IN THE SUPREME COURT OF VICTORIA
AT MELBOURNE
COMMON LAW DIVISION
GROUP PROCEEDINGS LIST

No. S ECI 2

BETWEEN:

DANIELLE BOPPING

First Plaintiff

and

MICHELLE LOUISE PEDERSEN

Second Plaintiff

and

MONASH IVF PTY LTD (ACN 006 942 990) and others according to the attached schedule

Defendants

THIRD AMENDED STATEMENT OF CLAIM

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*** Amendments between the statement of claim and amended statement of claim are marked up using single strike through and singe underline*

*** Amendments between the amended statement of claim and second amended statement of claim are marked up using double strike through and double underline*

*** Amendments between the second amended statement of claim and the third amended statement of claim are marked up using red underline*

A. PRELIMINARY

1. This proceeding is commenced as a representative proceeding pursuant to section 33C of the *Supreme Court Act* 1986 (Vic).

2. The plaintiffs bring this proceeding on their own behalf and on behalf of all other persons who:

(a) were patients of any of the defendants ~~the first defendant (**Monash IVF**)~~ between May 2019 and October 2020 (inclusive) (**relevant period**); ~~and/or~~

(b) ~~were patients of the second defendant (**Repromed**) in the relevant period;~~

and who

(i) received in vitro fertilisation (**IVF**) treatment provided by ~~Monash IVF, Repromed and/or the third defendant (**Monash IVF Group**)~~ any of the defendants; and/or

(ii) were provided the service of cell-free non-invasive pre-implantation genetic testing of their live embryos (fertilized eggs) for aneuploidy (**niPGT-A testing**) undertaken by or on behalf of any of the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~;

and

(iii) had embryos classified by or on behalf of any of the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ as abnormal (aneuploid) as a result of niPGT-A testing; and

(iv) had embryos destroyed, alternatively discarded, or did not proceed to embryo transfer (implanting into the uterus for the purpose of, inter alia, achieving live pregnancy) (**transfer**) as a result of the niPGT-A testing indicating embryos were positive for aneuploidy; and

(v) received written or oral notification from any of the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ that the niPGT-A testing of embryos by or on behalf of any of the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ has been suspended;

(c) were a spouse, or domestic partner of persons in (a) ~~or (b)~~;

(d) suffered loss and/or damage by way of:

A. psychiatric injury (as defined below) or physical inconvenience as a result of:

(i) receipt of the notification in ~~(b)~~(a)(v) above; and/or

(ii) the destruction of, and/or the failure to transfer, an embryo classified as aneuploidy as a result of the niPGT-A testing

(including without limitation, any psychiatric injury suffered as a result of the increased likelihood of the needless destruction of, or failure to transfer, an embryo incorrectly classified as aneuploidy as a result of the niPGT-A testing),

where "psychiatric injury in this group means nervous shock or another psychiatric or psychological injury, disturbance, disorder or condition which has been diagnosed as such in a diagnosis given to the person by a medical practitioner prior to 31 December 2021; and/or

B. financial loss as a result of:

(i) the niPGT-A testing; and/or

(ii) receipt of the notification in (a)(v) above; and/or

(iii) the destruction of, and/or the failure to transfer, an embryo classified as aneuploidy as a result of the niPGT-A testing;

(e) are the legal personal representatives of the estates of any deceased persons who came within paragraphs (a) to (d) above

(**group members**).

(In context, a reference to 'group members' in this statement of claim does not refer to persons referred to in paragraph 2(e~~de~~) above.)

3. The first plaintiff at all relevant times from in or about July 2017 was:

(a) a patient of ~~Monash IVF~~ the Eighth Defendant, Fertility Australia Pty Ltd (**Fertility Australia**);

(b) a consumer within the meaning of the *Australian Consumer Law* (Victoria), Schedule 2 of the *Competition and Consumer Act* 2010 (Cth) (**Australian Consumer Law**).

4. The second plaintiff at all relevant times from in or about 24 March 2020 was:

(a) a patient of the Second Defendant, Adelaide Fertility Centre Pty Ltd (**Repromed**);

(b) a consumer within the meaning of the Australian Consumer Law.

