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Details of Filing

Document Lodged:	Statement of Claim - Form 17 - Rule 8.06(1)(a)
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Important Information

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Form 17 Rule
8.06(1)(a)

Statement of Claim

No. of 20

Federal Court of Australia

District Registry: New South Wales

Division: General

Lisa Talbot

Applicant

ETHICON Sàrl and others

Respondents

Filed on behalf of (name & role of party) Lisa Talbot (Applicant)
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[Form approved 01/08/2011]

Part A – Introduction

(i) Group Members

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

   (a) in their own right; and

   (b) on behalf of persons (**Group Members**) who at any time after 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 Nonabsorable Prolene Soft Mesh and available as Anterior, Posterior or Combined Implant;

            (iii) the implants included in the Gynecare + 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 partes 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 Nonabsorable Prolene Soft Mesh and available in sheets of 10 x 1cm and 25 x 25cm,

      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 12 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 one or more of the Implant Complications or Implant Removal Complications pleaded in paragraphs 10 and 11 below in relation to the Mesh Implants and Tape Implants.

(ii) The Applicant

2. The Applicant (**Mrs Talbot**):

(a) was born on 19 September 1963;

(b) has given birth to two children;

(c) is a Tape Sub-Group Member by reason of the matters pleaded at paragraphs 48 to 54 below.

(iii) The Respondents

3. At all material times, the First Respondent (**Ethicon Sàrl**) and Second Respondent (**Ethicon, Inc.**)

   (a) were and are companies incorporated under the laws of Switzerland;

   (b) were and are foreign corporations 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) were and are in the business of manufacturing medical devices and marketing, promoting and supplying medical devices, including in Australia, and including the Implants, using the business names Johnson & Johnson Medical, Johnson & Johnson, Gynecare Worldwide and Ethicon Women's Health and Urology;

   (d) manufactured the Implants within the meaning of section 74A(1) of the TPA and section 7 of Schedule 2 of the CCA;

   (e) carried on the business of supplying the Implants in trade or commerce directly or through the Third Respondent (**Johnson & Johnson**) so as to be distributed to hospitals or alternatively to doctors in Australia for resupply to patients including the Applicant and Group Members; and

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

4. At all material times, the Third Respondent (**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;

   (d) acquired the Implants from Ethicon Sárl and in addition, or alternatively from Ethicon, Inc for distribution in trade or commerce to treating hospitals and in addition, or alternatively to treating doctors for resupply to patients including the Applicant and Group Members; and

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

PARTICULARS

Conduct of business in Australia by supplying the Implants

(A) the Prolift Implants from on or about June 2005 to on or about 15 August 2012;

(B) the Prolift + M Implants from on or about December 2009 to on or about 15 August 2012;

(C) the Prosima Implants from on or about April 2010 to on or about 15

August 2012;

(D) the Gynecare Gynemesh PS Implant from on or about July 2003 to on or about 18 August 2017;

(E) the TVT Implant from on or about October 1999 to on or about 17 January 2018 and from on or about 11 April 2018 to present;

(F) the TVT Secur Implant from on or about May 2007 to on or about March 2008;

(G) the TVT Abbrevo Implant from on or about October 2010 to on or about 17 January 2018 and from on or about 11 April 2018 to present;

(H) the TVT Obturator Implant from on or about March 2004 to on or about 17 January 2018 and from on or about 11 April 2018 to present;

(I) the TVT Exact Implant from on or about July 2010 to on or about 17 January 2018 and from on or about 11 April 2018 to present.

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

5. By reason of the matters pleaded at 3(f) and 4(e), Johnson & Johnson is the importer and deemed manufacturer of the Implants 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.

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

Part B – The Conditions, Implants and Complications

(i) The Conditions

7. 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 from 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 (**the POP 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.

8. 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

(**the SUI Symptoms**).

