No. S ECI 2019 02916
Case: S ECI 2019 02916
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IN THE SUPREME COURT OF VICTORIA
AT MELBOURNE
COMMON LAW DIVISION
MAJOR TORTS LIST

BETWEEN

PATRICE SARAH TURNER
Plaintiff

and

BAYER AUSTRALIA LTD ACN 000 138 714 AND OTHERS ACCORDING TO THE SCHEDULE
Defendants

AMENDED DEFENCE

Date of document: ~~11 September 2020~~ 1 May 2023
Filed on behalf of: the first to fourth, and sixth defendants
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In response to the Amended Statement of Claim dated ~~20 December 2019~~23 December 2022 (A**SOC**), the first to fourth and sixth defendants (**Defendants**) say as follows (defined terms bear the same meaning as in the ASOC, unless otherwise stated):

A. The Plaintiff and Group Members

1. In response to the allegations contained in paragraph 1, the Defendants:

   (a) refer to and repeat paragraphs 14 and 15 below in relation to the components and composition of the Essure Device;

   (b) say that:

      (i) the Essure Device was commercially supplied to patients in Australia via health care professionals and/or health care institutions in Australia during the period between about 2001 and 28 August 2017 (**Commercial Supply Period**), for the purpose of providing patients with permanent birth control (contraception) by bilateral occlusion of the fallopian tubes (**Essure Device Purpose**);

      (ii) the models of the Essure Device designated "ESS105" and "ESS505" (referred to in paragraph 1(b) of the ASOC) were not supplied in Australia at any time;

(iii) on about 1 August 2017, supply of the Essure Device in Australia was voluntarily ceased for business reasons;

(iv) on about 28 August 2017, the Essure Device was voluntarily withdrawn from the market in Australia; and

(v) on 9 February 2018, the Australian Register of Therapeutic Goods (**ARTG**) entry for the Essure Device was cancelled upon the request of Bayer Australia Ltd;

(c) otherwise, do not admit the allegations contained in paragraph 1.

2. The Defendants do not know and therefore do not admit the allegations contained in paragraph 2.

3. The Defendants do not know and therefore do not admit the allegations contained in paragraph 3.

4. The Defendants do not know and therefore do not admit the allegations contained in paragraph 4.

5. The Defendants do not know and therefore do not admit the allegations contained in paragraph 5.

6. The Defendants do not know and therefore do not admit the allegations contained in paragraph 6.

B. Allegations Regarding the Defendants

7. In response to the allegations contained in paragraph 7, the first defendant, Bayer Australia Ltd:

(a) admits the allegations contained in subparagraph (a);

(b) in response to the allegations contained in subparagraph (b):

(i) admits that from about 29 January 2018 until 9 February 2018, Bayer Australia Ltd was the registered sponsor of the Essure Device (then ARTG entry 174123) on the ARTG under the *Therapeutic Goods Act 1989* (Cth) (**TG Act**); and

(ii) otherwise, denies the allegations contained in that subparagraph;

(c) in response to the allegations contained in subparagraph (c):

(i) in respect of the allegations contained in subparagraph (c)(i):

A. says that from the time of the merger of Bayer Essure Inc with Conceptus Inc in about June 2013, the fifth and sixth defendants, Gytech and AMSL, as successive exclusive distributors of the Essure Device in Australia were responsible for the promotion and marketing of the Essure Device in Australia; and

B. otherwise, denies those allegations.

Particulars

From about August 2010 to about January 2015, the exclusive distributor of the Essure Device in Australia was Gytech. From about January 2015 to about August 2017, the exclusive distributor of the Essure Device in Australia was AMSL.

(ii) in respect of the allegations contained in subparagraph (c)(ii):

A. says that the reference to “marketing materials” is vague and embarrassing and liable to be struck out;

B. under cover of that objection, admits that some material published in Australia regarding the Essure Device during the period between about 1 July 2013 and August 2017 included the name of Bayer Australia Ltd; and

C. otherwise denies the allegations contained in subparagraph (c)(ii);

(d) denies the allegations contained in subparagraph (d).

7A. The second, third, fourth and sixth defendants do not admit the allegations contained in paragraph 7.

8. In response to the allegations contained in paragraph 8, the second defendant, Bayer AG:

(a) admits the allegations contained in subparagraph (a);

(b) in respect of the allegations contained in subparagraph (b), says that the reference to “the Bayer group of companies” is vague and embarrassing and liable to be struck out, and therefore, does not admit those allegations;

(c) in respect of the allegations contained in subparagraph (c), says that it is, relevantly, the owner of trademarks 1950359, 242139, 242143, and 1188965, but otherwise does not admit those allegations;

(d) in respect of the allegations contained in subparagraph (d):

(i) says that the reference to “marketing materials” is vague and embarrassing and liable to be struck out;

(ii) under cover of that objection, admits that some material published in Australia regarding the Essure Device during the period between about 1 July 2013 and August 2017 included one or more of the trademarks referred to in paragraph 8(c) above;

(iii) says that from the time of the merger of Bayer Essure Inc with Conceptus Inc in about June 2013, the fifth and sixth defendants, Gytech and AMSL, as successive exclusive distributors of the Essure Device in Australia, were responsible for the promotion and marketing of the Essure Device in Australia;

(iv) says that from between June 2013 and about 1 January 2017 Bayer AG was a holding company and did not carry on any business in Australia; and

(v) otherwise denies the allegations contained in subparagraph (d); and

(e) denies the allegations contained in subparagraph (e).

8B. The first, third, fourth and sixth defendants do not admit the allegations contained in paragraph 8.

9. In response to the allegations contained in paragraph 9, the third defendant, Bayer HealthCare LLC:

(a) denies the allegations contained in subparagraph (a), and says that at all relevant times, Bayer HealthCare LLC was a limited liability company registered in Delaware in the United States of America, and capable of being sued;

(b) in response to the allegations contained in subparagraph (b):

(i) says that Bayer HealthCare LLC is an indirect subsidiary of Bayer AG; and

(ii) otherwise, denies the allegations contained in subparagraph (b);

(c) in response to the allegations contained in subparagraph (c):

(i) admits that Bayer HealthCare LLC was responsible for design and development of the Essure Device between about 5 June 2013 and about 1 January 2016, and was responsible for limited manufacturing and assembly of the Essure Device between about 1 July 2013 to about 1 January 2016;

(ii) refers to and repeats paragraph 7(c)(i) above and admits that from about 1 July 2013 until about 31 May 2017, Bayer HealthCare LLC supplied the Essure Device for importation into Australia for distribution by Gytech and then AMSL;

(iii) says that:

A. from the time of the merger of Bayer Essure Inc with Conceptus Inc in about June 2013, the fifth and sixth defendants, Gytech and AMSL, as exclusive distributors of the Essure Device in Australia, were responsible for the promotion and marketing of the Essure Device in Australia for the respective periods set out in in paragraph 7(c)(i) above; and

B. the reference to “marketing materials” is vague and embarrassing and liable to be struck out;

(iv) under cover of that objection, admits that some material published in Australia regarding the Essure Device during the period between about 1 July 2013 and August 2017 included the name of Bayer HealthCare LLC; and

(v) otherwise, denies the allegations contained in subparagraph (c);

(d) in response to the allegations contained in subparagraph (d):

(i) refers to and repeats paragraph 1(b)(i) above regarding the period for which the Essure Device was commercially supplied in Australia and registered on the ARTG;

(ii) admits that from about May 2014 until about 9 February 2018, Bayer HealthCare LLC was the registered manufacturer of the Essure Device (ARTG entry 174123) on the ARTG under the TG Act; and

(iii) otherwise, denies the allegations contained in subparagraph (d);

(e) in response to the allegations contained in subparagraph (e):

(i) subject to paragraph 61(b)(i) below admits that for the period from about 5 June 2013 until about 9 February 2018, Bayer HealthCare LLC was a 'manufacturer' of the Essure Device in Australia within the meaning of s 7 of the Australian Consumer Law (**ACL**); and

(ii) otherwise, denies the allegations contained in subparagraph (e).

9A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 9.

10. In response to the allegations contained in paragraph 10, the fourth defendant, Bayer Essure Inc:

(a) admits the allegations contained in subparagraph (a) and says further that it is a corporation registered in Delaware, United States of America;

(b) admits the allegations contained in subparagraph (b);

(c) in response to the allegations contained in subparagraph (c):

(i) admits the allegations contained in subparagraph (c)(i) insofar as they concern Conceptus Inc for the period from about December 1999 to about 1 July 2013, but otherwise denies the allegations contained in that subparagraph; and

(ii) admits the allegations contained in subparagraph (c)(ii) insofar as they concern Conceptus Inc for the period from about 1999 to about 1 July 2013, but otherwise denies the allegations contained in that subparagraph;

(d) in response to the allegations contained in subparagraph (d):

(i) does not admit the allegations contained in subparagraph (d)(i);

(ii) in response to the allegations contained in subparagraph (d)(ii);

A. admits that during the period between about 1999 to about 1 July 2013, Conceptus Inc owned trademarks including (at various times) 723986, 723990 and 1317224; and

B. otherwise does not admit those allegations;

(iii) in response to the allegations contained in subparagraph (d)(iii):

A. says that the reference to "marketing materials" is vague and embarrassing and liable to be struck out;

B. under cover of that objection, says further that from about August 2010 to about January 2015, Gytech was the exclusive distributor of the Essure Device in Australia, and in this capacity was responsible for the promotion and marketing of the Essure Device in Australia; and

C. otherwise does not admit the allegations contained in subparagraph (d)(iii);

(iv) in response to the allegations contained in subparagraph (d)(iv), admits that from time to time between about December 1999 to about 1 May 2014, Conceptus Inc was the

registered manufacturer of the Essure Device listed on the ARTG (ARTG entry 72090, and 144330) under the TG Act; and

(v) otherwise, does not admit the allegations contained in subparagraph (d);

(e) in response to the allegations contained in subparagraph (e):

(i) subject to paragraphs 61(b)(i) and 62(a) below admits the allegations concerning Conceptus Inc for the period between about 1999 and about 1 May 2014; and

(ii) otherwise, denies the allegations contained in that subparagraph.