5. As at the time of the commencement of this proceeding there are 7 or more group members.

The defendants

6. The First Defendant, Monash IVF Pty Ltd (**Monash IVF**), at all relevant times:

(a) was and is a corporation capable of being sued;

(b) carried on business ~~in Australia~~ as a provider of fertility research and/or medical treatment services including IVF treatment, ~~in Australia,~~ including in Victoria, Tasmania and/or Queensland~~, including IVF treatment~~.

7. Repromed at all relevant times:

(a) was and is a corporation capable of being sued;

(b) carried on business ~~in Australia~~ as a provider of fertility research and/or medical treatment services including IVF treatment, in South Australia and the Northern Territory~~, including IVF treatment~~.;

8. The Third Defendant, Monash IVF Group Ltd (**Monash IVF Group**) at all relevant times:

(a) was and is an Australian public company capable of being sued;

(b) owned and/or controlled each of the other defendants ~~Monash IVF and Repromed~~;

(c) carried on business ~~in Australia~~ as a provider of fertility research and medical treatment services in Australia, including in Victoria, South Australia, the Northern Territory, Tasmania and Queensland.

8A. The Fourth Defendant, Monash IVF Auchenflower Pty Ltd (**Monash IVF Auchenflower**) at all relevant times:

(a) was and is a corporation capable of being sued;

(b) carried on business as a provider of fertility research and/or medical treatment services including IVF treatment, in Australia, including in Queensland.

8B. The Fifth Defendant, Palantrou Pty Ltd (**Palantrou**) at all relevant times:

(a) was and is a corporation capable of being sued;

(b) carried on business as a provider of fertility research and/or medical treatment services including IVF treatment, in Australia.

8C. The Sixth Defendant, Hobart IVF Pty Ltd (**Hobart IVF**) at all relevant times:

(a) was and is a corporation capable of being sued;

(b) carried on a business as a provider of fertility research and/or medical treatment services including IVF treatment, in Australia, including in Tasmania.

8D. The Seventh Defendant, Compass Fertility Pty Ltd (**Compass Fertility Pty Ltd**) at all relevant times:

(a) was and is a corporation capable of being sued;

(b) carried on business as a provider of fertility research and/or medical treatment services including IVF treatment, in Australia, including in Western Australia.

8E. The Eighth Defendant, Fertility Australia Pty Ltd at all relevant times:

(a) was and is a corporation capable of being sued;

(b) carried on business as a provider of fertility research and/or medical treatment services including IVF treatment, in Australia, including in New South Wales.

9. ~~The Monash IVF Group owns and controls the following Australian entities providing fertility related medical treatment including IVF treatment in Australia:~~