(ii) The Implants

9. The Implants are surgical implants that were:

(a) made, at least partly from polypropylene;

(b) implanted transvaginally; and

(c) implanted in such a way that they:

(i) passed through;

(ii) attached to, and in addition or alternatively,

(iii) were brought into proximity with the vagina and, in the case of the Tape Implants, the urethra.

(iii) The Implant Risks and Complications

10. By reason of one or more of the matters pleaded at paragraph 9, or in any event, the Implants had a risk of and in addition, or alternatively were susceptible to:

(a) causing a chronic inflammatory reaction of the tissues in which the Implants were implanted, attached and in addition, or alternatively, the surrounding tissues;

(b) the chronic inflammatory reaction resulting in the continuous regeneration of scar tissue within and surrounding the Implant for so long as it remained in

the body causing the Implant (separately or in conjunction with surrounding tissue) to contract;

(c) causing further complications, the likelihood of which could not be predicted for any patient, including:

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

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

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

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

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

(vi) erosion, extrusion of the Implant into surrounding organs, such as the bladder, urethra, or rectum with the risk of damage to those organs and pain;

(vii) difficulty voiding or defecating;

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

(ix) de novo stress urinary incontinence in the case of the Mesh Implants;

(x) recurrence of prolapse; and

(xi) infection.

(the complications referred to at subparagraphs (a) to (c) being the **Implant Complications**).

(d) Requiring reoperation or revision surgery associated with Implant Complications;

(e) Not fulfilling, in the case of the Mesh Implants, the Mesh Purpose (as defined at paragraph 12) or in the case of the Tape Implants, the Tape Purpose (as defined at paragraph 40).

11. Further, at all material times:

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

(b) Treatment of the Implant 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 Implant Complications may require one or more surgical procedures for the purpose of removing the Implants or parts thereof that were reasonably capable of being removed

(**the Implant Removal Complications**).

Part C – The Mesh Implants

(i) Purpose of the Mesh Implants

12. The Mesh Implants were designed and manufactured to:

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

(b) restore pelvic anatomy and pelvic function; and

(c) thereby alleviate the symptoms of pelvic organ prolapse.

(**the Mesh Purpose**).

13. The Mesh Purpose was known to Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively 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 stabilization 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, Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson, stated:

PELVIC RECONSTRUCTIVE SURGERY

Pelvic reconstructive surgery can be performed through the vagina orabdominally... During the procedure, the surgeon will reposition the prolapsed organ(s) and secure them to surrounding tissues andligaments...

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"* Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson 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 incision 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, Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson 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, Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson 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 were surgical treatment is indicated, either as mechanical support or bridging material for the fascial defect.

14. 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, Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson 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, Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson 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 of the Prosima Implant, Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson 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, Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson 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 minimal to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can go 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 Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson.

(F) In an undated publication entitled, *"A Solution: GYNECARE PROLIFT® Pelvic Floor Repair System"*, Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson 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,"* Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson 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, Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson 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 indicated, either as mechanical support or bridging material for the fascial defect.

(l) In an undated publication entitled *"Pelvic Organ Prolapse"*, Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson stated at page 13:

GYNECARE PROLIFT® Pelvic Floor Repair System is different from other surgical treatments
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.

15. 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.

16. 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 Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson.

PARTICULARS

(A) The Mesh Implants were designed and manufactured for the Mesh Purpose as pleaded at paragraph 12 above.

(B) The Implants had been marketed, promoted and in addition, or alternatively, supplied by Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson in the way pleaded at paragraphs 13 and 14 above as being reasonably fit for the Mesh Purpose; and in addition, or alternatively,

(C) The matters pleaded in paragraph 13 above.

(ii) Alternative treatments for POP

17. At all material times:

(a) reconstructive surgery for the treatment of 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 Implant Risks and 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 Implant Complications; or in the alternative

(ii) did not have a great risk of, and in addition, or alternatively was not materially more susceptible to causing, the Implant Complications; and

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

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

(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.

