NOTICE OF FILING AND HEARING

This document was lodged electronically in the FEDERAL COURT OF AUSTRALIA (FCA) on 14/07/2021 3:08:32 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:	NSD310/2021
File Title:	LISA TALBOT v ETHICON SARL & ORS
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA
Reason for Listing:	To Be Advised
Time and date for hearing:	To Be Advised
Place:	To Be Advised

Dated**:** 14/07/2021 5:07:41 PM 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.

Form 19

Rule 9.32

Amended Originating application starting a representative proceeding under Part IVA of the Federal Court of Australia Act 1976

No. 310 of 2021

Federal Court of Australia

District Registry: New South Wales

Division: General

Lisa Talbot

Applicant

ETHICON Sàrl and others

Respondent

To Respondents

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) Lisa Talbot (Lead Applicant)

Prepared by (name of person/lawyer) Rebecca Jancauskas

Law firm (if applicable) Shine Lawyers

Tel (07) 3006 6000 Fax (07) 3229 1999

Email rjancauskas@shine.com.au

Address for service (include state and postcode) Level 13, 160 Ann Street, Brisbane QLD 4000

.

Date:

……..

Signed by an officer acting with the authority

of the District Registrar

Details of claim

The Mesh Implants

On the ground stated in the accompanying Amended Statement of Claim, the Applicant claims that the Respondents each contravened sections 75AD, 74B, 74D and 52 of the *Trade Practices Act 1974* (Cth) (**Trade Practices Act**) and additionally, or alternatively, sections 138, 271, 272 and 18 of Schedule 2 of the *Competition and Consumer Act 2010* (Cth) (**Competition and Consumer Act**), and were negligent, and the Applicant claims relief as follows:

1. Declarations that:
   (a) The safety of the **Mesh Implants** (as defined in the Amended Statement of Claim) acquired by each of the Mesh Sub-Group Members (as defined in the 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 each of the Mesh Sub-Group Members were not reasonably fit for the Mesh Purpose, within the meaning of section 74B of the Trae Practices Act and section 55 of Schedule 2 of the Competition and Consumer Act.
   (c) The Mesh Implants acquired by 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 sections 54 and Schedule 2 of the Competition and Consumer Act;
   (d) The First Respondent (**Ethicon Sàrl**) and in addition, or alternatively, the Second Respondent (**Ethicon, Inc.**) and in addition, or alternatively, the Third Respondent (**Johnson & Johnson**) breached their duty of care to 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 10 of the 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 Amended Statement of Claim)

SEAL OF THE FEDERAL COURT OF AUSTRALIA
AUSTRALIA

and in addition, or alternatively, the **Implant Removal Complications** (as defined in the Amended Statement of Claim).

(e) In addition, or alternatively, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson breached their duty of care to each of the Mesh Sub-Group Members by continuing to design and manufacture, market and, in addition or alternatively, supply the Mesh Implants notwithstanding the matters referred to in subparagraph (d) above;

(f) In addition, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson breached their duty of care to each of 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;

(g) In addition, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson breached their duty of care to each of the Mesh Sub-Group Members by failing to conduct any, or any adequate, post market evaluation of the safety and efficacy of the Mesh Implants;

(h) In addition, or alternatively, Johnson & Johnson breached its duty of care to each of the Mesh Sub-Group Members by failing to conduct any, or any adequate, valuation of the safety and efficacy of the Mesh Implants before supplying, distributing, marketing or promoting them in Australia;

(i) In addition, or alternatively, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson breached their duty of care to each of the Mesh Sub-Group Members by failing to inform them or their treating hospitals and / or treating doctors:

(i) that the Mesh Implants had the characteristics pleaded at paragraph 10 of the 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 Amended Statement of Claim);

(iv) of the **Mesh Evaluation Matters** (as that term is defined in the Amended Statement of Claim);

(j) By marketing, promoting, distributing and supplying the Mesh Implants as being medical devices that were reasonably fit for the Mesh Purpose, in circumstances whereby:

