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Details of Filing

Document Lodged:	Statement of Claim - Form 17 - Rule 8.06(1)(a)
File Number:	NSD1590/2012
File Title:	Kathryn Gill & Ors v Ethicon Sarl & Ors
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA

Dated: 16/04/2018 10:41:09 AM AEST Registrar

Important Information

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Form 17
Rule 8.05(1)(a)

~~Fourth~~ Fifth Further Amended Statement of Claim

Amended on 13 April 2018, filed pursuant to an order of the Court 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

Filed on behalf of (name & role of party) Kathryn Gill and others (Applicants)
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Part A – Introduction

(i) Group Members

1. The Applicants bring this proceeding as a representative proceeding pursuant to Part IVA of the *Federal Court of Australia Act 1976* (Cth):

   (a) in their own right; and

   (b) on behalf of persons (**Group Members**) who at any time before 4 July 2017:

      (i) had surgery performed on them in Australia to implant one or more of the following implants (**Implants**):

         (A) mesh implants (**Mesh Implants**), consisting of:

            (i) the implants included in the Gynecare Prolift Total, Anterior and Posterior Pelvic Floor Repair Systems (**Prolift Implants**), which implants were made of Gynecare Gynemesh PS Nonabsorbable Prolene Soft Mesh and were available as Anterior, Posterior or Total Implants;

            (ii) the implants included in the Gynecare Prosima Anterior, Posterior and Combined Pelvic Floor Repair Systems (**Prosima Implants**), which implants were made of Gynecare Gynemesh PS Nonabsorbable Prolene Soft Mesh and available as an Anterior, Posterior or Combined Implant;

            (iii) the implants included in the Gynecare Prolift + M Total, Anterior and Posterior Pelvic Floor Repair Systems (**Prolift + M Implants**), which implants were made of Gynecare Gynemesh M, a mesh manufactured from approximately equal parts of absorbable polyglecaprone-25 monofilament fibre and non-absorbable polypropylene monofilament fibre and available as an Anterior, Posterior or Total Implant;

            (iv) the Gynecare Gynemesh PS implants (**Gynecare Gynemesh PS Implants**), which were made of Gynecare Gynemesh PS Nonabsorbable Prolene Soft Mesh and available in sheets of 10 x 15 cm and 25 x 25 cm,

         the Group Members who had surgery to implant one or more of the Mesh Implants being the **Mesh Sub-Group Members**; and

         (B) tension-free vaginal tapes (**Tape Implants**) consisting of:

            (i) the tape included in the TVT Tension-free Vaginal Tape System (**TVT Implant**);

(ii) the tape included in the TVT Abbrevo Continence System (**TVT Abbrevo Implant**);

(iii) the tape included in the TVT Obturator System (**TVT Obturator Implant**);

(iv) the tape included in the TVT Secur System (**TVT Secur Implant**); and

(v) the tape included in the TVT Exact System (**TVT Exact Implant**),

the Group Members who had surgery to implant one or more of the Tape Implants being the **Tape Sub-Group Members**;

(ii) were supplied with:

(A) one or more of the Mesh Implants by their treating hospital or doctor for the Mesh Purpose (as defined in paragraph 18 below); and in addition, or alternatively,

(B) one or more of the Tape Implants by their treating hospital or doctor for the Tape Purpose (as defined in paragraph 40 below); and

(iii) have suffered from one or more of:

(A) the Mesh Complications or Mesh Removal Complications pleaded in paragraphs 23 and 23A below in relation to the Mesh Implants; and in addition, or alternatively

(B) the Tape Complications or Tape Removal Complications pleaded in paragraphs 45 and 46 below in relation to the Tape Implants.

(ii) The Applicants

2. The First Applicant (**Mrs Gill**):

(a) was born on 4 December 1970;

(b) is married with two dependent children; and

(c) is a Mesh Sub-Group Member by reason of the matters pleaded at paragraphs 23D to 23P below.

2A. The Second Applicant (**Mrs Dawson**):

(a) was born on 23 March 1959;

(b) is married with three adult children; and

(c) is a Mesh Sub-Group Member by reason of the matters pleaded at paragraphs 23Q to 23AE below.

2B. The Third Applicant (**Mrs Sanders**):

(a) was born on 10 August 1946;

(b) is married with two adult children; and

(c) is a Tape Sub-Group Member by reason of the matters pleaded at 49 to 58 below.

(iii) The Respondents

3. At all material times, the First Respondent (**Ethicon Sàrl**):

(a) was and is a company incorporated under the laws of Switzerland;

(b) was and is a foreign corporation within the meaning of section 4 of the *Trade Practices Act 1974* (Cth) (**the TPA**) and section 4 of the *Competition and Consumer Act 2010* (Cth) (**the CCA**);

(c) was and is in the business of manufacturing medical devices and marketing, promoting and supplying medical devices, including in Australia, and including the Implants listed in sub-paragraph 3(d) below, using the business names Johnson & Johnson Medical, Johnson & Johnson, Gynecare Worldwide and Ethicon Women's Health and Urology;

(d) carried on in trade or commerce the business of manufacturing, marketing, promoting and supplying the following Implants:

(i) the Prolift Implants;

(ii) the Prolift + M Implants;

(iii) the Prosima Implants; and

(iv) the Tape Implants;

(e) manufactured the Implants pleaded at paragraph 3(d) above within the meaning of section 74A(1) of the TPA and section 7 of Schedule 2 of the CCA;

(f) did not have a place of business in Australia; and

(g) supplied the Implants pleaded at paragraph 3(d) above in trade or commerce to the Third Respondent (**Johnson & Johnson**).

4. At all material times, the Second Respondent (**Ethicon, Inc**.):

(a) was and is a company incorporated under the laws of the United States of America;

(b) was and is a foreign corporation within the meaning of section 4 of the TPA and section 4 of the CCA;

(c) was and is in the business of manufacturing medical devices and marketing, promoting and supplying medical devices, including in Australia, and including the Gynecare Gynemesh PS Implants, using the business names Johnson & Johnson Medical, Johnson & Johnson, Gynecare Worldwide and Ethicon Women's Health and Urology;

(d) carried on in trade or commerce the business of manufacturing, marketing, promoting and supplying the Gynecare Gynemesh PS Implants;

(e) manufactured the Implants pleaded at paragraph 4(d) above within the meaning of section 74A(1) of the TPA and section 7 of Schedule 2 of the CCA;

(f) did not have a place of business in Australia; and

(g) supplied the Gynecare Gynemesh PS Implants in trade or commerce to Johnson & Johnson.

5. At all material times, Johnson & Johnson:

(a) was and is a company incorporated in Australia;

(b) was and is a trading corporation within the meaning of section 4 of the TPA and section 4 of the CCA;

(c) did not manufacture any of the Implants; and

(d) from sometime in or about October 1999, imported the Implants into Australia;

PARTICULARS

Johnson & Johnson imported:

(A) the Prolift Implants from on or about June 2005;

(B) the Prolift + M Implants from on or about December 2009;

(C) the Prosima Implants from on or about April 2010;

(D) the Gynecare Gynemesh PS Implant from on or about 26 May 2003;

(E) the TVT Implant from on or about October 1999;

(F) the TVT Secur Implant from on or about May 2007;

(G) the TVT Abbrevo Implant from on or about October 2010;

(H) the TVT Obturator Implant from on or about March 2004;

(l) the TVT Exact Implant from on or about July 2010;

(e) acquired the Implants from Ethicon Sàrl and in addition, or alternatively, from Ethicon, Inc. for re-supply in trade or commerce to treating hospitals and in addition, or alternatively, to treating doctors (together, **the Treating Hospitals and/or Treating Doctors**):

(A) including Treating Hospitals and/or Treating Doctors that treated the Applicants and each of the Group Members; and

(B) which acquired the Implants for re-supply to the Applicants and each of the Group Members;

(f) marketed, promoted and supplied the Implants in Australia.

Part B – The Conditions and the Implants

(i) The Conditions

6. Pelvic organ prolapse (**POP**):

(a) can occur when pelvic support structures are damaged, weakened or otherwise compromised;

(b) involves one or more of the following organs descending into the vagina or past the vaginal opening:

(i) the bladder (being the cystocele form of POP);

(ii) the uterus (being the procidentia form of POP);

(iii) the rectum (being the rectocele form of POP);

(iv) pre-hysterectomy, the apex of the vagina (being apical prolapse);

(v) post-hysterectomy, the apex of the vagina (being vaginal vault prolapse); and

(vi) the bowel (being the enterocele form of POP); and

(c) may result in one or more of the following symptoms:

(i) problems with bowel movement;

(ii) problems with voiding;

(iii) problems during sexual intercourse;

(iv) vaginal bulge; and

(v) feelings of pelvic and in addition, or alternatively, vaginal fullness, heaviness, discomfort and/or pain.

6A. Stress urinary incontinence (**SUI**):

(a) can occur when pelvic support structures to the bladder and urethra are damaged, weakened or otherwise compromised; and

(b) involves urine involuntarily leaking from the urethra during moments of increased abdominal pressure such as with physical activity, coughing, sneezing or laughing

(ii) The Implants

7. The Implants are surgical implants that were:

(a) made, at least partly, from polypropylene;

(b) available in pre-cut shapes or uncut sheets;

(c) implanted transvaginally, abdominally and in addition, or alternatively, laparoscopically; and

(d) passed through, attached to and in addition, or alternatively, brought into proximity with the vagina and, in the case of the Tape Implants, the urethra.

