~~ Third Further Amended Statement of Claim);
   (d) In addition, AMS LLC breached its duty of care to the First Applicant and each of the Mesh Sub-Group Members by continuing to design, manufacture, market and, in addition or alternatively, supply the Mesh Implants notwithstanding the matters referred to in subparagraph (c) above;
   (e) In addition, or alternatively, AMS LLC breached its duty of care to the First Applicant and the Mesh Sub-Group Members by failing to conduct any, or any adequate, pre market evaluation of the safety and efficacy of the Mesh Implants;
   (f) In addition, or alternatively, AMS LLC breached its duty of care to the First Applicant and each of the Mesh Sub-Group Members by failing to inform them:
      (i) that the Mesh Implants had the characteristics pleaded at paragraph ~~9~~7 of the ~~Second~~ Third Further Amended Statement of Claim;

(ii) that the Mesh Implants had a risk of and, or alternatively were susceptible to, causing the Implant Complications and, or alternatively, the Implant Removal Complications; and in addition, or alternatively;

(iii) of the **Mesh Warning Matters** (as that term is defined in the ~~Second~~ Third Further Amended Statement of Claim);

(iv) of the **Mesh Evaluation Matters** (as that term~~s~~ is defined in the ~~Second~~ Third Further Amended Statement of Claim);

(g) ~~Astora Women's Health, LLC~~ The Respondent is liable to compensate the First Applicant and Mesh Sub-Group Members for the loss and damage each of them has suffered by reason of the conduct of AMS LLC referred to in subparagraphs (a) to (f) above.

2. Compensation or damages from ~~Astora Women's Health, LLC~~ the Respondent to ~~for~~ the Mesh Sub-Group Members on the following bases:

(a) Compensation pursuant to section 75AD of the Trade Practices Act or, as the case may be, compensation pursuant to section 138 of Schedule 2 of the Competition and Consumer Act; and

(b) Compensation pursuant to sections 74D(1) and 82(1) of the Trade Practices Act or, as the case may be, damages pursuant to sections 54, 271 and 272 of Schedule 2 of the Competition and Consumer Act.

3. Damages ~~Astora Women's Health, LLC~~ at common law ~~for~~ from the Respondent by reason of the conduct of AMS, LLC to the Mesh Sub-Group Members.

4. Interest on the amounts referred to in proposed orders 2, and 3 above.

5. Costs.

6. Such further or other orders as the Court thinks fit.

The Sling Implants

On the grounds stated in the accompanying ~~Second~~ Third Further Amended Statement of Claim, the Second Applicant claims that the Respondent is liable for contraventions by AMS LLC of sections 75AD and 74D of the Trade Practices Act and additionally, or alternatively, sections 138 of Schedule 2 of the Competition and Consumer Act, and for negligence by AMS LLC in the manufacture, marketing and supply of certain pelvic mesh systems intended to treat stress urinary incontinence, and each of the Sling Sub-Group Members claim relief as follows:

7. Declarations that:

(a) The safety of the Sling Implants (as defined in the ~~Second~~ Third Further Amended Statement of Claim) acquired by the Second Applicant and each of the Sling Sub-Group Members (as defined in the ~~Second~~ Third Further Amended Statement of Claim) was not such as persons generally were entitled to expect and had a defect for the purposes of sections 75AC(1) and

75AD(1) of the Trade Practices Act and a safety defect for the purposes of sections 9 and 138 of Schedule 2 of the Competition and Consumer Act;

(b) The Sling Implants acquired by the Second Applicant and each of the Sling Sub-Group Members were not of merchantable quality, or acceptable quality, within the meaning of section 74D of the Trade Practices Act and section 54 of Schedule 2 of the Competition and Consumer Act;

(c) AMS LLC breached its duty of care to the Second Applicant and each of the Sling Sub-Group Members by designing and manufacturing the Sling Implants in such a way that they had:

(i) the characteristics referred to in paragraph ~~9~~7 of the ~~Second~~ Third Further Amended Statement of Claim;

(ii) a risk of and in addition, or alternatively, were susceptible to, causing the Implant Complications (as defined in the ~~Second~~ Third Further Amended Statement of Claim) and, or alternatively, the Implant Removal Complications (as defined in the ~~Second~~ Third Further Amended Statement of Claim);