10A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 10.

11. The Defendants do not admit the allegations contained in paragraph 11.

12. In response to the allegations contained in paragraph 12, the sixth defendant, AMSL:

(a) admits the allegations contained in subparagraph (a);

(b) in response to the allegations contained in subparagraph (b):

(i) refers to and repeats paragraph 1(b)(i) above regarding the period for which the Essure Device was commercially supplied in Australia and registered on the ARTG;

(ii) admits that between about 23 January 2015 and 28 January 2018, AMSL was the registered sponsor of the Essure Device (ARTG entry 174123) listed on the ARTG under the TG Act;

(iii) admits that between 1 January 2015 and about 31 May 2017, AMSL imported (or arranged for the importation of) the Essure Device into Australia for distribution (which distribution occurred until about August 2017); and

(iv) otherwise, does not admit the allegations contained in subparagraph (b).

(c) in response to the allegations contained in subparagraph (c):

(i) says that the reference to “marketing materials” is vague and embarrassing and liable to be struck out;

(ii) under cover of that objection, admits that between about 1 January 2015 and about August 2017, AMSL promoted and marketed the Essure Device in Australia, and caused or permitted its name to be used in materials relating to the Essure Device during that time; and

(iii) otherwise, does not admit the allegations contained in subparagraph (c); and

(d) admits the allegations contained in subparagraph (d) for the period from about 1 January 2015 and about 1 August 2017.

12A. The first, second, third and fourth defendants do not admit the allegations contained in paragraph 12.

C. Allegations Regarding Design of the Essure Device

13. In response to the allegations contained in paragraph 13, the Defendants:

    (a) say that the reference to "at all material times" is vague and embarrassing and liable to be struck out; and

    (b) under cover of that objection, do not admit the allegations contained in that paragraph.

14. The Defendants admit the allegations contained in paragraph 14.

15. In response to the allegations contained in paragraph 15, the Defendants:

    (a) admit the allegations contained in subparagraph (a)(i);

    (b) admit the allegations contained in subparagraph (a)(ii);

    (c) admit the allegations contained in subparagraph (a)(iii);

    (d) in response to the allegations contained in subparagraph (a)(iv), say that each Essure Insert featured two platinum-iridium bands, but otherwise, do not admit those allegations;

    (e) in response to the allegations contained in subparagraph (a)(v), admit that a small amount of silver-tin solder was used to join the Inner Coil to the Outer Coil of the Essure Insert, but otherwise, do not admit those allegations;

    (f) admit the allegations contained in subparagraph (b);

    (g) in response to the allegations contained in subparagraph (c), admit the allegations in respect of the 'wound down' configuration of the Essure Insert in the disposable delivery system, but otherwise, do not admit those allegations;

    (h) in response to the allegations contained in subparagraph (d), admit the allegations in respect of the Outer Coil of the Essure Insert once deployed, but otherwise, do not admit those allegations;

    (i) in response to the allegations contained in subparagraph (e):

        (i) admit that the image contained in that subparagraph depicts the 'wound down' Essure Insert (not to scale) attached to the release catheter (comprising part of the disposable delivery system), as published in the 2014 Essure Clinical Resource Physician Training Manual~~; but~~

        ~~(ii) say further that the 2014 Essure Clinical Resource Physician Training Manual was a document distributed in the United States of America, not in Australia;~~.

    (j) in response to the allegations contained in subparagraph (f):

        (i) admit that the image contained in that subparagraph depicts the expanded Essure Insert (not to scale) as published in the 2014 Essure Clinical Resource Physician Training Manual; ~~but~~

(ii) ~~say further that the 2014 Essure Clinical Resource Physician Training Manual was a document distributed in the United States of America, not in Australia;~~ and

(k) deny the allegations contained in subparagraph (g).

16. In response to the allegations contained in paragraph 16, the Defendants:

(a) admit the allegations contained in subparagraph (a);

(b) admit the allegations contained in subparagraph (b);

(c) admit the allegations contained in subparagraph (c);

(d) in response to the allegations contained in subparagraph (d):

(i) admit that fallopian tubes are peristaltic;

(ii) say further that movement along fallopian tubes generally occurs one way, in the direction of the uterus; and

(iii) otherwise, do not admit the allegations contained in that subparagraph.

17. In response to the allegations contained in paragraph 17, the Defendants:

(a) admit the allegations contained in subparagraph (a);

(b) in response to the allegations contained in subparagraph (b):

(i) admit that the image contained in that subparagraph depicts the intended placement of the Essure Insert in a fallopian tube and the uterine cavity (not to scale) as published in the 2014 Essure Clinical Resource Physician Training Manual; but

(ii) ~~say further that the 2014 Essure Clinical Resource Physician Training Manual was a document distributed in the United States of America, not in Australia; and~~

(c) admit the allegations contained in subparagraph (c) in so far as they concern the disposable delivery system;

(d) in response to the allegations contained in subparagraphs (d) to (i):

(i) refer to and repeat paragraph 1(b)(i) above in respect of the Essure Device Purpose;

(ii) say that:

A. the Essure Insert was intended to be placed in the proximal section of each fallopian tube lumen, across the uterotubal junction;

B. once the Essure Insert was deployed, the Outer Coil expanded to conform to the varied diameters and shapes of fallopian tubes;

C. following deployment, the spring-like mechanism of the Outer Coil anchored the Essure Insert in the fallopian tube, and the PET fibers within the Essure Insert elicited tissue in-growth into the coils of the Essure Insert and around the PET fibres (being a local, occlusive and benign tissue response); and

D. this tissue in-growth produced long-term anchoring of the Essure Insert in the fallopian tube and occlusion of the fallopian tube at the immediate site of the Essure Insert, which occlusion operated to prevent pregnancy; and

(iii) otherwise, deny those allegations; and

(e) deny the allegations contained in subparagraph (j).

D. Allegations regarding Essure Insert

18. In response to the allegations contained in paragraph 18, the Defendants:

(a) refer to paragraph 17 above;

(b) in response to the allegations contained in subparagraph (a) say that, when deployed appropriately in accordance with the Instructions For Use, the Essure Insert disrupted the epithelium and the lamina propria of the fallopian tube; and

(c) otherwise, deny the allegations contained in paragraph 18.

19. In response to the allegations contained in paragraph 19, the Defendants:

(a) deny the allegations contained in subparagraphs (a) and (b), and say further that unsatisfactory location of the Essure Insert during the implantation process could be associated with the occurrence of migration, expulsion, breaking and perforation of the fallopian tube, uterus or bowel in some patients;

(b) in response to the allegations contained in subparagraph (c):

(i) say that, in respect of subparagraph (c)(i):

A. nickel is a metal found naturally in air, water and soil;

B. nickel is commonly found in the blood serum, urine, and hair follicles of healthy adults;

C. nickel alloys, including nitinol, are commonly used in medical devices;

D. nickel may be released at low levels from the Essure Insert following implantation; and

(ii) ~~the reference in this subparagraph to "other metals" is vague, embarrassing and liable to be struck out;~~in respect of subparagraph (c)(i) in relation to the reference in the Plaintiff's particulars dated 9 February 2023 to iron, chromium, titanium, tin:

A. refer to and repeat paragraph 15(a) above and say that in addition to nickel the Inner Coil of the Essure Insert contains iron and chromium;

B. refer to and repeat paragraph 15(b) above and say that the Outer Coil of the Essure Insert contains titanium;

C. refer to and repeat paragraph 15(e) above;

(iii) say further that:

A. any metal release rates were acceptable by reference to the relevant standards and regulatory requirements during the Supply Period;

B. the metals occur naturally in the human diet and the environment at higher levels than any release rates from the Essure Device; and

C. did not occur at levels which could cause a Failure Defect, Inherent Defect, Adverse Event, the Plaintiff's Implantation Injuries or the GM Implantation Injuries.

~~(ii)~~(iv) in respect of subparagraph (c)(ii):

A. refer to and repeat paragraph 1(b)(i) above in respect of the Essure Device Purpose; and

B. say that the use of the Essure Device was contraindicated for patients with particular gynaecological conditions involving pain and/or bleeding;

~~(iii)~~(v) otherwise, deny the allegations contained in subparagraph (c); and

(c) say further that during the Commercial Supply Period, publications were available to doctors and patients in Australia regarding the Essure Device that contained information and risk warnings about matters including the following:

(i) the fact that all medical procedures and implantable devices carry risks and that there were risks associated with implantation and use of the Essure Device; and

(ii) risks that may be associated with implantation, use and/or removal of the Essure Device included:

A. movement of the Essure Insert such as migration or expulsion from the fallopian tube;

B. breakage or fragmentation of the Essure Insert during removal;

C. perforation of or damage to internal organs such as the uterus during implantation or as a result of unsatisfactory location of the Essure Insert during the implantation process;

D. an allergic reaction to nickel-titanium;

E. pain; and

F. bleeding.

Particulars

Patient Information Brochures dated 2001, 2002-2003, 2004, 2005, 2008, 2009, 2011, 2014, 2015 and 2016; Instructions for Use dated 2013 and 2015; Physician Training Manual dated 2015. Further particulars may be provided after discovery.

20. In response to the allegations contained in paragraph 20, the Defendants:

    (a) refer to and repeat paragraphs 18 and 19 above; and

    (b) otherwise, deny the allegations contained in paragraph 20.