Part C – Importation and Supply of the Implants

(i) Importation and Deemed Manufacturer of the Implants

8. At all material times, Johnson & Johnson imported the Implants in Australia.

9. By reason of the matters pleaded at paragraphs 3(f), 4(f), 5(d) and 8 above, Johnson & Johnson is deemed to be the manufacturer of the Implants above by operation of section 74A(3) and (5) or alternatively section 74A(4) of the TPA and section 7 of Schedule 2 of the CCA.

(ii) Supply of the Implants to Group Members

10. Johnson & Johnson as importer and deemed manufacturer of the Implants supplied the Implants to Treating Hospitals and/or Treating Doctors for the purpose of re-supply to consumers, including to each of the Group Members.

11. Each of the Treating Hospitals and/or Treating Doctors acquired the Implants from Johnson & Johnson for re-supply to other persons, including to each of the Group Members.

12. Each of the Group Members was supplied with an Implant by their Treating Hospital and in addition, or alternatively Treating Doctor on the advice of their Treating Doctor.

PARTICULARS

(A) Particulars in respect of Mrs Gill's case are pleaded at paragraphs 23D to 23P below.

(B) Particulars in respect of Mrs Dawson's case are pleaded at paragraphs 23Q to 23Y below.

(C) Particulars in respect of Mrs Sanders' case are pleaded at paragraphs 49 to 58 below.

(D) Particulars of each of the other Group Members' Treating Hospitals and Treating Doctors may be provided after the trial of common issues.

13. The price of the Implants acquired by each of the Group Members did not, respectively, exceed $40,000.

(iii) Trade and Commerce in Australia

14. The marketing, promotion and supply of the Implants by Ethicon Sárl and in addition, or alternatively, by Ethicon, Inc. to Johnson & Johnson, and in addition, or alternatively, to the Treating Hospitals and/or Treating Doctors, was in trade and commerce between Australia and places outside of Australia, namely Switzerland and in addition, or alternatively, the United States of America.

15. Further or in the alternative:

(a) the Treating Hospitals received representations made by Johnson & Johnson and in addition, or alternatively, by Ethicon Sárl and in addition, or alternatively, by Ethicon, Inc. in the distribution and supply of the Implants in Australia; and in addition, or alternatively

(b) the Treating Doctors received representations made by Johnson & Johnson and in addition, or alternatively, by Ethicon Sàrl and in addition, or alternatively Ethicon, Inc. in marketing and promoting the Implants in Australia.

16. By virtue of paragraph 14 above and, or alternatively, paragraph 15 above, the marketing, promotion and supply of the Implants by Ethicon Sárl and in addition, or alternatively, by Ethicon, Inc. to Johnson & Johnson, and in addition, or alternatively to the Treating Hospitals and/or Treating Doctors, was in trade and commerce in Australia.

17. Further or in the alternative the marketing, promotion and supply of the Implants by Johnson & Johnson, on behalf of Ethicon Sárl and in addition, or alternatively, Ethicon, Inc. to the Treating Hospitals and/or Treating Doctors, was in trade and commerce in Australia.

Part D – The Mesh Implants

(i) Purpose of the Mesh Implants

18. The Mesh Implants were designed and manufactured to:

(a) be used during pelvic surgery for the treatment of POP;

(b) restore pelvic anatomy and pelvic function; and

(c) thereby alleviate the symptoms pleaded in paragraph 6(c) above,

(**the Mesh Purpose**).

19. The Mesh Purpose was known to Ethicon Sárl, Ethicon, Inc. and Johnson & Johnson.

PARTICULARS

Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson supplied, distributed, marketed and promoted the Mesh Implants as being medical devices that were designed to be used for the Mesh Purpose:

Generally

(A) In an Australian Register of Therapeutic Goods (**ARTG**) Public Summary entry number 94490 the intended purpose was stated as*:*

"For tissue reinforcement and long lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse".

(B) In an ARTG Public Summary entry number 117686 the intended purpose was stated as:

"Total, anterior and posterior pelvic floor repair system for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse".

The Prolift Implants

(C) In a Gynecare Prolift Pelvic Organ Prolapse brochure, Johnson & Johnson, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. stated:

PELVIC RECONSTRUCTIVE SURGERY

Pelvic reconstructive surgery can be performed through the vagina or abdominally… During the procedure, the surgeon will reposition the prolapsed organ(s) and secure them to surrounding tissues and ligaments…

GYNECARE PROLIFT Pelvic Floor Repair System,,, simplifies the repairing process by using a synthetic mesh to keep prolapsed organs in place, rather than grafts and attachments. Once in place, the synthetic mesh works with your body to create pelvic support.

The procedure is designed to restore normal anatomy, which means patients can resume sexual intimacy, normal physical activity and may avoid the need for hysterectomy as long as the uterus is not diseased.

(D) In a Gynecare Prolift brochure titled *"Get the facts, Be Informed, Make YOUR Best Decision"* Johnson & Johnson, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. stated:

A new and revolutionary minimally invasive surgical procedure using GYNECARE PROLIFT employs a specially designed supportive soft mesh placed in the pelvis to restore pelvic support. GYNECARE PROLIFT mesh is designed for placement utilizing a minimally invasive technique performed through very small incisions inside the vagina.

It can be completed in less than half the time of traditional surgery. Patients may experience less pain, quicker recovery and go home the next day.

It allows for restoration of sexual function by restoring normal vaginal anatomy.

…

…Despite which of the [prolapse] defects you are experiencing, repair with GYNECARE PROLIFT will correct these defects and restore normal support.

The Prosima Implants

(E) In the Instructions for Use of the Prosima Pelvic Floor Repair System, Johnson & Johnson, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. stated:

The GYNECARE PROSIMA Pelvic Floor Repair Systems, through the placement of GYNECARE GYNEMESH PS Nonabsorbable PROLENE Soft Mesh Implants are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor, either as mechanical support or bridging material for the fascial defect.

The Prolift + M Implants

(F) In the Instructions for Use of the Prolift + M Pelvic Floor Repair System, Johnson & Johnson, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. stated:

The GYNECARE PROLIFT + M Total, Anterior and Posterior Pelvic Floor Repair Systems, through the placement of GYNECARE GYNEMESH M Partially Absorbable Mesh, are indicated for tissue reinforcement and long lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is indicated, either as mechanical support or bridging material for the fascial defect.

The Gynecare Gynemesh PS Implants

(G) In the Instructions for Use for the Gynecare Gynemesh PS Nonabsorbable PS Soft Mesh, Johnson & Johnson, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. stated at pages 2 and 5:

GYNECARE GYNEMESH PS is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Further Particulars

(H) Further particulars as to the Respondents' knowledge of the Mesh Purpose may be provided following completion of the review of the Respondents' discovery.

20. Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson marketed, promoted, distributed and supplied the Mesh Implants as being medical devices that were reasonably fit for the Mesh Purpose.

PARTICULARS

(A) In the Instructions for Use for the Prolift Implant, Johnson & Johnson, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. stated at pages 2 and 5:

'GYNECARE GYNEMESH PS is mesh constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE Polypropylene Suture … This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. … Animal studies show that implantation of GYNEMESH PS mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.'

(B) In the Instructions for Use for the Prolift + M Implant, Johnson & Johnson, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. stated at page 4:

'Animal studies show that implantation of GYNECARE GYNEMESH M Mesh elicits a minimum to mild inflammatory reaction which is followed by collagen tissue ingrowth through the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. In GYNECARE GYNEMESH M Mesh implanted subcutaneously in rats … [t]he polypropylene portion is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.'

(C) In the Instructions for Use for the Prosima Implant, Johnson & Johnson, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. stated at pages 10 and 12:

'GYNECARE GYNEMESH PS is mesh constructed of knitted filaments of extruded polypropylene … This material, when used as a suture, has been reported to be nonreactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. … Animal studies show that implantation of GYNECARE GYNEMESH PS elicits a minimal to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft

and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.'

(D) In the Instructions for Use for the Gynecare Gynemesh PS Implant, Johnson & Johnson, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. stated at page 2:

'This material, when used as a suture, has been reported to be non-reactive … Animal studies show that implantation of PROLENE *mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.'*

(E) Publication dated 2006 and entitled 'The system that takes you there … GYNECARE PROLIFT Systems – Designed to enhance your surgical technique with an innovative, standardized system' by Johnson & Johnson, Ethicon, Inc. and in addition, or alternatively, Ethicon Sárl.

(F) In an undated publication entitled 'A Solution: GYNECARE PROLIFT® Pelvic Floor Repair System', Johnson & Johnson, Ethicon, Inc. and in addition, or alternatively, Ethicon Sárl stated:

'Current peer-reviewed data shows that the GYNECARE PROLIFT® *kit is an effective pelvic floor repair device with high patient satisfaction.'*

(G) In an undated publication entitled 'Pelvic Organ Prolapse: Get the Facts, Be Informed, Make YOUR Best Decision', Johnson & Johnson, Ethicon, Inc. and in addition, or alternatively, Ethicon Sárl stated at pages 10 and 13:

*'**How is GYNECARE PROLIFT different from other surgical alternatives?***

…

It allows for the restoration of sexual function by restoring normal vaginal anatomy.

…

How does GYNECARE PROLIFT work?

…

Despite which of the defects you are experiencing, repair with GYNECARE PROLIFT *will correct these defects and restore normal support.*

…

What are the risks?

All surgical procedures present some risks. Although rare, complications associated with the procedure include injury to blood vessels of the pelvis, nerve damage, difficulty urinating, bladder and bowel injury. There is also a small risk of the mesh material becoming exposed into the vaginal canal.'