(d) In addition or alternatively AMS LLC breached its duty of care to the Second Applicant and each of the Sling Sub-Group Members by continuing to design, manufacture, market and, in addition or alternatively, supply the Sling Implants notwithstanding the matters referred to in subparagraph (c) above;

(e) In addition, or alternatively, AMS LLC breached its duty of care to the Second Applicant and each of the Sling Sub-Group Members by failing to conduct any, or any adequate pre-market evaluation of the safety and efficacy of the Sling Implants;

(f) AMS LLC breached its duty of care to the Second Applicant and each of the Sling Sub-Group Members by failing to inform them:

(i) that the Sling Implants had the characteristics referred to in paragraph ~~9~~7 of the ~~Second~~ Third Further Amended Statement of Claim;

(ii) that the Sling Implants had a risk of, and in addition, or alternatively, a susceptibility to causing the Implant Complications and, or alternatively, the Implant Removal Complications;

(iii) of the **Sling Warning Matters** (as that term is defined in the ~~Second~~ Third Further Amended Statement of Claim);

(iv) of the **Sling Evaluation Matters** (as that term is defined in the ~~Second~~ Third Further Amended Statement of Claim).

(g) ~~Astora Women's Health, LLC~~ The Respondent is liable to compensate the Second Applicant and Sling Sub-Group Members for the loss and damage each of them has suffered by reason of the conduct of AMS LLC referred to in subparagraphs (a) to (f) above.

8. Compensation or damages from ~~Astora Women's Health LLC~~ the Respondent ~~by reason of the conduct of AMS, LLC for~~ to the Second Applicant and the Sling Sub-Group Members on the following bases:

(a) Compensation pursuant to section 75AD of the Trade Practices Act or, as the case may be, compensation pursuant to section 138 of Schedule 2 of the Competition and Consumer Act; and

(b) Compensation pursuant to section 74D(1) and 82(1) of the Trade Practices Act or, as the case may be, damages pursuant to sections 54, 271 and 272 of Schedule 2 of the Competition and Consumer Act.

9. Damages at common law from ~~Astora Women's Health, LLC~~ the Respondent by reason of the conduct of AMS, LLC ~~at common law for~~ to the Sling Sub-Group Members.

10. Interest on the amounts referred to in proposed orders 8, and 9 above.

11. Costs.

12. Such further or other orders as the Court thinks fit.

Questions common to claims of group members

DEFINITIONS

In these questions, the following definitions have been adopted:

Competition and Consumer Act means the *Competition and Consumer Act 2010* (Cth)

Implants means the Mesh Implants and Sling Implants.

Mesh Implant means the implants referred to in subparagraph 1(b)(i)(A) of the Second Further Amended Statement of Claim.

Sling Implant means the implants referred to in subparagraph 1(b)(i)(B) of the Second Further Amended Statement of Claim.

Trade Practices Act means the *Trade Practices Act 1974* (Cth)

THE PURPOSE OF THE IMPLANTS

The purpose of the Mesh Implants

1. Were the Mesh Implants 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**).

2. If the answer to question 1 is "yes", did the RespondentAMS LLC know that that was the purpose of the Mesh Implants?

3. If the answer to question 1 is "yes", did the RespondentAMS LLC market, promote, distribute and supply the Mesh Implants as being reasonably fit for that purpose?

The purpose of the Sling Implants

4. Were the Sling Implants designed and manufactured 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**).

5. If the answer to question 6 is "yes", did the RespondentAMS LLC know that that was the purpose of the Sling Implants?

6. If the answer to question 6 is "yes", did the RespondentAMS LLC market, promote, and supply the Sling Implants as being reasonably fit for that purpose?

DID THE IMPLANTS HAVE A RISK OF AND, IN ADDITION, OR ALTERNATIVELY, WERE THEY SUSCEPTIBLE TO CAUSING THE ALLEGED COMPLICATIONS?

The Implant Risks and Complications

7. Is it the case that the Implants had a risk of and, in addition or alternatively, were susceptible to:

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

(ii) damage to or entrapment of nerves in the scar tissue surrounding the Implant resulting in severe 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

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

(the matters in (a) to (d) are referred to as the **Implant Complications**)?

8. If question 7 is answered "yes", in whole or in part, what is the magnitude of this risk or susceptibility and the potential seriousness to an individual if it materialises?

9. How, if at all, are the answers to questions 7 and 8 affected by factors such as individual patient presenting symptoms, clinical presentation and medical history, the type of implant and surgical technique used in the implant surgery?