SEAL OF THE FEDERAL COURT OF AUSTRALIA
AUSTRALIA

(i) the Mesh Implants had a risk of, and in addition or alternatively, were susceptible to the Implant Complications and Implant Removal Complications, and/or not fulfilling that purpose; and

(ii) Group Members, their treating doctors and / or treating hospitals were not informed of the Mesh Warning Matters and Mesh Evaluation Matters

Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson engaged in conduct that was misleading or deceptive or was more likely to mislead or deceive the Mesh Sub-Group Members;

(k) By marketing, promoting, distributing and supplying the Mesh Implants without providing the proper warning set out in Schedule A (as attached to this Amended originating application), Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson, engaged in conduct that was misleading and deceptive or was more likely to mislead or deceive the Mesh Sub-Group Members.

2. Compensation or damages from Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson 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 74B(1) and 82(1) of the Trace Practices Act or, as the case may be, damages pursuant to sections 55, 346 or in addition or alternatively 237 or in addition or alternatively 259(4) of Schedule 2 of the Competition and Consumer Act;

(c) 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, 259(4), 271 and 272 of Schedule 2 of the Competition and Consumer Act.

(d) Damages pursuant to section 82(1) of the Trade Practices Act, or as the case may be, damages pursuant to sections 236 or in addition or alternatively 237 of Schedule 2 of the Competition and Consumer Act.

3. Damages from Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson at common law for 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 Tape Implants

On the grounds stated in the accompanying Amended Statement of Claim, the Applicant claims that the Respondent contravened sections 75AD, 74B, 74D and 52 of the Trade Practices Act and additionally, or alternatively, sections 138, 271, 272 and 18 of Schedule 2 of the Competition and Consumer Act, and were negligent, and the Applicant each of the Tape Sub-Group Members claim relief as follows:

7. Declarations that:

(a) The safety of the Tape Implants (as defined in the Amended Statement of Claim) acquired by the Applicant and each of the Tape Sub-Group Members (as defined in the 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 section 9 and 138 of Schedule 2 of the Competition and Consumer Act;

(b) The Tape Implants acquired by the Applicant and each of the Tape Sub-Group Members were not reasonably fit for the Tape Purpose (as that term is defined in the Amended Statement of Claim) within the meaning of section 74B of the Trade Practices Act and section 55 of Schedule 2 of the Competition and Consumer Act;

(c) The Tape Implants acquired by the Applicant and each of the Tape 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;

(d) Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson breached their duty of care to the Applicant and each of the Tape Sub-Group Members by designing and manufacturing the Tape Implants in such a way that they had:

(i) the characteristics referred to in paragraph 10 of the Amended Statement of Claim;

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

(e) In addition, or alternatively, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson breached their duty of care to the Applicant

SEAL OF THE FEDERAL COURT OF AUSTRALIA
AUSTRALIA

and each of the Tape Sub-Group Members by continuing to design, and in addition or alternatively manufacture the Tape Implants notwithstanding the matters referred to in subparagraph (d) above;

(f) In addition, prior to 30 June 2020, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson breached their duty of care to the Applicant and each of the Tape Sub-Group Members by continuing to market, and in addition or alternatively, supply the Tape Implants notwithstanding the matters referred to in paragraph 47 of the Amended Statement of Claim and subparagraph (d) above;

(g) In addition, or alternatively, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson breached their duty of care to the Applicant and each of the Tape Sub-Group Members by failing to conduct any, or any adequate pre-market evaluation of the safety and efficacy of the Tape Implants;

(h) In addition, or alternatively, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson breached their duty of care to the Applicant and each of the Tape Sub-Group Members by failing to conduct any, or any adequate post market evaluation of the safety and efficacy of the Tape Implants;

(i) In addition, or alternatively, Johnson & Johnson breached its duty of care to the Applicant and each of the Tape Sub-Group Members by failing to conduct any, or any adequate evaluation of the Tape Implants before supplying, distributing and marketing or promoting them in Australia;

(j) Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson breached their duty of care to the Applicant and each of the Tape Sub-Group Members by failing to inform them and, or alternatively the treating doctors and treating hospitals, prior to 30 June 2020 (for the reasons set out in the particulars to paragraph 47 of the Amended Statement of Claim):

  (i) that the Tape Implants had the characteristics referred to in paragraph 10 of the Amended Statement of Claim;

  (ii) that the Tape 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 **Tape Warning Matters** (as that term is defined in the Amended Statement of Claim);

  (iv) of the **Tape Evaluation Matters** (as that term is defined in the Amended Statement of Claim).

