IN THE SUPREME COURT OF VICTORIA
AT MELBOURNE
~~MAJOR TORTS LIST~~
GROUP PROCEEDINGS LIST

No. SECI 2019 02916

BETWEEN

PATRICE TURNER Plaintiff

-and-

BAYER AUSTRALIA LIMITED (ACN 000 138 714) and others Defendants
(in accordance with the Schedule to the Further Amended Writ)

AMENDED STATEMENT OF CLAIM

Filed pursuant to order 2 of the orders made by the Honourable Justice Keogh on 22 December 2022 and rule 36.04(1)(b) of the Supreme Court (General Civil Procedure) Rules 2016 (Vic)

Date of document:	~~20 December 2019~~ 23 December 2022		
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A. THE PLAINTIFF AND GROUP MEMBERS

Group Members

1. The Plaintiff brings this proceeding as a representative proceeding pursuant to Part 4A of the *Supreme Court Act 1986* (Vic) on her own behalf and on behalf of all persons who received an implant of one or more of the permanent contraceptive medical devices in Australia marketed, labelled or identified as:

    a. a "STOP" device; or

    b. an "Essure" device (including models ESS105, ESS205, ESS305 and ESS505);

    (collectively, the **Essure Device**) at any time on or prior to 31 December 2018, and has suffered harm as a result of the Essure Device.

2. At the commencement of this proceeding there are more than seven group members who make the claims set out in this statement of claim against each of the Defendants.

The Plaintiff

3. The Plaintiff was born on 2 April 1986.

4. On 25 September 2013, the Plaintiff underwent a hysteroscopic sterilisation procedure, in which a microinsert from the Essure Device was implanted into each of her fallopian tubes.

4A Following implantation, the Plaintiff suffered the following injuries (**Plaintiff's Implantation Injuries**):

    a. disruption of the inner layers of the uterine horn and/or fallopian tubes;

    b. the development of acute and then chronic or persistent chronic inflammation in the fallopian tubes and/or endometrium;

    c. the development of associated symptoms or conditions of:

        i) severe, sharp and stabbing pain in the pelvis and lower abdomen;

        ii) ongoing pain, discomfort and feeling of heaviness in the lower back, radiating to the pelvis and lower abdomen;

        iii) dysmenorrhoea;

        iv) menorrhagia;

v) dyspareunia;

vi) fatigue, headaches, joint and muscle pain, nausea and general feelings of unwellness;

d. bilateral removal of the fallopian tubes and uterus (with the preservation of ovaries) by laparoscopic hysterectomy on 25 June 2018 (the **Plaintiff's Hysterectomy**);

e. the following psychiatric injuries resulting from, and secondary to, the injuries detailed in (a) to (d) (including the associated symptoms and conditions):

i) mild ongoing residual traumatisation features; and

ii) chronic adjustment disorder with depressed and anxious mood, now resolved.

~~5. Subsequent to having the Essure Device implantations, the Plaintiff developed a series of ongoing and worsening symptoms, including serious pain, dysmenorrhoea and menorrhagia.~~

~~6. On 25 June 2018, as a result of her symptoms, the Plaintiff underwent a laparoscopic hysterectomy with removal of fallopian tubes and preservation of ovaries and removed the microinserts.~~

B. THE DEFENDANTS

7. The First Defendant (**Bayer Australia Ltd**):

a. was and is a corporation incorporated in Australia and capable of being sued;

b. from about 2017 until 2018, was the sponsor of the Essure Device for the purposes of the *Therapeutic Goods Act 1989* (Cth) (***TG Act***);

c. from about 2014:

i) promoted and marketed in Australia the Essure Device; and/or

ii) caused or permitted its name to be used in marketing materials relating to the Essure Device; and

d. by reason of the matters alleged in the preceding sub-paragraphs, was a manufacturer of the Essure Device within the meaning of section 7 of the

Competition and Consumer Act 2010 (Cth) Schedule 2 – The Australian Consumer Law (the ***Australian Consumer Law***).

8. The Second Defendant (**Bayer AG**):

    a. was and is a corporation registered in Germany and capable of being sued;

    b. is the parent company to the Bayer group of companies;

    c. is the owner of the trademark "Bayer" and the Bayer Cross logo;

    d. from about 2013 to 2018, caused or permitted the brand name "Bayer" and the Bayer Cross logo to be used in marketing materials related to the Essure Device; and

    e. by reason of the matters alleged in the preceding sub-paragraphs, was a manufacturer of the Essure Device within the meaning of section 7 of the *Australian Consumer Law*.

9. The Third Defendant (**Bayer HealthCare LLC**):

    a. was and is a corporation registered in the United States of America and capable of being sued;

    b. is a wholly owned subsidiary of Bayer AG;

    c. from about 2013:

        i) designed, developed and manufactured the Essure Device;

        ii) supplied the Essure Device for importation into Australia for distribution;

        iii) promoted and marketed in Australia the Essure Device;

        iv) caused or permitted its name to be used in marketing materials relating to the Essure Device;

    d. from about 2014, was listed on the Australian Register of Therapeutic Goods (**ARTG**) as the manufacturer of the Essure Device; and

e. by reason of the matters alleged in the preceding sub-paragraphs, was a manufacturer of the Essure Device within the meaning of section 7 of the *Australian Consumer Law*.

10. The Fourth Defendant (**Bayer Essure Inc**):

a. was and is a corporation registered in the United States of America and capable of being sued;

b. has the following corporate history:

i) from 1992 to 25 October 2013, was named Conceptus Inc;

ii) by an agreement effective 5 June 2013, Conceptus Inc was acquired by Evelyn Acquisition Company, a wholly owned subsidiary of the Third Defendant (Bayer HealthCare LLC). Upon acquisition, Evelyn Acquisition Company merged with Conceptus Inc and, among other things, all debts, liabilities and duties of Conceptus Inc vested in the surviving company (Conceptus Inc);

iii) from 5 June 2013, Conceptus Inc continued as a wholly owned subsidiary of Bayer HealthCare LLC;

iv) on 25 October 2013, Conceptus Inc changed its name from Conceptus Inc to Bayer Essure Inc;

c. from about 1999 until about 2013 (as Conceptus Inc) and from 2013 to about 2018, (as Bayer Essure Inc):

i) designed, developed and manufactured the Essure Device; and

ii) supplied the Essure Device for importation into Australia.

d. from about 1999 until about 2014 (as Conceptus Inc):

i) promoted and marketed in Australia the Essure Device;

ii) owned the trademark “Conceptus” and the Conceptus logo;

iii) caused or permitted the name “Conceptus Inc”, the brand name “Conceptus” and the Conceptus logo to be used in marketing materials relating to the Essure Device;

iv) was listed on the ARTG as the manufacturer of the Essure Device; and

e. by reason of the matters alleged in the preceding sub-paragraphs:

i) manufactured the Essure Device within the meaning of section 74A of the *Trade Practices Act 1974* (Cth) (***Trade Practices Act***); and

ii) was a manufacturer of the Essure Device within the meaning of section 7 of the *Australian Consumer Law*.