(H) In the Prolift Implant System Instructions for Use for the Implants, Johnson & Johnson, Ethicon, Inc. and in addition, or alternatively, Ethicon Sárl stated at page 2:

'The GYNECARE PROLIFT™ Total, Anterior, and Posterior Pelvic Floor Repair System are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.'

(I) In an undated publication entitled 'Pelvic Organ Prolapse', Johnson & Johnson, Ethicon, Inc. and in addition, or alternatively, Ethicon Sárl stated at page 13:

'GYNECARE PROLIFT® Pelvic Floor Repair System is different from other surgical alternatives
Traditional surgeries may be done either through the vagina or the abdomen. … GYNECARE PROLIFT® Pelvic Floor Repair System, however, simplifies the repairing process by using a synthetic mesh to keep prolapsed organs in place, rather than grafts and other attachments. Once in place, the synthetic mesh works with your body to create pelvic support. The procedure is designed to restore normal anatomy'.

21. The purpose for which the Mesh Implants were commonly acquired, and the purpose for which one or more of the Mesh Implants was acquired by each of the Mesh Sub-Group Members, was for the Mesh Purpose.

PARTICULARS

(A) Particulars in respect of Mrs Gill's case are pleaded at paragraphs 23D to 23P below.

(B) Particulars in respect of Mrs Dawson's case are pleaded at paragraphs 23Q to 23AE below.

(C) Particulars of each of the other Mesh Sub-Group Members' case may be provided after the trial of common issues.

22. The purpose for which the Mesh Implants were commonly supplied and acquired, and the purpose for which one or more of the Mesh Implants was acquired by each of the Mesh

Sub-Group Members, being the Mesh Purpose, was known to Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson.

PARTICULARS

(A) the Mesh Implants were designed and manufactured for the Mesh Purpose pleaded at paragraph 18 above;

(B) the Implants had been marketed, promoted and in addition, or alternatively, supplied by Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, by Johnson & Johnson in the way pleaded at paragraphs 19 and 20 above as being reasonably fit for the Mesh Purpose; and in addition, or alternatively,

(C) the matters pleaded in paragraph 19 above are repeated.

(ii) Mesh Risks and Mesh Complications

23. At all material times, by reason of:

(a) the material of which the Mesh Implants were constructed;

(b) the design of the Mesh Implants;

(c) the anatomical structures, tissues and location in which the Mesh Implants were implanted, passed through, attached to and in addition, or alternatively, with which the Mesh Implants were brought into proximity; and in addition, or alternatively,

(cc) the technique by which the Mesh Implants were designed to be implanted,

or in any event, the Mesh Implants had a risk of and in addition, or alternatively were susceptible to:

(d) causing a chronic inflammatory reaction, or an inflammatory reaction which is not minimal or transient in nature, of the tissues in which the Mesh Implants were implanted, attached and in addition, or alternatively, the surrounding tissues;

(e) erosion and in addition, or alternatively, extrusion and in addition or alternatively protrusion and in addition, or alternatively, exposure of the Mesh Implants through tissue in which the Mesh Implants were implanted, attached and in addition, or alternatively, surrounding tissues;

(f) requiring, by reason of the matters in sub-paragraph (e) above, surgery to remove the Mesh Implant or part of the Mesh Implant; and in addition, or alternatively,

(g) causing further complications including:

(i) chronic pain;

(ii) dyspareunia and in addition, or alternatively, apareunia;

(iii) difficulty voiding and in addition, or alternatively, defecating;

(iv) offensive discharge;

(v) recurrence of a POP;

(vi) de novo or recurrent urinary incontinence;

(vii) damage to surrounding organs, nerves, ligaments, tissue and in addition, or alternatively, blood vessels;

(viii) haemorrhage;

(ix) infection;

(x) leg weakness;

(xi) reoperation or revision surgery associated with complications, including those listed above; and in addition, or alternatively

(xii) psychiatric injury;

(collectively, the matters in (d) to (g) above are referred to as the **Mesh Complications**), and

(h) not fulfilling the Mesh Purpose.

PARTICULARS

(A) The material the Mesh Implants were made of includes polypropylene;

(B) The design of the Mesh Implants includes the pore size, filament structure and weave, tensile strength, elasticity, density and porosity of the material used in the Mesh Implants;

(C) The anatomical structures, tissues and location in which the Mesh Implants were implanted, attached to, passed through and in addition, or alternatively, with which the Mesh Implants were brought into proximity, were the walls and apex of the vagina. The vagina is a clean contaminated environment that cannot be completely sterilised;

(D) All Mesh Implants were implanted by being passed through the vagina, apart from the Gynecare Gynemesh PS Implant when used in sacral colpopexy or sacral hysteropexy (in which cases it was inserted abdominally or laparoscopically), but it and all Mesh

Implants were implanted, attached and in addition, or alternatively, brought into proximity with the vagina;

(E) The composition of the polypropylene material comprising the Mesh Implants means that, when Mesh Implants were inserted through, implanted within, attached to or brought into proximity with the clean contaminated vagina bacteria was more likely to be attracted to the surface of the Mesh Implants than repelled which made the Mesh Implants susceptible to the risk of bacterial adhesion and an inflammatory response occurring;

(F) The design of the Implants including the pore size, filament structure and weave, tensile strength, elasticity, density and porosity of the Implants had the effect of:

(i) promoting bacterial colonisation;

(ii) aggravating any inflammatory response;

(iii) increasing the risk of degradation of the Mesh Implants;

(iv) rendering the Mesh Implants incompatible with and in addition, or alternatively, unsuitable for the anatomical location or tissues in which the Implants were implanted, attached or located; and

(v) increasing the risk of the Mesh Complications;

(G) The material the Mesh Implants were made of and the design of the Mesh Implants:

(i) made the inflammatory response susceptible to develop into a chronic inflammatory reaction and in addition, or alternatively, total infection of the Mesh Implants; and in addition, or alternatively

(ii) rendered the Mesh Implants susceptible to one or more of the following:

(A) scar plate formation;

(B) contraction;

(C) shrinking;

(D) fraying;

(E) roping;

(F) curling;

(G) bunching;

(H) banding;

(I) deforming;

(J) collapsing;

(K) elongating;

(L) oxidative degradation;

(M) not being inert; and

(N) bridging fibrosis;

(H) The effects of any inflammatory response increased the risk of and in addition, or alternatively, susceptibility to degradation of the Mesh Implants; and

(I) Degradation of the Mesh Implants meant they were susceptible to the release of chemical compounds from the polypropylene, which enhanced any inflammatory response and promoted the occurrence of the Mesh Complications. Degradation also changed the physical properties of the Mesh Implants (including flaking and surface cracking).

23A. Further, at all material times:

(a) the Mesh Implants were designed to be permanent implants and were difficult or impossible safely to remove from patients suffering from one or more of the Mesh Complications;

(b) treatment of the Mesh Complications was difficult or impossible, or alternatively carried with it the risk of new or aggravated complications; and in addition, or alternatively

(c) treatment of the Mesh Complications may require one or more surgical procedures to attempt to remove the Mesh Implants or such parts thereof that may be reasonably capable of being removed.

(the **Mesh Removal Complications**).

23B. At all material times:

(a) reconstructive surgery for the treatment for POP could be undertaken without the use of Mesh Implants (**Native Tissue Repair**);

(b) Native Tissue Repair was as effective in treating POP, or in the alternative was not materially less effective in treating POP, as reconstructive surgery for the treatment for POP undertaken using Mesh Implants;

(c) in addition to sub-paragraph (b) above, Native Tissue Repair was as effective in achieving the Mesh Purpose, or in the alternative was not materially less effective in achieving the Mesh Purpose, as reconstructive surgery for the treatment for POP undertaken using Mesh Implants;

(d) Native Tissue Repair did not have the risks of, and in addition, or alternatively, was not susceptible to causing, the Mesh Complications and the Mesh Removal Complications;

(e) in addition to sub-paragraph (d) above, Native Tissue Repair:

(i) did not have the risk of, and in addition, or alternatively, was not susceptible to causing, the Mesh Complications pleaded in paragraph 23(d), (e) and (f) above; and

(ii) did not have as great a risk of, and in addition, or alternatively, was not materially more susceptible to causing, the Mesh Complications pleaded in paragraph 23(g) above than reconstructive surgery for the treatment for POP undertaken using Mesh Implants;

(f) Native Tissue Repair was an accepted method of reconstructive surgery for the treatment for POP;

(g) in addition, or alternatively Native Tissue Repair was safer or, in the alternative, was not materially less safe in treating POP, as reconstructive surgery for the treatment of POP undertaken using Mesh Implants; and

(h) in addition, or alternatively Native Tissue Repair was as safe in achieving the Mesh Purpose, or in the alternative was not materially less safe in achieving the Mesh Purpose, as reconstructive surgery for the treatment of POP undertaken using Mesh Implants.

23BA. Prior to the release in Australia of the Mesh Implants and/or the supply, distribution, marketing or promotion in Australia of the Mesh Implants, none of the Respondents undertook any, or in the alternative any adequate, clinical or other evaluation of the risks, including long-term risks, and effectiveness, including the long-term effectiveness, associated with the use of the Mesh Implants, including:

(a) the risk of occurrence of the Mesh Complications;

(b) the risk of occurrence of the Mesh Removal Complications;

(c) whether reconstructive surgery for the treatment of POP undertaken using Mesh Implants was more effective, or in the alternative was not materially less effective than Native Tissue Repair in treating POP;

(d) whether reconstructive surgery for the treatment of POP undertaken using Mesh Implants was safer, or in the alternative was not materially less safe than Native Tissue Repair in treating POP;

(e) whether the technique by which the Mesh Implants were designed to be inserted was reliable and reproducible;

(**the Mesh Evaluation Matters**).