10. If question 8 is answered "yes", in whole or in part:

(a) were the Implants difficult or impossible safely to remove from patients; and, in addition or alternatively

(b) was treatment of the Implant Complications difficult or impossible, or alternatively did it carry with it the risk of new or aggravated complications

(the matters in (a) and (b) are referred to as the **Implant Removal Complications**)?

THE AVAILABILITY OF ALTERNATIVE TREATMENTS

Alternatives to the Mesh Implants

If the answer to either or both of questions 7 and 10 is "yes":

11. At all material times, could pelvic organ prolapse be treated without the use of the Mesh Implants (**Native Tissue Repair**)?

12. Is Native Tissue Repair as effective in treating pelvic organ prolapse, or in the alternative not materially less effective in treating pelvic organ prolapse, as reconstructive surgery for the treatment of pelvic organ prolapse undertaken using Mesh Implants?

13. Is Native Tissue Repair as safe in treating pelvic organ prolapse, or in the alternative not materially less safe in treating pelvic organ prolapse, as reconstructive surgery for the treatment of pelvic organ prolapse undertaken using Mesh Implants?

14. Does Native Tissue Repair have the risk of, and in addition, or alternatively, is it susceptible to causing, any of the:

(a) Implant Complications; and

(b) Implant Removal Complications?

15. How, if at all, are the answers to questions 12 to 14 affected by factors such as individual patient presenting symptoms, clinical presentation and medical history, the type of implant and surgical technique used in the implant surgery?

Alternatives to the Sling Implants

If the answer to either or both of questions 7 and 10 is "yes":

16. At all material times, were there a number of alternative treatments available for the treatment of stress urinary incontinence (**Alternative SUI Treatments**)?

17. Were the Alternative SUI Treatments as effective in treating stress urinary incontinence, or alternatively not materially less effective in treating stress urinary incontinence as surgery using Sling Implants?

18. Were the Alternative SUI Treatments as safe in treating stress urinary incontinence, or alternatively not materially less safe in treating stress urinary incontinence as surgery using Sling Implants?

19. Is it the case that the Alternative SUI Treatments did not have the risk of, and in addition or alternatively, were not susceptible to causing the:

    (a) Implant Complications; and

    (b) Implant Removal Complications?

20. How, if at all, are the answers to questions 17 to 19 affected by factors such as individual patient presenting symptoms, clinical presentation and medical history, the type of implant and surgical technique used in the implant surgery?

THE INFORMATION AND WARNINGS PROVIDED BY THE RESPONDENT AMS LLC

Information and warnings concerning the Mesh Implants

21. If any of questions 7, 10 and, or alternatively, all of questions 11 to 15 are answered "yes", did the RespondentAMS LLC fail to give any, or any sufficient, information or warning as to those matters to group members, hospitals and/or doctors?

Information and warnings concerning the Sling Implants

22. If any of questions 7, 10 and, or alternatively, all of questions 16 to 20 are answered "yes", did the RespondentAMS LLC fail to give any, or any sufficient information or warning to group members, its hospitals and/or doctors?

PRE AND POST MARKET EVALUATION OF THE IMPLANTS

Pre and post market evaluation of the Mesh Implants

23. Did the RespondentAMS LLC fail to conduct any, or any adequate, evaluation of the safety and efficacy of the Mesh Implants before supplying, distributing, marketing or promoting them in Australia?

24. Did the RespondentAMS LLC fail to conduct any, or any adequate, evaluation of the safety and efficacy of the Mesh Implants after supplying, distributing, marketing or promoting them in Australia?

Pre and post market evaluation of the Sling Implants

25. Did the RespondentAMS LLC fail to conduct any, or any adequate, evaluation of the safety and efficacy of the Sling Implants before supplying, distributing, marketing or promoting them in Australia?

26. Did the RespondentAMS LLC fail to conduct any, or any adequate, evaluation of the safety and efficacy of the Sling Implants after supplying, distributing, marketing or promoting them in Australia?

FIRST SET OF CONSUMER PROTECTION CLAIMS: WERE THE IMPLANTS DEFECTIVE?

Were the Mesh Implants defective?