SEAL OF THE FEDERAL COURT OF AUSTRALIA
AUSTRALIA

(k) By, prior to 30 June 2020, marketing, promoting , distributing and supplying the Tape Implants as being medical devices that were reasonably fit for the Tape Purpose, in circumstances whereby:

(i) The Tape Implants had a risk of, and in addition or alternatively, were susceptible to the Tape Complications and Tape Removal Complications, and/or not fulfilling the Tape Purpose; and

(ii) Group Members, their treating doctors and/or treating hospitals were not informed of the Tape Warning Matters and Tape Evaluation Matters

Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson engaged in conduct that was misleading or deceptive or was likely to mislead or deceive the Tape Sub-Group Members.

(l) By, prior to 30 June 2020, marketing, promoting, distributing and supplying the Tape Implants without providing the proper warning set out in Schedule A (as attached to this Amended originating application), Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson engaged in conduct that was misleading or deceptive or was likely to mislead or deceive the Tape Sub-Group Members, prior to that date.

8. Compensation or damages from Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson for the Applicant and the Tape 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;

(b) Compensation pursuant to section 74B(1) and 82(1) of the Trade Practices Act, or as the case may be, damages pursuant to sections 55, 236 or in addition or alternatively 237 or in addition or alternatively 259(4) of Schedule 2 of the Competition and Consumer Act;

(c) 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, 259(4), 271 and 272 of Schedule 2 of the Competition and Consumer Act; and

(d) Damages pursuant to section 82(1) of the Trade Practices Act or, as the case may be, damages pursuant to sections 236 or in addition or alternatively 237 of Schedule 2 of the Competition and Consumer Act.

9. Damages from Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson at common law for the Tape Sub-Group Members.

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

11. Costs.

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

Questions common to claims of group members

DEFINITIONS

In these questions, the following definitions have been adopted:

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

CE mark means Conformité Européenne mark applied as a declaration by a manufacturer that its product conforms to the requirements of the European Council Directive 93/42/EEC issued on 14 June 1993 as amended from time to time.

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

Ethicon Devices means the SUI Devices and the POP Devices.

group members means the "Group Members" as defined in paragraph 1(b) of the ~~Fifth Further~~ Amended Statement of Claim.

POP means pelvic organ prolapse.

POP Devices means the medical devices used for the treatment of pelvic organ prolapse known by the trade names Gynecare Gynemesh Prolene Soft (Gynemesh PS), Gynecare Prolift Pelvic Floor Repair System (Prolift), Gynecare Prolift+M Pelvic Floor Repair System (Prolift+M) and Gynecare Prosima Pelvic Floor Repair System (Prosima).

SUI means stress urinary incontinence.

SUI Devices means the medical devices used for the treatment of stress urinary incontinence known by the trade names Gynecare Tension-free Vaginal Tape System (TVT), Gynecare TVT Obturator System (TVT-O), Gynecare TVT Secur System (TVT Secur), Gynecare TVT Exact Continence System (TVT Exact) and Gynecare TVT Abbrevo Continence System (TVT Abbrevo).