21. In response to the allegations contained in paragraph 21, the Defendants:

    (a) refer to and repeat paragraph 1(b)(i) above in respect of the Essure Device Purpose;

    (b) refer to and repeat paragraphs 19 and 20 above; and

    (c) admit that once deployed as described in paragraph 17(d) above, and in particular, following the occurrence of the tissue in-growth and long-term anchoring referred to in that paragraph, the Essure Insert was not designed to be removed and might require surgery to effect its removal in such circumstances;

    (d) say further that:

        (i) if such surgery were required, it might, in some cases, include a salpingectomy or a hysterectomy;

        (ii) during the Commercial Supply Period, publications were made available to doctors and patients in Australia regarding the Essure Device that contained information and risk warnings about matters including the following:

            A. the fact that all medical procedures and implantable devices carry risks and that there were risks associated with implantation and use of the Essure Device;

            B. the Essure Device procedure was permanent and not reversible;

            C. removal of the Essure Insert may require surgery; and

            D. if surgical removal of the Essure Insert was required, a salpingectomy or hysterectomy might be required; and

Particulars

Patient Information Brochures dated 2001, 2002-2003, 2004, 2005, 2008, 2009, 2011, 2014, 2015 and 2016; Instructions for Use dated 2013 and 2015; Physician Training Manual dated 2015. Further particulars may be provided after discovery.

    (e) otherwise, deny the allegations contained in paragraph 21.

22. In response to the allegations contained in paragraph 22, the Defendants:

    (a) refer to and repeat paragraph 21 above; and

    (b) otherwise, deny the allegations contained in paragraph 22.

E. Alleged injuries

23. In respect of the allegations contained in paragraph 23, the Defendants:

(a) do not admit that the Plaintiff or group members suffered injuries as a result of having an Essure Insert implanted (or at all); and

(b) otherwise deny the allegations contained in paragraph 23.

F. Marketing materials

24. In response to the allegations contained in paragraph 24, the Defendants:

(a) refer to and repeat paragraphs 7 to 12 above;

(b) say that the reference to "marketing material" is vague and embarrassing and liable to be struck out;

(c) under cover of that objection, say that:

(i) the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as alleged in paragraph 1(b)(i) above;

(ii) during the Commercial Supply Period:

A. the Essure Device was commercially supplied to patients in Australia via health care professionals and/or health care institutions in Australia, for implantation by a doctor in the manner described in paragraph 17(d) above (**Essure Device Procedure**); and

B. publications were made available to doctors and patients in Australia regarding the Essure Device that contained information and risk warnings about matters including those referred to in paragraphs 19 and 21 above;

(iii) during the period from about August 2010 to about January 2015, Gytech was the exclusive distributor of the Essure Device in Australia, and in that capacity and during that time period, was responsible for promoting and marketing the Essure Device in Australia;

(iv) during the period from about January 2015 to about August 2017, AMSL was the exclusive distributor of the Essure Device in Australia, and in that capacity and during that time period, was responsible for promoting and marketing the Essure Device in Australia; and

(v) the Patient Information Booklets referred to in particular (iii) of paragraph 24(a) of the ASOC were not marketing materials; and

(d) otherwise deny the allegations contained in paragraph 24.

25. In response to the allegations contained in paragraph 25, the Defendants:

(a) refer to and repeat paragraph 24 above;

(b) say further that:

(i) prior to a doctor carrying out an Essure Device Procedure, that doctor would, as a matter of course, have:

A. consulted with the patient and discussed their personal circumstances relevant medical history, individual contraception needs, alternative contraceptive options and the relative risks and benefits of each and any other relevant considerations;

B. as a result of that doctor's specialist training, skill and experience, synthesised and assessed all relevant information including:

1) information provided by the patient about their personal circumstances, medical history, individual contraception needs and any other relevant considerations;

2) information provided by the Australian supplier and information from other sources about the Essure Device and Essure Device Procedure; and

3) information available about alternative contraceptive options;

C. provided to the patient information and advice about the Essure Device Purpose, its manner of operation, and the Essure Device Procedure, and information, advice and warnings about any risks associated with the Essure Device (such as those referred to in paragraphs 19 and 21 above) relevant to that patient; and

D. having regard to these matters, determined their recommendation as to the most appropriate course or option for the patient in all of the circumstances (which may have been the implantation of the Essure Device, the use or implementation of some other form of contraception, or no further action);

(ii) in the circumstances described in paragraph 25(b)(i) above, it was reasonable for the Defendants (or any of them) to expect that any patient considering undergoing an Essure Device Procedure and receiving one or more Essure Inserts would be informed by their doctor to the degree that the doctor considered appropriate of:

A. the availability of alternative contraceptive options including surgical and non-surgical options and options including and not including an implantable device; and

B. the risks and benefits associated with any alternative contraceptive options under consideration and of the Essure Device, including those referred to in paragraphs 19 and 21 above; and

(c) otherwise, deny the allegations contained in paragraph 25.

G. Regulatory history

26. In response to the allegations contained in paragraph 26, the Defendants:

    (a) say that from about December 1999 to about 9 February 2018, the Essure Device was listed on the ARTG in accordance with the national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in Australia established under the TG Act and the delegated legislation made pursuant to that Act;

    (b) refer to and repeat paragraph 1(b)(i) above regarding the period for which the Essure Device was commercially supplied in Australia and registered on the ARTG; and

    (c) otherwise, deny the allegations contained in paragraph 26.

Particulars

ARTG Certificate of Listing of a Medical Device with listing number: AUST L 72090 recording Bepen Pty Ltd as sponsor; ARTG Certificate of Listing of a Medical Device with listing number: AUST L 72090 recording Conceptus (Australia) Pty Ltd as sponsor; ARTG Certificate of Listing from TGA to Conceptus (Australia) Pty Ltd "Notification of approval of a variation to a listing of therapeutic devices"; ARTG Certificate of Inclusion of a Medical Device with Listing Number 144330 recording N Stenning & Co Pty Ltd as sponsor; ARTG Certificate issued to Gytech Pty Ltd for Approval to Supply for ARTG Identifier 174123; ARTG Certificate issued to Australasian Medical & Scientific Limited for Approval to Supply for ARTG Identifier 174123; ARTG Certificate issued to Bayer Australia Ltd for Approval to Supply for ARTG Identifier 174123. Further particulars may be provided after discovery.

27. In response to the allegations contained in paragraph 27, the Defendants:

    (a) refer to and repeat paragraph 26;

    (b) say that an Essure Device was entered on the ARTG as a Class III Medical Device from 6 September 2007 at the latest;

    (c) admit that an Essure Device was entered on the ARTG as a Class III Medical Device on 23 July 2010; and

    (d) otherwise do not admit the allegations contained in paragraph 27.

Particulars

ARTG Certificate of Inclusion of a Medical Device with Listing Number 144330 recording N Stenning & Co Pty Ltd as sponsor; ARTG Certificate issued to Gytech Pty Ltd for Approval to Supply for ARTG Identifier 174123.

28. In response to the allegations contained in paragraph 28, the Defendants:

    (a) say that:

(i) on or about 30 August 2017, the Therapeutic Goods Administration (**TGA**) published a statement on its website which among other things, stated incorrectly, that AMSL had issued a hazard alert for the Essure Device in consultation with the TGA;

(ii) on or about 4 October 2017, AMSL, in consultation with the TGA, issued a hazard alert in respect of the Essure Device; and

(b) otherwise deny the allegations contained in paragraph 28.

Particulars

Update to Urgent Medical Device Recall/ Hazard Alert dated 4 October 2017

29. In response to the allegations contained in paragraph 29, the Defendants:

(a) refer to and repeat paragraph 28 above;

(b) say that the alert dated on or about 4 October 2017 in respect of the Essure Device relevantly stated as follows:

> *Post-marketing information suggests that some patients may not always be fully informed of the various possible device and procedure related complications before they choose whether to proceed with ESSURE .There have been reports of changes in menstrual bleeding, unintended pregnancy, chronic pain, perforation and migration of the device, allergy/hypersensitivity, or immune-type reactions. Some of these reports were considered serious and resulted in removal of the device, which involved abdominal surgery or hysterectomy* […]

(c) otherwise, deny the allegations contained in paragraph 29.

30. In response to paragraph 30, the Defendants:

(a) refer to and repeat paragraph 1(b) above regarding the period for which the Essure Device was commercially supplied in Australia and registered on the ARTG;

(b) refer to and rely on paragraph 26 above; and

(c) otherwise admit the allegations contained in paragraph 30.

31. The Defendants admit the allegations contained in paragraph 31.

32. In response to the allegations contained in paragraph 32, the Defendants:

(a) refer to and repeat paragraph 1(b)(i) above regarding the period for which the Essure Device was commercially supplied in Australia and registered on the ARTG; and

(b) otherwise, do not admit the allegations contained in paragraph 32.

33. In response to the allegations contained in paragraph 33, the Defendants:

(a) admit that, subject to production of the documents at trial and reliance on them for their full terms and effect:

(i) the government of South Australia (SA Health) issued documents in about October 2018 that were entitled “Essure contraceptive device: Frequently Asked Questions”, “Essure Patient Information Brochure” and “Information for General Practitioners: Management of patients with the Essure implant contraceptive device”;

(ii) those documents referred to adverse events and/or complications which were alleged to be associated with the Essure Device; and

(b) otherwise deny the allegations contained in paragraph 33, and say that those allegations are not material to any cause of action pleaded against them and should be struck out.

34. In response to the allegations contained in paragraph 34, the Defendants:

(a) admit that, subject to production of the document at trial and reliance on it for its full terms and effect:

(i) the Government of Western Australia (Department of Health) issued a document in 2018 entitled “Essure contraceptive device FAQs”;

(ii) the document referred to adverse events and/or complications which were alleged to be associated with the Essure Device; and

(b) otherwise deny the allegations contained in paragraph 34, and say that those allegations are not material to any cause of action pleaded against them and should be struck out.

