Federal Court of Australia

District Registry: New South Wales

Division: General No: NSD310/2021

LISA TALBOT
Applicant

ETHICON SARL and others named in the schedule
Respondent

No: NSD1590/2012

KATHRYN GILL and others named in the schedule
Applicant

ETHICON SARL and another named in the schedule
Respondents

ORDER

JUDGE: JUSTICE LEE

DATE OF ORDER: 24 March 2022

WHERE MADE: Sydney

BY CONSENT, THE COURT ORDERS THAT:

In proceeding NSD310/2021

1. Pursuant to s 33ZB of the *Federal Court of Australia Act 1976* (Cth) (**Act**), the Court answers the common questions raised in this proceeding as set out in Annexure 1 to these orders and those answers are binding on all group members who have not opted out and who have received an Implant (as defined in the amended statement of claim) on or prior to 30 June 2020.

2. The proceeding be adjourned to 9:30am on 15 August 2022.

In proceeding NSD1590/2012

3. Pursuant to sections 33ZF, 37P(2) and 54A of the Act, and Division 28.6 of the *Federal Court Rules2011* (**FCR**):

    a. The questions set out in Annexure 2 to this order (**Relevant Questions**) be

referred to Julian Sexton SC (**Referee**) for the purposes of the Referee conductingan inquiry into the Relevant Questions (**Reference**) and making a report in writing to the Court on the Relevant Questions stating, with reasons, the Referee's opinion on the Relevant Questions (**Report**).

b. The Reference shall commence on the date of this Order.

c. The Referee is to consider and implement such manner of conducting the Reference as will, without undue formality or delay, enable a just, efficient, timely and cost effective resolution of the Reference to allow completion of the Report including, if the Referee thinks fit, the making of inquiries inperson or by telephone or in writing.

4. Further to Order 1 above, the Referee may make such enquiries as the Referee considers appropriate or necessary for the purpose of the Reference but without limiting this order, the Referee may obtain the assistance of an independent barrister nominated by the Court in the conduct of the Reference and the preparation and drafting of the report (**Counsel Assisting**).

5. The first, second and third Applicants (**Applicants**) and the first, second and third Respondents (**Respondents**) are to deliver to the Referee and Counsel Assisting forthwith, copies of the following documents:

a. this order;

b. Transcript of Conferral before Lee J, Registrar Priestley and Registrar Legge, dated 22 December 2021;

c. Transcript of Case Management Hearing before Lee J, dated 24 February 2022;

d. Transcript of Case Management Hearing before Lee J, dated 24 March 2022;

e. FCR Division 28.6;

f. each of the Applicants' Schedules of Damages which supported the entry of judgment in favour of each Applicant in this proceeding on 3 March 2020;

g. the Court's reasons for judgment in *Gill v Ethicon Sarl (No 5)* [2019] FCA 1905;

h. the Court's reasons for judgment and orders answering common questions in *Gill v Ethicon Sàrl (No 6)* [2020] FCA 279 as varied by the Full Court's judgment in *Ethicon Sàrl v Gill (No 2)* [2021] FCAFC 52; and

i. a glossary of key terms.

6. By a date to be fixed by the Referee, the Referee is to confer with (and may invite submissions from) the parties and, insofar as necessary, Counsel Assisting, as to:

a. the identity and number of sample group members; and

b. the method by which the Relevant Questions are to be assessed, documented and adjudicated, including as to the medical records, evidence and submissions required to assess, document and adjudicate Relevant Questions.

7. By 31 July 2022, the Referee is to provide a report answering the Relevant Questions (the **Assessments Report**).

8. The Referee is to submit the Assessments Report to the Court in accordance with FCR 28.66, addressed to the New South Wales District Registrar, on or before 31 July 2022.

9. The Referee:

a. is not bound to conduct the Reference in accordance with the rules of evidence;

b. in the Assessments Report will, to the extent it was necessary for the Referee to make any findings of fact in order to express his or her opinion on the Relevant Questions:

i. make a statement of the facts found by the Referee from which theCourt may draw such inferences as it thinks fit; and

ii. submit any questions arising on the Reference for the decision of the Court, and provide alternative opinions on the Relevant Questions, depending on how the Court determines any question submitted to the Court; and

c. should include in the Assessments Report the reasoning processes that led the Referee to the conclusions made and must specify any amount of damages found to be payable to any sample group member and the manner of determining that amount.

10. If, for any reason, the Referee is unable to comply with the order for delivery of the Assessments Report to the Court by the date provided for in this order, the Referee is to provide to the District Registrar an interim Assessments Report setting out the reasons for such inability andan application to extend the time within which to deliver the Assessments Report to the Court to a date when the Referee will be able to provide the Report.

