Case: S ECI 2019 02916
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Rule 14.04

IN THE SUPREME COURT OF VICTORIA
AT MELBOURNE
COMMON LAW DIVISION
MAJOR TORTS LIST

S ECI 2019 02916

BETWEEN

PATRICE SARAH TURNER

Plaintiff

AND

BAYER AUSTRALIA LTD (ACN 000 138 714)
(and others in accordance with the attached schedule)

Defendants

DEFENCE

Date of document: 15 September 2020
Filed on behalf of: Fifth Defendant
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In answer to the plaintiff's statement of claim indorsed on the writ and dated 20 December 2019, Gytech says as follows:

A. The Plaintiff and Group Members

1 – 6. Gytech not know and therefore does not admit the allegations in paragraphs 1 – 6. Gytech says further the models of the Essure Device designated "ESS105", "ESS205" and "ESS505" (referred to in paragraph 1(b) of the SOC) were not supplied by it.

B. The Defendants

7 – 10. Gytech does not plead to the allegations in paragraphs 7 – 10 as no allegations are made against it.

11(a). Gytech admits the allegations in paragraph 11(a).

11(b). As to all of paragraph 11(b) Gytech denies the allegations and says further Conceptus and Gytech entered into a distribution agreement for the distribution of the Essure Device in Australia, effective as of 19 August 2010 (**Distribution Agreement**), which was due to expire on 19 August 2013. As of 1 July 2013 the Distribution Agreement was assigned from Conceptus to the Third Defendant, Bayer HeathCare LLC. The Distribution Agreement was subsequently extended to expire on 31 December 2014 (**Extension Agreement**).

Particulars

Copies of the Distribution Agreement and the Extension Agreement can be viewed at the offices of the Fifth Defendant's lawyers by prior appointment in usual office hours.

11(c). Gytech denies the allegations in paragraph 11(c).

12. Gytech does not plead to the allegations in paragraph 12 as no allegations are made against it.

C. Design of the Essure Device

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

(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, does not admit the allegations contained in that paragraph.

14. Gytech admits the allegations in paragraph 14.

15(a)(i). Gytech admits the allegations contained in paragraph 15(a)(i).

15(a)(ii). Gytech admits the allegations contained in paragraph 15(a)(ii).

15(a)(iii). Gytech admits the allegations contained in paragraph 15(a)(iii).

15(a)(iv). In response to the allegations contained in paragraph 15(a)(iv), Gytech says that each Essure Insert featured two platinum-iridium bands, but otherwise, do not admit those allegations.

15(a)(v). In response to the allegations contained in paragraph 15(a)(v), Gytech admits 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.

15(b). Gytech admits the allegations contained in paragraph 15(b).

15(c). In response to the allegations contained in paragraph 15(c), Gytech admit the allegations in respect of the 'wound down' configuration of the Essure Insert in the disposable delivery system, but otherwise, does not admit those allegations.

15(d). In response to the allegations contained in paragraph 15(d), Gytech admits the allegations in respect of the Outer Coil of the Essure Insert once deployed, but otherwise, does not admit those allegations.

15(e). In response to the allegations contained in paragraph 15(e), Gytech admits 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).

15(f). In response to the allegations contained in paragraph 15(f), Gytech:

(i) admits that the image contained in that subparagraph depicts the expanded Essure Insert (not to scale).

15(g). Gytech denies the allegations contained in paragraph 15(g).

16(a). Gytech admits the allegations contained in paragraph 16(a).

16(b). Gytech admits the allegations contained in paragraph 16(b).

16(c). Gytech admits the allegations contained in paragraph 16(c).

16(d). In response to the allegations contained in paragraph 16(d), Gytech:

(i) admits that fallopian tubes are peristaltic;

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

(iii) otherwise, does not admit the allegations contained in paragraph 16(d).

17. In relation all of paragraph 17, and to the Statement of Claim, Gytech says the purpose of the Essure Device was to provide patients with permanent birth control (contraception) by bilateral occlusion of the fallopian tubes (**Essure Device Purpose**). Gytech otherwise responds to the allegations in the subparagraphs to paragraph 17 as follows:

17(a). Gytech admits the allegations contained in paragraph 17(a).

17(b). In response to the allegations contained in paragraph 17(b), Gytech:

(i) admits that the image contained in that paragraph depicts the intended placement of the Essure Insert in a fallopian tube and uterine cavity (not to scale).

17(c). Gytech admits the allegations contained in paragraph 17(c) in so far as they concern the disposable delivery system.

17(d)-(i). Gytech refers to and repeats the Essure Device Purpose and says that:

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

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

(iii) 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).

(iv) 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.