35. In response to the allegations contained in paragraph 35, the Defendants:

(a) admit that, subject to production of the documents at trial and reliance on them for their full terms and effect:

(i) the Government of Queensland (Queensland Health) issued documents entitled “Patient Information Sheet: Essure permanent contraception device” and “Clinician Information Sheet: Essure permanent contraception device”;

(ii) those documents referred to adverse events and/or complications which were alleged to be associated with the Essure Device; and

(b) otherwise deny the allegations contained in paragraph 35, and say that it is not material to any cause of action pleaded against them and should be struck out.

36. In response to the allegations contained in paragraph 36, the Defendants, subject to production of the document at trial and reliance on it for its full terms and effect:

(a) admit that the United States Food and Drug Administration (**FDA**) issued a document captioned "FDA News Release" and entitled “FDA takes additional action to better understand safety of Essure, inform patients of potential risks” on or about 29 February 2016;

(b) say that:

(i) this document announced draft guidance and a mandatory "boxed warning" proposed by the FDA for permanent hysteroscopically placed sterilization devices;

(ii) this document referred to the existence of potential risks which it alleged to be associated with the Essure Device;

(iii) the FDA approach sought to encourage additional discussions between doctors and their patients with the boxed warning which stated, “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”; and

(iv) this document, and the draft guidance referred to in it, followed the FDA Advisory Committee meeting of the Obstetrics and Gynecology Devices Panel on 24 September 2015 at which the FDA Advisory Committee recognised that it appeared that not all doctors were providing warnings about risks to their patients who were considering the Essure Device for the Essure Device Purpose; and

(c) otherwise deny the allegations contained in paragraph 36.

Particulars

FDA, “Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization” 31 October 2016, Guidance 1500051.

37. In response to the allegations contained at paragraph 37, the Defendants, subject to production of the document at trial and reliance on it for its full terms and effect:

(a) say that:

(i) this document announced that Bayer HealthCare LLC was working with Health Canada to update the product labelling for the Essure Device to include a new "boxed warning" section;

(ii) this document referred to the existence of potential risks which were alleged to be associated with the Essure Device; and

(b) otherwise deny the allegations contained in paragraph 37.

38. The Defendants admit the allegations contained in paragraph 38.

39. In response to the allegations contained in paragraph 39, the Defendants, subject to production of the document at trial and reliance on it for its full terms and effect:

(a) refer to and repeat paragraph 36(b) above;

(b) say further that:

(i) this document contained guidance proposed by the FDA in respect of permanent hysteroscopically-placed sterilization devices (including but not limited to the Essure device);

(ii) the header of the document on each page stated: “Contains Nonbinding Recommendations”;

(iii) the document stated at p 4 that:

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on the FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations […]

(iv) the document stated under the heading "Introduction" (p 4):

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

(v) The document stated under the heading "Scope" (p 6):

This guidance identifies the content and format of certain labelling components for permanent, hysteroscopically-placed tubal implants that are intended for sterilization. The guidance applies to all devices of this type, regardless of the insert material composition, location of intended implantation, or exact method of delivery.

(c) say that the guidance for a "boxed warning" and a patient decision checklist were expressed to be applicable to all permanent hysteroscopically-placed sterilization devices, not specifically to the Essure Device; and

(d) otherwise deny the allegations contained in paragraph 39.

40. The Defendants deny the allegations contained in paragraph 40.

41. In response to the allegations contained in paragraph 41, the Defendants, subject to production of the order at trial and reliance on it for its full terms and effect:

(a) refer to and repeat paragraph 36(b) above;

(b) admit that on about 9 April 2018, the FDA issued an order to restrict the sale and distribution of the Essure Device in the Unites States of America;

(c) refer to and repeat paragraph 1(b) above regarding the period for which the Essure Device was commercially supplied in Australia and registered on the ARTG, and say further that the order was issued after the Essure Device had ceased to be supplied in Australia, and after its ARTG registration had been voluntarily cancelled in February 2018; and

(d) otherwise do not admit the allegations contained in paragraph 41, and say those allegations are not material to any cause of action pleaded against them and should be struck out.

42. In response to the allegations contained in paragraph 42, the Defendants:

    (a) say that "the Bayer group" is not defined, and to that extent, the allegations contained in this paragraph are embarrassing and liable to be struck out;

    (b) under cover of that objection, say further that the decision to voluntarily discontinue the Essure Device in Australia and the United States of America was a commercial decision and did not result from a change in the quality, safety or efficacy of the Essure Device for the Essure Device Purpose; and

    (c) otherwise, do not admit the allegations contained in paragraph 42 and say that those allegations are not material to any cause of action pleaded against them and should be struck out.

H. Supply and acquisition of the Essure device

43. The Defendants do not know, and therefore do not admit the allegations contained in paragraph 43.

44. In response to the allegations contained in paragraph 44, the Defendants:

    (a) say that, as stated in paragraph 1(b)(i) above, the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017;

    (b) refer to and repeat paragraph 26 above;

    (c) admit that Bayer Essure Inc and/or Bayer HealthCare LLC supplied the Essure Device for importation into and distribution in Australia to:

        (i) Bepen Pty Ltd between about 1 December 1999 and about 6 November 2000;

        (ii) Conceptus (Australia) Pty Ltd between about 6 November 2000 and about January 2005;

        (iii) N Stenning & Co Pty Ltd between about January 2005 and about August 2010;

        (iv) Gytech between about August 2010 and about January 2015; and

        (v) AMSL between about January 2015 and August 2017; and

    (d) otherwise, deny the allegations contained in paragraph 44.

45. In response to the allegations contained in paragraph 45, the Defendants:

    (a) refer to and repeat paragraphs 1(b), 7 to 12, 26 and 44 above;

    (b) deny the allegations in respect of Bayer Australia Ltd;

(c) admit that to the extent that the Essure Device was supplied in the Commercial Supply Period by Bayer Essure Inc and/or Bayer HealthCare LLC to Conceptus (Australia) Pty Ltd, N Stenning & Co Pty Ltd, Gytech and/or AMSL as admitted in paragraph 44 above for the purpose of commercial resupply to patients, such supply was conduct in trade or commerce between Australia and places outside of Australia (but further refer to paragraphs 61 and 62 below, and deny that the consumer protection provisions relied upon in the ASOC applied or apply to either Bayer Essure Inc or Bayer HealthCare LLC);

(d) say that, to the extent that the supply referred to in subparagraph 45(c) was for commercial resupply to patients, such resupply occurred via health care professionals and/or health care institutions in the manner pleaded in paragraphs 24 to 25 above; and

(e) otherwise, do not admit the allegations contained in that paragraph.

46. In response to the allegations contained in paragraph 46, the Defendants:

(a) say that as stated in paragraph 1(b)(i) above, the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017;

(b) say further that during that period, the Essure Device was supplied to patients via health care professionals and/or health care institutions in the manner pleaded in paragraphs 24 to 25 above, and the Essure Device was only available to a patient upon the recommendation of their doctor;

(c) admit that Gytech (for the period from about August 2010 to about January 2015) and AMSL (for the period from about January 2015 to August 2017) imported the Essure Device into Australia for commercial resupply by health care professionals and/or health care institutions to patients in the manner pleaded in paragraphs 24 to 25 and 44 to 45 above and refer to and repeat those paragraphs; and

(d) otherwise, do not know, and therefore do not admit the allegations contained in paragraph 46.

47. The Defendants do not know, and therefore do not admit the allegations contained in paragraph 47.

48. In response to the allegations contained in paragraph 48, the Defendants:

(a) refer to and repeat paragraphs 45 and 46 above;

(b) admit that the supply of the Essure Device during the Commercial Supply Period to health care professionals and/or health care institutions (for commercial resupply to patients) in the manner pleaded in paragraphs 24 to 25 and 44 to 45 above was in trade or commerce within Australia; and

(c) otherwise, deny the allegations contained in paragraph 48.

49. In respect of the allegations contained in paragraph 49, the Defendants:

    (a) refer to and repeat paragraphs 45 and 46 above;

    (b) admit the allegations in respect of Essure Devices that were commercially supplied by entities and persons in Australia to the Plaintiff and/or group members (or any of them) in Australia during the Commercial Supply Period; and

    (c) otherwise, do not know, and therefore do not admit, the allegations contained in paragraph 49.

50. In response to the allegations contained in paragraph 50, the Defendants:

    (a) do not know, and therefore do not admit, the price paid by the Plaintiff and group members (or any of them) for the Essure Device; and

    (b) otherwise, admit that the cost of an Essure Device that was commercially supplied to a patient in Australia during the Commercial Supply Period did not exceed $40,000.

51. In respect of the allegations contained in paragraph 51, the Defendants:

    (a) refer to and repeat paragraph 53 below;

    (b) under cover of the contents of that paragraph, say that insofar as the Essure Device was commercially supplied to and implanted into a patient in Australia during the Commercial Supply Period, they admit that such supply and implantation constituted an acquisition for personal use by that patient; and

    (c) otherwise, do not admit the allegations contained in paragraph 51.

52. In respect of the allegations contained in paragraph 52, the Defendants:

    (a) admit that, to the extent that supply of the Essure Device to the Plaintiff and/or group members (or any of them) occurred in the manner described in paragraphs 50(b) and 51(b) above, such supply was made to those persons as consumers within the meaning of section 4B of the *Trade Practices Act 1974* (Cth) (**TPA**) and section 3 of the ACL; and

    (b) otherwise, do not know, and do not admit, the allegations contained in paragraph 52.

53. In response to the allegations contained in paragraph 53, the Defendants:

    (a) refer to and repeat paragraph 1(b)(i) above in respect of the Essure Device Purpose; and

    (b) otherwise, deny the allegations contained in paragraph 53.

54. In respect of the allegations contained in paragraph 54, the Defendants:

    (a) refer to and repeat paragraph 51(b) above, and say that insofar as the Essure Device was commercially supplied to and acquired by a patient in Australia during the Commercial Supply Period for the purpose described in paragraph 51 of the ASOC, they admit that those Essure Devices constituted 'goods' within the meaning of sections 4 and 74A(2)(a) of the TPA and section 2 of the ACL; and

    (b) otherwise, do not admit the allegations contained in paragraph 54.