23C. At all material times, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson failed to give any, or any sufficient, information or warning to the Mesh Sub-Group Members, their Treating Hospitals and/or Treating Doctors:

(a) of:

(i) the risk or susceptibility of the Mesh Implants to cause one or more of the Mesh Complications;

(ii) the risk or susceptibility of the Mesh Implants to cause one or more of the Mesh Removal Complications;

(b) of the matters pleaded in paragraph 23B above; and in addition, or alternatively

(c) of the Mesh Evaluation Matters;

(d) that the chronic inflammatory response to the Mesh Implants may be affected by conditions which affect the immune response and healing, including autoimmune and connective tissue disorders.

(**the Mesh Warning Matters**).

(iii) Mrs Gill's Mesh Implant

23D. Prior to 12 January 2007, Mrs Gill:

(a) was suffering from a symptomatic, grade 3 utero-vaginal prolapse;

(b) had a cystourethrocele; and

(c) had a rectocele.

23E. Prior to 12 January 2007, Dr Chapple, Mrs Gill's Treating Doctor, advised Mrs Gill of the option to treat Mrs Gill's POP by use of a Mesh Implant in vaginal reconstructive surgery.

23F. By reason of the matters pleaded in paragraph 23C above, at no time before 12 January 2007 was Mrs Gill informed of the Mesh Warning Matters in respect of the Mesh Implant.

23G. On or about 12 January 2007, on the advice of Dr Chapple, Mrs Gill had pelvic reconstructive surgery, during the course of which she was implanted with a Prolift Implant.

PARTICULARS

Mrs Gill was implanted with a Prolift Total Implant by Dr Chapple at Joondalup Private Hospital in Perth, Western Australia. The Prolift Implant was supplied to Mrs Gill by Dr Chapple and in addition, or alternatively, by Joondalup Private Hospital.

23H. The purpose for which Mrs Gill received the Prolift Implant was for the Mesh Purpose, namely:

(a) to be used during pelvic reconstructive surgery to treat her cystourethrocele and rectocele;

(b) to restore her pelvic anatomy and pelvic function; and

(c) thereby to alleviate the symptoms associated with the conditions pleaded in paragraph 23D above.

23I. Following the implantation of the Prolift Implant and prior to 10 September 2007, Mrs Gill experienced:

(a) 2cm mesh erosion of the Prolift Implant in the anterior vaginal wall;

(b) chronic pain;

(c) dyspareunia; and

(d) vaginal bleeding.

23J. On or about 10 September 2007, Mrs Gill underwent a cystoscopy and revision surgery in order to excise eroded mesh from the anterior vaginal wall (**the Gill First Revision Surgery**).

PARTICULARS

The Gill First Revision Surgery was performed by Dr Yin at the Hollywood Private Hospital in Perth, Western Australia.

23K. Following the Gill First Revision Surgery and prior to 20 June 2008, Mrs Gill experienced:

(a) further mesh erosion of the Prolift Implant at the anterior right arm and the posterior left arm;

(b) chronic pain;

(c) tenderness; and

(d) dyspareunia.

23L. On or about 20 June 2008, Mrs Gill had a further revision surgery in order to excise the eroded mesh of the anterior right arm and posterior left arm of the Prolift Implant (**the Gill Second Revision Surgery**).

PARTICULARS

The Gill Second Revision Surgery was performed by Dr Robyn Leake assisted by Dr Yin at the Hollywood Private Hospital in Perth, Western Australia.

23M. Following the Second Revision surgery and prior to 8 August 2013, Mrs Gill experienced:

(a) 2cm further mesh exposure in the anterior vaginal wall distal to the cervix;

(b) chronic pain;

(c) dyspareunia;

(d) urinary leakage; and

(e) vaginal bleeding.

23N. On or about 8 August 2013, Mrs Gill underwent a further revision surgery in order to excise the further exposed mesh (**the Gill Third Revision Surgery**).

PARTICULARS

The Gill Third Revision Surgery was performed by Dr Caroline Dowling at St Vincent's Private Hospital in East Melbourne, Victoria.

23O. Following the Gill Third Revision Surgery, Mrs Gill has suffered:

(a) constant pain increasing especially after intercourse and any heavy activity such as travelling;

(b) shooting pain originating in the pelvic region;

(c) visceral pain with bowel action;

(d) a persistent residual suture distal to the cervix on the anterior vaginal wall;

(e) a recurrent POP;

(f) dyspareunia;

(g) urinary incontinence;

(h) vaginal bleeding;

(i) generalised anxiety disorder;

(j) adjustment disorder with depressed mood; and

(k) chronic pain disorder.

23P. By reason of the matters pleaded at paragraphs 23D to 23O above, Mrs Gill has suffered loss and damage.

PARTICULARS

(A) Personal injury including one or more of the Mesh Complications and Mesh Removal Complications including, in respect of the Gill First, Second and Third Revision Surgeries, the complications pleaded at paragraphs 23L, 23K, 23M and 23O above and psychiatric injury including generalised anxiety disorder, adjustment disorder with depressed mood and/or chronic pain disorder.

(B) Health care expenses.

(C) Additional out of pocket expenses.

(D) Economic loss.

(E) The need for gratuitous and in addition, or alternatively, commercial care.

(F) Non-economic loss.

(G) Additional particulars may be provided following the service of evidence.

(iv) Mrs Dawson's Mesh Implant

23Q. Prior to 8 May 2009, Mrs Dawson:

(a) had a vaginal prolapse;

(b) had a cystocele descending to 1cm above the introitus; and

(c) had a rectocele descending to 1cm above the introitus.

23R. Prior to 8 May 2009, Mrs Dawson's Treating Doctor advised Mrs Dawson of the option to treat Mrs Dawson's POP by use of a Mesh Implant in vaginal reconstructive surgery.

23S. By reason of the matters pleaded in paragraph 23C above, at no time before 8 May 2009 was Mrs Dawson informed of the Mesh Warning Matters in respect of the Mesh Implant.

23T. On or about 8 May 2009, on the advice of her Treating Doctors, Mrs Dawson had pelvic reconstructive surgery, during the course of which she was implanted with a Gynecare Gynemesh PS Implant.

PARTICULARS

Mrs Dawson was implanted with a Gynecare Gynemesh PS Implant by Dr Jeanette Lim at The St John of God Hospital, Melbourne. The Gynecare Gynemesh PS Implant was supplied to Mrs Dawson by Dr Lim and in addition, or alternatively, by The St John of God Hospital.

23U. The purpose for which Mrs Dawson received the Gynecare Gynemesh PS Implant was for the Mesh Purpose, namely:

(a) to be used during pelvic reconstructive surgery to treat her cystocele and rectocele;

(b) to restore her pelvic anatomy and pelvic function; and

(c) thereby to alleviate the symptoms associated with the conditions pleaded in paragraph 23Q above.

23V. Following the implantation of the Gynecare Gynemesh PS Implant and prior to 14 October 2009, Mrs Dawson experienced:

(a) a mesh erosion in the anterior vaginal wall;

(b) dragging prolapse sensation;

(c) right para coccygeal and buttock pain;

(d) de novo stress urinary incontinence;

(e) dyspareunia;

(f) chronic pain;

(g) incomplete defecation;

(h) generalised vaginal tenderness; and

(i) major depressive disorder.

23W. On or about 14 October 2009, Mrs Dawson underwent revision surgery in order to excise the mesh erosion in the anterior vaginal wall (**the Dawson Revision Surgery**).

PARTICULARS

The Dawson Revision Surgery was performed by Dr Jeanette Lim at the St John of God Hospital.

23X. Following the Dawson Revision Surgery, Mrs Dawson has suffered:

(a) right para coccygeal and buttock pain;

(b) stress urinary incontinence;

(c) dyspareunia;

(d) chronic pain;

(e) incomplete defecation;

(f) generalised vaginal tenderness; and

(g) in addition or in the alternative to paragraph 23V(i), major depressive disorder.

23Y. On or about 31 January 2014, Ms Dawson had a further revision surgery to excise the left arm of her Gynecare Gynemesh PS Implant (the **Dawson Second Revision Surgery**).

PARTICULARS

The Dawson Second Revision Surgery was performed by Dr Peter Dwyer at the Mercy Hospital for Women.

23Z. Following the Dawson Second Revision Surgery and before 15 May 2015, Ms Dawson experienced:

(a) dyspareunia;

(b) gluteal pain;

(c) chronic pain;

(d) mesh extrusion;

(e) tissue granulation; and

(f) in addition or in the alternative to paragraphs 23V(i) and/or 23X(g), major depressive disorder.

23AA. On or about 15 May 2015 Ms Dawson underwent a further revision surgery (the **Dawson Third Revision Surgery**) in order to excise mesh from the anterior vaginal wall, vault and vaginal wall.

PARTICULARS

The Dawson Third Revision Surgery was performed by Dr Lore Schierlitz at the Mercy Hospital for Women.

23AB. Following the Dawson Third Revision Surgery and before 30 October 2015, Ms Dawson experienced:

(a) mesh exposure;

(b) dyspareunia; and

(c) in addition or in the alternative to paragraphs 23V(i), 23X(g) and/or 23Z(f), major depressive disorder.