   (a) ~~Monash IVF;~~

   (b) ~~Monash IVF Holdings Pty Ltd;~~

   (c) ~~Monash IVF Group Acquisitions Pty Ltd;~~

   (d) ~~Monash IVF Finance Pty Ltd;~~

   (e) ~~Repromed;~~

   (f) ~~Repromed Finance Pty Ltd;~~

   (g) ~~Repromed Holdings Pty Ltd;~~

   (h) ~~Repromed Australia Pty Ltd;~~

   (i) ~~Repromed NZ Holding Pty Ltd;~~

   (j) ~~Healthbridge Enterprises Pty Ltd;~~

   (k) ~~Healthbridge Shared Services Pty Ltd;~~

   (l) ~~Healthbridge IVF Holdings Pty Ltd;~~

   (m) ~~Healthbridge Repromed Pty Ltd;~~

   (n) ~~Palantrou Pty Ltd;~~

   (o) ~~ACN 166702487 Pty Ltd;~~

   (p) ~~ACN 169060495 Pty Ltd;~~

   (q) ~~ACN 166701819 Pty Ltd;~~

   (r) ~~My IVF Pty Ltd;~~

   (s) ~~Monash Ultrasound Pty Ltd;~~

   (t) ~~Monash Reproductive Pathology & Genetics Pty Ltd;~~

   (u) ~~Monash IVF Auchenflower Pty Ltd (formerly Wesley Monash IVF Pty Ltd);~~

   (v) ~~Yoncat Pty Ltd;~~

   (w) ~~Sydney Ultrasound for Women Partnership;~~

   (x) ~~Ultrasonic Diagnostic Services Trust No. 2;~~

(y) ~~ACN 604384661 Pty Ltd;~~

(z) ~~Ultrasonic Diagnostic Services Pty Ltd;~~

~~(aa) Fertility Australia Pty Ltd;~~

~~(bb) Fertility Australia Trust;~~

~~(cc) MVF Sunshine Coast Pty Ltd (formerly HBIVF Johor Bahru Lab Pty Ltd);~~

~~(dd) Hobart IVF Pty Ltd; and~~

~~(ee) Gold Coast Ultrasound for Women Pty Ltd Australia.~~

~~**Particulars**~~

~~Annual reports of the Monash IVF Group for 2019 and 2020.~~

10. At all relevant times, the defendants:

(a) ~~Monash IVF;~~

(b) ~~Repromed; and/or~~

(c) ~~the Monash IVF Group~~

supplied fertility related medical treatment services including IVF treatment (**Services**) to the plaintiffs and group members in trade or commerce within the meaning of section 2 of the Australian Consumer Law.

Particulars of the Services

The Services comprised the delivery by the defendants to the plaintiffs and group members of niPGT-A testing as part of the supply or some or all of the following services:

(a) fertility health check;

(b) ovulation induction;

(c) egg timer test;

(d) in vitro fertilisation;

(e) ICSI - intracytoplasmic sperm injection;

(f) IUI - assisted insemination;

(g) egg freezing;

(h) supply of donor eggs;

(i) sperm retrieval;

(j) semen analysis;

(k) sperm health test;

(l) sperm freezing;

(m) supply of donor sperm;

(n) surrogacy;

(o) preimplantation genetic testing/preconception genetic screening;

(p) preimplantation genetic testing for aneuploidy screening.

The plaintiffs refer to *https://monashivf.com/services* and *https://repromed.com.au/fertility-treatment*.

Further particulars of the Services provided to the plaintiffs are provided at paragraphs 24 and 27 below.

Particulars of the Services provided to the group members shall be provided following the trial of common questions.

10A. Further or in the alternative to paragraph 10, at all times throughout the relevant period, each of:

(a) Monash IVF;

(b) Repromed;

(c) Monash IVF Auchenflower;

(d) Palantrou;

(e) Hobart IVF;

(f) Compass Fertility;

(g) Fertility Australia;

(**the Subsidiary Providers**) were agents of Monash IVF Group when they were providing and conducting business in relation to the Services to the plaintiffs and group members.

Particulars

The Subsidiary Providers had at least ostensible authority to act as agent for and represented the interests of, or were acting under the effective control of, or subject to the direction of, Monash IVF Group, in that they:

(i) each represented themselves to the world in their promotional material as 'part of the Monash IVF Group' or 'in association with the Monash IVF Group';

(ii) each distributed promotional and informational material to their patients bearing the logo or name of Monash IVF Group;

(iii) each had their accounts consolidated into the accounts of Monash IVF Group, by reason of the latter controlling each of the former;

(iv) each were controlled by Monash IVF Group, by reason of the latter holding all or a controlling portion of the shares of each of the former;

(v) each when presenting invoices to their customers, did not disclose their individual names other than for the purposes of identifying a bank account, and instead styled their invoices with the logo and/or contact details of Monash IVF Group;

(vi) in the case of Subsidiary Providers other than Compass Fertility, shared the same registered as Monash IVF Group.

Further particulars may be provided after discovery.

10B. At all relevant times, Monash IVF Group and or Repromed employed or engaged persons who were involved in the development, clinical trials, and commercial

offering of the niPGT-A testing for embryos of customers of the defendants, including:

(a) Professor Michelle Lane;

(b) Professor Kelton Tremellen;

(c) Dr Deirdre Zander-Fox;

(d) Dr Leanne Pacella-Ince;

(e) Dr Francesca Bell;

(f) Dr Hamish Hamilton;

(g) Dr Richard Henshaw;

(h) Professor Luk Rombauts;

(i) Dr Kee Ong;

(j) Michael Knapp; and

(k) Tedd Fuell;

(l) Dr Sameer Jatkar;

(m) Jayne Mullen;

(n) Brett Comer;

(o) Malik Jainudeen;

(p) Dr Yanhe Liu;

(q) Rebecca Redden;

(r) Tod Fullston.