11. The Fifth Defendant (**Gytech Pty Ltd**):

a. was and is a corporation incorporated in Australia and capable of being sued;

b. from about 2010 until the end of 2015:

i) was the sponsor of the Essure Device for the purposes of the *TG Act*;

ii) imported, or caused to be imported, the Essure Device into Australia for distribution;

iii) promoted and marketed in Australia the Essure Device;

iv) caused or permitted its name to be used in marketing materials relating to the Essure Device; and

c. by reason of the matters alleged in the preceding sub-paragraphs:

i) manufactured the Essure Device within the meaning of section 74A of the *Trade Practices Act*; and

ii) was a manufacturer of the Essure Device within the meaning of section 7 of the *Australian Consumer Law.*

12. The Sixth Defendant (**Australasian Medical and Scientific Limited**):

a. at all material times was and is a corporation incorporated in New Zealand and registered in Australia as a foreign company and capable of being sued;

b. from about 2015 until about 2017:

i) was the sponsor of the Essure Device for the purposes of the *TG Act*;

ii) imported, or caused to be imported, the Essure Device into Australia for distribution;

c. from about 2014:

i) promoted and marketed in Australia the Essure Device;

ii) caused or permitted its name to be used in marketing materials relating to the Essure Device; and

d. by reason of the matters alleged in the preceding sub-paragraphs, was a manufacturer of the Essure Device within the meaning of section 7 of the *Australian Consumer Law.*

C. DESIGN OF THE ESSURE DEVICE

13. The matters pleaded at paragraphs 14 to 17, below are pleaded at all material times.

14. The Essure Device was comprised of:

a. a micro-insert;

b. a disposable delivery system; and

c. a disposable introducer.

15. The micro-insert in the Essure Device (**the Essure Insert**):

a. was comprised of:

i) a 316L stainless steel inner coil (**the Inner Coil**);

ii) a chromium-doped nitinol (nickel-titanium alloy) outer coil (**the Outer Coil**);

iii) polyethylene terephthalate (**PET**) fibres;

iv) platinum-iridium bands and bump;

v) silver-tin solder;

b. was a spring-like device;

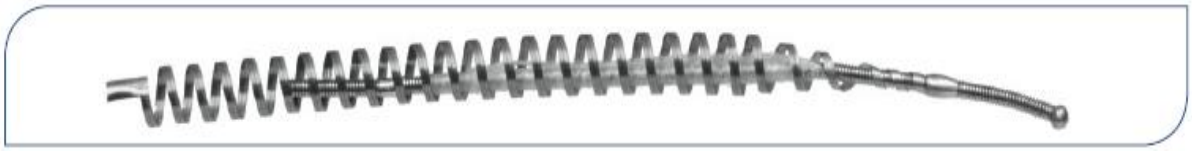
c. was wound down such that it was approximately 4cm in length and 0.8mm in diameter;

d. expanded up to approximately 2.0 mm in diameter when released;

e. figure 1a (below), obtained from the 2014 Essure Clinical Resource Physician Training Manual, is a depiction (not to scale) of the wound-down Essure Insert;

f. figure 1b (below), obtained from the 2014 Essure Clinical Resource Physician Training Manual, is a depiction (not to scale) of the expanded Essure Insert; and

g. a cross-section of the Outer Coil was rectangular with sharp corners.



16. A woman's fallopian tubes:

a. have soft tissue walls;

b. are a dynamic environment;

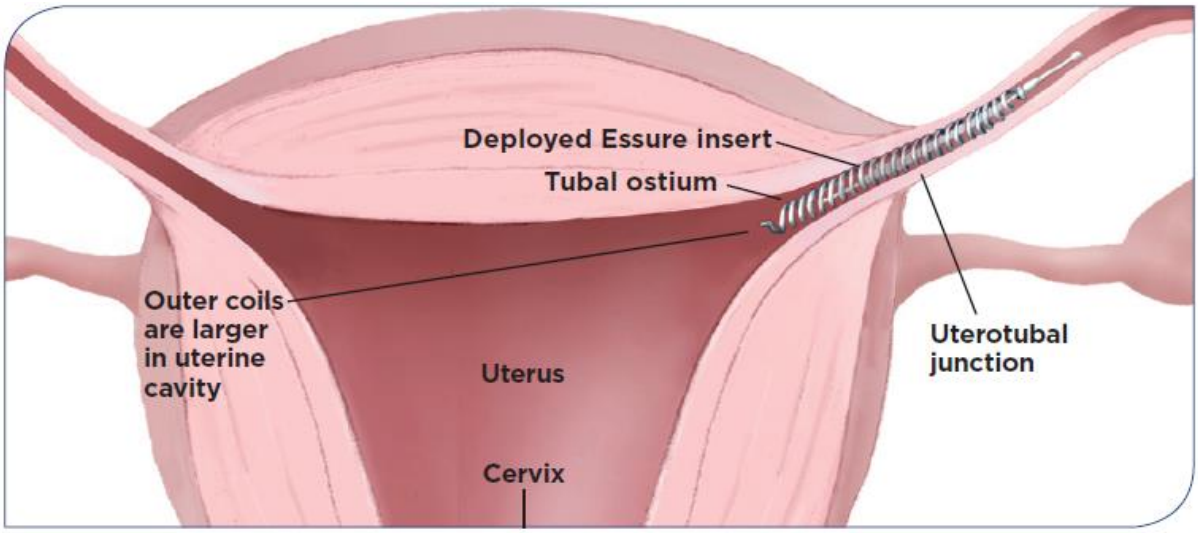
c. vary in size and diameter, depending on the individual; and

d. are peristaltic organs with movement in both directions.

17. The Essure Device was designed to operate as follows:

a. the wound-down Essure Insert was inserted through a woman's vagina and cervix and placed into her fallopian tube(s) and uterine cavity using the disposable delivery system and/or disposable introducer;

b. figure 1c (below), obtained from the 2014 Essure Clinical Resource Physician Training Manual, is a depiction (not to scale) of the intended placement of the Essure Insert in a fallopian tube and uterine cavity;



c. the Essure Insert was released from the disposable delivery system and/or disposable introducer and the Outer Coil expanded;

d. on expansion, the edges of the Outer Coil disrupted the soft tissue in the walls of the fallopian tube and the Essure Insert anchored in the fallopian tube;

e. the initial presence of the Essure Insert triggered an acute inflammatory response;

f. the continued presence of the Essure Insert triggered a foreign body and/or chronic inflammatory response;

g. the acute and chronic inflammatory responses and/or foreign body responses resulted in, among other things, tissue in-growth into the coils of the Essure Insert and around the PET fibres;

h. the tissue in-growth around the Essure Insert caused occlusion of the fallopian tube(s);

i. occlusion of the fallopian tube(s) prevented pregnancy; and

j. the Essure Insert operated as an intrauterine device.

D. ESSURE INSERT DEFECTS

18. At all material times, by reason of one or more of the matters alleged in paragraphs 14 to 17, the Essure Insert:

a. disrupted the inner layers of the uterine horn and/or the fallopian tubes;

b. caused initial acute inflammation in the fallopian tubes and/or endometrium;

c. caused ongoing chronic inflammation in the fallopian tubes and/or endometrium; and/or

d. incited a foreign body response to the Essure Insert in the fallopian tubes and/or endometrium and/or uterine cavity

(**the Inherent Defects**).

19. At all material times, by reason of one or more of the matters alleged in paragraphs 14 to 17 there was a risk that, following implantation, the Essure Insert:

a. would:

i. migrate, including into the abdominal cavity;

ii. be expulsed from the fallopian tube and/or uterus;

iii. break or fragment;

iv. corrode;

v. fatigue; and/or

b. would perforate the fallopian tube, uterus or other organs such as the bowel; and/or

c. would:

i. leach nickel or other metals into the body of the recipient; and/or

ii. exacerbate pelvic pain or menstrual bleeding conditions.