11. The Referee, the Applicants and the Respondents have liberty to seek directions with respect to any matter arising in the Reference and the Referee and Counsel Assisting has leave to communicate with the Associate to Justice Lee without notification to theparties to the proceedings.

12. Any application to adopt the Assessments Report or seek any other order under FCR 28.67 is to be filed and served by 12 August 2022 and be returnable for directions at 9:30am on Monday, 15 August 2022.

Costs

13. Without affecting the powers of the Court as to costs, the parties to be jointly and severally liable for the fees payable to the Referee and, if appointed, the independent barrister.

Date that entry is stamped: 10 April 2022

Registrar

Schedule

No: NSD310/2021

Federal Court of Australia

District Registry: New South Wales

Division: General

Interested Person	DEFENCE HEALTH
Interested Person	TEACHERS FEDERATION HEALTH LIMITED
Interested Person	LATROBE REGIONAL HOSPITAL
Second Respondent	ETHICON, INC.
Third Respondent	JOHNSON & JOHNSON MEDICAL PTY LIMITED ACN 000 160 403

ANNEXURE 1

Definitions

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 para 1(b) of the Amended Statement of Claim.

JJM means Johnson & Johnson Medical Pty Limited.

Manufacturers means the first and second respondents, Ethicon Sàrl and Ethicon, Inc.

POP means pelvic organ prolapse.

POP devices means the medical devices used for the treatment of pelvic organ prolapse known by the trade names:

(a) Gynecare Gynemesh Prolene Soft (Gynemesh PS),

(b) Gynecare Prolift Pelvic Floor Repair System (Prolift),

(c) Gynecare Prolift+M Pelvic Floor Repair System (Prolift+M) and

(d) 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:

(a) Gynecare Tension-free Vaginal Tape System (TVT),

(b) Gynecare TVT Obturator System (TVT-O),

(c) Gynecare TVT Secur System (TVT Secur),

(d) Gynecare TVT Exact Continence System (TVT Exact) and

(e) Gynecare TVT Abbrevo Continence System (TVT Abbrevo).

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

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THE PURPOSE FOR WHICH THE ETHICON DEVICES WERE ACQUIRED

Q1: What was the purpose for which the POP Devices were acquired?

A: The POP devices were acquired for the purpose of treating pelvic organ prolapse in women and, more particularly, for the purpose of treating the condition more effectively, or at least as effectively as other surgical interventions, and with fewer risks to safety.

Q2: What was the purpose for which the SUI Devices were acquired?

A: The SUI devices were acquired for the purpose of treating stress urinary incontinence in women and, more particularly, for the purpose of treating the condition more effectively, or at least as effectively as other surgical interventions, and with fewer risks to safety.

COMPLICATIONS THAT CAN BE CAUSED BY THE ETHICON DEVICES

Q3: Can the Ethicon devices cause the following complications:

(a) a chronic inflammatory reaction of the tissues surrounding the implanted device also known as a foreign body response, which is affected by conditions which affect the immune response and healing, including autoimmune and connective tissue disorders;

(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) psychiatric injury;

(m) the need for 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 might prove difficult or impossible, including aggravation of existing complications?

A: Yes.

Q4: Can the POP Devices also cause the following complications:

(a) Difficulty defecating; and

(b) recurrence of prolapse?

A: Yes.

Q5: Are each of the complications referred to in question 3 and 4 clinically significant?

A: Yes.

Q6: Are the complications confined to the transvaginal use of mesh?

A: No, they extend to mesh implanted transabdominally.

Q7: Can the complications occur many years after implantation?

A: Yes.

Q8: Is it necessary for group members to prove the mechanism by which the Ethicon devices caused the complications they suffered as a result of implantation of those devices?

A: No.

BIOCOMPATIBILITY ISSUES

Q9: Can the pores of the mesh used in the Ethicon devices deform and collapse under mechanical load?

A: Yes.

Q10: Does deformation and collapse of the pores of the mesh used in the Ethicon devices cause bridging fibrosis and fibrotic bridging?

A: Yes.

Q11: Is bridging fibrosis of clinical significance?

A: Yes. It can cause or contribute to contraction of the mesh which, in turn, can cause complications such as mesh exposure, erosion, chronic pain and dyspareunia.

NEGLIGENCE

Duty of Care

Q12: Did the respondents owe a duty of care to group members?

A: Yes. The respondents owed a duty to take reasonable care to avoid injury to consumers.

Q13: Did the manufacturers of the Ethicon Devices (Ethicon Sàrl and Ethicon Inc.) owe the group members a duty to take reasonable care in the design, testing, evaluation, supply, and marketing those of the Ethicon Devices?

A: Yes.

Q14: Did the supplier of the Ethicon Devices (Johnson & Johnson Medical Pty Limited) owe the group members a duty to take reasonable care in the supply and marketing of the Ethicon devices?