Particulars

Insofar as the plaintiffs are presently able to say, relevantly:

(i) Professor Michelle Lane was:

(A) From around September 2007, a Scientific Director of Repromed;

(B) Between 2006 and December 2018, a director of Repromed;

(C) From 2016 on the management team of the Monash IVF Group as

Regional Manager, and from 2018 as Director of Research & Development;

until her death on 4 February 2020.

(ii) Professor Kelton Tremellen was:

(A) From at least September 2012, Medical Director and Approved Pathology Provider at Repromed;

(B) From 2006 until December 2018 a director of Repromed.

(iii) Dr Deirdre Zander-Fox was:

(A) From at least October 2017 Regional Scientific Director of Repromed;

(B) at a date unknown after 2017 Scientific Director at the Monash IVF Group;

(C) From 2021 on the Management Team of the Monash IVF Group as Chair of the Group Scientific Advisory Committee.

(iv) Dr Leanne Pacella-Ince was a PGS/PGD Coordinator at Repromed from at least 28 May 2015.

(v) Dr Francesca Bell was a research associate at Repromed from at least September 2016.

(vi) Dr Hamish Hamilton was:

(A) From at least 2011, Deputy Scientific Director at Repromed;

(B) From 2016 on the Management Team of the Monash IVF Group, as a General Manager of South Australia and Northern Territory, and from 2020 as Chief Operating Officer.

(vii) Dr Richard Henshaw:

(A) From at least December 2010 a Medical Director at Repromed;

(B) From 2006 and continuing until 2021, a director of Repromed;

(C) Between 2016 - 2021 was the executive director of the board of the Monash IVF Group.

(viii) Professor Luk Rombauts from at least 2016, Group Medical Director of and on the management team of the Monash IVF Group.

(ix) Dr Kee Ong as senior IVF Specialist at the Monash IVF Group

(x) Michael Knapp was:

(A) From 2006 a director of Repromed;

(B) From 2016 on the Management team of the Monash IVF as Group CFO and from 2017 to 2018 as company secretary;

(C) From 2019 on the board of directors of the Monash IVF Group as Chief Executive Officer & Managing Director.

(xi) Tedd Fuell was employed from 2016 by the Monash IVF Group as Group Quality Risk and Compliance Manager, and from around 2021 Chief Compliance & Risk Officer.

(xii) Dr Sameer Jatkar was Clinician/Fertility Specialist at Monash IVF Victoria from no later than 2 October 2018 until no earlier than 15 April 2019;

(xiii) Jayne Mullen was a Scientific Director of Monash IVF from November 2016 to July 2020;

(xiv) Brett Comer was the Chief Operating Officer of Monash IVF Group from at least 2018 until 27 March 2020;

(xv) Malik Jainudeen was the Chief Financial Officer (CFO) and company secretary of Monash IVF Group from 15 April 2019 to present, interim CFO of Monash IVF Group October 2018 to April 2019, Group Manager – Strategy and Finance of Monash IVF Group from June 2014 to at least October 2018;

(xvi) Dr Yanhe Liu was a Scientific Director of Monash IVF Group (Qld) Group

from March 2020 until December 2021;

(xvii) Rebecca Redden was from January 2019 to March 2020 operations manager at Repromed and from April 2020 to at least July 2023 regional manager of Repromed;

(xviii) Tod Fullston was the Coordinator of Reproductive Genetics at Repromed from about the end of 2016 until present.

Particulars of the details of employment and engagement should be within the knowledge of the defendants and additional particulars can be provided upon discovery including of relevant employment contracts.

10C. The acts and omissions of the employees and agents alleged in paragraphs 10B above and 16A and 62 below were performed in the course of and within the scope of their employment or engagement relevant to the development of niPGT-A testing, clinical trials for niPGT-A testing, and offering niPGT-A testing commercially for embryos of customers of the defendants.