23AC. On or about 30 October 2015 Ms Dawson underwent a further revision surgery (the **Dawson Fourth Revision Surgery**) in order to excise mesh from the posterior and anterior vaginal walls.

PARTICULARS

The Dawson Fourth Revision Surgery was performed by Dr Lore Schierlitz at the Mercy Hospital for Women.

23AD. Following the Dawson Fourth Revision Surgery, Ms Dawson experienced:

(a) chronic pain;

(b) fatigue;

(c) dyspareunia; and

(d) in addition or in the alternative to paragraphs 23V(i), 23X(g), 23Z(f) and/or 23AB(c), major depressive disorder.

23AE. By reason of the matters pleaded at paragraphs 23Q to 23AD above, Mrs Dawson has suffered loss and damage.

PARTICULARS

(A) Personal injury including one or more of the Mesh Complications and Mesh Removal Complications including, in respect of the Dawson Revision Surgery, the complications pleaded at paragraphs 23V and 23AD above.

(B) Health care expenses.

(C) Additional out of pocket expenses.

(D) Economic loss.

(E) The need for gratuitous and in addition, or alternatively, commercial care.

(F) Non-economic loss.

(G) Additional particulars may be provided following the service of evidence.

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

24. The Mesh Implants were goods within the meaning of sections 4 and 74A(2)(a) of the TPA, and sections 2 and 271 of Schedule 2 of the CCA.

25. The Mesh Implants were supplied to each of the Mesh Sub-Group Members as consumers within the meaning of section 4B of the TPA and section 3 of Schedule 2 of the CCA.

26. By reason of:

(a) the fact that:

(i) the Mesh Implants were designed and manufactured by the Respondents for the Mesh Purpose pleaded at paragraph 18 above;

(ii) the Mesh Purpose was known to the Respondents, as pleaded at paragraph 19 above;

(iii) the Respondents marketed, promoted and supplied the Mesh Implants as reasonably fit for the Mesh Purpose, as pleaded at paragraph 20 above;

(iv) the purposes for which the Mesh Implants were commonly supplied and acquired and the purpose for which one or more of the Mesh Implants were acquired by each of the Mesh Sub-Group Members was for the Mesh Purpose, as pleaded at paragraph 21 above; and

(v) the purposes for which the Mesh Implants were commonly supplied and acquired and the purpose for which one or more of the Mesh Implants were acquired by each of the Mesh Sub-Group Members, being the Mesh Purpose, was known to the Respondents, as pleaded at paragraph 22 above;

(b) the fact that prior to the release in Australia of the Mesh Implants and the supplying, distributing, marketing or promoting in Australia of the Mesh Implants, the Respondents did not undertake any, or in the alternative any adequate, clinical or other evaluation of the Mesh Evaluation Matters, as pleaded at paragraph 23BA above;

(c) the matters pleaded in paragraphs 23, 23A, 23B, and in addition, or alternatively, 23C above; and in addition, or alternatively,

(d) the fact that none of the packaging of the Mesh Implants, their Instructions For Use, nor any other document or other source of information disseminated by the Respondents, or any of them, to Mesh Sub-Group Members, Treating Hospitals or Treating Doctors, gave any (or any sufficient) warning, advice or information as to some or all of the Mesh Warning Matters,

the safety of the Mesh Implants was not such as persons generally were entitled to expect and the Mesh Implants had a defect for the purposes of sections 75AC(1) and 75AD(1) of the TPA and, or alternatively, a safety defect for the purposes of sections 9 and 138 of Schedule 2 of the CCA.27. By reason of the matters pleaded at paragraph 26(a) to (d) above, the Mesh Implants were not reasonably fit for the Mesh Purpose, within the meaning of section 74B of the TPA and section 55 of Schedule 2 of the CCA.

28. By reason of the matters pleaded at paragraph 26(a) to (d) above, the Mesh Implants acquired by each of the Mesh Sub-Group Members were not of merchantable quality within the meaning of section 74D(3) of the TPA, or acceptable quality within the meaning of section 54 of Schedule 2 of the CCA.

29. In the premises, each of the Mesh Sub-Group Members has suffered loss and damage, by reason of the fact that:

(a) the safety of any of the Mesh Implants was not such as persons generally were entitled to expect as pleaded at paragraph 26 above ;

(b) the Mesh Implants were not fit for the Mesh Purpose as pleaded at paragraph 27 above ; and in addition, or in the alternative

(c) the Mesh Implants were not of merchantable quality as pleaded in paragraph 28 above .

PARTICULARS

(A) In respect of Mrs Gill, the particulars to paragraph 23P above are repeated.

(B) In respect of Mrs Dawson, the particulars to paragraph 23Y above are repeated.

(C) Particulars of each of the other Mesh Sub-Group Members' loss and damage may be provided after the trial of common issues but is expected to include:

(i) personal injury including one or more of the Mesh Complications and Mesh Removal Complications ;

(ii) health care expenses;

(iii) other out of pocket expenses;

(iv) economic loss;

(v) the need for gratuitous and in addition, or alternatively, commercial care; and

(vi) non-economic loss.

30. In the premises, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson are liable to compensate each of the Mesh Sub-Group Members for their loss and damage pursuant to:

(a) section 75AD of the TPA, or section 138 of Schedule 2 of the CCA, as the case may be;

(b) sections 74B(1) and 82(1) of the TPA, or sections 55, and 236 or in addition or alternatively 237 or in addition or alternatively 259(4) of Schedule 2 of the CCA, as the case may be; and in addition, or alternatively

(c) sections 74D(1) and 82(1) of the TPA, or sections 54, and 259(4), 271 and 272 of Schedule 2 of the CCA, as the case may be.

(vi) Claims in Negligence

31. Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. owed each of the Mesh Sub-Group Members a duty to exercise reasonable care and skill in the design, manufacture, marketing and supply of the Mesh Implants.

31A. Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc.:

(a) designed and manufactured the Mesh Implants for the Mesh Purpose pleaded at paragraph 18 above;

(b) knew or ought to have known of the Mesh Purpose, as pleaded at paragraph 19 above;

(c) marketed, promoted and supplied the Mesh Implants as reasonably fit for the Mesh Purpose, as pleaded at paragraph 20 above;

(d) knew or ought to have known that the purposes for which the Mesh Implants were commonly supplied and acquired and the purpose for which one or more of the Mesh Implants were acquired by each of the Mesh Sub-Group Members, was the Mesh Purpose, as pleaded at paragraph 22 above; and

(e) did not undertake any, or in the alternative, any adequate clinical or other evaluation of the Mesh Evaluation Matters prior to the release in Australia of the

Mesh Implants and the supplying, distributing, marketing or promoting in Australia of the Mesh Implants, as pleaded at paragraph 23BA above.

32. In the circumstances pleaded at paragraph 31A(a) to (e) above, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. designed, manufactured, marketed and in addition, or alternatively, supplied the Mesh Implants containing:

(a) the characteristics pleaded at paragraph 23 above; and in addition, or alternatively

(b) a risk of, and in addition, or alternatively, a susceptibility to causing the Mesh Complications and in addition, or alternatively, the Mesh Removal Complications.

32A. In addition to paragraph 32 above, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. continued to design, manufacture, market and in addition, or alternatively, supply the Mesh Implants notwithstanding the matters pleaded in paragraph 32 above.

32B. In addition, or alternatively, to paragraph 32A above, in addition to paragraph 32 above Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. failed to conduct any, or any adequate, evaluation of the safety and effectiveness of the Mesh Implants in treating POP after releasing them in Australia.

32C. Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc.:

(a) failed to inform any of the Mesh Sub-Group Members of:

(i) the matters pleaded in paragraphs 23BA and 32(a) and (b) above; and in addition, or alternatively

(ii) the Mesh Warning Matters; and

(b) further or in the alternative, failed to inform:

(i) Johnson & Johnson;

(ii) Treating Hospitals; and in addition, or alternatively

(iii) Treating Doctors,

of the matters pleaded in sub-paragraph 32C(a) above.

33. By reason of the matters pleaded at paragraphs 31A to 32C above, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. breached the duty of care to each of the Mesh Sub-Group Members pleaded at paragraph 31 above.

34. By reason of the matters pleaded at paragraphs 31 to 33 above, each of the Mesh Sub-Group Members has suffered loss or damage.

PARTICULARS

The particulars to paragraph 29 above are repeated.

35. In addition, or in the alternative, to the matters pleaded at paragraphs 31 to 34 above, Johnson & Johnson owed each of the Mesh Sub-Group Members a duty to exercise reasonable care and skill in the supply and marketing of the Mesh Implants.

35A. Johnson & Johnson:

(a) knew or ought to have known of the Mesh Purpose, as pleaded at paragraph 19 above;

(b) marketed, promoted and supplied the Mesh Implants as reasonably fit for the Mesh Purpose, as pleaded at paragraph 20 above;

(c) knew or ought to have known that the purposes for which the Mesh Implants were commonly supplied and acquired and the purpose for which one or more of the Mesh Implants were acquired by each of the Mesh Sub-Group Members, was the Mesh Purpose, as pleaded at paragraph 22 above; and

(d) did not undertake any, or in the alternative, any adequate clinical or other evaluation of the Mesh Evaluation Matters prior to the release in Australia of the Mesh Implants and the supplying, distributing, marketing or promoting in Australia of the Mesh Implants, as pleaded at paragraph 23BA above.