I. Allegations of statutory breach

Allegations concerning quality

55. In response to the allegations contained in paragraph 55, the Defendants:

    (a) refer to and repeat paragraphs 1(b)(i), 18to 22, 24 to 26 and 46(b) above; and

    (b) otherwise deny the allegations contained in paragraph 55.

56. In response to the allegations contained in paragraph 56, the Defendants:

    (a) refer to and repeat paragraph 55 above;

    (b) deny the allegations contained in paragraph 56; and

    (c) say further that if, which is denied, the Essure Device (in the context of commercial supply to patients in Australia during the Commercial Supply Period) is found to have been not of merchantable quality within the meaning of s 74D of the TPA and/or not of acceptable quality within the meaning of s 54 of the ACL:

        (i) the Essure Device was not of merchantable quality, further or alternatively, not of acceptable quality, only by reason of acts, defaults and/or omissions of the doctors who:

            A. carried out the Essure Device Procedure; and/or

            B. engaged (alternatively, were required to engage) in the process of consultation, advice and warning prior to implantation referred to in paragraphs 24 to 25 above;

        for the purpose of the defence afforded by s 74D(2)(a) of the TPA and/or s 271(2)(a) of the ACL (those doctors being persons other than the Defendants, their employees or agents); and

(ii) further or alternatively, the reasons why the Essure Device was not of merchantable quality, or acceptable quality, were specifically drawn to the attention of the Plaintiff and group members by:

A. the information and risk warnings referred to in paragraphs 19 to 21 above; and/or

B. further or alternatively, the process of consultation, advice and warning carried out by doctors prior to implantation referred to in paragraphs 24 to 25 above;

for the purpose of the defence afforded by s 74D(2)(b) of the TPA and/or s 54(4) of the ACL.

57. In response to the allegations contained in paragraph 57, the Defendants:

(a) in respect of the Inherent Defects alleged, refer to and repeat paragraph 18 above and deny that loss or damage was reasonably foreseeable as a result of those matters (or any of them);

(b) in respect of the Failure Defects alleged:

(i) refer to and repeat paragraph 19 above;

(ii) say that to the extent that the existence of any of the risks alleged to comprise the Failure Defects are admitted in that paragraph, they admit that the possibility of loss or damage resulting from those risks was reasonably foreseeable at or from the time of which those risks were known;

(c) in respect of the risk of Adverse Events alleged:

(i) refer to and repeat paragraph 20 above;

(ii) say that to the extent that the existence of any of the risks alleged to comprise the Adverse Events are admitted in that paragraph, they admit that the possibility of loss or damage resulting from those risks was reasonably foreseeable at and from the time of which those risks were known;

(d) in respect of the Removal Limitation alleged:

(i) refer to and repeat paragraphs 21 and 22 above;

(ii) say that in the circumstances described in those paragraphs, the possibility of loss or damage resulting from the matters described as the Removal Limitation was reasonably foreseeable; and

(e) otherwise, deny the allegations contained in paragraph 57.

Allegations concerning defects

58. In response to the allegations contained in paragraph 58, the Defendants:

    (a) refer to and repeat paragraph 55 above; and

    (b) otherwise deny the allegations contained in paragraph 58.

59. In response to the allegations contained in paragraph 59, the Defendants:

    (a) refer to and repeat paragraphs 55 to 58 above;

    (b) deny the allegations contained in paragraph 59; and

    (c) say further that if, which is denied, the Essure Device (in the context of commercial supply to patients in Australia during the Commercial Supply Period) is found to have had a 'defect' within the meaning of section 75AC of the TPA and/or a 'safety defect' within the meaning of section 9 of the ACL:

        (i) at the time of supply of the Essure Device by their actual manufacturer, no such defect, further or alternatively, no such safety defect, existed, for the purpose of the defence afforded by s 75AK(1)(a) of the TPA and/or s 142(a) of the ACL, and any such defect (alternatively, safety defect) came into existence at a later date by reason of acts, defaults and/or omissions of the doctors who:

            A. carried out the Essure Device Procedure; and/or

            B. engaged (alternatively, were required to engage) in the process of consultation, advice and warning prior to implantation referred to in paragraphs 24 to 25 above;

        (ii) further or alternatively, the state of scientific or technical knowledge at the relevant time of supply of the Essure Device was not such as to enable that defect, further or alternatively, that safety defect, to be discovered, for the purpose of the defence afforded by s 75AK(1)(c) of the TPA and/or s 142(c) of the ACL.

Allegations concerning loss and damage

60. In response to the allegations contained in paragraph 60, the Defendants:

    (a) refer to and repeat paragraphs 55 to 59 above; and

    (b) otherwise deny the allegations contained in paragraph 60.

61. In response to the allegations contained in paragraph 61, the Defendants:

    (a) refer to and repeat paragraphs 55 to 60 above;

    (b) refer to and repeat paragraphs 7 to 12 above and say further that:

        (i) at no time did Bayer AG, Bayer HealthCare LLC or Bayer Essure Inc carry on business in Australia, and as such none is subject to the consumer protection provisions of the ACL relied upon in the ASOC;

(ii) further or alternatively, if which is denied, any one or more of Bayer AG, Bayer HealthCare LLC or Bayer Essure Inc is subject to the consumer protection provisions of the ACL:

A. at no time was Bayer Australia Ltd a 'manufacturer' for the purpose of sections 138, 271 and/or 272 of the ACL, and therefore, is not liable under any of those sections;

B. at no time was Bayer AG a 'manufacturer' for the purpose of sections 138, 271 and/or 272 of the ACL, and therefore, is not liable under any of those sections;

C. at no time other than between about June 2013 and about 9 February 2018 was Bayer HealthCare LLC a 'manufacturer' for the purpose of sections 138, 271 and/or 272 of the ACL, and therefore, any liability attaching to it in its capacity as a manufacturer under any of those sections (which liability is denied, for the reasons set out in paragraphs 55 to 60 above) is limited to that period;

D. at no time other than between about 1999 and 1 July 2013 (as Conceptus Inc) and otherwise 1 May 2014 was Bayer Essure Inc a 'manufacturer' for the purpose of sections 138, 271 and/or 272 of the ACL, and therefore, any liability attaching to it in its capacity as a manufacturer under any of those sections (which liability is denied, for the reasons set out in paragraphs 55 to 60 above) is limited to that period; and

E. at no time other than between about January 2015 and August 2017 was AMSL a 'manufacturer' for the purpose of sections 138, 271 and/or 272 of the ACL, and therefore, any liability attaching to it in its capacity as a manufacturer under any of those sections (which liability is denied, for the reasons set out in paragraphs 55 to 60 above) is limited to that period; and

(c) otherwise deny the allegations contained in paragraph 61.

62. In response to the allegations contained in paragraph 62, the fourth defendant, Bayer Essure Inc says that:

(a) at no time did Bayer Essure Inc carry on business in Australia, and as such, it is not subject to section 74D(1) and section 75AD of the TPA;

(b) if which is denied, Bayer Essure Inc is subject to section 74D(1) and section 75AD of the TPA, it:

(i) refers to and repeats paragraphs 55 to 60 above;

(ii) refers to and repeats paragraph 10 above and say further that at no time other than between about 1999 and 1 July 2013 (as Conceptus Inc) and otherwise 1 May 2014 was Bayer Essure Inc a 'manufacturer' for the purpose of sections 74D(1) and/or 75AD of the TPA, and therefore, any liability attaching to it in its capacity as a

manufacturer under any of those sections (which liability is denied, for the reasons set out in paragraphs 55 to 60 above) is limited to that period; and

(c) otherwise denies the allegations contained in paragraph 62.

62A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 62.

J. Alleged liability in negligence – Bayer Essure Inc

Allegations concerning duty of care

63. In response to the allegations contained in paragraph 63, the fourth defendant, Bayer Essure Inc:

(a) says that:

(i) the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as referred to in paragraph 1(b)(i) above;

(ii) during the Commercial Supply Period:

A. the Essure Device was commercially supplied to patients in Australia via health care professionals and/or health care institutions in Australia (as pleaded in paragraph 24 above); and

B. implantation of the Essure Device was carried out (alternatively, was required to be carried out) by doctors pursuant to the process of consultation, advice and warning referred to in paragraphs 24 and 25 above;

(b) refers to and repeats paragraphs 10 and 62 above and denies that Bayer Essure Inc owed the Plaintiff and/or group members the duty of care alleged in paragraph 63; and

(c) otherwise, denies the allegations contained in paragraph 63.

63A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 63.

64. In response to the allegations contained in paragraph 64, the fourth defendant, Bayer Essure Inc:

(a) says that:

(i) the reference to “at all material times” is vague and embarrassing and liable to be struck out; and

(ii) the reference to alleged knowledge by Bayer Essure Inc of “the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation” in a rolled-up way and without specification of at what time the knowledge of each such matter is alleged to have existed or arisen is vague and embarrassing, and liable to be struck out;

(b) under cover of those objections:

(i) refers to and repeats paragraphs 10, 55, 56(c) and 59(c) above; and

(ii) otherwise denies the allegations contained in paragraph 64.

64A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 64.

65. In response to the allegations contained in paragraph 65, the fourth defendant, Bayer Essure Inc:

(a) says that the reference to "at all material times" is vague and embarrassing and liable to be struck out;

(b) under cover of that objection, refers to and repeats paragraphs 10, 55, 56(c) and 59(c) above; and

(c) otherwise denies the allegations contained in paragraph 65.

65A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 65.