27. If any of:

(a) All of questions 1 to 3;

(b) Questions 7 or 10;

(c) All of questions 11 to 15; and, in addition or alternatively

(d) Question 21;

is answered "yes", is it the case that the safety of any of the Mesh Implants was not such as persons generally were entitled to expect such that the Mesh Implant/s had:

(i) a defect for the purposes of section 75AC(1) and 75AD(1) of the *Trade Practices Act*; and or alternatively;

(ii) a safety defect for the purposes of sections 9 and 138 of Schedule 2 of the *Competition and Consumer Act*,

having regard to all relevant circumstances?

28. If question 27 is answered "yes", was the state of scientific or technical knowledge not such as to enable the RespondentsAMS LLC to discover the defect or safety defect, if found to exist?

Were the Sling Implants defective?

29. If any of:

(a) All of questions 1 to 3;

(b) Questions 7 or 10;

(c) All of questions 16 to 20; and, or alternatively

(d) Question 22;

is answered "yes", is it the case that the safety of any of the Sling Implants was not such as persons generally were entitled to expect such that the Sling Implants had:

(i) a defect for the purposes of section 75AC(1) and 75AD(1) of the *Trade Practices Act*; and or alternatively

(ii) a safety defect for the purposes of sections 9 and 138 of Schedule 2 of the *Competition and Consumer Act,*

having regard to all relevant circumstances?

30. If question 29 is answered "yes", was the state of scientific or technical knowledge not such as to enable the respondent to discover the defect or safety defect, if found to exist?

SECOND SET OF CONSUMER PROTECTION CLAIMS: WERE THE IMPLANTS NOT OF MERCHANTABLE OR ACCEPTABLE QUALITY?

Were the Mesh Implants not of merchantable or acceptable quality?

31. If any of:

(a) All of questions 1 to 3;

(b) Questions 7 or 10;

(c) Questions 23 and 24; and, in addition or alternatively

(d) Question 21;

is answered "yes" is it the case that any of the Mesh Implants was not of:

(i) merchantable quality within the meaning of section 74D(3) of the *Trade Practices Act*; or

(ii) acceptable quality within the meaning of section 54 of Schedule 2 of the *Competition and Consumer Act*,

having regard to all relevant circumstances?

Were the Sling Implants not of merchantable or acceptable quality?

32. If any of:

(a) All of questions 1 to 3;

(b) Questions 7 or 10;

(c) Questions 25 and 26; and, or alternatively

(d) Question 22;

is answered "yes" is it the case that any of the Sling Implants was not of:

(i) merchantable quality within the meaning of section 74D(3) of the *Trade Practices Act*; or

(ii) acceptable quality within the meaning of section 54 of Schedule 2 of the *Competition and Consumer Act*,

having regard to all relevant circumstances?

GENERAL NEGLIGENCE QUESTION: THE SCOPE OF THE DUTY, IF ANY, OWED BY THE MANUFACTURERS TO GROUP MEMBERS

Did the manufacturer of the Implants owe a duty to group members?

33. Did the respondentAMS LLC owe any group member a duty to exercise reasonable care and skill in the design, manufacture and supply of the Implants, whether by reason of questions 1 to 3 and, or alternatively, 4 to 6 being answered "yes" or otherwise?

FIRST SET OF NEGLIGENCE CLAIMS: THE DESIGN, MANUFACTURE, MARKETING AND SUPPLY OF THE IMPLANTS

The Design, Manufacture, Marketing and Supply of the Mesh Implants

34. If the answer to question is "yes", and if questions 7 or 10 are answered "yes", then having regard to the answer to question 33, did the respondentAMS LLC breach its duty by designing, manufacturing, marketing and in addition, or alternatively, supplying the Mesh Implants containing such characteristics or having a risk or susceptibility to the Implant Complications and/or Implant Removal Complications?

35. If the answer to question 34 is "yes", and any of questions 7 or 10 are answered "yes", then having regard to the answer to question 33, did the respondentAMS LLC breach that duty by continuing to design, manufacture, market and in addition, or alternatively, supply the Mesh Implants containing such characteristics or having a risk or susceptibility to the Implant Complications and/or Implant Removal Complications?

The Design, Manufacture, Marketing and Supply of the Sling Implants

36. If the answer to question 33 is "yes", and any of questions 7 or 10 are answered "yes", then having regard to the answer to question 33, did the respondentAMS LLC breach its duty to group members by designing, manufacturing, marketing and in addition, or alternatively, suppling the Sling Implants containing such characteristics or having a risk or susceptibility to the Implant Complications and/or Implant Removal Complications?