(**the Failure Defects**).

Particulars

Further particulars may be provided following discovery and the filing of expert evidence.

20. At all material times, by reason of one or more of the Inherent Defects and/or of the Failure Defects, there was a risk that the Essure Insert would cause:

a. pain or increased pain, including serious, chronic and/or recurring pain;

b. new, increased or worsened menorrhagia (heavy menstrual bleeding);

c. new, increased or worsened dysmenorrhoea (intense uterine cramping and pain); and/or

d. damage to internal organs.

(**the Adverse Events**).

Particulars

Further particulars may be provided following discovery and the filing of expert evidence.

21. Once anchored into the fallopian tube(s), the Essure Insert:

a. was not designed to be removed;

b. was unlikely to be able to removed without surgery; and

c. could likely only be removed by:

i) a salpingectomy (removal of fallopian tubes); or

ii) a hysterectomy (removal of uterus).

22. By reason of the matters alleged in the preceding paragraph, in the event that a woman experienced Adverse Events or other complications associated with the Essure Insert, she would be unable to resolve the Adverse Events or other complications through removal of the Essure Insert without abdominal surgery and likely the removal of one or more organs (**the Removal Limitation**).

E. INJURIES

23. By reason of one or more of the Inherent Defects, the Failure Defects and/or the Removal Limitation and/or the occurrence of one or more of the Adverse Events, the Plaintiff and group members suffered injuries as a result of implantation of the Essure Insert.

Particulars

(i) The Plaintiff refers to and repeats paragraphs 5 and 6 above in relation to her injuries.

(ii) Particulars for the group members will be provided following the trial of the common issues.

F. MARKETING MATERIALS

24. On various dates between 1999 and 2018:

a. Bayer Australia Ltd, Bayer AG, Bayer HealthCare LLC, Bayer Essure Inc, Gytech Pty Ltd and Australasian Medical and Scientific Limited published, or caused to be published, or held itself out as responsible for, marketing material (the **Marketing Material**) relating to the Essure Device that was directed at potential recipients of the Essure Device or Devices.

Particulars

(i) Across the period 1999 to 2018, information brochures relating to the Essure Device were published for provision to potential recipients of the Essure Device or Devices.

(ii) By reason of the roles of Bayer Australia Ltd, Bayer AG, Bayer HealthCare LLC, Bayer Essure Inc, Gytech Pty Ltd and Australasian Medical and Scientific Limited as alleged at paragraphs 7 to 12 regarding the manufacture, sponsorship pursuant to the Therapeutic Goods Administration (**TGA**), importation, supply, promotion and marketing of the Essure Device at the times alleged therein, it may be inferred that, in the times alleged, each of those defendants was responsible for the publication of the information brochures for provision to patients.

(iii) Further to (ii):

a. In or around 1999, Bayer Essure Inc (then Conceptus Inc) as manufacturer published or caused to be published in Australia a brochure relating to the Essure Device for provision to patients (**1999 Patient Information Booklet**).

b. In or around 2001, Bayer Essure Inc (then Conceptus Inc) as manufacturer published or caused to be published in Australia two brochures relating to the Essure Device for provision to patients (**2001 Patient Information Booklets**).

c. In or around 2002, Bayer Essure Inc (then Conceptus Inc) as manufacturer published or caused to be published in Australia a brochure relating to the Essure Device for provision to patients (**2002 Patient Information Booklet**).

d. In or around 2005, Bayer Essure Inc (then Conceptus Inc) as manufacturer published or caused to be published in Australia a brochure relating to the Essure Device for provision to patients (**2005 Patient Information Booklet**).

e. In or around 2009, Bayer Essure Inc (then Conceptus Inc) as manufacturer published or caused to be published in Australia a brochure relating to the Essure Device for provision to patients (**2009 Patient Information Booklet**).

f. In or around 2011, Bayer Essure Inc (then Conceptus Inc) as manufacturer, and Gytech Pty Ltd as sponsor published or caused to be published in Australia a brochure relating to the

Essure Device for provision to patients (**2011 Patient Information Booklet**).

g. In or around 2014, Bayer HealthCare LLC as manufacturer, Australasian Medical and Scientific Limited as sponsor, Bayer AG and/or Bayer Australia Ltd published or caused to be published in Australia a brochure relating to the Essure Device for provision to patients (**2014 Patient Information Booklet**).

(iv) from at least 2003 onwards, one or more of Bayer Essure Inc (previously Conceptus Inc), Bayer HealthCare LLC and Bayer AG published or caused to be published websites relating to the Essure Device which were accessible to patients in Australia at the URLs http://www.essure.com.au and http://www.essure.com.

(v) Further particulars may be provided following discovery.

25. The Marketing Material did not or did not adequately disclose the existence of the Inherent Defects, the Failure Defects, the risk of Adverse Events, and/or the Removal Limitation (the **Marketing Conduct**).

Particulars

(i) The Marketing Material did not contain express references to the Inherent Defects, the Failure Defects, the risk Adverse Events and/or the Removal Limitation.

(ii) To the extent that the Marketing Material made any references to any one or more of the Inherent Defects, the Failure Defects, the Adverse Events and/or the Removal Limitation, any risks were downplayed and/or were represented as rare and/or temporary.

(iii) The general impression given by the Marketing Material was that the Essure Device was safe, gentle and had a low impact on the body.

(iv) There was no or no adequate reference to the Essure Insert operating as an intrauterine device nor to any increased risks associated with the Essure Device and any pain or bleeding conditions.

(v) Further particulars to be provided after discovery.

G. REGULATORY HISTORY

26. From around 1999 until around 2018, the Essure Device was supplied in Australia.

27. On 23 July 2010, the Essure Device was placed on the ARTG as a 'Class III' 'Medical Device' in accordance with the *TG Act*.

Governmental Alerts and Warnings in Australia

28. On 30 August 2017, Australasian Medical and Scientific Limited, in consultation with the TGA, issued a 'hazard alert' in respect of the Essure Device (the **Essure Hazard Alert**).

Particulars

(i) The hazard alert is recorded on the TGA website at https://www.tga.gov.au/alert/essure-contraceptive-device.

(ii) A 'hazard alert' is issued for an implanted therapeutic good with a deficiency or potential deficiency relating to its safety, quality, performance or efficacy because implanted goods (medical devices or biologicals or medicines) cannot be recalled. The hazard alert will typically contain precautionary information issued to healthcare professionals about issues or deficiencies relating to an implanted therapeutic good and advice about the ongoing management of affected patients. A hazard alert may also be issued in conjunction with a recall notice for affected products that have not yet been implanted: see https://www.tga.gov.au/about-australian-recall-actions.

29. The Essure Hazard Alert stated, *inter alia*, that:

a. some patients who had the device implanted may not have been fully informed of the possible device risks before choosing to have the Essure Device implanted;

b. there had been reports of changes in menstrual bleeding, unintended pregnancy, chronic pain, perforation, migration of the device, and allergy/hypersensitivity or immune-type reactions as a result of the Essure Device; and

c. some of the reports referred to in the preceding subparagraph were considered serious and resulted in removal of the Essure Device, which involved abdominal surgery.

