NOTICE OF FILING AND HEARING

This document was lodged electronically in the FEDERAL COURT OF AUSTRALIA (FCA) on 13/04/2018 3:35:30 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:	NSD1590/2012
File Title:	Kathryn Gill & Ors 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**:** 16/04/2018 10:41:16 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.

Form 19
Rule 9.32

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

Amended on 13 April 2018 and filed pursuant to an order made on 9 April 2018.

No. 1590 of 2012

Federal Court of Australia

District Registry: New South Wales

Division: General

Kathryn Gill

First Applicant

Diane Dawson

Second Applicant

Ann Sanders

Third Applicant

ETHICON Sàrl and others

Respondents

To the 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) Kathryn Gill and others (Applicants)
Prepared by (name of person/lawyer) Rebecca Jancauskas, Shine Lawyers
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 grounds stated in the accompanying ~~Fourth~~ Fifth Further Amended Statement of Claim, the First and Second Applicants claim 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 First and Second Applicants claim relief as follows:

1. Declarations that:
   (a) The safety of the **Mesh Implants** (as defined in the ~~Fourth~~ Fifth Further Amended Statement of Claim) acquired by the First and Second Applicants and each of the **Mesh Sub-Group Members** (as defined in the ~~Fourth~~ Fifth 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 and Second Applicants and each of the Mesh Sub-Group Members were not reasonably fit for the **Mesh Purpose** (as that term is defined in the ~~Fourth~~ Fifth Further 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 Mesh Implants acquired by the First and Second Applicants 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;
   (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 the First and Second Applicants 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 23 of the ~~Fourth~~ Fifth Further Amended Statement of Claim; and in addition, or alternatively,
      (ii) a risk of and in addition, or alternatively, were susceptible to, causing the **Mesh Complications** (as defined in the ~~Fourth~~ Fifth Further Amended Statement of Claim) and in addition, or alternatively, the **Mesh Removal**

Complications (as defined in the ~~Fourth~~ Fifth Further Amended Statement of Claim);

(e) In addition, or alternatively, Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson breached their duty of care to the First and Second Applicants 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 (d) above;

(f) In addition, or alternatively, Ethicon Sàrl and, or alternatively, Ethicon, Inc. breached their duty of care to the First and Second Applicants 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;

(g) In addition, or alternatively, Ethicon Sàrl and, or alternatively, Ethicon, Inc. breached their duty of care to the First and Second Applicants and 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 and Johnson breached its duty of care to the First and Second Applicants and the Mesh Sub-Group Members 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;

(i) In addition, or alternatively, Ethicon Sàrl and, or alternatively, Ethicon, Inc., breached their duty of care to the First and Second Applicants and each of the Mesh Sub-Group Members by failing to inform them, Johnson & Johnson, or the **Treating Hospitals and/or Treating Doctors** (as those terms are defined in the ~~Fourth~~ Fifth Further Amended Statement of Claim):

  (i) that the Mesh Implants had the characteristics pleaded at paragraph 23 of the ~~Fourth~~ Fifth Further Amended Statement of Claim;

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

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

  (iv) of the **Mesh Evaluation Matters**;

(j) Johnson and Johnson breached its duty of care to the First and Second Applicants and each of the Mesh Sub-Group Members by failing to inform them, or the Treating Hospitals and/or Treating Doctors:

  (i) that the Mesh Implants had the characteristics pleaded at paragraph 23 of the ~~Fourth~~ Fifth Further Amended Statement of Claim;

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

(iii) of the Mesh Warning Matters;

(iv) of the Mesh Evaluation Matters (as that term is defined in the ~~Fourth~~ Fifth Further Amended Statement of Claim);

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

(i) the Mesh Implants had a risk of, and in addition or alternatively, were susceptible to the Mesh Complications and Mesh Removal Complications, and/or not fulfilling the Mesh 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 likely to mislead or deceive the Mesh Sub-Group Members~~.~~;

(l) By marketing, promoting, distributing and supplying the Mesh Implants without providing the proper warning set out in CRT.010.021.0001 (as attached to this 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 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;

(b) Compensation pursuant to sections 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 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.

2A. An Injunction pursuant to section 80 of the Trade Practices Act or, as the case may be, section 232 of Schedule 2 of the Competition and Consumer Act, restraining Ethicon, Inc. and Johnson & Johnson from supplying, distributing, marketing or promoting the Gynecare Gynemesh PS Implants (as defined in the Fifth Further Amended Statement of Claim) in Australia without providing the proper warning set out in CRT.010.021.0001 (as attached to this originating application), until further order of the Court.

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 ~~Fourth~~ Fifth Further Amended Statement of Claim, the Third Applicant claims that the Respondents each 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 Third Applicant and each of the Group Members claim relief as follows:

7. Declarations that:

(a) The safety of the Tape Implants (as defined in the ~~Fourth~~ Fifth Further Amended Statement of Claim) acquired by the Third Applicant and each of the Tape Sub-Group Members (as defined in the ~~Fourth~~ Fifth 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 Tape Implants acquired by the Third Applicant and each of the Tape Sub-Group Members were not reasonably fit for the Tape Purpose (as that term is defined in the ~~Fourth~~ Fifth Further 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 Third 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, and in addition, or alternatively, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson, breached their duty of care to the Third 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 45 of the ~~Fourth~~ Fifth Further Amended Statement of Claim;

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

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

(f) In addition, or alternatively, Ethicon Sàrl and, or alternatively, Ethicon Inc. breached their duty of care to the Third 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;

(g) In addition, or alternatively, Ethicon Sàrl and, or alternatively, Ethicon Inc. breached their duty of care to the Third 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;