(iii) Evaluation and warnings in respect of the Mesh Implants

18. Prior to the release in Australia of the Mesh Implants and the supply, distribution, marketing or promotion in Australia of the Mesh Implants, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson did not undertake adequate clinical or other evaluation of the risks associated with the effectiveness including long-term risks and long-term effectiveness, associated with the use of the Mesh Implants, including:

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

(b) the risk of occurrence of the Implant 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**).

19. At all material times, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson failed to give sufficient warning or warning to the Mesh Sub-Group Members (directly or by providing sufficient information or warning to their treating hospital and/or treating doctors)

(a) of:

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

(iv) the Implant Removal Complications; and in addition, or alternatively;

(v) the Mesh Evaluation Matters;

(b) of the matters pleaded in paragraph 18 above;

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

(**the Mesh Warning Matters**).

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

20. 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.

21. 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.

22. By reason of:

(a) the fact that:

(i) The Mesh Implants were designed and manufactured by Ethicon Sárl,

Ethicon, Inc., and in addition, or alternatively Johnson & Johnson for the Mesh Purpose;

(ii) The Mesh Purpose was known to Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson, as pleaded at paragraph 13 above;

(iii) Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson marketed, promoted and supplied the Mesh Implants as reasonably fit for the Mesh Purpose, as pleaded at paragraph 14 above;

(iv) The purposes for which the Mesh Implants were commonly supplied and the purpose for which one or more of the Mesh Implants were acquired by each of the Tape Group-Members was for the Mesh Purpose, as pleaded at paragraph 15 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 Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson, as pleaded at paragraph 16 above.

(b) the fact that prior to the release in Australia of the Mesh Implants and the supply, distribution, marketing or promotion in Australia of the Mesh Implants, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson did not undertake adequate clinical or other evaluation of the Mesh Evaluation Matters; and

(c) the matters pleaded in paragraphs 10, 11, or alternatively paragraph 17; and in addition, or alternativey;

(d) the fact that neither the packaging of the Mesh Implants, their Instructions for Use, nor any other document or any other source of information disseminated by Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson gave 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 section 75AC(1) and 75AD(1) of the TPA, and or alternatively, a safety defect for the purposes of section 9 and 138 of Schedule 2 of the CCA.

23. By reason of the matters pleaded at paragraph 22(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.

24. By reason of the matters pleaded at paragraph 22(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.

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

(a) the safety of the Mesh Implants was not such as persons generally were entitled to expect as pleaded at paragraph 22 above;

(b) the Mesh Implants were not fit for the Mesh Purpose as pleaded at paragraph 23 above; and in addition, or in the alternative

(c) the Mesh Implants were not of merchantable or acceptable quality as pleaded in paragraph 24 above.

PARTICULARS

(A) Particulars of each of the other 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 Implant Complications and Implant Removal Complications;

(ii) health care expenses;

(iii) out of pocket expenses;

(iv) economic loss;

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

(vi) non-economic loss.

26. In the premises, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson is 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) Section 74D(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

27. Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson 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.

28. Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson:
    (a) designed and manufactured the Mesh Implants for the Mesh Purpose;
    (b) knew of the Mesh Purpose as pleaded at paragraph 13 above;
    (c) marketed, promoted and supplied the Mesh Implants as reasonably fit for the Mesh Purpose, as pleaded at paragraph 14 above; and
    (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 15 above; and
    (e) did not undertake adequate clinical or other evaluation of the Mesh Evaluation Matters prior to release in Australia of the Mesh Implants and the supply, distribution, marketing or promotion in Australia of the Mesh Implants as pleaded at paragraph 16 above.

29. In the circumstances pleaded at paragraph 28 above, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson designed, manufactured, marketed and in addition or alternatively, supplied the Mesh Implants containing:
    (a) the characteristics pleaded at paragraph 10 above; and in addition, or alternatively;
    (b) a risk of, and in addition or alternatively, a susceptibility to causing the Implant Complications and in addition, or alternatively, the Implant Removal Complications.