30. In about August 2017, Australasian Medical and Scientific Limited 'recalled' unused stock of the Essure Device in Australia and withdrew the device from the Australian market.

Particulars

(i) The recall and withdrawal is recorded on the TGA website at https://www.tga.gov.au/alert/essure-contraceptive-device.

(ii) A 'recall' is conducted to remove therapeutic goods permanently from the market or from use when there are deficiencies or potential deficiencies in safety, quality, efficiency, performance or presentation:https://www.tga.gov.au/about-australian-recall-actions.

31. The Essure Device has not been supplied in Australia following the recall and withdrawal referred to in the preceding paragraph.

32. On 9 February 2018, the TGA removed the Essure Device from the ARTG.

33. In or about October 2018, the South Australian Government published documents titled "Essure contraceptive device: Frequently Asked Questions", "Information for General Practitioners: Management of patients with the Essure implant contraceptive device" and "Essure Patient Information Brochure", regarding reports of adverse events and complications associated with the Essure Device.

34. In or about December 2018, the Department of Health, Western Australia, published a document titled "Essure contraceptive device FAQs", regarding reports of adverse events and complications associated with the Essure Device.

35. In or about August 2019, the Queensland Government published documents titled "Patient information sheet: Essure permanent contraception device" and "Clinician information sheet: Essure permanent contraception device", regarding reports of adverse events and complications associated with the Essure Device.

Governmental Alerts and Warnings Overseas and Withdrawal of the Essure Device

36. On 29 February 2016, the United States Food and Drug Administration (**FDA**) published a document titled "FDA takes additional action to better understand safety of Essure, inform patients of potential risks", regarding reports of adverse events and complications associated with the Essure Device and noting that the agency intended to require a mandatory boxed warning on the product.

37. On 31 May 2016, Health Canada published a document titled "Essure (permanent birth control system) – Risk of Serious Complications", regarding reports of adverse events and complications associated with the Essure Device and noting that the product labelling for Essure would be updated to include a new "Boxed Warning" section to reflect this safety information.

38. On 31 October 2016, the FDA published a document titled "Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization" (**Second FDA Alert**).

39. The Second FDA Alert:

    a. reported adverse events and complications associated with the Essure Device;

b. required that a boxed warning be included on labelling of the Essure Device with recommended text as follows:

i) "WARNING: Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System for Permanent Birth Control during discussion of the benefits and risks of the device."

c. required that a patient checklist be added to the labelling.

40. Following implementation of the measures set out in the Second FDA Alert, there was an approximately 70 percent decline in sales of the Essure Device in the United States of America.

41. On 9 April 2018, the FDA issued an order restricting the sale and distribution of the Essure Device.

Particulars

(i) In the FDA news release titled 'FDA restricts sale and distribution of Essure to protect women and to require that patients receive risk information' and dated 9 April 2018, the FDA:

a. stated that, despite the measures set out in the Second FDA Alert, some patients were not receiving information about the risks associated with the Essure Device; and

b. therefore, implemented further measures to ensure that prospective patients were informed of the risks associated with the Essure Device.

42. By the end of 2018, the Essure Device was no longer sold or distributed globally by any entity within the Bayer group.

Particulars

(i) The Plaintiff refers to:

a. a news release from 'Bayer' titled 'Bayer to voluntarily discontinue U.S. sales of Essure at end of 2018 for business reasons' and dated 20 July 2018, which stated that 'Bayer' would discontinue sale and distribution of the Essure Device in the United States of America from 31 December 2018; and

b. an article published in the Washington Post titled 'Sales of Essure birth control implant to be halted by Bayer; U.S. last to

sell controversial device' and dated 21 July 2018, in which it was reported that in September 2017 'Bayer' had announced that it was ending sales of the Essure Device outside the United States of America.

(ii) Further particulars may be provided following discovery.

H. SUPPLY AND ACQUISITION OF THE ESSURE DEVICE

43. In the period from around 1999 until around 31 December 2018, the Plaintiff and group members received an implant or implants of the Essure Device or Essure Devices.

44. Bayer Essure Inc and/or Bayer HealthCare LLC supplied the Essure Device:

a. from around 1999 until around 2007, to Bepen Pty Ltd;

b. further and in the alternative to a., from around 1999 until around 2006, to Conceptus (Australia) Pty Ltd;

c. from around 2007 until around 2010, to N. Stenning & Co Pty Ltd (in liq);

d. from around 2010 until the end of 2015, to Gytech Pty Ltd;

e. from around 2015 until around 2017, to Australasian Medical and Scientific Limited; and

f. from around 2017 until 2018, to Bayer Australia Ltd;

for importation into and distribution in Australia.

45. The supply of the Essure Device by Bayer Essure Inc and/or Bayer HealthCare LLC to any or all of Bepen Pty Ltd, Conceptus (Australia) Pty Ltd, N. Stenning & Co Pty Ltd (in liq), Gytech Pty Ltd, Australasian Medical and Scientific Limited and Bayer Australia Ltd (together, the **Australian Suppliers**) was:

a. for resupply to consumers; and

b. in trade or commerce between Australia and places outside Australia.

Particulars

As to subparagraph b., the Essure Devices were manufactured by Bayer Essure Inc and/or Bayer HealthCare LLC outside Australia and imported into Australia for supply to the Australian Suppliers.

46. From:

    a. around 1999 until around 2007, Bepen Pty Ltd;

    b. further and in the alternative to a., around 1999 until around 2006, Conceptus (Australia) Pty Ltd;

    c. around 2007 until around 2010, N. Stenning & Co Pty Ltd (in liq);

    d. around 2010 until the end of 2015, Gytech Pty Ltd;

    e. around 2015 until around 2017, Australasian Medical and Scientific Limited; and

    f. around 2017 until 2018, Bayer Australia Ltd;

    imported into Australia the Essure Device and supplied the devices to treating hospitals or doctors and/or pharmacies (the **Intermediary Suppliers**) for resupply to consumers.

47. The Plaintiff and each group member were supplied with the Essure Device by an Intermediary Supplier.

48. The supply of the Essure Device to Intermediary Suppliers by the Australian Suppliers was in trade or commerce within Australia.

49. The supply of the Essure Device to the Plaintiff and each group member by the Intermediary Suppliers was in trade or commerce within Australia.

50. The price paid by the Plaintiff and group members for the Essure Devices, further and alternatively the price at which at the time of acquisition the Essure Devices could have been acquired by the Plaintiff and group members was less than $40,000.

51. By reason of the matters alleged in paragraph 53 below, the Essure Devices were ordinarily acquired for personal use.

52. By reason of the matters alleged in the preceding two paragraphs, the Essure Devices were supplied to the Plaintiff and group members as consumers within the meaning of section 4B of the *Trade Practices Act* and section 3 of the *Australian Consumer Law*.

53. The purpose for which the Essure Devices were commonly acquired and supplied, and the purpose for which one or more of the Essure Devices were acquired by the Plaintiff and group members, was to prevent pregnancy through implantation of a mechanical insert that could be left permanently in the body (the **Essure Device Purpose**).

Particulars

(i) The Plaintiff acquired Essure Devices, which were implanted in accordance with paragraph 4 above, because she was seeking a permanent contraceptive.

(ii) Particulars for group members will be provided following the trial of the common issues.