66. In response to the allegations contained in paragraph 66, the fourth defendant, Bayer Essure Inc:

(a) says that the reference to "at all material times" is vague and embarrassing and liable to be struck out;

(b) under cover of that objection, says that:

(i) the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as referred to in paragraph 1(b)(i) above;

(ii) during the Commercial Supply Period:

A. the Essure Device was commercially supplied to patients in Australia via health care professionals and/or health care institutions in Australia (as pleaded in paragraph 24 above); and

B. implantation of the Essure Device was carried out (alternatively, was required to be carried out) by doctors pursuant to the process of consultation, advice and warning referred to in paragraphs 24 to 25 above;

(c) refers to and repeats paragraphs 10, 55, 56(c) and 59(c) above, and denies that it owed the Plaintiff and group members (or any of them) the duty of care alleged in paragraph 66 at any time during the Commercial Supply Period, alternatively, during the Commercial Supply Period from about 1 July 2013 onwards; and

(d) otherwise, denies the allegations contained in paragraph 66.

66A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 66.

Allegations concerning standard of care

67. In response to the allegations contained in paragraph 67, the fourth defendant, Bayer Essure Inc:

(a) says that the reference to "at all material times" is vague and embarrassing and liable to be struck out;

(b) under cover of that objection:

(i) refers to and repeats paragraphs 55, 56(c) and 59(c) above; and

(ii) refers to and repeats paragraph 1(b)(i) above regarding the period for which the Essure Device was commercially supplied in Australia and registered on the ARTG; and

(c) otherwise denies the allegations contained in paragraph 67.

67A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 67.

68. In response to the allegations contained in paragraph 68, the fourth defendant, Bayer Essure Inc:

(a) says that the reference to "at all material times" is vague and embarrassing and liable to be struck out;

(b) under cover of that objection:

(i) refers to and repeats paragraphs 55, 56(c) and 59(c) above; and

(ii) refers to and repeats paragraph 1(b)(i) above regarding the period for which the Essure Device was commercially supplied in Australia and registered on the ARTG; and

(c) otherwise denies the allegations contained in paragraph 68.

68A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 68.

69. In response to the allegations contained in paragraph 69, the fourth defendant, Bayer Essure Inc:

(a) refers to and repeats paragraphs 10, 67 and 68 above; and

(b) denies the allegations contained in paragraph 69.

69A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 69.

70. In response to the allegations contained in paragraph 70, the fourth defendant, Bayer Essure Inc:

(a) refers to and repeats paragraphs 10, 55, 56(c) and 59(c) above; and

(b) otherwise denies the allegations contained in paragraph 70.

70A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 70.

Allegations concerning breach of duty

71. In response to the allegations contained in paragraph 71, the fourth defendant, Bayer Essure Inc:

(a) refers to and repeats paragraphs 55, 56(c), 59(c) and 63 above;

(b) otherwise denies the allegations contained in paragraph 71; and

(c) says further that if, which is denied, Bayer Essure Inc is found to have engaged in any of the conduct alleged in paragraph 71 of the ASOC in breach of duty, for the reasons referred to in paragraph 10 above, it denies that it engaged in any such conduct at any time from about 1 July 2013 onwards.

71A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 71.

72. In response to the allegations contained in paragraph 72, the fourth defendant, Bayer Essure Inc:

(a) refers to and repeats paragraphs 55, 56(c), 59(c) and 66 above;

(b) otherwise denies the allegations contained in paragraph 72; and

(c) says further that if, which is denied, Bayer Essure Inc is found to have engaged in any of the conduct alleged in paragraph 72 of the ASOC in breach of duty, for the reasons referred to in paragraph 10 above, it denies that it engaged in any such conduct at any time from about 1 July 2013 onwards.

72A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 72.

Allegations concerning causation

73. In response to the allegations contained in paragraph 73, the fourth defendant, Bayer Essure Inc:

(a) says that the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as referred to in paragraph 1(b)(i) above;

(b) refers to paragraphs 55, 56(c), 59(c) and 71 above; and

(c) otherwise denies the allegations contained in paragraph 73.

73A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 73.

74. In response to the allegations contained in paragraph 74, the fourth defendant, Bayer Essure Inc:

(a) says that:

(i) the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as referred to in paragraph 1(b)(i) above;

(ii) it does not know and therefore does not admit:

A. receipt of one or more of the Essure Device by the Plaintiff and group members (or any of them) during the Commercial Supply Period; and

B. any harm, loss or damage alleged to have been suffered by the Plaintiff and group members (or any of them);

(b) refers to paragraphs 55, 56(c), 59(c) and 72 and denies that it breached the duty of care in the manner alleged in paragraph 72(a) of the ASOC or at all:

(c) says further that if, which is denied, Bayer Essure Inc is found to have breached the duty of care in the manner alleged in paragraph 72(a) of the ASOC:

(i) the Plaintiff and the group members (or any of them) would have:

A. acquired the Essure Device and undergone the Essure Device Procedure; and/or

B. further or alternatively, acquired contraception with which equal or greater risk was associated;

even if one or more warnings of the type referred to in paragraph 72(a) of the ASOC had been provided by Bayer Essure Inc, such that any breach of duty by Bayer Essure Inc (which is denied) did not cause or materially contribute to those group members' harm, loss or damage; and

(ii) further or alternatively, any harm, loss or damage suffered by the Plaintiff and group members (or any of them) was the result of failure by the relevant doctor who carried out the Essure Device Procedure to:

A. properly carry out the Essure Device Procedure; and/or

B. properly carry out the process of consultation, advice and warning referred to in paragraphs 24 to 25 above,

such that any breach of duty by Bayer Essure Inc (which is denied) was not relevantly a cause of those group members' harm, loss or damage; and

(d) otherwise denies the allegations contained in paragraph 74.

74A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 74.

75. In response to the allegations contained in paragraph 75, the fourth defendant, Bayer Essure Inc:

(a) refers to paragraphs 55, 56(c), 59(c) and 72 above; and

(b) otherwise denies the allegations contained in paragraph 75.

75A. The first, second, third and sixth defendants do not admit the allegations contained in paragraph 75.

K. Alleged liability in negligence – Bayer Healthcare LLC

Allegations concerning duty of care

76. In response to the allegations contained in paragraph 76, the third defendant, Bayer HealthCare LLC:

    (a) says that:

        (i) the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as referred to in paragraph 1(b)(i) above;

        (ii) during the Commercial Supply Period:

            A. the Essure Device was commercially supplied to patients in Australia via health care professionals and/or health care institutions in Australia (as pleaded in paragraph 24 above); and

            B. implantation of the Essure Device was carried out (alternatively, was required to be carried out) by doctors pursuant to the process of consultation, advice and warning referred to in paragraphs 24 to 25 above;

    (b) refers to and repeats paragraph 9 above; and

    (c) otherwise, denies the allegations contained in that paragraph.

76A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 76.

77. In response to the allegations contained in paragraph 77, the third defendant, Bayer HealthCare LLC:

    (a) says that:

        (i) the reference to "at all material times" is vague and embarrassing and liable to be struck out; and

        (ii) the reference to alleged knowledge by Bayer HealthCare LLC of "the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation" in a rolled-up way and without specification of at what time the knowledge of each such matter is alleged to have existed or arisen is vague and embarrassing, and liable to be struck out;

    (b) under cover of that objection:

        (i) says that the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as referred to in paragraph 1(b)(i) above;

        (ii) refers to and repeats paragraphs 9, 55, 56(c) and 59(c) above; and

        (iii) otherwise denies the allegations contained in paragraph 77.

77A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 77.

78. In response to the allegations contained in paragraph 78, the third defendant, Bayer HealthCare LLC:

(a) says that the reference to "at all material times" is vague and embarrassing and liable to be struck out;

(b) under cover of that objection, refers to and repeats paragraphs 9, 55, 56(c) and 59(c) above; and

(c) otherwise denies the allegations contained in paragraph 78.

78A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 78.

79. In response to the allegations contained in paragraph 79, the third defendant, Bayer HealthCare LLC:

(a) says that the reference to "at all material times" is vague and embarrassing and liable to be struck out;

(b) under cover of that objection, says that:

(i) the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as referred to in paragraph 1(b)(i) above;

(ii) during the Commercial Supply Period:

A. the Essure Device was commercially supplied to patients in Australia via health care professionals and/or health care institutions in Australia (as pleaded in paragraph 24 above); and

B. implantation of the Essure Device was carried out (alternatively, was required to be carried out) by doctors pursuant to the process of consultation, advice and warning referred to in paragraphs 24 to 25 above;

(c) refers to and repeats paragraphs 9, 55, 56(c) and 59(c) above, and denies that it owed the Plaintiff and group members (or any of them) the duty of care alleged in paragraph 79 at any time during the Commercial Supply Period, alternatively, during the Commercial Supply Period from about 1 May 2014 onwards; and

(d) otherwise, denies the allegations contained in paragraph 79.

79A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 79.

Allegations concerning standard of care

80. In response to the allegations contained in paragraph 80, the third defendant, Bayer HealthCare LLC:

(a) says that the reference to "at all material times" is vague and embarrassing and liable to be struck out;

(b) under cover of that objection:

(i) refers to and repeats paragraphs 55, 56(c) and 59(c) above; and

(ii) refers to and repeats paragraph 1(b)(i) above regarding the period for which the Essure Device was commercially supplied in Australia and registered on the ARTG; and

(c) otherwise denies the allegations contained in paragraph 80.

80A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 80.

81. In response to the allegations contained in paragraph 81, the third defendant, Bayer HealthCare LLC:

(a) says that the reference to "at all material times" is vague and embarrassing and liable to be struck out;

(b) under cover of that objection:

(i) refers to and repeats paragraphs 55, 56(c) and 59(c) above; and

(ii) refers to and repeats paragraph 1(b)(i) above regarding the period for which the Essure Device was commercially supplied in Australia and registered on the ARTG; and

(c) otherwise denies the allegations contained in paragraph 81.

81A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 81.

82. In response to the allegations contained in paragraph 82, the third defendant, Bayer HealthCare LLC:

(a) refers to and repeats paragraphs 9, 80 and 81 above; and

(b) otherwise denies the allegations contained in paragraph 82.

82A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 82.