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

THE PURPOSE OF THE ETHICON DEVICES

The purpose of the POP Devices

1. What was the purpose of the POP Devices?

The purpose of the SUI Devices

2. What was the purpose of the SUI Devices?

COMPLICATIONS THAT COULD BE CAUSED BY THE ETHICON DEVICES

3. Can the Ethicon Devices cause the following reactions:

    (a) a chronic inflammatory reaction of the tissues surrounding the implanted device;

    (b) extrusion or erosion of the mesh into surrounding organs, including the vaginal wall, bladder or urethra;

    (c) infection;

    (d) chronic pain;

    (e) dyspareunia and/or apareunia;

    (f) difficulty voiding;

    (g) offensive vaginal discharge;

    (h) de novo or recurrent urinary incontinence;

    (i) damage to surrounding organs, nerves, ligaments, tissue and/or blood vessels;

    (j) haemorrhage;

    (k) leg weakness;

    (l) indirectly, psychiatric injury;

    (m) reoperation or revision surgery associated with complications;

    (n) the need to remove the implanted device or part of the implanted device;

    (o) complications associated with the removal of the implanted device or part of the implanted device (which removal might prove difficult or impossible) including aggravation of existing complications; and

(p) that the chronic inflammatory response to the implanted device is affected by conditions which affect the immune response and healing, including autoimmune and connective tissue disorders?

(q) de novo or recurrent urinary incontinence;

(r) difficulty voiding and in addition or alternatively difficulty defecating; and

(s) recurrence of prolapse?

4. Are each of the complications referred to in questions 3 clinically significant?

5. What is the magnitude of the risk of each of the complications referred to in questions 3 occurring?

6. What is the potential seriousness of the complications if they materialise?

7. Are the complications confined to the transvaginal use of mesh?

8. Can the complications occur many years after implantation?

9. Did Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson know that each of the Ethicon Devices could cause each of the complications referred to in question 3?

MECHANISM OF THE COMPLICATIONS

10. Is it necessary for group members to prove the mechanism by which the Ethicon Devices caused the complications which they suffered as a result of their Ethicon Devices?

BIOCOMPATIBILITY ISSUES

11. What type of foreign body or inflammatory response is caused by the Ethicon Devices?

12. Is some chronic foreign body or inflammatory response an intended outcome of implantation of the Ethicon Devices so as to create a desired level of fibrosis?

13. Can the chronic foreign body response or inflammatory response to the Ethicon Devices be greater than necessary to create the desired level of fibrosis?

14. Can the foreign body reaction to the implantation of the Ethicon Devices be clinically significant?

15. Can the foreign body reaction to the implantation of the Ethicon Devices cause any of the complications other than chronic inflammation?

16. Do the pores of the mesh used in the Ethicon Devices deform and collapse under mechanical load?

17. Does deformation and collapse of the pores of the mesh used in the Ethicon Devices result in complications of fibrotic bridging, scar plate formation and/or excessive scarring?

18. Is fibrotic bridging of clinical significance?

19. Is mesh shrinkage or contraction of clinical significance?

20. Does the mesh used in the Ethicon Devices cause pain? If so, is the pain attributable to nerve entrapment?

21. Does Prolene mesh oxidise in vivo?

22. Does oxidisation of Prolene mesh in vivo have clinical significance?

REGULATORY CLEARANCE OF THE DEVICES

23. Does the entry of the Ethicon Devices on the Australian Register of Therapeutic Goods, or the fact that the Ethicon Devices bore the “CE mark”, demonstrate that the products met applicable regulatory standards?

24. Was the “CE marking” of any of the Ethicon devices justified at the time the marks were applied or at any time thereafter?

25. If there was no “CE marking”, would the Ethicon devices have been supplied in Australia?

PERFORMANCE OF THE DEVICES

26. Were the techniques designed by Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson for transvaginal implantation of the Ethicon Devices able to be reproduced consistently?

27. Have the SUI Devices ever been shown to be safer or more effective in the long-term than alternative non-mesh treatments?

28. Have the POP Devices ever been shown to be safer or more effective in the long-term than alternative non-mesh treatments?

29. Were the POP Devices ever safe for general use in the wide range of patients for whom they were indicated and promoted?

30. Were the POP Devices (except for Gynemesh PS) ever suitable for use outside the context of a clinical trial in which participants were provided with appropriate warnings about the nature and extent of the potential complications?