54. By reason of the matters alleged in paragraph 51, the Essure Devices were goods within the meaning of sections 4 and 74A(2)(a) of the *Trade Practices Act* and section 2 of the *Australian Consumer Law.*

I. STATUTORY BREACHES

Acceptable Quality

55. By reason of all or any of the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation, the Essure Devices acquired by the Plaintiff and group members:

a. were not as fit for the Essure Device Purpose;

b. were not as free from defects; and/or

c. were not as safe,

as would be expected by a reasonable consumer.

Particulars

(i) The Plaintiff refers to the matters alleged at paragraphs 18 to 25.

(ii) Further particulars may be provided following discovery.

56. By reason of the matters alleged in the previous paragraph, the Essure Devices acquired by the Plaintiff and group members:

a. were not of merchantable quality within the meaning of sections 74D(1) and 74D(3) of the *Trade Practices Act*; and/or

b. were not of acceptable quality within the meaning of section 54 of the *Australian Consumer Law*.

57. It was reasonably foreseeable that loss or damage would be suffered by the Plaintiff and group members as a result of the Inherent Defects, the Failure Defects, the risk of Adverse Events and/or the Removal Limitation.

Particulars

(i) The Plaintiff refers to:

1. The matters alleged in paragraphs 15, 16 and 17, such that each of the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation were inherent in the Essure Device.
2. The results of clinical trials which were published from at least about 2001, or other studies such as the Study 16974 and the SUCCES II study into implantation or use of the Essure Device which showed that the device carried with it the risk of adverse effects including perforation, migration, pain, cramping and bleeding.
3. Scientific literature or other information or material linking the Adverse Events and other complications to the Essure Device which was available to the Defendants.
4. Scientific literature or other information or material relating more generally to matters identified in the Inherent Defects and Failure Defects and their link to the risk of the Adverse Events and other complications which was available to the Defendants.

(ii) Further particulars may be provided following discovery.

Safety Defect

58. By reason of all or any of the Inherent Defects, the Failure Defects, the Adverse Events and the Removal Limitation, along with the Marketing Conduct, the safety of the Essure Devices acquired by the Plaintiff and group members was not such as persons generally are entitled to expect.

Particulars

(i) The Plaintiff refers to the matters alleged at paragraphs 18 to 25.

(ii) Further particulars may be provided following discovery.

59. By reason of the matters alleged in the preceding paragraph, the Essure Devices had a defect within the meaning of section 75AC of the *Trade Practices Act* and/or a safety defect within the meaning of section 9 of the *Australian Consumer Law*.

Loss and Damage

60. The Plaintiff and group members have suffered loss and damage by reason of:

    a. the Essure Devices not being of merchantable quality and/or acceptable quality, as alleged in paragraph 56; and/or

    b. the Essure Devices having a defect and/or safety defect as alleged in paragraphs 58 and 59.

Particulars

(i) The Plaintiff and group members received the Essure Device or Devices and had the Essure Insert implanted.

(ii) The Plaintiff refers to paragraphs 5, 6 and 23 in relation to her injuries.

(iii) Particulars for the group members will be provided following the trial of the common issues.

61. In the premises, Bayer Australia Ltd, Bayer AG, Bayer HealthCare LLC, Bayer Essure Inc, Gytech Pty Ltd and Australasian Medical and Scientific Limited are liable to compensate the Plaintiff and group members for their loss and damage pursuant to:

    a. Sections 271 and/or 272 of the *Australian Consumer Law*; and/or

    b. Section 138 of the *Australian Consumer Law*.

62. In the premises, Bayer Essure Inc is liable to compensate the Plaintiff and group members for their loss and damage pursuant to:

    a. Section 74D(1) of the *Trade Practices Act*; and/or

    b. Section 75AD of the *Trade Practices Act*.

J. LIABILITY OF BAYER ESSURE INC IN NEGLIGENCE

Duty of Care

63. Bayer Essure Inc (previously Conceptus Inc) owed the Plaintiff and group members who received the Essure Device or Devices in the period between about 1999 and about 2018 a duty to exercise reasonable care to prevent harm arising from the Essure Device or Devices.

Particulars

(i) The Plaintiff and those group members and Bayer Essure Inc were in the relationship of manufacturer and consumer.

(ii) The relevant product was a medical device that was to be implanted in the body and to remain there permanently.

64. Further, at all material times Bayer Essure Inc (previously Conceptus Inc) knew or ought to have known that the Essure Device had the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation.

Particulars

(i) The Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation were or gave rise to risks of which Bayer Essure Inc knew or ought to have known by reason of the matters set out in the particulars to paragraph 57.

(ii) Further particulars may be provided following discovery.

65. At all material times, it was reasonably foreseeable to Bayer Essure Inc (previously Conceptus Inc) that individuals:

a. who were considering a procedure to implant the Essure Device or Devices may suffer harm arising from the Essure Device or Devices if they were not warned or not adequately warned about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation; and

b. who had a procedure to implant the Essure Device or Devices may suffer harm or further harm arising from the Essure Device or Devices if information disclosing the Inherent Defects, Failure Defects and/or the risk of Adverse Events was not made available to those individuals.

66. In the premises, at all material times, Bayer Essure Inc owed the Plaintiff and group members, a duty to inform them of the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation to prevent harm or prevent further harm arising from the Essure Device.

Standard of care

67. At all material times:

a. the Inherent Defects, the Failure Defects, the Adverse Events and/or the Removal Limitation were or gave rise to risks of harm which were foreseeable; and

Particulars

(i) The Inherent Defects, the Failure Defects, the Adverse Events and the Removal Limitation were or gave rise to risks of which Bayer Essure Inc knew or ought to have known by reason of the matters set out in the particulars to paragraph 57;

(ii) Further particulars may be provided following discovery.

b. the Inherent Defects, Failure Defects, Adverse Events and/or Removal Limitation were or gave rise to risks which were not insignificant.

Particulars

(i) The Plaintiff refers to and repeats the particulars to the preceding subparagraph.

(ii) The Plaintiff says further that:

1. for the Plaintiff and some group members, the Adverse Events, caused by one or more of the Inherent Defects and Failure Defects, were sufficiently significant to require a surgical procedure to remove the Essure Insert or Inserts to alleviate the Adverse Events;

2. government health agencies published warnings and alerts about, required that warnings be provided with, and restricted or ceased the sale of the Essure Device, as alleged in paragraphs 26 to 42;

3. sales of the Essure Device declined by approximately 70 percent in the USA following the inclusion of a boxed warning on the label of the Essure Device and the requirement that a patient checklist be added to the labelling; and

4. the nature of the Removal Limitation is inherently not insignificant.

(iii) Further particulars may be provided following discovery.

68. At all material times:

a. the probability of harm resulting from the Inherent Defects, the Failure Defects, the risk of Adverse Events and/or the Removal Limitation if care was not taken was not insignificant; and

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67.

b. the likely seriousness of harm resulting from the Inherent Defects, Failure Defects, the risk of Adverse Events and/or Removal Limitation was significant.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67(b).

69. By reason of the matters alleged in the preceding two paragraphs, a reasonable person in the position of Bayer Essure Inc would have:

    a. not designed, developed or manufactured the Essure Device; and/or

    b. not distributed or supplied for sale in Australia the Essure Device.

70. Further, and alternatively, a reasonable person in the position of Bayer Essure Inc would have taken reasonable care to ensure that:

    a. the Essure Device was promoted or marketed to potential recipients of the Essure Device with warnings or adequate warnings about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation.