37. If the answer to question 33 is "yes", and any of questions 7 or 10 are answered "yes", then having regard to the answer to question 33, did the respondentAMS LLC breach its duty to group members by continuing to design, manufacture, market and in addition, or alternatively, supply the Sling Implants containing such characteristics or having a risk or susceptibility to the Implant Complications and/or Implant Removal Complications?

SECOND SET OF NEGLIGENCE CLAIMS: PRE AND POST MARKET EVALUATION OF THE IMPLANTS

Pre and post market evaluation of the Mesh Implants

38. If the answer to question 33 is "yes", and any of questions 7, 10 and/or 23 is answered "yes", then having regard to the answer to question 33, did the respondentAMS LLC breach its duty by failing to conduct any, or any adequate, evaluation of the safety and efficacy of the Mesh Implants before supplying, distributing, marketing or promoting them in Australia?

39. If the answer to question 33 is "yes", and any of questions 7, 10 and/or 24 is answered "yes", then having regard to the answer to question 33, did the respondentAMS LLC breach its duty by failing to conduct any, or any adequate, evaluation of the safety and efficacy of the Mesh Implants after supplying, distributing, marketing or promoting them in Australia?

Pre and post market evaluation of the Sling Implants

40. If the answer to question 33 is "yes", and any of questions 7, 10 and/or 25 is answered "yes", then having regard to the answer to question 33, did the respondentAMS LLC breach its duty by failing to conduct any, or any adequate, evaluation of the safety and efficacy of the Sling Implants before supplying, distributing, marketing or promoting them in Australia?

41. If the answer to question 33 is "yes", and any of questions 7, 10 and/or 26 is answered "yes", then having regard to the answer to question 33, did the respondentAMS LLC breach its duty by failing to conduct any, or any adequate evaluation of the safety and efficacy of the Sling Implants after supplying, distributing, marketing or promoting them in Australia?

THIRD SET OF NEGLIGENCE CLAIMS: FAILURE TO INFORM OF RISKS, COMPLICATIONS AND ALTERNATIVES

Failure to inform of the risks, complications and alternatives in relation to the Mesh Implants

42. If the answer to question 33 is "yes", and:

    (a) any of questions 7, 10 and/or 21 is answered "yes"; and, or alternatively

(b) questions 38 or 39 is answered "yes"

then, having regard to the answer to question 33, did the respondentAMS LLC breach its duty to the group members by failing to inform them, treating hospitals, and, in addition or alternatively, treating doctors of the risks, complications, and/or alternative treatments in relation to the Mesh Implants, as the case may be?

Failure to inform of the risks, complications and alternatives in relation to the Sling Implants

43. If the answer to question 33 is "yes", and:

(a) any of questions 7, 10 and/or 22 are answered "yes"; and, or alternatively

(b) questions 40 or 41 is answered "yes"

then, having regard to the answer to question 33, did the respondentAMS LLC breach its duty to the group members by failing to inform them, treating hospitals, and, in addition or alternatively, treating doctors of the risks, complications, and/or alternative treatments in relation to the Sling Implants, as the case may be?

Date: 1 May 2021

Questions common to claims of Group Members

DEFINITIONS

AMS means American Medical Systems LLC.

AMS Devices means the SUI Devices and the POP Devices.

Australian Consumer Law means Schedule 2 of the Competition and Consumer Act.

Competition and Consumer Act means the *Competition and Consumer Act 2010* (Cth).

Group Members means the group members defined in para 1 (b) of the Third Further Amended Statement of Claim.

Manufacturer means the respondent, AMS.

POP means pelvic organ prolapse.

POP Devices means the medical devices used for the treatment of pelvic organ prolapse known by the trade names Perigee Transobturator Anterior Prolapse Repair System (with IntePro or IntePro Lite), Apogee Vaginal Vault and Posterior Prolapse Repair System (with IntePro or IntePro Lite), Elevate Anterior and Apical Prolapse Repair System and Elevate Apical and Posterior Prolapse Repair System.

SUI means stress urinary incontinence.

SUI Devices means the medical devices used for the treatment of stress urinary incontinence known by the trade names Sparc Sling System, Monarc Subfascial Hammock System, MiniArc Single Incision Sling, MiniArc Precise Single-Incision Sling, MiniArc Pro Single-Incision Sling System and RetroArc Retropubic Sling System.

Trade Practices Act means the *Trade Practices Act 1974* (Cth).