30. In addition to paragraph 29 above, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson continued to design, manufacture, market and in addition or alternatively, supply the Mesh Implants notwithstanding the matters pleaded in paragraph 28 above.

31. In addition, or alternatively, to paragraphs 28 and 29 above, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson failed to conduct adequate evaluation of the safety and effectiveness of the Mesh Implants in treating POP after releasing them in Australia.

32. Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson:
    (a) failed to inform any of the Mesh Sub-Group Members of:
        (i) the matters pleaded in paragraphs 28 and 29(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 paragraphs 29(a) and (b) above; and in addition, or alternatively the Mesh Warning Matters.

33. By reason of the matters pleaded at paragraphs 28 to 32 above, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson breached their duty of care to each of the Mesh Sub-Group Members pleaded at paragraph 27 above.

34. By reason of the matters pleaded at paragraphs 28 to 33 above, each fo the Mesh Sub-Group Members has suffered loss or damage for which each claims damages from Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson.

    PARTICULARS

    The particulars to paragraph 25 are repeated.

35. In the premises, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson is 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

36. Further and in the alternative, the matters pleaded at paragraphs 3(e), 4, 12, 13, 14, 10, 11, 17, 18, 19, 28, 29, 30 and 32 are repeated.

37. By reason of the matters pleaded at paragraph 36 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.

38. By reason of the matters pleaded at paragraphs 36 and 37 above, each of the Mesh Sub-Group Members has suffered loss or damage.

39. 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 D- The Tape Implants

(i) Purpose of the Tape Implants

40. Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson marketed the Tape Implants as being designed to:

(a) be implanted in women for the safe and effective surgical treatment of pure or predominate stress urinary incontinence;

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

(c) alleviate safely and effectively involuntary urine leakage caused by stress incontinence.

(**the Tape Purpose**).

41. The Tape Purpose was known to Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, Johnson & Johnson.

PARTICULARS

In distributing, supplying, marketing and, or alternatively, promoting the Tape Implants, Ethicon Sàrl, Ethicon Inc., and in addition, or alternatively, 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 Tape 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 Tape 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 Tape 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 Secur System Instructions for Use stated: *The GYNECARE TVT SECUR System is intended for use in women as a sub-urethral Tape for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.*

42. Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, 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 of the TVT Implant, Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson 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 Tape 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, Ethicon, Inc. and in addition, or alternatively, Johnson &

Johnson 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 andis 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 degradationor weakening by the action of tissue enzymes. ... The GYNECARE TVT SECUR System is intended for use in women as a sub-urethral Tape forthe 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, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson 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, Ethicon, Inc. and in addition, or alternatively,

Johnson & Johnson stated at pages 1 and 6:

The GYNECARE TVT OBTURATOR device is a ... PROLENE PolypropyleneMesh ... 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-reactiveand 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 theinterstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation orweakening by the action of tissue enzymes.

(E) In an undated publication entitled "*Gynecare TVT*", Ethicon Sàrl, Ethicon, Inc. and in addition, or alternatively, Johnson & Johnson 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 Sárl, Ethicon, Inc., and in addition, or alternatively 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 Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson in the way outlined at paragraph 42 as being reasonably fit for the Tape Purpose; and/or

(C) the matters set out in paragraphs 41 to 42 above are repeated.

(ii) Availability of alternative treatments

45. 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 Tape Implants;

PARTICULARS

The Alternative Treatments included:

(A) open colpsuspension (Burch procedure);

(B) laparascopic colpsuspension;

(C) fascial (or native tissue or autologous) Tape 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 Implant Complications or the Implant Removal Complications; and

(e) in addition to subparagraph 41(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 Implant Complications or the Implant Removal Complications; and

(ii) did not have a greater risk of, and in addition or alternatively, were not

materially more susceptible to causing, the Implant Complications.

(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 undertaking using Tape Implants;

(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.