36. In the circumstances pleaded at paragraph 35A(a) to (d) above, Johnson & Johnson marketed and in addition, or alternatively, supplied the Mesh Implants containing:

(a) the characteristics pleaded at paragraph 23 above; and in addition, or alternatively

(b) a risk of, and in addition, or alternatively, a susceptibility to causing the Mesh Complications and in addition, or alternatively, the Mesh Removal Complications.

36A. Johnson & Johnson continued to market and in addition, or alternatively, supply the Mesh Implants notwithstanding the matters pleaded in paragraph 36 above.

36B. In addition, or alternatively, to paragraph 36A above, Johnson & Johnson failed to conduct any, or any adequate, evaluation of the safety and effectiveness of the Mesh Implants in treating POP after releasing them in Australia.

36C. Johnson & Johnson:

(a) failed to inform any of the Mesh Sub-Group Members of:

(i) the matters pleaded in paragraphs 23BA and 36(a) and (b) above; and in addition, or alternatively

(ii) the Mesh Warning Matters; and

(b) further or in the alternative, failed to inform:

(i) Treating Hospitals; and in addition, or alternatively

(ii) Treating Doctors,

of the matters pleaded in sub-paragraph 36C(a) above.

37. By reason of the matters pleaded at paragraphs 35A to 36C above, Johnson & Johnson breached the duty of care to each of the Mesh Sub-Group Members pleaded at paragraph 35 above.

38. By reason of the matters pleaded at paragraphs 35 to 37 above, each of the Mesh Sub-Group Members has suffered loss or damage.

PARTICULARS

The particulars to paragraph 29 above are repeated.

39. In the premises, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson are liable for the loss or damage suffered by each of the Mesh Sub-Group Members.

(vii) Misleading Conduct Claims under the TPA and the Australian Consumer Law

39A. Further and in the alternative, the matters pleaded in paragraphs 5, 15, 16, 17, 18, 19, 20, 23, 23A, 23B, 23BA and 23C, 31A, 32, 32A, 35A, 36 and 36C are repeated.

39B. By reason of the matters pleaded at paragraph 39A, each of the Respondents engaged in conduct that was misleading or deceptive or likely to mislead or deceive in contravention of section 52 of the TPA and section 18 of Schedule 2 of the CCA.

39C. By reason of the matters pleaded at paragraphs 39A and 39B, each of the Mesh Sub-Group Members has suffered loss and damage.

39D. In the premises, each of the Respondents is liable for the loss or damage suffered by each of the Mesh Sub-Group Members, pursuant to section 82(1) of the TPA or sections 236 or in addition or alternatively 237 of Schedule 2 of the CCA, as the case may be.

Part E – The Tape Implants

(i) Tape Purpose

40. The Tape Implants were designed and manufactured to:

    (a) be implanted in women for the safe and effective surgical treatment of pure or predominant SUI;

    (b) provide urethral support safely and effectively in patients; and

    (c) alleviate involuntary urine leakage from SUI

    (the **Tape Purpose**).

41. The Tape Purpose was known to Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson.

Particulars

In distributing, supplying, marketing and, or alternatively, promoting the Tape Implants, Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson stated:

Generally

(A) An undated online publication entitled 'A solution: GYNECARE TVT Tension-free Support for Incontinence' states:

"With over 1.5 million women treated worldwide – more than any other incontinence treatment of its type – GYNECARE TVT is clinically proven, safe and effective.

GYNECARE TVT™ is designed to stop urine leakage the way your body was designed to – by supporting your urethra. Normally, the urethra is supported by the pelvic floor muscles to maintain a tight seal and prevent involuntary urine leakage. In women with SUI, weakened pelvic floor muscles and connective tissue can't support the urethra in its normal position, which is why urine leakage occurs. To correct this, your doctor will insert a ribbon-like strip of mesh, under the urethra to provide support whenever you stress this area, such as during a cough or sneeze. This helps the urethra to remain closed when appropriate, preventing involuntary urine leakage."

The TVT Implant

(B) The Gynecare TVT System Instructions for Use stated:

The GYNECARE TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI) for female urinary incontinence resulting from urethral hypermobility and/or sphincter deficiency.

The TVT Abbrevo Implant

(C) The Gynecare TVT ABBREVO Continence System Instructions for Use stated:

The GYNECARE TVT ABBREVO Continence System is intended for use in women as a suburethral sling for the treatment of SUI resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The TVT Obturator Implant

(D) The Gynecare TVT Obturator System Instructions for Use stated:

The Gynecare TVT Obturator device is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The TVT Secur Implant

(E) The Gynecare TVT Secure System Instructions for Use stated:

The GYNECARE TVT SECUR System is intended for use in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Further particulars

(F) Further particulars may be provided following completion of the review of the Respondents' discovery.

42. Ethicon Sàrl, Ethicon, Inc. and/or Johnson & Johnson marketed, promoted and supplied the Tape Implants as being medical devices that were reasonably fit for the Tape Purpose.

Particulars

(A) In the Instructions for Use for the TVT Implant, Ethicon Sàrl and/or Ethicon, Inc. stated at pages 2 and 5:

"PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene … This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process that interlinks each fiber junction and which provides for elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body. … The GYNECARE TVT device is intended to be used as a pubourethral sling for treatment of Stress Urinary Incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. … Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue, which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.'

(B) In the Instructions for Use for the TVT Secur Implant, Ethicon Sàrl and/or Ethicon, Inc. stated at page 11:

'Animal studies show that implantation of PROLENE mesh and the absorbable fleece sandwich material made from VICRYL and PDS yarn elicit a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue, that can grow through the interstices of the mesh system as the fleece portion is being absorbed, thus incorporating the mesh into adjacent tissue. The PROLENE material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. … The GYNECARE TVT SECUR System is intended for use in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.'

(C) In the Instructions for Use for the TVT Abbrevo Implant, Ethicon Sàrl and/or Ethicon, Inc. stated at pages 7 and 8:

'The GYNECARE TVT ABBREVO Implant Assembly is a … device which consists of … PROLENE Polypropylene Mesh. … PROLENE Mesh is constructed of knitted monofilaments of extruded polypropylene, identical in composition to that used in PROLENE Polypropylene non-absorbable Surgical Sutures. This material, when used as a suture, has been reported to be non-reactive and to retain its strength

indefinitely in clinical use. … Animal studies show that implantation of PROLENE *Mesh elicits a minimal inflammatory reaction in tissues and stimulates the deposition of a thin fibrous layer of tissue that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.'*

(D) In the Instructions for Use for the TVT Obturator Implant, Ethicon Sàrl and/or Ethicon, Inc. stated at pages 1 and 6:

'The GYNECARE TVT OBTURATOR *device is a …* PROLENE *Polypropylene Mesh …* PROLENE *Mesh is constructed of knitted monofilaments of extruded polypropylene strands, identical in composition to that used in* PROLENE *polypropylene non-absorbable surgical sutures. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use.* PROLENE *mesh is knitted by a process that interlinks each fibre junction and that providing elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body … Animal studies show that implantation of* PROLENE *Mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.'*

(E) In an undated publication entitled 'Gynecare TVT', Ethicon, Inc. and/or Ethicon Sárl stated at page 2:

*'Long-term clinical efficacy and safety … Proven safety demonstrated across multiple clinical studies *Low incidence of reported serious complications; * Low retention rate … *Low risk of urethral erosion'.*

43. The purpose for which the Tape Implants were commonly acquired, and the purpose for which one or more of the Tape Implants was acquired by each of the Tape Sub-Group Members, was for the Tape Purpose.

44. The purpose for which the Tape Implants were commonly supplied and acquired, and the purpose for which one or more of the Tape Implants was acquired by each of the Tape Sub-Group Members was known to Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson.

PARTICULARS

(A) The Tape Implants were designed and manufactured for the Tape Purpose;

(B) The Tape Implants had been marketed, promoted and/or supplied by Ethicon Sàrl, Ethicon, Inc. and/or Johnson & Johnson in the way outlined at paragraphs 41 and 42 of this Third Further Amended Statement of Claim as being reasonably fit for the Tape Purpose; and/or

(C) The matters set out in paragraph 40-43 above are repeated

(ii) Tape Risks and Tape Complications

45. At all material times, by reason of:

(a) the material of which the Tape Implants were constructed;

(b) the design of the Tape Implants;

(c) the anatomical structures, tissues and location in which the Tape Implants were implanted, passed through, attached to and in addition, or alternatively, with which the Tape Implants were brought into proximity; and in addition, or alternatively

(cc) the technique by which the Tape Implants were designed to be implanted,

or in any event, the Tape Implants had a risk of and/or were susceptible to causing complications including:

(d) a chronic inflammatory reaction of the tissues surrounding or attached to the Tape Implants;

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

(f) infection;

(g) chronic pain;

(h) dyspareunia and in addition, or alternatively, apareunia;

(i) difficulty voiding;

(j) offensive discharge;

(k) de novo or recurrent urinary incontinence;

(l) damage to surrounding organs, nerves, ligaments, tissue and in addition, or alternatively, blood vessels;

(m) haemorrhage;

(n) leg weakness;

(o) psychiatric injury; and in addition, or alternatively

(p) reoperation or revision surgery associated with complications, including those listed above.

(the complications at (d) to (p) above are referred to as the **Tape Complications**).