83. In response to the allegations contained in paragraph 83, the third defendant, Bayer HealthCare LLC:

(a) refers to and repeats paragraphs 9, 55, 56(c) and 59(c) above; and

(b) otherwise denies the allegations contained in paragraph 83.

83A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 83.

Allegations concerning breach of duty

84. In response to the allegations contained in paragraph 84, the third defendant, Bayer HealthCare LLC:

(a) refers to and repeats paragraphs 55, 56(c), 59(c) and 76 above;

(b) otherwise denies the allegations contained in paragraph 84; and

(c) says further that if, which is denied, Bayer HealthCare LLC is found to have engaged in any of the conduct alleged in paragraph 84 of the ASOC in breach of duty, for the reasons referred to in paragraph 9 above, it denies that it engaged in any such conduct prior to about June 2013.

84A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 84.

85. In response to the allegations contained in paragraph 85, the third defendant, Bayer HealthCare LLC:

(a) refers to and repeats paragraphs 55, 56(c), 59(c) and 79 above;

(b) otherwise denies the allegations contained in paragraph 84; and

(c) says further that if, which is denied, Bayer HealthCare LLC is found to have engaged in any of the conduct alleged in paragraph 84 of the ASOC in breach of duty, for the reasons referred to in paragraph 9 above, it denies that it engaged in any such conduct during the Commercial Supply Period prior to about June 2013.

85A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 85.

Allegations concerning causation

86. In response to the allegations contained in paragraph 86, the third defendant, Bayer HealthCare LLC:

(a) says that the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as referred to in paragraph 1(b)(i) above;

(b) refers to paragraphs 55, 56(c), 59(c) and 84 above; and

(c) otherwise denies the allegations contained in paragraph 86.

86A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 86.

87. In response to the allegations contained in paragraph 87, the third defendant, Bayer HealthCare LLC:

(a) says that the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as referred to in paragraph 1(b)(i) above

(b) refers to paragraphs 55, 56(c), 59(c) and 85 above;

(c) says further that if, which is denied, Bayer HealthCare LLC is found to have breached the duty of care in the manner alleged in paragraph 85(a) of the ASOC:

(i) the group members (or any of them) who are alleged to have received the Essure Device during the Commercial Supply Period from about 2014 onwards would have:

A. acquired the Essure Device and undergone the Essure Device Procedure; and/or

B. further or alternatively, acquired contraception with which equal or greater risk was associated;

even if one or more warnings of the type referred to in paragraph 85(a) of the ASOC had been provided by Bayer HealthCare LLC, such that any breach of duty by Bayer HealthCare LLC (which is denied) did not cause or materially contribute to those group members' harm, loss or damage; and

(ii) further or alternatively, any harm, loss or damage suffered by the Plaintiff and group members (or any of them) was the result of failure by the relevant doctor who carried out the Essure Device Procedure to:

A. properly carry out the Essure Device Procedure; and/or

B. properly carry out the process of consultation, advice and warning referred to in paragraphs 24 to 25 above,

such that any breach of duty by Bayer HealthCare LLC (which is denied) was not relevantly a cause of those group members' harm, loss or damage; and

(d) otherwise denies the allegations contained in paragraph 87.

87A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 87.

88. In response to the allegations contained in paragraph 88, the third defendant, Bayer HealthCare LLC:

(a) refers to paragraphs 55, 56(c), 59(c) and 85 above; and

(b) otherwise denies the allegations contained in paragraph 88.

88A. The first, second, fourth and sixth defendants do not admit the allegations contained in paragraph 88.

L. Alleged liability in negligence – Gytech Pty Ltd

Allegations concerning duty of care

89. The Defendants do not admit the allegations contained in paragraph 89.

90. The Defendants do not admit the allegations contained in paragraph 90.

91. The Defendants do not admit the allegations contained in paragraph 91.

Allegations concerning standard of care

92. The Defendants do not admit the allegations contained in paragraph 92.

93. The Defendants do not admit the allegations contained in paragraph 93.

94. The Defendants do not admit the allegations contained in paragraph 94.

Allegations concerning breach of duty

95. The Defendants do not admit the allegations contained in paragraph 95.

Allegations concerning causation

96. The Defendants do not admit the allegations contained in paragraph 96.

97. The Defendants do not admit the allegations contained in paragraph 97.

M. Alleged liability in negligence – AMSL

Allegations concerning duty of care

98. In response to the allegations contained in paragraph 98, the sixth defendant, AMSL:

    (a) says that:

        (i) the reference to "at all material times" is vague and embarrassing and liable to be struck out; and

        (ii) the reference to alleged knowledge by AMSL of "the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation" in a rolled-up way and without specification of at what time the knowledge of each such matter is alleged to have existed or arisen is vague and embarrassing, and liable to be struck out;

    (b) under cover of that objection:

        (i) says that the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as referred to in paragraph 1(b)(i) above;

        (ii) refers to and repeats paragraphs 12, 55, 56(c) and 59(c) above; and

        (iii) otherwise denies the allegations contained in paragraph 98.

98A. The first, second, third and fourth defendants do not admit the allegations contained in paragraph 98.

99. In response to the allegations contained in paragraph 99, the sixth defendant, AMSL:

(a) says that the reference to "at all material times" is vague and embarrassing and liable to be struck out;

(b) under cover of that objection, refers to and repeats paragraphs 12, 55, 56(c) and 59(c) above; and

(c) otherwise denies the allegations contained in paragraph 99.

99A. The first, second, third and fourth defendants do not admit the allegations contained in paragraph 99.

100. In response to the allegations contained in paragraph 100, the sixth defendant, AMSL:

(a) says that:

(i) the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as referred to in paragraph 1(b)(i) above;

(ii) during the Commercial Supply Period:

A. the Essure Device was commercially supplied to patients in Australia via health care professionals and/or health care institutions in Australia (as pleaded in paragraph 24 above); and

B. implantation of the Essure Device was carried out (alternatively, was required to be carried out) by doctors pursuant to the process of consultation, advice and warning referred to in paragraphs 24 to 25 above;

(b) refers to and repeats paragraph 12 above and says that the effective date of the distribution agreement between AMSL and Bayer HealthCare LLC was 1 January 2015;

(c) refers to and repeats paragraphs 55, 56(c) and 59(c) above, and denies that it owed the Plaintiff and group members (or any of them) the duty of care alleged in paragraph 100 at any time during the Commercial Supply Period, alternatively, during the Commercial Supply Period prior to 1 January 2015 onwards; and

(d) otherwise, denies the allegations contained in paragraph 100.

100A. The first, second, third and fourth defendants do not admit the allegations contained in paragraph 100.

Allegations concerning standard of care

101. In response to the allegations contained in paragraph 101, the sixth defendant, AMSL:

(a) says that the reference to "at all material times" is vague and embarrassing and liable to be struck out;

(b) under cover of that objection:

(i) refers to and repeats paragraphs 55, 56(c) and 59(c) above; and

(ii) refers to and repeats paragraph 1(b)(i) above regarding the period for which the Essure Device was commercially supplied in Australia and registered on the ARTG; and

(c) otherwise denies the allegations contained in paragraph 101.

101A. The first, second, third and fourth defendants do not admit the allegations contained in paragraph 101.

102. In response to the allegations contained in paragraph 102, the sixth defendant, AMSL:

(a) says that the reference to "at all material times" is vague and embarrassing and liable to be struck out;

(b) under cover of that objection:

(i) refers to and repeats paragraphs 55, 56(c) and 59(c) above; and

(ii) refers to and repeats paragraph 1(b)(i) above regarding the period for which the Essure Device was commercially supplied in Australia and registered on the ARTG; and

(c) otherwise denies the allegations contained in paragraph 102.

102A. The first, second, third and fourth defendants do not admit the allegations contained in paragraph 102.

103. In response to the allegations contained in paragraph 103, the sixth defendant, AMSL:

(a) refers to and repeats paragraphs 12, 55, 56(c) and 59(c) above; and

(b) otherwise denies the allegations contained in paragraph 103.

103A. The first, second, third and fourth defendants do not admit the allegations contained in paragraph 103.

Allegations concerning breach of duty

104. In response to the allegations contained in paragraph 104, the sixth defendant, AMSL:

(a) refers to and repeats paragraphs 55, 56(c), 59(c) and 100 above;

(b) otherwise denies the allegations contained in paragraph 104; and

(c) says further that if, which is denied, AMSL is found to have engaged in any of the conduct alleged in paragraph 104 of the ASOC in breach of duty, for the reasons referred to in paragraph 12 above, it denies that it engaged in any such conduct prior to 1 January 2015.

104A. The first, second, third and fourth defendants do not admit the allegations contained in paragraph 104.

Allegations concerning causation

105. In response to the allegations contained in paragraph 105, the sixth defendant, AMSL:

(a) refers to paragraphs 55, 56(c), 59(c) and 104 above;

(b) says further that if, which is denied, AMSL is found to have breached the duty of care in the manner alleged in paragraph 105 of the ASOC:

(i) the group members (or any of them) who are alleged to have received the Essure Device during the Commercial Supply Period from about 2015 to 2017 would have:

A. acquired the Essure Device and undergone the Essure Device Procedure; and/or

B. further or alternatively, acquired contraception with which equal or greater risk was associated;

even if one or more warnings of the type referred to in paragraph 85(a) of the ASOC had been provided by AMSL, such that any breach of duty by AMSL (which is denied) was not relevantly a cause of those group members' harm, loss or damage; and

(ii) further or alternatively, any harm, loss or damage suffered by the Plaintiff and group members (or any of them) was the result of failure by the relevant doctor who carried out the Essure Device Procedure to:

A. properly carry out the Essure Device Procedure; and/or

B. properly carry out the process of consultation, advice and warning referred to in paragraphs 24 to 25 above,

such that any breach of duty by AMSL (which is denied) was not relevantly a cause of those group members' harm, loss or damage; and

(c) otherwise denies the allegations contained in paragraph 105.