Particulars

(i) Any information or brochure relating to the Essure Device to be provided to prospective patients who are considering a procedure to implant the Essure Device or Devices should have clearly and prominently disclosed the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation.

(ii) The Plaintiff refers to the boxed warning alleged at paragraph 39(b) as an example of a warning that includes elements of the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation.

(iii) Further particulars may be provided following discovery.

    b. information disclosing the Inherent Defects, the Failure Defects and the risk of Adverse Events was made available to persons who had already received the Essure Device.

Particulars

(i) Any information or brochure relating to the Essure Device, including any website, should have clearly and prominently disclosed the Inherent Defects, the Failure Defects and the risk of Adverse Events.

(ii) The Plaintiff refers to the boxed warning alleged at paragraph 39(b) as an example of a warning that includes elements of the Inherent Defects, the Failure Defects and/or the risk of Adverse Events.

(iii) Further particulars may be provided following discovery.

Breach of duty

71. In breach of its duty of care, Bayer Essure Inc:

    a. designed, developed and manufactured; and

    b. distributed or supplied for sale in Australia

the Essure Device with the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation.

72. In breach of its duty of care, Bayer Essure Inc:

    a. promoted or marketed the Essure Device without warning or without adequate warning about the Inherent Defects, the Failure Defects, the risk of Adverse Events and/or the Removal Limitation; and/or

Particulars

The Plaintiff refers to and repeats the particulars to paragraphs 24 and 25.

    b. failed to make available to the Plaintiff and group members who had already received the Essure Device information disclosing the Inherent Defects, the Failure Defects and/or the risk of Adverse Events.

Particulars

(i) The Plaintiff refers to and repeats the particulars to paragraph 24 and 25.

(ii) Bayer Essure Inc did not take any or any adequate additional steps to provide the Plaintiff and group members with any additional information.

Causation

73. As a result of the breaches alleged in paragraph 71, the Plaintiff and group members who had received the Essure Device or Devices in the period between about 1999 and about 2018 suffered harm and/or loss and damage.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 23.

74. As a result of the breach alleged in paragraph 72(a), the Plaintiff and group members who had received the Essure Device or Devices in the period between about 1999 and about 2018:

a. underwent procedures for the implant of the Essure Insert in their fallopian tubes and uterine cavity; and

b. suffered harm and/or loss and damage by reason thereof.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 23.

75. As a result of the breach alleged in paragraph 72(b), the Plaintiff and group members who had received the Essure Device or Devices in the period between about 1999 and about 2018 delayed taking action to address the harm and thereby suffered further harm.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 23.

K. LIABILITY OF BAYER HEALTHCARE LLC IN NEGLIGENCE

Duty of Care

76. At all material times from about 2014, Bayer HealthCare LLC owed group members who received the Essure Device or Devices in the period from about 2014 a duty to exercise reasonable care to prevent harm arising from the Essure Device or Devices.

Particulars

(i) Those group members and Bayer HealthCare LLC were in the relationship of manufacturer and consumer.

(ii) The relevant product was a medical device that was to be implanted or had been implanted in the body and to remain there permanently.

77. Further, at all material times from about 2014, Bayer HealthCare LLC knew or ought to have known that the Essure Device had the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation.

Particulars

(i) The Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation were or gave rise to risks of which Bayer HealthCare LLC knew or ought to have known by reason of the matters set out in the particulars to paragraph 57.

(ii) Further particulars may be provided following discovery.

78. At all material times from about 2014, it was reasonably foreseeable to Bayer HealthCare LLC that individuals:

a. who were considering a procedure to implant the Essure Device or Devices may suffer harm arising from the Essure Device or Devices if they were not warned or not adequately warned about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation; and

b. who had a procedure to implant the Essure Device or Devices may suffer harm or further harm arising from the Essure Device or Devices if information disclosing the Inherent Defects, Failure Defects and/or the risk of Adverse Events was not made available to those individuals.

79. In the premises, at all material times from about 2014, Bayer HealthCare LLC owed the Plaintiff and group members, whether they had received the Essure Device or Devices prior to or after about 2014, a duty to inform them of the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation to prevent harm or prevent further harm arising from the Essure Device.

Standard of care

80. At all material times:

a. the Inherent Defects, the Failure Defects, the Adverse Events and/or the Removal Limitation were or gave rise to risks of harm which were foreseeable; and

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 57.

b. the Inherent Defects, Failure Defects, the Adverse Events and/or Removal Limitation were or gave rise to risks which were not insignificant.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67.

81. At all material times:

a. the probability of harm resulting from the Inherent Defects, the Failure Defects, the Adverse Events and/or the Removal Limitation if care was not taken was not insignificant; and

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67(a).

b. the likely seriousness of harm resulting from the Inherent Defects, Failure Defects, the Adverse Events and/or Removal Limitation was significant.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67(b).

82. By reason of the matters alleged in the preceding two paragraphs, a reasonable person in the position of Bayer HealthCare LLC would have:

a. not designed, developed or manufactured the Essure Device; and/or

b. not distributed or supplied for sale in Australia the Essure Device.

83. Further, and alternatively, a reasonable person in the position of Bayer HealthCare LLC would have taken reasonable care to ensure that:

a. the Essure Device was promoted or marketed to potential recipients of the Essure Device with warnings or adequate warnings about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 70(a).

b. information disclosing the Inherent Defects, the Failure Defects and the risk of Adverse Events was made available to persons who had already received the Essure Device.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 70(b).

Breach of duty

84. In breach of its duty of care, Bayer HealthCare LLC:

a. designed, developed and manufactured; and

b. distributed or supplied for sale in Australia,

the Essure Device with the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation.

85. In breach of its duty of care, Bayer HealthCare LLC:

a. promoted or marketed the Essure Device without warning or without adequate warning about the Inherent Defects, the Failure Defects, the Adverse Events and the Removal Limitation; and/or

Particulars

The Plaintiff refers to and repeats the particulars to paragraphs 24 and 25.

b. failed to make available to the Plaintiff and group members who had already received the Essure Device information disclosing the Inherent Defect the Failure Defect and/or the risk of Adverse Events.

Particulars

(i) The Plaintiff refers to and repeats the particulars to paragraphs 24 and 25.

(ii) Bayer HealthCare LLC did not take any or any adequate additional steps to provide the Plaintiff and group members with any additional information.

Causation

86. As a result of the breaches alleged in paragraph 84, the group members who had received the Essure Device or Devices from about 2014 suffered harm and/or loss and damage.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 23.

87. As a result of the breaches alleged in paragraph 85(a), the group members who had received the Essure Device or Devices from about 2014:

a. underwent procedures for the implant of the Essure Insert in their fallopian tubes and uterine cavity; and

b. suffered harm and/or loss and damage by reason thereof.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 23.

88. As a result of the breaches alleged in paragraph 85(b), the Plaintiff and group members, whether they had received the Essure Device or Devices prior to or after about 2014, delayed taking action to address the harm and thereby suffered further harm.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 23.

L. LIABILITY OF GYTECH PTY LTD IN NEGLIGENCE

89. At all material times from about 2010 until the end of 2015, Gytech Pty Ltd knew or ought to have known that the Essure Device had the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation.

Particulars

(i) The Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation were or gave rise to risks of which Gytech Pty Ltd knew or ought to have known by reason of the matters set out in the particulars to paragraph 57.

(ii) Further particulars may be provided following discovery.