(iii) Evaluation and warnings in respect of the Tape Implants

46. Prior to the release in Australia of the Tape Implants and the supply, distribution, marketing or promotion in Australia of the Tape Implants, , Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson did not undertake adequate clinical or other evaluation of the risks associated with the effectiveness of, including long-term risks and long-term effectiveness associated with the use of the Tape Implants, including:

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

(b) the risk of occurrence of the Implant 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 designed to be inserted as reliable and reproducible

(**the Tape Evaluation Matters**).

47. On or prior to 30 June 2020, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively 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 Implant Complications;

(ii) the Implant Removal Complications;

(iii) the Tape Evaluation Matters;

(b) of the matters pleaded in paragraph 46 above; and in addition, or alternatively

(c) 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

(**the Tape Warning Matters**).

PARTICULARS

Pursuant to *Gill v Ethicon Sarl* (No 6) [2020] FCA 279 an injunction was granted enjoining Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson, from 30 June 2020, supplying, distributing, marketing or promoting the Tape Implants (other than TVT Secur Implant) without including in the Instructions for Use and patient information leaflets and any promotional material relating to the Tape Implants requisite warnings and advice in respect of the Tape Warning matters.

(iv) Mrs Talbot's Tape Implant

48. Prior to 5 August 2019, Mrs Talbot experienced symptoms of and was diagnosed with SUI.

49. On 5 August 2019, on the advice of Dr Jeannette Lim, Urogynaecologist (**Dr Lim**) Mrs Talbot underwent the implantation of the TVT Exact Implant.

PARTICULARS

Mrs Talbot was implanted with a TVT Exact Implant at Ballarat Health Service Hospital, Victoria by Dr Lim. The TVT Exact Implant was supplied to Mrs Talbot by Dr Lim and in addition, or alternatively, Ballarat Health Service, Victoria.

50. At no time before 5 August 2019 was Mrs Talbot informed of the Tape Warning Matters in respect of the Tape Implants.

51. The purpose for which Mrs Talbot received the TVT Exact Implant was the Tape Purpose.

52. Following the implantation of the TVT Exact Implant and prior to 17 October 2019, Mrs Talbot experienced an Implant Complication, namely, erosion.

53. On 16 October 2019, Dr Lim performed surgery under anaesthetic to excise the erosion of the TVT Exact Implant in the right parauthreal sulcus.

PARTICULARS

The surgery was performed by Dr Lim at St John of God Ballarat Hospital, Victoria.

54. By reason of the matters pleaded in paragraphs 48 to 53 above, Mrs Talbot has suffered loss and damage for which she claims damages from Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson.

PARTICULARS

(A) Personal injury including one or more of the Implant Complications and the Implant Removal Complications;
(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; and
(F) Non-economic loss.

Additional Particulars may be provided following the service of evidence.

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

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

56. 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.

57. By reason of:

(a) the fact that:

(i) the Tape Implants were designed and manufactured by Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson for the Tape Purpose;

(ii) the Tape Purpose was known to Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson, as pleaded at paragraph 41 above;

(iii) On or prior to 30 June 2020 by reason of the matters pleaded at the particulars to paragraph 47, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson marketed and promoted and supplied the Tape Implants as reasonably fit for the Tape Purpose, as pleaded at paragraph 42;

(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 Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson, as pleaded at paragraph 44 above.

(b) the matters pleaded in paragraphs 10, 11, and, or alternatively 45 above;

(c) the fact that prior to the release in Australia of the Tape Implants and the supply, distribution, marketing or promotion in Australia of the Tape Implants, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson did not undertake adequate clinical or other evaluation of the Tape Evaluation Matters; and, or alternatively

(d) the fact that, prior to 30 June 2020, notwithstanding the matters pleaded at paragraph 47 above, neither the packaging of the Tape Implants, their Instructions for Use, nor any other document or any other source of information disseminated by Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson gave sufficient warning, advice or information as to some or all of the Tape Warning Matters

the safety of the Tape Implants were not such as persons generally were entitled to expect and the Tape Implants had a defect for the purposes of section 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.