(h) In addition, or alternatively, Johnson & Johnson breached its duty of care to the Third 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, marketing or promoting them in Australia;

(i) Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc, breached their duty of care to the Third Applicant and each of the Tape Sub-Group Members by failing to

inform them, Johnson & Johnson, and, or alternatively, the Treating Doctors and Treating Hospitals:

(i) that the Tape Implants had the characteristics referred to in paragraph 45 of the ~~Fourth~~ Fifth Further Amended Statement of Claim;

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

(iii) of the **Tape Warning Matters** (as that term is defined in the ~~Fourth~~ Fifth Amended Statement of Claim);

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

(j) Johnson & Johnson breached its duty of care to the Third Applicant and each of the Tape Sub-Group Members by failing to inform them and, or alternatively, the Treating Doctors and Treating Hospitals:

(i) that the Tape Implants had the characteristics referred to in paragraph 45 of the ~~Fourth~~ Fifth Further Amended Statement of Claim;

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

(iii) of the Tape Warning Matters

(iv) of the Tape Evaluation Matters.

(k) By 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 marketing, promoting, distributing and supplying the Tape Implants without providing the proper warning set out in CRT.010.021.0001 (as attached to this 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.

8. Compensation or damages from Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson for 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.
   (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.

8A. An Injunction pursuant to section 80 of the Trade Practices Act or, as the case may be, section 232 of Schedule 2 of the Competition and Consumer Act, restraining Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson from supplying, distributing, marketing or promoting the Tape Implants in Australia without providing the proper warning set out in CRT.010.021.0001 (as attached to this originating application), until further order of the Court.

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 or other orders as the Court thinks fit.

Questions common to claims of group members

[NOTE THIS TO BE ADVISED FOLLOWING RESPONDENTS' NOTIFYING THEIR POSITION]

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: 13 April 2018

Signed by Alissa McKillop on behalf of
Rebecca Jancauskas
Lawyer for the Applicants

Schedule

No.1590 of 2012

Federal Court of Australia
District Registry: New South Wales
Division: General

Applicants

First Applicant:	Kathryn Gill
Second Applicant:	Diane Dawson
Third Applicant:	Ann Sanders

Respondents

First Respondent:	Ethicon Sàrl
Second Respondent:	Ethicon, Inc.
Third Respondent:	Johnson & Johnson Medical Pty Limited (ACN 000 160 403)

Date: 13 April 2018

Form 59
Rule 29.02(1)

No. NSD 1590 of 2012

Federal Court of Australia

District Registry: New South Wales

Division: General

Kathryn Gill and others

Applicants

Ethicon Sárl and others

Respondents

Proper Warning

The implant is designed to and will elicit an acute inflammatory reaction followed by a chronic inflammatory response in all patients. The chronic inflammatory response will result in continuously regenerating scar tissue within and surrounding the implant for as long as the implant is in the body. The scar tissue will cause the implant to contract to some degree in all patients. It is not possible to predict the severity of the chronic inflammatory response of any individual patient. There is a risk that in some patients the severity of the chronic inflammatory response will result in adverse outcomes. That risk is not rare. It is not possible to identify in advance the patients who will have that response. At risk patients include healthy patients. The severity of a patient's chronic inflammatory response can be affected by physical activity and mechanical loading of the pelvic floor. It may be affected by conditions which affect the immune response and healing, including autoimmune and connective tissue disorders. The mechanical forces in the pelvic floor are unknown and may influence the compatibility and function of the implant. The adverse events which may result are:

(a) by reason of excessive contraction of the implant or otherwise, severe chronic pain with potentially life altering consequences with or without psychiatric injury;
(b) damage to or entrapment of nerves in the scar tissue surrounding the implant or otherwise, resulting in severe chronic pain with potentially life altering consequences with or without psychiatric injury;
(c) by reason of excessive contraction of the implant or otherwise, de novo dyspareunia including severe chronic dyspareunia and consequently apareunia;
(d) 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;
(e) erosion or extrusion of the implant into the vaginal canal resulting in pain suffered by the patient or her sexual partner or both;
(f) 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;
(g) by reason of excessive contraction of the implant or otherwise, difficulty voiding or defecating;
(h) by reason of excessive contraction of the implant or otherwise, de novo stress or urge incontinence,

(i) infection.

Each of the risks may eventuate regardless of the skill of the surgeon. They are not rare. If any of those adverse events eventuate, they will likely persist for so long as the implant remains in the patient. Removal of the implant in whole or in part will not necessarily alleviate the patient's condition. 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 resulting in adverse outcomes including severe chronic pain which may not be able to be treated.

Surgery to remove the whole or part of the implant may result in recurrence of the original condition the mesh was designed to treat.

Surgery to remove the whole or part of the implant may make remedying the original condition of the patient which the implant was designed to alleviate more difficult to treat.

Successful treatment of erosion by excision will not necessarily prevent further erosion or other future adverse outcomes.

Whether the implant is or remains inert for the remainder of a patient's life is unknown. The implant is made from polypropylene. It is known that polypropylene undergoes oxidative degradation in vivo. Degradation may affect the mechanical properties of the implant and the severity of the chronic inflammatory response to it.

Use of the implant may result in fraying and fragmentation of the implant or the release of polypropylene particles which may affect the severity of the chronic inflammatory response to the implant.

The adverse outcomes may not materialise until years after implantation and the risk of the adverse outcomes are life-long risks for so long as the implant remains in the patient.

Insufficient clinical testing of the implant has been undertaken to determine the safety of the implant and its long-term effectiveness.

The long-term safety of the implant has not been studied and is unknown.

The long-term efficacy of the implant has not been studied and is unknown.

Whether the safety and efficacy of the implant is the same as or better than non-mesh treatment alternatives has not yet been established.