(v) otherwise, deny the allegations in paragraph 17(d) – (i).

17(j). Gytech denies the allegations contained in paragraph 17(j).

D. Essure Insert Defects

18. Gytech refers to paragraph 17 above and says further, 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. Gytech otherwise denies the allegations contained in paragraph 18.

19. In relation to the whole of paragraph 19, Gytech says that during the period in which it was the distributor of the Essure Device in Australia (19 August 2010 to 31 December 2014 (**Gytech 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:

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; and

B. 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 2009, 2011, 2014.
Instructions for Use dated 2013.
Further particulars may be provided after discovery.

Gytech otherwise responds to the allegations in the subparagraphs to paragraph 19 as follows:

19(a). Gytech denies the allegations in paragraph 19(a) and says 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.

19(b). Gytech denies the allegations in paragraph 19(b) and says 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.

19(c)(i). In respect of paragraph 19(c)(i) Gytech denies the allegations and says further:

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

E. the reference in paragraph 19(c)(i) to “other metals” is vague, embarrassing and liable to be struck out.

19(c)(ii). In respect of paragraph 19(c)(ii) Gytech denies the allegations and says further:

A. it refers to and repeat paragraph 17 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.

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

(a) refers to and repeats paragraphs 18 and 19 above; and

(b) otherwise denies the allegations contained in paragraph 20.

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

(a) refers to and repeats paragraph 17 above in respect of the Essure Device Purpose;

(b) refers to and repeats paragraphs 19 and 20 above; and

(c) admit that once deployed as described in paragraph 17(d)-(i) 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 Gytech 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.

Particulars

Patient Information Brochures dated 2009, 2011 and 2014
Instructions for Use dated 2013
Further particulars may be provided after discovery.

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

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

(a) refers to and repeat paragraph 0 above; and

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

E. Injuries

23. Gytech denies the allegations in paragraph 23.

F. Marketing Materials

24. (a) Gytech says that the reference to "marketing material" is vague and embarrassing and liable to be struck out.

(b) Under cover of that objection, Gytech says that insofar as the allegations relate to it, and are limited to Gytech Supply Period, it admits that it provided to hospitals and day surgeries and, in respect of the Australian Capital Territory only, a supplier supplying hospitals and day surgeries (**health care institutions**) certain Marketing Material relating to the Essure Device which was supplied to it by Conceptus, and (possibly) later, companies in the Bayer group of companies. It otherwise denies the allegations in paragraph 24.

Particulars

It was a requirement of the Distribution Agreement that Gytech return to Conceptus (later Bayer HeathCare LLC) all data, prospectuses, and materials, including all copies of accumulated data, advertising and promotional materials, samples, and instruments, relating to the Essure Device within thirty (30) days after expiration or termination of the Distribution Agreement.

Further particulars of Marketing Materials will be provided after discovery.

25. Gytech denies the allegations in paragraph 25.

G. Regulatory History

26. Gytech does not admit the allegations in paragraph 26, but admits it was supplied in the Gytech Supply Period.

27. Gytech admits the allegations in paragraph 27.

28 – 42. Gytech does not plead to the allegations in paragraphs 28 – 42 as no allegations are made against it.

H. Supply and Acquisition of the Essure Device

43. Gytech does not know and therefore does not admit the allegations in paragraph 43.

44. Insofar as the allegations in paragraph 44 relate to it, Gytech denies the allegations and says further Conceptus and then Bayer HealthCare LLC supplied the Essure Device to Gytech in the Gytech Supply Period. Gytech otherwise does not plead to the allegations in paragraph 44.

45. Insofar as the allegations in paragraph 45 relate to it, Gytech admits the allegations.

46. Gytech denies the allegations in paragraph 46, and says further Gytech imported into Australia the Essure Device in the Gytech Supply Period, and supplied the devices to health care institutions, who supplied the Essure Device to patients.

47. Gytech does not know and therefore does not admit the allegations in paragraph 47.

48. Insofar as the allegations in paragraph 48 relate to it, Gytech admits the allegations, but only insofar as the Intermediary Suppliers are limited to health care institutions.

49. Gytech admits 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 Gytech Supply Period. Gytech otherwise does not know and does not admit the allegations in paragraph 49.

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

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

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

    (a) refers to and repeats paragraph 53 below;

    (b) under cover of the contents of that paragraph, says that insofar as the Essure Device was commercially supplied by it during the Gytech Supply Period to, and was implanted into a patient

in Australia, it admits that such supply and implantation constituted an acquisition for personal use by that patient; and

(c) Gytech otherwise does not admit the allegations in paragraph 51.

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

(a) admits 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, does not know, and does not admit, the allegations contained in paragraph 52.