58. By reason of the matters pleaded at paragraphs 57(a) to (d) and the particulars pleaded at paragraph 47 above, prior to 30 June 2020, 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.

59. By reason of the matters pleaded at paragraphs 57(a) to (d) and the particulars pleaded at paragraph 47 above, prior to 30 June 2020, 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.

60. In the premises, each of the Tape Sub-Group Members has suffered loss and damage by reason of the fact that prior to 30 June 2020:

(a) the safety of any of the Tape Implants was not such as persons generally were entitled to expect as pleaded at paragraph 57 above; and in addition, or alternatively

(b) prior to 30 June 2020, the Tape Implants were not fit for the Tape Purpose as pleaded at paragraph 58 above; and in addition, or in the alternative

(c) the Tape Implants were not of merchantable or acceptable quality as pleaded in paragraph 59 above.

PARTICULARS

(A) In respect of Mrs Talbot, the particulars to paragraphs 48 to 54 above are repeated.

(B) Particulars of each of the 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 Implant 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.

61. In the premises, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson is 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) Section 74D(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

62. Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson 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.

63. Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson:

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

(b) knew of the Tape Purpose;

(c) prior to 30 June 2020, marketed, promoted and supplied the Tape Implants as reasonably fit for the Tape Purpose as pleaded at paragraph 42 above;

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

(e) did not undertake adequate clinical or other evaluation of the Tape Implants prior to the release in Australia or the Tape Implants and the supply, distribution, marketing or promotion in Australia of the Tape Implants, as pleaded at paragraph 46 above.

64. In the circumstances pleaded at paragraph 63 above, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson designed, manufactured, marketed and in addition, or alternatively, supplied the Tape Implants containing:

(a) the characteristics pleaded at paragraph 10 above; and in addition, or alternatively;

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

65. In addition to paragraph 64 above, Ethicon Sárl, Ethicon, Inc., and in addition, or

alternatively Johnson & Johnson continued to design, manufacture, and in addition, or alternatively, supply the Tape Implants notwithstanding the matters pleaded at 69 above.

66. Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson continued to market the Tape Implants prior to 30 June 2020 notwithstanding the matters pleaded at paragraphs 47 and 64 above.

67. In addition, or alternatively to paragraphs 65 and 66 above, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson failed to conduct adequate evaluation of the safety and effectiveness of the Tape Implants in treating SUI after releasing them in Australia.

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

69. Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson:

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

(i) the matters pleaded in paragraphs 63 and 64(a) and (b) above; and, or alternatively;

(ii) the Tape Warning Matters, as pleaded at paragraph 47 above.

(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 paragraph 64(a) and (b) above.

70. By reason of the matters pleaded at paragraphs 62 to 69 above, Ethicon Sárl, Ethicon, Inc., and in addition, or alternatively Johnson & Johnson breached its duty of care to each of the Tape Sub-Group Members.

71. By reason of the matters pleaded at paragraphs 62 to 70 above, each of the Tape Sub-Group Members has suffered loss or damage.

PARTICULARS

The particulars to paragraph 54 are repeated.

72. In the premises, Ethicon Sárl, 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

73. The matters pleaded in paragraphs 4, 10, 11, 40, 41, 42, 45, 46, 47, 63, 74, 70 are repeated.

74. By reason of the matters pleaded at paragraph 73 above, 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.

75. By reason of the maters pleaded at paragraph 73 and 74 above, each of the Tape Sub-Group Members has suffered loss and damage.

76. 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: 07 April 2021

Signed by Rebecca Jancauskas
Lawyer for the Applicant

This pleading was prepared by Rebecca Jancauskas of Shine Lawyers.

Schedule

No. of 20

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

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

Date: 07 April 2021

Certificate of lawyer

I Rebecca Jancauskas certify to the Court that, in relation to the statement of claim filed on behalf of the Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 07 April 2021

Signed by Rebecca Jancauskas
Lawyer for the Applicant