NEGLIGENCE

Duty of Care

31. Did Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson owe a duty of care to group members?

32. Did the manufacturers of the Ethicon Devices (Ethicon Sàrl and Ethicon Inc.) owe the group members in Australia a duty to take reasonable care in the design, testing, evaluation, supply and marketing of those of the Ethicon Devices they manufactured?

33. Did the supplier of the Ethicon Devices (Johnson & Johnson Medical Pty Limited) owe the group members in Australia a duty to take reasonable care in the supply and marketing of the Ethicon Devices?

34. What was the scope or content of Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson ' duty of care in relation to the supply and marketing of the Ethicon devices?

Breach

Pre-market Evaluation

35. Did Ethicon Sàrl and Ethicon Inc. breach their duty of care in Australia by failing to undertake adequate pre-market evaluations of the safety and efficacy of the Ethicon Devices?

Post-market Evaluation

36. Did Ethicon Sàrl and Ethicon Inc. breach their duty of care in Australia by failing to undertake adequate post-market evaluations of the Ethicon Devices from the time of their supply?

Information

37. For the period from 4 July 2017 up to 30 June 2020, did Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson breach their duty of care to Group Members by failing to provide adequate warnings as to the risks associated with the implantation of those devices?

38. What warnings and other information should Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson have provided in respect of the Ethicon Devices?

39. To whom should the warnings or other information have been provided?

General Causation

40. But for Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson ' negligent pre-market evaluations:
    (a) Would any of the Ethicon devices have been on the Australian market?
    (b) Would any group members have received an Ethicon device and suffered damage from its implantation?

APPLICATION OF THE STATUTORY CAUSES OF ACTION TO ETHICON SÀRL, ETHICON, INC. AND IN ADDITION, OR ALTERNATIVELY, JOHNSON & JOHNSON THAT ARE INCORPORATED OVERSEAS

41. Do the statutory causes of action (being claims of misleading or deceptive conduct and product liability claims) apply to Ethicon Sàrl and Ethicon Inc. even though those respondents are incorporated overseas and neither have a place of business in Australia?

MISLEADING OR DECEPTIVE CONDUCT

42. From 4 July 2017, was Ethicon Sàrl's, Ethicon, Inc.'s and in addition, or alternatively, Johnson & Johnson ' conduct, in marketing the Ethicon Devices, conduct that was misleading or deceptive or likely to mislead or deceive within the meaning of s 52 of the Trade Practices Act or s 18 of the Australian Consumer Law?

43. In what way was Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnsons' conduct misleading or deceptive or likely to mislead or deceive?

DEFECTIVE GOODS

44. Is it sufficient for a group member to establish that she has suffered an injury caused by reason of an Ethicon Device being a defective product for the purposes of s 75AD(c) if she establishes that her injury is a complication that has been found to result from implantation of an Ethicon Device?

POP Devices

45. Were the POP Devices defective within the meaning of ss 75AC and 75AD of the Trade Practices Act and did they have a safety defect within the meaning of ss 9 and 138 of the Australian Consumer Law?

46. Which of Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson is liable if any applicant or group member proves that they have suffered injury because of the defect, or safety defect, in a POP Device?

SUI Devices

47. Were the SUI Devices defective within the meaning of s 75AC of the Trade Practices Act and did they have a safety defect within the meaning of s 9 of the Australian Consumer Law?

48. Which of Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson is liable if any applicant or group member proves that they have suffered injury because of the defect, or safety defect, in an SUI Device?

Availability of a State-of-the-art Defence

49. Did Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson establish a defence within the meaning of s 75AK(1)(c) of the *Trade Practices Act* of s 142(c) of the *Australian Consumer* Law?

UNFITNESS FOR PURPOSE AND UNMERCHANTABLE QUALITY

POP Devices – Lack of fitness for purpose

50. Were the POP Devices reasonably fit for the purpose identified in answer to question 1 within the meaning of s 74B of the Trade Practices Act or s 55 of the Australian Consumer Law?