90. At all material times from about 2010 onwards, it was reasonably foreseeable to Gytech Pty Ltd that individuals:

a. who were considering a procedure to implant the Essure Device or Devices may suffer harm arising from the Essure Device or Devices if they were not warned or not adequately warned about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation; and

b. who had a procedure to implant the Essure Device or Devices may suffer harm or further harm arising from the Essure Device or Devices if information disclosing the Inherent Defects, Failure Defects and/or the risk of Adverse Events was not made available to those individuals.

91. In the premises, from about 2010 onwards, Gytech Pty Ltd owed the Plaintiff and each group member, whether they had received the Essure Device or Devices prior to or after about 2010, a duty to inform them of the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation to prevent harm or prevent further harm arising from the Essure Device.

Standard of care

92. At all material times:

a. the Inherent Defects, the Failure Defects, the Adverse Events and/or the Removal Limitation were or gave rise to risks of harm which were foreseeable; and

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 57.

b. the Inherent Defects, Failure Defects, Adverse Events and/or the Removal Limitation were risks which were not insignificant.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67.

93. At all material times:

a. the probability of harm resulting from the Inherent Defects, Failure Defects, the risk of Adverse Events and/or the Removal Limitation if care was not taken was not insignificant; and

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67(a).

b. the likely seriousness of harm resulting from the Inherent Defects, Failure Defects, the risk of Adverse Events and/or the Removal Limitation was significant.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67(b).

94. By reason of the matters alleged in the preceding two paragraphs, a reasonable person in the position of Gytech Pty Ltd would have taken reasonable steps to ensure that:

a. the Essure Device was promoted or marketed to potential recipients of the Essure Device with warnings or adequate warnings about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation; and

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 70(a).

b. information disclosing the Inherent Defects, the Failure Defect and the risk of Adverse Events was made available to persons who had already received the Essure Device.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 70(b).

Breach of duty

95. In breach of its duty of care, Gytech Pty Ltd:

a. promoted or marketed the Essure Device without warning or without adequate warning about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation; and/or

Particulars

The Plaintiff refers to and repeats the particulars to paragraphs 24 and 25.

b. failed to make available to the Plaintiff and group members who had already received the Essure Device information disclosing the Inherent Defects, the Failure Defects and/or the risk of Adverse Events.

Particulars

(i) The Plaintiff refers to and repeats the particulars to paragraphs 24 and 25.

(ii) Gytech Pty Ltd did not take any or any adequate additional steps to provide the Plaintiff and group members with any additional information.

Causation

96. As a result of the breaches alleged in paragraph 95(a), the Plaintiff and group members who received the Essure Device or Devices in the period from about 2010 until about 2015:

    a. underwent procedures for the implant of the Essure Insert in their fallopian tubes and uterine cavity; and

    b. suffered harm and/or loss and damage by reason thereof.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 23.

97. As a result of the breaches alleged in paragraph 95(b), the Plaintiff and group members, whether they received the Essure Device or Devices prior to or after 2010, delayed taking action to address the harm and thereby suffered further harm.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 23.

M. LIABILITY OF AUSTRALASIAN MEDICAL AND SCIENTIFIC LIMITED IN NEGLIGENCE

98. At all material times from about 2015 onwards, Australasian Medical and Scientific Limited knew or ought to have known that the Essure Device had the Inherent Defects, the the Failure Defects, the risk of Adverse Events and the Removal Limitation.

Particulars

(i) The Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation were or gave rise to risks of which Australasian Medical and Scientific Limited knew or ought to have known by reason of the matters set out in the particulars to paragraph 57.

(ii) Further particulars may be provided following discovery.

99. At all material times from about 2015, it was reasonably foreseeable to Australasian Medical and Scientific Limited that individuals:

    a. who were considering a procedure to implant the Essure Device or Devices may suffer harm arising from the Essure Device or Devices if they were not warned or

not adequately warned about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation; and

b. who had a procedure to implant the Essure Device or Devices may suffer harm or further harm arising from the Essure Device or Devices if information disclosing the Inherent Defects, the Failure Defects and/or the risk of Adverse Events was not made available to those individuals.

100. In the premises, from about 2014 onwards, Australasian Medical and Scientific Limited owed the Plaintiff and each group member, whether they received the Essure Device or Devices prior to or after 2014, a duty to inform them of the Inherent Defects, the Failure Defects, the Adverse Events and the Removal Limitation to prevent harm or prevent further harm arising from the Essure Device.

Standard of care

101. At all material times:

a. the Inherent Defects, the Failure Defects, the Adverse Events and/or the Removal Limitation were or gave rise to risks of harm which were foreseeable; and

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 57.

b. the Inherent Defects, Failure Defects, the Adverse Events and/or Removal Limitation were risks which were not insignificant.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67.

102. At all material times:

a. the probability of harm resulting from the Inherent Defects, Failure Defects, the risk of Adverse Events and/or the Removal Limitation if care was not taken was not insignificant; and

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67(a).

b. the likely seriousness of harm resulting from the Inherent Defects, the Failure Defects, the risk of Adverse Events and/or the Removal Limitation was significant.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67(b).

103. By reason of the matters alleged in the preceding two paragraphs, a reasonable person in the position of Australasian Medical and Scientific Limited would have taken reasonable steps to ensure that:

a. the Essure Device was promoted or marketed to potential recipients of the Essure Device with warnings or adequate warnings about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 70(a).

b. information disclosing the Inherent Defects, the Failure Defects and/or the risk of Adverse Events was made available to persons who had already received the Essure Device.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 70(b).

Breach of duty

104. In breach of its duty of care, Australasian Medical and Scientific Limited:

a. promoted or marketed the Essure Device without warning or without adequate warning about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation; and/or

Particulars

The Plaintiff refers to and repeats the particulars to paragraphs 24 and 25.

b. failed to make available to the Plaintiff and group members who had already received the Essure Device information disclosing the Inherent Defects, the Failure Defects and/or the risk of Adverse Events.

Particulars

(i) The Plaintiff refers to and repeats the particulars to paragraphs 24 and 25.

(ii) Australian Medical and Scientific Limited did not take any or any adequate additional steps to provide the Plaintiff and group members with any additional information.

Causation

105. As a result of the breaches alleged in paragraph 104, group members who received the Essure Device or Devices in the period from about 2015 until about 2017:

a. underwent procedures for the implant of the Essure Insert in their fallopian tubes and uterine cavity; and

b. suffered harm and/or loss and damage by reason thereof.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 23.

106. As a result of the breaches alleged in paragraph 104, the Plaintiff and group members, whether they received the Essure Device or Devices prior to or after 2015, delayed taking action to address the harm and thereby suffered further harm.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 23.

N. LIABILITY OF BAYER AUSTRALIA LTD IN NEGLIGENCE

107. At all material times from about 2014, Bayer Australia Ltd knew or ought to have known that the Essure Device had the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation.

Particulars

(i) The Inherent Defects, the Failure Defects, the Adverse Events and the Removal Limitation were or gave rise to risks of which Bayer Australia Ltd knew or ought to have known by reason of the matters set out in the particulars to subparagraph 57.

(ii) Further particulars may be provided following discovery.

108. At all material times from about 2014, it was reasonably foreseeable to Bayer Australia Ltd that individuals:

a. who were considering a procedure to implant the Essure Device or Devices may suffer harm arising from the Essure Device or Devices if they were not warned or not adequately warned about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation; and

b. who had a procedure to implant the Essure Device or Devices may suffer harm or further harm arising from the Essure Device or Devices if information disclosing the Inherent Defects, the Failure Defects and/or the risk of Adverse Events was not made available to those individuals.