REACTIONS AND COMPLICATIONS CAUSED BY THE AMS DEVICES

1. Can the AMS Devices cause the following reactions:

   (a) 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 AMS Devices (separately or in conjunction with surrounding tissue) to contract?

2. Can the AMS Devices cause the following complications:

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

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

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

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

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

(f) erosion or extrusion of the AMS Devices surrounding organs such as the bladder, urethra or rectum with the risk of damage to those organs and pain;

(g) difficulty voiding or defecating;

(h) de novo urge incontinence and/or urge incontinence;

(i) de novo stress urinary incontinence in the case of the POP Devices;

(j) infection; and/or

(k) requiring reoperation or revision surgery associated with the complications referred to at (a) – (j) above?

3. Are each of the complications referred to in question 2 clinically significant?

4. Can the complications occur many years after implantation?

5. Is it necessary for the Group Members to prove the mechanism by which the AMS Devices caused the complications they suffered as a result of implantation of those devices?

BIOCOMPATIBILITY ISSUES

6. Can the pores of the mesh used in the AMS Devices deform and collapse under mechanical load?

7. Does deformation and collapse of the pores of the mesh used in the AMS Devices cause bridging, fibrosis or fibrotic bridging?

8. Is fibrotic bridging of clinical significance?

REGULATORY CLEARANCE OF THE AMS DEVICES

9. Does the entry of the AMS Devices on the Australian Register of Therapeutic Goods demonstrate that the products met applicable regulatory standards?

NEGLIGENCE

10. Did AMS LLC owe a duty of care to Group Members?

11. Did AMS LLC breach its duty of care by failing to undertake adequate pre-market evaluations of the safety and efficacy of the AMS Devices?

12. Did AMS LLC breach its duty of care by failing to undertake adequate post-market evaluations of the safety and efficacy of the AMS Devices?

13. During the period of time from first supply in Australia of each of the AMS Devices until 31 July 2018, did AMS LLC breach its duty of care to Group Members by failing to provide any adequate information, advice or warnings about the above-mentioned complications and the absence of any clinical or other evaluation of the risks?

14. In what respects was the information, advice or warnings provided by AMS LLC about the complications inadequate?

THE STATUTORY CAUSES OF ACTION

15. Do the causes of action under the Trade Practices Act or the Australian Consumer Law apply to AMS LLC even though it was incorporated overseas and did not have a place of business in Australia?

DEFECTIVE GOODS

16. Did the POP Devices or any of them have a defect within the meaning of s 75AC of the Trade Practices Act and a safety defect within the meaning of s9 of the Australian Consumer Law in that the safety of their safety was not such as persons are generally entitled to expect?

17. Did the SUI Devices or any of them have a defect within the meaning of s 75AC of the Trade Practices Act and a safety defect within the meaning of s 9 of the Australian Consumer Law in that their safety was not such as persons generally are entitled to expect?

18. Is the Respondent liable to compensate a group member who can prove she suffered an injury because of the defect, or safety defect, in a POP Device?

19. Is the Respondent liable to compensate a group member who can prove she suffered an injury because of the defect, or safety defect, in a SUI Device?

20. Did the Respondent establish a state of art defence within s 75AK(1)(c) of the Trade Practices Act of s 142(c) of the Australian Consumer Law?

UNMERCHANTABLE QUALITY

21. Were the POP Devices not of merchantable quality, within the meaning of s74D(1) of the Trade Practices Act, or acceptable quality, within the meaning of s 54 of the Australian Consumer Law, in that they were not as fit for the purpose for which goods of that kind are commonly bought as it is reasonable to expect having regard to all relevant circumstances?

22. Were the SUI Devices not of merchantable quality, within the meaning of s74D(1) of the Trade Practices Act, or acceptable quality, within the meaning of s54 of the Australian Consumer Law, in that they were not as fit for the purpose for which goods of that kind are commonly bought as it is reasonable to expect having regard to all relevant circumstances?

LIABILITY OF THE RESPONDENT

23. Is the Respondent the successor to the liabilities owed by AMS LLC to the Applicants and Group Members?

Applicants' address

The Applicants' address for service is:

Place: Shine Lawyers

Email: rjancauskas@shine.com.au

The Applicants' address is Level 13, 160 Ann Street, Brisbane QLD 4000.

Service on the Respondents

It is intended to serve this application on all Respondents.

Date: ~~1 March 2021~~ 14 April 2021

Signed by Rebecca Jancauskas,
Lawyer for the Applicants