A: Yes.

Breach

Pre-market Evaluation

Q15: Did the manufacturers breach their duty of care to the group members by failing to undertake adequate pre-market evaluations of the safety and efficacy of the Ethicon devices?

A: Yes.

Post-market Evaluation

Q16: Did the manufacturers breach their duty of care to the group members by failing to undertake adequate post-market evaluations of the safety and efficacy of the Ethicon devices from the time of their supply until 4 July 2017?

A: Yes.

Information

Q17: During the period from the time of first supply in Australia of each of the Ethicon devices until the date on which the Ethicon devices were supplied with a warning in the terms set out in order 2 made by the Court on 6 March 2020 in proceedings NSD1590 of 2012, did the respondents breach their 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 adequate clinical or other evaluation of the risks?

A: Yes, throughout the period, except that they did not breach their duty of care by failing to warn of the risk of psychiatric injury.

Q18: During the period referred to in question 17, in what respects was the information, advice or warnings provided by the respondents about the complications inadequate?

A: During the period from the time of first supply in Australia of each of the Ethicon devices until the date on which the Ethicon devices were supplied with a warning in the terms set out in order 2 made by the Court on 6 March 2020 in proceedings NSD1590 of 2012, save as indicated below, the respondents failed to disclose or make adequate disclosure of the following matters:

(a) that the mesh used in the Ethicon devices was designed to, and would invariably elicit in patients, an acute inflammatory reaction followed by a chronic inflammatory response;

(b) that in some patients the chronic inflammatory response will have adverse effects;

(c) that it is not possible to predict which patients will be adversely affected but they include healthy patients;

(d) that the severity of a patient's chronic inflammatory response can be affected by conditions which affect the immune response and healing, such as autoimmune and connective tissue disorders;

(e) that the severity of a patient's chronic inflammatory response can be affected by physical activity and mechanical loading of the pelvic floor;

(f) that the mechanical forces in the pelvic floor may influence the compatibility and function of the implant;

(g) that the adverse effects of the chronic inflammatory response in some patients include:

(i) infection, rather than merely the potentiation of infection;

(ii) that erosion of the mesh into the vaginal canal could cause infection which might be difficult to treat and cause offensive vaginal discharge and pain;

(iii) that erosion of the mesh into surrounding organs, such as the bladder, urethra or rectum, could cause pain and damage those organs;

(iv) damage to nerves in the scar tissue surrounding the implant or elsewhere (except for Gynemesh PS from 16 March 2013, Prolift from 1 October 2009, and Prolift+M from 12 December 2008);

(v) chronic pain, which may be severe;

(vi) dyspareunia, which may be severe and become chronic;

(vii) apareunia;

(viii) leg weakness;

(ix) *de novo* or recurrent incontinence (except TVT from 7 October 2015, TVT-O from 22 September 2015, TVT Abbrevo from 24 September 2015, TVT Exact from 18 September 2015, Gynemesh PS from 16 March 2013, Prolift from 1 October 2009, Prolift+M from 12 December 2008);

(x) difficulty voiding (except for TVT from 7 October 2015, TVT-O from 22 September 2015, TVT Abbrevo from 24 September 2015, TVT Exact from 18 September 2015, Gynemesh PS from 16 March 2013, Prolift from 1 October 2009, Prolift+M from 12 December 2008);

(xii) vaginal discharge (except TVT from 7 October 2015, TVT-O from 22 September 2015, TVT Abbrevo from 24 September 2015, TVT Exact from 18 September 2015, Gynemesh PS from 3 April 2015); and

(xiii) (in the case of the POP devices only) recurrent prolapse (except for Gynemesh PS from 16 March 2013, Prolift from 1 October 2009, and Prolift+M from 12 December 2008) and pain on defaecation;

(h) that the adverse events may occur years after implantation and the risk will endure for as long as the implant remains in the body;

(i) that the adverse events may occur regardless of the skill of the surgeon;

(j) that the true incidence of the adverse events is unknown but they are not rare;

(k) that removal of the implant in whole or in part will not necessarily alleviate the patient's symptoms;

(l) that removal of part of an implant can be difficult and removal of the whole may be practically impossible;

(m) that mesh removal surgery 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;

(n) that surgery to remove the whole or part of an implanted SUI device can result in recurrence of stress urinary incontinence;

(o) that surgery to remove the whole or part of an implanted POP device can result in recurrence of pelvic organ prolapse; and

(p) that removal of eroded mesh will not necessarily prevent further erosions or other adverse events.

General Causation

Q19: But for the respondents' negligent pre-market evaluations:

(a) would any of the Ethicon devices have been on the Australian market at any time?

A: No.