109. In the premises, Bayer Australia Ltd owed the Plaintiff and each group member a duty to inform them of the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation to prevent harm or prevent further harm arising from the Essure Device.

Standard of care

110. At all material times:

a. the Inherent Defects, the Failure Defects, the Adverse Events and/or the Removal Limitation were or gave rise to risks of harm which were foreseeable; and

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 57.

b. the Inherent Defects, Failure Defects, the Adverse Events and/or the Removal Limitation were risks which were not insignificant.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67.

111. At all material times:

a. the probability of harm resulting from the Inherent Defects, Failure Defects, the risk of Adverse Events and/or the Removal Limitation if care was not taken was not insignificant; and

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67(a).

b. the likely seriousness of harm resulting from the Inherent Defects, Failure Defects, the risk of Adverse Events and/or the Removal Limitation was significant.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 67(b).

112. By reason of the matters alleged in the preceding two paragraphs, a reasonable person in the position of Bayer Australia Ltd would have taken reasonable steps to ensure that:

a. the Essure Device was promoted or marketed to potential recipients of the Essure Device with warnings or adequate warnings about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 70(a).

b. information disclosing the Inherent Defects, the Failure Defects and/or the risk of Adverse Events was made available to persons who had already received the Essure Device.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 70(b)

Breach of duty

113. In breach of its duty of care, Bayer Australia Ltd:

a. promoted or marketed the Essure Device to the Plaintiff and group members without warning or without adequate warning about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation; and/or

Particulars

The Plaintiff refers to and repeats the particulars to paragraphs 24 and 25.

b. failed to make available to the Plaintiff and group members who had already received the Essure Device information disclosing the Inherent Defects, Failure Defects and/or the risk of Adverse Events.

Particulars

(i) The Plaintiff refers to and repeats the particulars to paragraphs 24 and 25.

(ii) Bayer Australia Ltd did not take any or any adequate additional steps to provide the Plaintiff and group members with any additional information.

Causation

114. As a result of the breaches alleged in paragraph 113, the group members who received the Essure Device or Devices in the period from about 2014:

a. underwent procedures for the implant of the Essure Insert in their fallopian tubes and uterine cavity; and

b. suffered harm and/or loss and damage by reason thereof.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 23.

115. As a result of the breaches alleged in paragraph 113, the Plaintiff and group members who received the Essure Device or Devices delayed taking action to address the harm and thereby suffered further harm.

Particulars

The Plaintiff refers to and repeats the particulars to paragraph 23.

O. COMMON QUESTIONS OF LAW OR FACT

The questions of law or fact common to the claims of the Plaintiff and each of the Group Members or subgroup members are:

116. Were each of the Defendants manufacturers of the Essure Device within the meaning of section 74A of the *Trade Practices Act* and/or section 7 of the *Australian Consumer Law* (and during what time periods)?

117. Were the following present in the Essure Device (as pleaded):

a. the Inherent Defects;

b. the Failure Defects;

c. the risk of Adverse Events;

d. the Removal Limitation?

118. Was the Marketing Material published or caused to be published by each of the Defendants (and during which time periods)?

119. Did the Marketing Material disclose or adequately disclose (and during which time periods) the existence of:

a. the Inherent Defects;

b. the Failure Defects;

c. the risk of Adverse Events; and/or

d. the Removal Limitation?

120. What was the regulatory history of the Essure Device?

121. Did Bayer Essure Inc and/or Bayer HealthCare LLC (and during which time periods):

a. supply the Essure Device for importation and distribution from outside Australia into Australia;

b. re-supply by Intermediary Suppliers to consumers within Australia?

122. Were the Plaintiff and group members consumers within the meaning of section 4B of the *Trade Practices Act* and section 3 of the *Australian Consumer Law*?

123. Was the purpose for which the Essure Devices were commonly acquired and supplied, and the purpose for which one or more of the Essure Devices was acquired by the Plaintiff and group members, to prevent pregnancy through implantation of a mechanical insert that could be left permanently in the body?

124. Were the Essure Devices:

a. not of merchantable quality within the meaning of section 74D(1) and 74D(3) of the *Trade Practices Act*; and/or

b. not of acceptable quality within the meaning of section 54 of the *Australian Consumer Law*?

125. Did the Essure Devices have a safety defect within the meaning of:

a. section 75AC of the *Trade Practices Act*;

b. section 9 of the *Australian Consumer Law?*

126. Was it reasonably foreseeable (and during which time periods) that loss or damage would be suffered by the Plaintiff and group members as a result of the Inherent Defects, the Failure Defects, the risk of Adverse Events and/or the Removal Limitation?

127. Did Bayer Essure Inc owe the Plaintiff and group members:

a. a duty to exercise reasonable care to prevent harm from the Essure Device or Devices?

b. a duty to inform them of the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation to prevent harm or prevent further harm arising from the Essure Device?

128. Did Bayer HealthCare LLC owe the Plaintiff and group members:

a. who received the Essure Device or Devices in the period between about 2014 and 2018, a duty to exercise reasonable care to prevent harm from the Essure Device or Devices?

b. a duty to inform them of the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation to prevent harm or prevent further harm arising from the Essure Device (whether they had received the Essure Device or Devices prior to or after about 2014)?

129. Did Gytech Pty Ltd owe the Plaintiff and each Group Member a duty to inform them of the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation to prevent harm or prevent further harm arising from the Essure Device?

130. Did Australian Medical and Scientific Limited owe the Plaintiff and each Group Member a duty to inform them of the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation to prevent harm or prevent further harm arising from the Essure Device?

131. Did Bayer Australia Ltd owe the Plaintiff and each Group Member a duty to inform them of the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation to prevent harm or prevent further harm arising from the Essure Device?

132. What was the applicable standard of care for each of the relevant time periods in relation to:

a. design, development and manufacture of the Essure Device?

b. promotion and marketing of the Essure Device?

133. Did Bayer Essure Inc (from about 1999 to about 2018) and/or Bayer HealthCare LLC (from 2014 to 2018) breach its duty of care in:

a. designing, developing, manufacturing; and

b. distributing or supplying for sale in Australia

the Essure Device with the Inherent Defects, the Failure Defects, the risk of Adverse events and the Removal Limitation?

134. Did Bayer Essure Inc (from about 1999 to 2018), Bayer HealthCare LLC (from about 2014 to 2018), Gytech Pty Ltd (from about 2010 to 2015), Australasian Medical and Scientific Limited (from about 2015 to 2017), Bayer Australia Ltd (From about 2017 to 2018) breach its duty of care in:

a. promoting or marketing to potential recipients of the Essure Device without warning or adequate warning of the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation; and/or

b. failing to make available to the Plaintiff and group members who had already received the Essure Device information disclosing the Inherent Defects, Failure Defects and/or the risk of Adverse Events?

AND THE PLAINTIFF CLAIMS:

A. Damages.

B. Interest pursuant to statute.

C. Costs.

F FORSYTH

M SZYDZIK

F RYAN

E LEVINE

M GUO

Dated the ~~20th day of December 2019~~ 23rd day of December 2022

Slater and Gordon Lawyers
Lawyers for the Plaintiff