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

(a) refers to and repeats paragraph 17 above in respect of the Essure Device Purpose; and

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

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

(a) refers to and repeats paragraph 51(b) above, and says further that insofar as the Essure Device was commercially supplied to and acquired by a patient in Australia during the Gytech Supply Period for the purpose described in paragraph 51 of the SOC, 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, does not know, and does not admit, the allegations contained in paragraph 54

I. Statutory Breaches

55. Gytech denies the allegations in paragraph 55.

56. Gytech denies the allegations in paragraph 56 and says further if the Essure Device was not of merchantable quality, or not of acceptable quality (which is denied), 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 of the Essure Device/s;

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

57. Gytech denies the allegations in paragraph 57.

58. Gytech denies the allegations in paragraph 58.

59. Gytech denies the allegations in paragraph 59 and says further;

(a) if, which is denied, the Essure Device (in the context of commercial supply to patients in Australia during the Gytech 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 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 in the Gytech Supply Period 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.

60. Gytech denies the allegations in paragraph 60.

61. Insofar as the allegations relate to Gytech, it denies the allegations in paragraph 61.

62. Gytech does not plead to the allegations in paragraph 62 as no allegations are made against it.

J. Liability of Bayer Essure Inc In Negligence

63 – 66. Gytech does not plead to the allegations in paragraphs 63 – 66 as no allegations are made against it.

67 - 68. Insofar as the allegations relate to Gytech, it denies the allegations in paragraph 67 – 68.

69 – 72. Gytech does not plead to the allegations in paragraph 69 – 72 as no allegations are made against it.

73 – 75. Gytech does not plead to the allegations in paragraph 73 – 75 as no allegations are made against it.

K. Liability of Bayer HealthCare LLC In Negligence

74 - 79. Gytech does not plead to the allegations in paragraphs 74 – 79 as no allegations are made against it.

80 – 81. Insofar as the allegations relate to Gytech, it denies the allegations in paragraph 80 – 81.

82 – 88. Gytech does not plead to the allegations in paragraph 82 – 88 as no allegations are made against it.

L. Liability of Gytech Pty Ltd In Negligence

89. Gytech denies the allegations in paragraph 89.

90. Gytech denies the allegations in paragraph 90.

91. Gytech denies the allegations in paragraph 91.

92. Gytech denies the allegations in paragraph 92.

93. Gytech denies the allegations in paragraph 93.

94. Gytech denies the allegations in paragraph 94.

95. Gytech denies the allegations in paragraph 95.

96. Gytech denies the allegations in paragraph 96.

97. Gytech denies the allegations in paragraph 97.

M. Liability of Australasian Medical and Scientific Limited In Negligence

98 – 100. Gytech does not plead to the allegations in paragraphs 98 – 100 as no allegations are made against it.

101 – 102. Insofar as the allegations relate to Gytech, it denies the allegations in paragraph 101 – 102.

103 – 106. Gytech does not plead to the allegations in paragraph 103 – 106 as no allegations are made against it.

N. Liability of Bayer Australia Ltd In Negligence

107 – 109. Gytech does not plead to the allegations in paragraphs 107 – 109 as no allegations are made against it.

110 – 111. Insofar as the allegations relate to Gytech, it denies the allegations in paragraph 110 – 111.

112 – 115. Gytech does not plead to the allegations in paragraph 112 – 115 as no allegations are made against it.

O. Common Questions of Law or Fact

116 - 134. In response to common questions pleaded at paragraphs 116 to 134 of the SOC, Gytech does 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

135. Further to the matters set out in this defence, Gytech 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

136. To the extent that the Plaintiff's claim in this matter is subject to the Wrongs Act 1958 (Vic), Gytech relies 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).

137. Further, pending receipt of particulars of the Plaintiff and the group members' claims in this proceeding, Gytech refers to and relies 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).

Dated: 15 September 2020

MILLS OAKLEY
Solicitors for Fifth Defendant

SCHEDULE OF PARTIES

PATRICE SARAH TURNER

Plaintiff

and

BAYER AUSTRALIA LTD (ACN 000 138 714)

First Defendant

and

BAYER AKTIENGESELLSCHAFT

Second Defendant

and

BAYER HEALTHCARE LLC

Third Defendant

and

BAYER ESSURE INC

Fourth Defendant

and

GYTECH PTY LIMITED (ACN 076 599 570)

Fifth Defendant

and

AUSTRALASION MEDICAL & SCIENTIFIC LIMITED (ARBN 051 991 372)

Sixth Defendant

and

LAKE REGIONAL MEDICAL INC

Seventh Defendant

and

INTEGER HOLDINGS CORPORATION

Eighth Defendant