105A. The first, second, third and fourth defendants do not admit the allegations contained in paragraph 105.

106. In response to the allegations contained in paragraph 106, the sixth defendant, AMSL:

(a) refers to paragraphs 55, 56(c), 59(c) and 104 above; and

(b) otherwise denies the allegations contained in paragraph 106.

106A. The first, second, third and fourth defendants do not admit the allegations contained in paragraph 106.

N. Alleged liability in negligence – Bayer Australia Ltd

Allegations concerning duty of care

107. In response to the allegations contained in paragraph 107, the first defendant, Bayer Australia Ltd:

(a) says that:

(i) the reference to "at all material times" is vague and embarrassing and liable to be struck out; and

(ii) the reference to alleged knowledge by Bayer Australia Ltd of "the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation" in a rolled-up way and without specification of at what time the knowledge of each such matter is alleged to have existed or arisen is vague and embarrassing, and liable to be struck out;

(b) under cover of that objection:

(i) says that the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as referred to in paragraph 1(b)(i) above;

(ii) refers to and repeats paragraphs 7, 55, 56(c) and 59(c) above; and

(iii) otherwise denies the allegations contained in paragraph 107.

107A. The second, third, fourth and sixth defendants do not admit the allegations contained in paragraph 107.

108. In response to the allegations contained in paragraph 108, the first defendant, Bayer Australia Ltd:

(a) says that the reference to "at all material times" is vague and embarrassing and liable to be struck out;

(b) under cover of that objection, refers to and repeats paragraphs 7, 55, 56(c) and 59(c) above; and

(c) otherwise denies the allegations contained in paragraph 108.

108A. The second, third, fourth and sixth defendants do not admit the allegations contained in paragraph 108.

109. In response to the allegations contained in paragraph 109, the first defendant, Bayer Australia Ltd:

(a) says that:

(i) the Commercial Supply Period for the Essure Device in Australia was between about 2001 and 28 August 2017, as referred to in paragraph 1(b)(i) above;

(ii) during the Commercial Supply Period:

A. the Essure Device was commercially supplied to patients in Australia via health care professionals and/or health care institutions in Australia (as pleaded in paragraph 24 above); and

B. implantation of the Essure Device was carried out (alternatively, was required to be carried out) by doctors pursuant to the process of consultation, advice and warning referred to in paragraphs 24 to 25 above;

(b) refers to and repeats paragraphs 7, 55, 56(c) and 59(c) above, and denies that it owed the Plaintiff and group members (or any of them) the duty of care alleged in paragraph 109 at any time during the Commercial Supply Period, alternatively, during the Commercial Supply Period prior to about June 2013; and

(c) otherwise, denies the allegations contained in paragraph 109.

109A. The second, third, fourth and sixth defendants do not admit the allegations contained in paragraph 109.

Allegations concerning standard of care

110. In response to the allegations contained in paragraph 110, the first defendant, Bayer Australia Ltd:

(a) says that the reference to “at all material times” is vague and embarrassing and liable to be struck out;

(b) under cover of that objection:

(i) refers to and repeats paragraphs 55, 56(c) and 59(c) above; and

(ii) refers to and repeats paragraphs 1(b)(i) and 26 above; and

(c) otherwise denies the allegations contained in paragraph 110.

110A. The second, third, fourth and sixth defendants do not admit the allegations contained in paragraph 110.

111. In response to the allegations contained in paragraph 111, the first defendant, Bayer Australia Ltd:

(a) says that the reference to “at all material times” is vague and embarrassing and liable to be struck out;

(b) under cover of that objection:

(i) refers to and repeats paragraphs 55, 56(c) and 59(c) above; and

(ii) refers to and repeats paragraph 26 above; and

(c) otherwise denies the allegations contained in paragraph 111.

111A. The second, third, fourth and sixth defendants do not admit the allegations contained in paragraph 111.

112. In response to the allegations contained in paragraph 112, the first defendant, Bayer Australia Ltd:

(a) refers to and repeats paragraphs 7, 55, 56(c) and 59(c) above; and

(b) otherwise denies the allegations contained in paragraph 112.

112A. The second, third, fourth and sixth defendants do not admit the allegations contained in paragraph 112.

Allegations concerning breach of duty

113. In response to the allegations contained in paragraph 113, the first defendant, Bayer Australia Ltd:

(a) refers to and repeats paragraphs 55, 56(c), 59(c) and 109 above;

(b) otherwise denies the allegations contained in paragraph 113; and

(c) says further that if, which is denied, Bayer Australia Ltd is found to have engaged in any of the conduct alleged in paragraph 113 of the ASOC in breach of duty, for the reasons referred to in paragraph 7 above, it denies that it engaged in any such conduct prior to about June 2013.

113A. The second, third, fourth and sixth defendants do not admit the allegations contained in paragraph 113.

Allegations concerning causation

114. In response to the allegations contained in paragraph 114, the first defendant, Bayer Australia Ltd:

(a) refers to paragraphs 55, 56(c), 59(c) and 113 above;

(b) says further that if, which is denied, Bayer Australia Ltd is found to have breached the duty of care in the manner alleged in paragraph 113 of the ASOC:

(i) the group members (or any of them) who are alleged to have received the Essure Device during the Commercial Supply Period from about 2014 would have:

A. acquired the Essure Device and undergone the Essure Device Procedure; and/or

B. further or alternatively, acquired contraception with which equal or greater risk was associated;

even if one or more warnings of the type referred to in paragraph 113 of the ASOC had been provided by Bayer Australia Ltd, such that any breach of duty by Bayer Australia Ltd (which is denied) did not cause or materially contribute to those group members' harm, loss or damage; and

(ii) further or alternatively, any harm, loss or damage suffered by the Plaintiff and group members (or any of them) was the result of failure by the relevant doctor who carried out the Essure Device Procedure to:

A. properly carry out the Essure Device Procedure; and/or

B. properly carry out the process of consultation, advice and warning referred to in paragraphs 24 to 25 above,

such that any breach of duty by Bayer Australia Ltd (which is denied) was not relevantly a cause of those group members' harm, loss or damage; and

(c) otherwise denies the allegations contained in paragraph 114.

114A. The second, third, fourth and sixth defendants do not admit the allegations contained in paragraph 114.

115. In response to the allegations contained in paragraph 115, the first defendant, Bayer Australia Ltd:

(a) refers to paragraphs 55, 56(c), 59(c) and 113 above; and

(b) otherwise denies the allegations contained in paragraph 115.

115A. The second, third, fourth and sixth defendants do not admit the allegations contained in paragraph 115.

O. Common questions of law and fact

116. In response to common questions pleaded at paragraphs 116 to 134 of the ASOC, the Defendants do not admit that the questions as framed:

(a) involve common issues of law or fact;

(b) alternatively, that insofar as those questions are found to be common, that they are common to the Plaintiff and all group members.

P. Limitations

117. Further to the matters set out in this defence, the Defendants will rely upon any applicable limitation periods that may apply in respect of any of the claims made by the Plaintiff and group members, once allegations and particulars of the date on which and place at which they allege injuries were suffered are provided.

Particulars

The legislation relied upon in this regard includes but is not limited to the *Limitation Act 1969* (NSW), the *Limitation of Actions Act 1958* (Vic), the *Limitation of Actions Act 1974* (QLD), the *Limitation Act 2005* (WA), the *Limitation Act 1935* (WA), the *Limitation Act 1985* (ACT), the *Limitation Act 1974* (Tas), the *Limitation of Actions Act 1936* (SA), the *Limitation Act 1981* (NT), the *Trade Practices Act 1974* (Cth) (including, in particular, ss 74J, 75AO, 82, and Division 2 of Part VIB) and the *Competition and Consumer Act 2010* (Cth) (including, in particular, Division 2 of Part VIB, and ss 143 and 236 of the ACL).

Further particulars will be provided following receipt of the relevant allegations and particulars from the Plaintiff and group members.

Q. Applicable tort reform legislation

118. To the extent that the Plaintiff's claim in this matter is subject to the *Wrongs Act 1958* (Vic), the Defendants rely upon the provisions of that Act and say that she is not entitled to recover damages for non-economic loss unless she has suffered "significant injury".

Particulars

Section 28LE, *Wrongs Act 1958 (*Vic).

119. Further, pending receipt of particulars of the Plaintiff and the group members' claims in this proceeding, the Defendants refer to and rely upon the applicable State and federal civil liability legislation in respect of the determination of those claims.

Particulars

The legislation relied upon in this regard includes but is not limited to the *Civil Liability Act 2002* (NSW), the *Wrongs Act 1958* (Vic), the *Civil Liability Act 2003* (QLD), the *Civil Liability Act 2002* (WA), the *Civil Law (Wrongs) Act 2002* (ACT), the *Civil Liability Act 2002* (Tas), the *Civil Liability Act 1936* (SA), the *Personal Injuries (Liabilities and Damages) Act 2003* (NT), Part VIB of the *Trade Practices Act 1974* (Cth), and Part VIB of the *Competition and Consumer Act 2010* (Cth).

D Collins

K A Brazenor

DATED: 1 May 2023 ~~11 September 2020~~

.....
Clayton Utz
Solicitors for the first to fourth and sixth defendants

SCHEDULE OF PARTIES

PATRICE SARAH TURNER	Plaintiff
and	
BAYER AUSTRALIA LTD ACN 000 138 714	First defendant
BAYER AKTIENGESELLSCHAFT	Second defendant
BAYER HEALTHCARE LLC	Third defendant
BAYER ESSURE INC	Fourth defendant
GYTECH PTY LTD ACN 076 599 570	Fifth defendant
AUSTRALASIAN MEDICAL & SCIENTIFIC LIMITED ABN 28 051 991 372	Sixth defendant
LAKE REGION MEDICAL INC	Seventh defendant
INTEGER HOLDINGS CORPORATION	Eighth defendant

Dated: 1 May 2023 ~~11 September 2020~~