(b) would any group member have received an Ethicon device and suffered damage from its implantation?

A: No.

THE STATUTORY CAUSES OF ACTION

Q20: Do the causes of action under the Trade Practices Act or the Australian Consumer Law apply to Ethicon Sàrl and Ethicon, Inc. even though they are incorporated overseas and neither have a place of business in Australia?

A: Yes.

MISLEADING OR DECEPTIVE CONDUCT

Q21: Between the first supply in Australia of the Ethicon devices and 4 July 2017, was the respondents' 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?

A: Yes.

Q22: Why was the respondents' conduct misleading or deceptive or likely to mislead or deceive during the period identified in question 21?

A: In circumstances where:

(a) the Ethicon devices caused the complications identified in the answer to common question 3 above; and

(b) the respondents failed to disclose or make adequate disclosure of the matters identified in the answer to common question 18 above, throughout the period from the first supply in Australia of the Ethicon devices to 4 July 2017, the conduct of the respondents in the marketing and promoting of the Ethicon devices was conduct that was misleading and deceptive or conduct likely to mislead and deceive.

DEFECTIVE GOODS

Q23: 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 s 9 of the Australian Consumer Law in that their safety was not such as persons generally are entitled to expect?

A: Yes, all of them. The safety of those devices was not such as persons generally are entitled to expect because they exposed women to significant risks of injury against which inadequate precautions were taken and in respect of which misleading representations were made. The mesh kits were only ever suitable for use in the context of a clinical trial and then only with appropriate warnings about the nature and extent of the complications.

Q24: 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?

A: Yes, all of the SUI Devices that were supplied without a warning in the terms set out in order 2 made by the Court on 6 March 2020 in proceedings NSD1590 of 2012 had 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 because, taking into account all the relevant circumstances, including the way in which and the purposes for which they were marketed, the use of the CE mark in relation to them, the deficiencies in the warnings and other information supplied by the respondents they exposed women to significant risks of injury against which inadequate precautions were taken and in respect of which misleading representations were made.

Q25: Which of the respondents is liable to compensate a group member who can prove she suffered an injury because of a defect, or safety defect, in a POP device?

A: Ethicon Sàrl and JJM are jointly and severally liable to compensate group members who suffered an injury because of a defect, or safety defect, in Prolift, Prolift+M or Prosima. Ethicon, Inc and JJM are jointly and severally liable to compensate group members who suffered an injury because of a defect, or safety defect, in Gynemesh PS.

Q26: Which of the respondents is liable to compensate a group member who can prove she suffered an injury because of a defect, or safety defect, in a SUI device?

A: Ethicon Sàrl and JJM are jointly and severally liable to compensate group members who suffered an injury because of a defect, or safety defect, in any of the SUI devices.

Availability of a State-of-the-art Defence

Q27: Is a state of the art defence within s 75AK(1)(c) of the Trade Practices Act or s 142(c) of the Australian Consumer Law available to the respondents?

A: No.

UNFITNESS FOR PURPOSE AND UNMERCHANTABLE QUALITY

POP Devices – Lack of fitness for purpose

Q28: Were the POP devices reasonably fit for the purpose for which they were acquired?

A: No.

SUI Devices – Lack of fitness for purpose

Q29: Were the SUI devices reasonably fit for the purpose for which they were acquired during the period that they were supplied without a warning in the terms set out in order 2 made by the Court on 6 March 2020 in proceedings NSD1590 of 2012?

A: No.

POP Devices – Not of merchantable quality or acceptable quality

Q30: Were the POP Devices not as fit for the purpose of which goods of that kind are commonly bought as it is reasonable to expect having regard to all of the relevant circumstances?

A: No.

SUI Devices – Not of merchantable quality or acceptable quality

Q31: Were the SUI Devices not as fit for the purpose of which goods of that kind are commonly bought as it is reasonable to expect having regard to all of the relevant circumstances during the period that they were supplied without a warning in the terms set out in order 2 made by the Court on 6 March 2020 in proceedings NSD1590 of 2012?

A: No.

ANNEXURE 2

For each sample group member:

1. Is the individual a Group Member, as defined in paragraph 1 of the Fifth Further Amended Statement of Claim?

2. Did the Group Member suffer injury, loss or damage caused by any of:

    a. the defect in the Implant;

    b. the Respondents' negligent:

        i. evaluation of the Implant;

        ii. failure to provide adequate warnings in respect of the Implant;

    c. the Respondents' misleading or deceptive conduct?

3. In respect of any injury, loss or damage found in answer to Question 2 above, what is the amount of damages payable to the Group Member and under which legislative regime?

4. Are any of the Group Member's claims statute-barred?

5. If any of the Group Member's claims is statute-barred, should leave be granted to extend the applicable period of limitation?