Particulars

(A) The material the Tape Implants were made of includes polypropylene;

(B) The design of the Tape Implants includes the pore size, filament structure and weave, tensile strength, elasticity, density and porosity of the material used in the Tape Implants;

(C) The anatomical structures, tissues and location in which the Tape Implants were implanted, attached to, passed through and in addition, or alternatively, with which the Tape Implants were brought into proximity included the vagina, which is a clean contaminated environment that cannot be completely sterilised;

(D) The Tape Implants were implanted by being passed through the vagina which is a clean contaminated environment that cannot be completely sterilized;

(E) The composition of the polypropylene material means that, when inserted through, attached to or brought into proximity with the clean contaminated vagina bacteria was more likely to be attracted to the surface of the Tape Implants than repelled which made the Tape Implants susceptible to the risk of bacterial adhesion and an

inflammatory response occurring. The inflammatory response was enhanced by the presence of bacteria;

(F) The design of the Implants including the pore size, filament structure and weave, tensile strength, elasticity, density and porosity of the Implants had the effect of:

(i) promoting bacterial colonisation;

(ii) aggravating any inflammatory response;

(iii) increasing the risk of degradation of the Implants;

(iv) rendering the Tape Implants incompatible with the anatomical location in which the Tape Implants are placed; and

(v) increasing the risk of complications;

(G) The material the Tape Implants were made of and the design of the Implants:

(i) made the inflammatory response susceptible to develop into a chronic inflammatory reaction and in addition, or alternatively, total infection of the Tape Implants;

(ii) rendered the Tape Implants susceptible to one or more of the following:

(a) scar plate formation;

(b) contraction;

(c) shrinkage;

(d) fraying;

(e) roping;

(f) curling;

(g) bunching;

(h) banding;

(i) deforming;

(j) collapsing;

(k) elongating;

(l) oxidative degradation;

(m) not being inert; and/or

(n) bridging fibrosis;

(H) The effects of any inflammatory response increased the risk of and/or susceptibility to degradation of the Tape Implants;

(I) Degradation of the Tape Implants means they were susceptible to the release of chemical compounds from the polypropylene, which enhanced any inflammatory response and promoted the occurrence of complications. Degradation also changed the physical properties of the Tape Implants (including flaking and surface cracking); and

(J) The TVT Obturator Implants and Abbrevo Implants were implanted by passing through the obturator membrane, which had a risk of and/or was susceptible to cause pain including groin pain and/or thigh pain.

46. Further, at all material times:

(a) The Tape Implants were designed to be permanent implants and were difficult or impossible safely to remove from patients suffering from one or more of the Tape Complications;

(b) Treatment of the Tape Complications was difficult or impossible, or alternatively carried with it the risk of new or aggravated complications; and in addition, or alternatively

(c) Treatment of the Tape Complications may require one or more surgical procedures to attempt to remove the Tape Implants or such parts thereof that may be reasonably capable of being removed

(**Tape Removal Complications**).

47. Further, or alternatively, at all material times:

(a) there were alternative treatments available for the treatment of SUI (**Alternative Treatments**) which could be undertaken without the use of TVT Implants;

Particulars

The Alternative Treatments included:

(A) open colposuspension (Burch procedure);
(B) laparoscopic colposuspension;
(C) fascial (or native tissue or autologous) sling repair; and
(D) non-surgical treatments including but not limited to pelvic floor exercises.

(b) The Alternative Treatments were accepted methods of treating SUI;

(c) The Alternative Treatments were as effective in treating SUI, or alternatively were not materially less effective in treating SUI as surgery for the treatment of SUI undertaken using Tape Implants;

(d) The Alternative Treatments did not have the risks of causing, and were not susceptible to cause, some or all of the Tape Complications or the Tape Removal Complications; and

(e) In addition to sub-paragraph 47(d) above, or alternatively, the Alternative Treatments:

(i) did not have the risks of, and in addition or alternatively, were not susceptible to causing, the Tape Complications pleaded in paragraph 45(d) or (e) above or the Tape Removal Complications; and

(ii) did not have a greater risk of, and in addition, or alternatively, were not materially more susceptible to causing, the Tape Complications pleaded in paragraph 45(f)-(p) above.

(f) In addition, or alternatively, the Alternative Treatments were as safe in treating SUI, or, in the alternative, were not materially less safe in treating SUI, as surgery for the treatment of SUI undertaken using Tape Implants; and

(g) In addition, or alternatively, the Alternative Treatments were as safe in achieving the Tape Purpose, or in the alternative, were not materially less safe in achieving the Tape Purpose, as surgery for the treatment of SUI undertaken using Tape Implants.

47A. Prior to the release in Australia of the Tape Implants and the supply, distribution, marketing or promotion in Australia of the Tape Implants, none of the Respondents undertook any, or in the alternative, any adequate clinical or other evaluation of the risks, including long-term risks, and effectiveness, including the long-term effectiveness, associated with the use of the Tape Implants, including:

(a) the risk of occurrence of the Tape Complications;

(b) the risk of occurrence of the Tape Removal Complications;

(c) whether surgery for the treatment of SUI undertaken using Tape Implants was more effective, or in the alternative was not materially less effective than the Alternative Treatments in treating SUI;

(d) whether surgery for the treatment of SUI undertaken using Tape Implants was safer, or in the alternative was not materially less safe than the Alternative Treatments in treating SUI;

(e) whether the technique by which the Tape Implants were to be inserted was reliable and reproducible,

(**the Tape Evaluation Matters**).

48. Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson failed to give any, or any sufficient, information or warning to the Tape Sub-Group Members, their Treating Hospitals and/or their Treating Doctors:

(a) of:

(i) the risk or susceptibility of the Tape Implants to cause one or more of the Tape Complications;

(ii) the Tape Removal Complications;

(b) of the matters pleaded in paragraph 47 above; and, in addition or alternatively;

(c) of the Tape Evaluation Matters;

(d) that the chronic inflammatory response to the Tape Implants may be affected by conditions which affect the immune response and healing, including autoimmune and connective tissue disorders.

(**Tape Warning Matters**).

(iii) Applicant's Implant

49. Prior to 12 March 2001, Mrs Sanders had:

(a) been suffering SUI for a period of approximately 7 years;

(b) consulted Dr John Taylor, Urologist, at King Edward Memorial Hospital in Perth, Western Australia (**KEMH**) in respect of her SUI symptoms (on or about 17 October 2000);

(c) undergone urodynamic testing; and

(d) on Dr Taylor's recommendation, been placed on the waiting list at KEMH for a TVT sling procedure to address her SUI.

50. By reason of the matters pleaded in paragraph 48 above, at no time before 12 March 2001 was Mrs Sanders informed of the Tape Warning Matters in respect of TVT Implants.

51. On 12 March 2001, on the advice of Dr John Taylor and other practitioners at KEMH, Mrs Sanders underwent the implantation of a TVT Implant.

Particulars

Mrs Sanders was implanted with a TVT Implant at KEMH by Dr McNeil.

52. The purpose for which Mrs Sanders received the TVT Implant was the Tape Purpose.

53. Following the TVT Implant, Mrs Sanders experienced:

(a) an anterior tape (mesh) erosion;

(b) urinary urgency and urge incontinence;

(c) recurrent urinary tract infections;

(d) dyspareunia;

(e) leg weakness;

(f) groin pain; and

(g) inflammation of the bladder.

54. On 19 May 2011:

(a) Mrs Sanders consulted Dr Alanagh Gilbert, Consultant Gynaecologist, at KEMH complaining of symptoms associated with the conditions pleaded at paragraph 53 herein;

(b) Dr Gilbert noted complaints of discomfort in the vagina which had become worse recently, urgency and urge incontinence and recurrent urinary tract infections;

(c) On examination, Dr Gilbert identified an area of tape (mesh) erosion anteriorly;

(d) Dr Gilbert scheduled Mrs Sanders for an examination under anaesthetic, a cystoscopy and revision surgery in order to excise the eroded vaginal mesh.

55. On 8 August 2011 Mrs Sanders underwent an examination under anaesthetic, a cystoscopy and revision surgery in order to excise eroded vaginal mesh at mid urethra (the **Revision Surgery**).

Particulars

(A) The Revision Surgery was performed by Dr John Phillipe Daborn at King Edward Memorial Hospital in Perth, Western Australia.

56. Following the Revision Surgery, Mrs Sanders continues to experience:

(a) pain and discomfort;

(b) symptoms of urgency and urge incontinence;

(c) SUI;

(d) apareunia;

(e) leg weakness;

(f) recurrent, regular urinary tract infections;

(g) discomfort urinating; and

(h) adjustment disorder with depressed mood.

57. The conditions pleaded in paragraphs 53 and 56 together with the need for the Revision Surgery are the direct consequence of the matters pleaded in paragraphs 45, 46 and in addition, or alternatively, 48 above.

58. In the premises, as a result of the TVT implant Mrs Sanders has suffered loss and damage.

Particulars

The loss or damage includes but is not limited to:

A. personal injury including:

1. an anterior mesh erosion;

2. recurrence of stress urinary incontinence;

3. symptoms of urgency and urge incontinence;

4. recurrent urinary tract infections;

5. inflammation of the bladder;

6. adjustment disorder with depressed mood;

B. health care expenses;

C. other out of pocket expenses;

D. economic loss;

E. the need for gratuitous and/or commercial care;

F. non-economic loss.

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

59. The Tape Implants were goods within the meaning of sections 4 and 74A(2)(a) of the TPA, and sections 2 and 271 of Schedule 2 of the CCA.

60. The Tape Implants were supplied to each of the Tape Sub-Group Members as consumers within the meaning of section 4B of the TPA and section 3 of Schedule 2 of the CCA.