SUI Devices – Lack of fitness for purpose

51. Were the SUI Devices reasonably fit for the purpose identified in answer to question 2 within the meaning of s 74B of the Trade Practices Act or s 55 of the Australian Consumer Law?

POP Devices – Not of merchantable quality or acceptable quality

52. Were the POP Devices not of merchantable quality, within the meaning of s 74D 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?

SUI Devices – Not of merchantable quality or acceptable quality

53. Were the SUI Devices not of merchantable quality, within the meaning of s 74D 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?

Representative action

The Applicant brings this application as a representative party under Part IVA of the *Federal Court of Australia Act 1976.*

Applicant's address

The Applicant's address for service is:

Place: Shine Lawyers

Email: rjancauskas@shine.com.au

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

Service on the Respondents

It is intended to serve this application on the Respondents

Date: 14 July 2021

……..

Signed by Rebecca Jancauskas

Lawyer for the Applicant

Schedule

Federal Court of Australia No: 310 of 2021

District Registry: New South Wales

Division: General

Applicant: Lisa Talbot

First Respondent: Ethicon Sàrl and others

Second Respondent: Ethicon, Inc.

Third Respondent: Johnson & Johnson Medical Pty Limited (ACN 000 160 403)

Date: 14 July 2021

Schedule A

Proper Warning

PROLENE mesh is designed to, and will elicit in all patients, an acute inflammatory reaction followed by a chronic inflammatory response. The chronic inflammatory response will result in continuously regenerating scar tissue within and surrounding the implant for as long as the implant remains in the body. The scar tissue will cause the mesh to contract to some degree in all patients. It is not possible to predict the severity of the chronic inflammatory response in any individual patient. In some patients the chronic inflammatory response will have adverse effects. It is not possible to identify in advance the patients who will experience those effects, although some patients are at greater risk than others. Complications might also occur in patients without any known risk factors.

The severity of a patient's chronic inflammatory response can be affected by physical activity and mechanical loading of the pelvic floor. It can also be affected by conditions which affect the immune response and healing, such as autoimmune and connective tissue disorders. The mechanical forces in the pelvic floor may influence the compatibility and function of the implant.

The adverse events which may result include:

(a) infection;
(b) erosion of the mesh into the vaginal canal resulting in infection which may be difficult to treat, cause offensive vaginal discharge and pain;
(c) erosion of the mesh into surrounding organs such as the bladder, urethra or rectum which may cause pain and damage those organs;
(d) damage to nerves in the scar tissue surrounding the implant or elsewhere;
(e) punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, which may require surgical repair;
(f) pain, which may be severe and chronic;
(g) pain with sexual intercourse (dyspareunia), which may be severe and may become chronic;
(h) loss of sexual function (apareunia), which may be ongoing and may not resolve in some patients;
(i) leg weakness and other neuromuscular problems which may include acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area;
(j) de novo urge urinary incontinence or recurrence of stress urinary incontinence;
(k) difficulty voiding; and
(l) vaginal discharge.

SEAL OF THE FEDERAL COURT OF AUSTRALIA
AUSTRALIA

Adverse events may occur years after implantation. The risk will endure for as long as the implant remains in the patient.

Each of these events may occur regardless of the skill of the surgeon.

While the true incidence of these complications is unknown, they are not rare.

One or more revision surgeries may be necessary to treat the adverse reactions associated with PROLENE Mesh. Revision surgeries may not resolve complications and are associated with a risk of adverse reactions. PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

Removal of the implant in whole or in part will not necessarily alleviate the patient's symptoms. Removal of part of the implant can be difficult. Removal of the whole of the implant may be practically impossible. Surgery to remove the whole or part of an implant can result in further scarring and tissue damage which, in turn, may have adverse outcomes including severe chronic pain which may not be able to be satisfactorily treated. Surgery to remove the whole or part of the implant may also result in recurrence of stress urinary incontinence.

Removal of the eroded mesh will not necessarily prevent further erosions or other adverse events.