61. By reason of:

(a) the fact that:

(i) the Tape Implants were designed and manufactured by the Respondents for the Tape Purpose;

(ii) the Tape Purpose was known to the Respondents, as pleaded at paragraph 41 above;

(iii) the Respondents marketed, promoted and supplied the Tape Implants as reasonably fit for the Tape Purpose, as pleaded at paragraph 42 above;

(iv) the purposes for which the Tape Implants were commonly supplied and the purpose for which one or more of the Tape Implants were acquired by each of the Tape Sub-Group Members was for the Tape Purpose, as pleaded at paragraph 43 above; and

(v) the purposes for which the Tape Implants were commonly supplied and acquired and the purpose for which one or more of the Tape Implants were acquired by each of the Tape Sub-Group Members, being the Tape Purpose, was known to the Respondents, as pleaded at paragraph 44 above;

(b) the matters pleaded in paragraphs 45, 46, 47 and, or alternatively, 48 above; and, or alternatively

(c) the fact that none of the packaging of the Tape Implants, their Instructions For Use, nor any other source of information disseminated by the Respondents, or any of them, to Tape Sub-Group Members, Treating Hospitals or Treating Doctors gave any (or any sufficient) warning, advice or information as to some or all of the Tape Warning Matters

the safety of the Tape Implants was not such as persons generally were entitled to expect and the Tape Implants had a defect for the purposes of sections 75AC(1) and 75AD(1) of the TPA and, or alternatively, a safety defect for the purposes of sections 9 and 138 of Schedule 2 of the CCA.

62. By reason of the matters pleaded at paragraph 61(a) to (c) above, the Tape Implants were not reasonably fit for the Tape Purpose, within the meaning of section 74B of the TPA and section 55 of Schedule 2 of the CCA.

63. By reason of the matters pleaded at paragraph 61(a) to (c) above, the Tape Implants acquired by each of the Tape Sub-Group Members were not of merchantable quality within the meaning of section 74D(3) of the TPA, or acceptable quality within the meaning of section 54 of Schedule 2 of the CCA.

64. In the premises, each of the Tape Sub-Group Members has suffered loss and damage, by reason of the fact that:

(a) the safety of any of the Tape Implants was not such as persons generally were entitled to expect as pleaded at paragraph 51 above;

(b) the Tape Implants were not fit for the Tape Purpose as pleaded at paragraph 52 above; and in addition, or in the alternative

(c) the Tape Implants were not of merchantable quality as pleaded in paragraph 53 above.

PARTICULARS

Particulars of each of the other Tape Sub-Group Members' loss and damage may be provided after the trial of common issues but is expected to include:

(i) personal injury including one or more of the Tape Complications or Removal Complications;

(ii) health care expenses;

(iii) other out of pocket expenses;

(iv) economic loss;

(v) the need for gratuitous and in addition, or alternatively, commercial care; and

(vi) non-economic loss.

65. In the premises, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson are liable to compensate each of the Tape Sub-Group Members for their loss and damage pursuant to:

(a) section 75AD of the TPA, or section 138 of Schedule 2 of the CCA, as the case may be;

(b) sections 74B(1) and 82(1) of the TPA, or sections 55, and 236 or in addition or alternatively 237 or in addition or alternatively 259(4) of Schedule 2 of the CCA, as the case may be; and in addition, or alternatively

(c) sections 74D(1) and 82(1) of the TPA, or sections 54, and 259(4), 271 and 272 of Schedule 2 of the CCA, as the case may be.

(v) Claims in Negligence

66. Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. owed each of the Tape Sub-Group Members a duty to exercise reasonable care and skill in the design, manufacture, marketing and supply of the Tape Implants.

67. Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc.:

(a) designed and manufactured the Tape Implants for the Tape Purpose;

(b) knew of the Tape Purpose;

(c) marketed, promoted and supplied the Tape Implants as reasonably fit for the Tape Purpose; and

(d) knew or ought to have known that the purposes for which the Tape Implants were commonly supplied and acquired and the purpose for which one or more of the Tape Implants were acquired each of the Tape Sub-Group Members, was the Tape Purpose; and

(e) did not undertake any, or in the alternative, any adequate, clinical or other evaluation of the Tape Implants prior to the release in Australia of the Tape Implants and the supply, distribution, marketing or promotion in Australia of the Tape Implants, as pleaded at paragraph 47A above.

68. In the circumstances pleaded at paragraph 67(a) to (e) above, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. designed, manufactured, marketed and in addition, or alternatively, supplied the Tape Implants containing:

(a) the characteristics pleaded at paragraph 45 above; and in addition, or alternatively

(b) a risk of, and in addition, or alternatively, a susceptibility to causing the Tape Complications and, or alternatively, the Tape Removal Complications.

68A. In addition to paragraph 68 above, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. continued to design, manufacture, market and in addition, or alternatively, supply the Tape Implants notwithstanding the matters pleaded in paragraph 68 above.

68B. In addition, or alternatively, to paragraph 68A above, in addition to paragraph 68 above Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. failed to conduct any, or any adequate evaluation of the safety and effectiveness of the Tape Implants in treating SUI after releasing them in Australia.

68C Further, or alternatively, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively Johnson & Johnson, failed to conduct any, or any adequate evaluation of the long-term safety and effectiveness of the Tape Implants in treating SUI after releasing them in Australia.

69. Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc.:

(a) failed to inform any of the Tape Sub-Group Members of:

(i) the matters pleaded in paragraphs 47A and 68(a) and (b) above; and, or alternatively

(ii) the Tape Warnings Matters

(b) further or in the alternative, failed to inform:

(i) Johnson & Johnson;

(ii) Treating Hospitals; and in addition, or alternatively

(iii) Treating Doctors,

of the matters pleaded in this sub-paragraph 69(a) above.

72. By reason of the matters pleaded at paragraphs 68 to 69 above, Ethicon Sàrl and in addition, or alternatively, Ethicon, Inc. breached its duty of care to each of the Tape Sub-Group Members.

73. By reason of the matters pleaded at paragraphs 66 to 72 above, each of the Tape Sub-Group Members has suffered loss or damage.

PARTICULARS

The particulars to paragraph 58 above are repeated.

74. In addition, or in the alternative, to the matters pleaded at paragraphs 66 to 73 above, Johnson & Johnson owed each of the Tape Sub-Group Members a duty to exercise reasonable care and skill in the supply and marketing of the Tape Implants.

75. Johnson & Johnson:

    (a) knew of the Tape Purpose;

    (b) marketed, promoted and supplied the Tape Implants as reasonably fit for the Tape Purpose;

    (c) knew or ought to have known that the purposes for which the Tape Implants were commonly supplied and acquired and the purpose for which one or more of the Tape Implants were acquired each of the Tape Sub-Group Members, was the Tape Purpose; and

    (d) did not undertake any, or in the alternative, any adequate clinical or other evaluation of the Tape Evaluation Matters prior to the release in Australia of the Tape Implants and the supply, distribution, marketing and promotion in Australia of the Tape Implants as pleaded at paragraph 47A above.

76. In the circumstances pleaded at paragraph 75(a) to (c) above, Johnson & Johnson marketed and in addition, or alternatively, supplied the Tape Implants containing:

    (a) the characteristics set out in paragraph 45 above; and in addition, or alternatively,

    (b) a risk of, and in addition, or alternatively, a susceptibility to causing the Tape Complications and, or alternatively, the Tape Removal Complications.

77. Johnson & Johnson:

    (a) failed to inform any of the Tape Sub-Group Members of:

        (i) the matters pleaded in paragraphs 47A and 76(a) and (b) above; and, or alternatively

        (ii) the Tape Warning Matters; and

    (b) further or in the alternative, failed to inform:

        (i) Treating Hospitals; and in addition, or alternatively

        (ii) Treating Doctors,

        of the matters pleaded in sub-paragraph (a) above.

79. By reason of the matters pleaded at paragraphs 74 to 78 above, Johnson & Johnson breached its duty of care to each of the Tape Sub-Group Members.

80. By reason of the matters pleaded at paragraphs 73 to 79 above, each of the Tape Sub-Group Members has suffered loss or damage.

PARTICULARS

The particulars to paragraph 58 above are repeated.

81 In the premises, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson are liable for the loss or damage suffered by each of the Tape Sub-Group Members.

(vi) Misleading Conduct Claims under the TPA and CCA

82. The matters pleaded in paragraphs 5, 15, 16, 17, 40, 41, 42, 45, 46, 47, 47A, 48, 67, 68, 69, 75, 76 and 77 are repeated.

83. By reason of the matters pleaded at paragraph 82, each of the Respondents engaged in conduct that was misleading or deceptive or likely to mislead or deceive in contravention of section 52 of the TPA and section 18 of Schedule 2 of the CCA, as the case may be.

84. By reason of the matters pleaded at paragraphs 82 and 83, each of the Tape Sub-Group Members has suffered loss and damage.

85. In the premises, each of the Respondents is liable for the loss or damage suffered by each of the Tape Sub-Group Members, pursuant to section 82(1) of the TPA or sections 236 or in addition or alternatively 237 of Schedule 2 of the CCA, as the case may be.

Date: 13 April 2018

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

This pleading was prepared by Rebecca Jancauskas and Alissa McKillop of Shine Lawyers and AJL Bannon, DE Graham, ZM Hillman and APL Naylor of counsel.

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

Certificate of lawyer

I Rebecca Jancauskas certify to the Court that, in relation to the Fifth Further Amended Statement of Claim filed on behalf of the Applicants, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 13 April 2018

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