10D. By reason of the matters pleaded in paragraphs 10B and 10C above, Monash IVF Group and Repromed are vicariously liable for the acts and omissions of the employees and agents relevant to the development of niPGT-A testing, clinical trials for niPGT-A testing, and offering niPGT-A testing commercially for embryos of customers of the defendants.

Particulars

The plaintiffs refer to and rely on the particulars joined to paragraphs 10B above and 16A and 62 below.

10E. Further, the acts and omissions of the senior employees on the management team, board members and directors alleged in paragraphs 10B above and 16A below, specifically:

(a) Dr Henshaw;

(b) Michael Knapp;

(c) Professor Lane;

(d) Professor Tremellen;

(e) Professor Luk Rombauts;

(f) Dr Hamilton;

were performed in the course of and within the scope of their position as a senior employee on the management team, board member or director on behalf of the relevant company in relation to the development of niPGT-A testing, clinical trials for niPGT-A testing, and offering niPGT-A testing commercially for embryos of customers of the defendants.

10F. By reason of the matters pleaded in paragraphs 10B and 10E above, Monash IVF Group and Repromed are vicariously liable for the acts and omissions of the senior employees on the management team, board members and directors identified in paragraph 10E above relating to the development of niPGT-A testing, clinical trials for niPGT-A testing, and offering niPGT-A testing commercially for embryos of customers of the defendants.

IVF research and treatment

11. The first IVF pregnancy in the world was achieved in 1973.

Particulars

IVF is a medical procedure whereby an egg is fertilized by sperm in a test tube or elsewhere outside the body.

12. At all relevant times, each of the defendants tested embryos of patients in its IVF program for the correct number of chromosomes prior to transfer:.

(a) ~~Monash IVF; and~~

(b) ~~Repromed; alternatively~~

(c) ~~the Monash IVF Group~~

~~tested embryos of patients in its IVF program for the correct number of chromosomes prior to transfer.~~

Particulars

~~Monash IVF and Repromed, their servants or agents, alternatively the Monash IVF Group~~ The defendants conducted pre-implantation genetic testing for aneuploidy (**PGT-A**) by taking a sample of the embryo's DNA by:

(i) embryo cell biopsy (**embryo biopsy**); and/or

(ii) collecting DNA from the culture media that the embryo has been growing in while in the laboratory (**niPGT-A**).

Only embryos which are found to be chromosomally normal for the tested chromosomes are considered suitable for transfer (see the Monash IVF Group Fact Sheet' as defined in paragraph 63 below).

13. At all relevant times:

(a) concordance between results of niPGT-A and standard pre-implantation genetic screening by embryo biopsy did not support clinical application of niPGT-A;

(b) niPGT-A was unsuitable for use as a diagnostic test to determine ploidy status of embryos.

Particulars

The plaintiffs refer~~s~~ to results of testing published in scientific literature and other information and material available prior to May 2019 which indicated that further research of niPGT-A was needed in order to evaluate its potential for clinical application, including:

(i) *Mitochondrial DNA content in embryo culture medium is significantly associated with human embryo fragmentation,* Human Reproduction, Vol.28, No.10 pp. 2652–2660, 2013, (S. Stigliani, P. Anserini, P.L.

Venturini and P. Scaruffi);

(ii) *New Advances of Preimplantation and Prenatal Genetic Screening and Noninvasive Testing as a Potential Predictor of Health Status of Babies,* BioMed Research International, 2014(Tanya Milachich);

(iii) *Advances in preimplantation genetic diagnosis/screening,* Science China, Life Sciences, 2014 (Yan Li Ying, Wei Yuan, Huang Jin, Zhu Xiao Hui, Shi Xiao Dan, Xia Xi, Yan Jie, Lu Cui Ling, Lian Ying, Li Rong, Liu Ping & Qiao Jie);

(iv) *Nuclear and mitochondrial DNA in blastocoele fluid and embryo culture medium: evidence and potential clinical use,* 2016 (Elizabeth R. Hammond, Andrew N. Shelling, and Lynsey M. Cree);

(v) *Noninvasive chromosome screening of human embryos by genome sequencing of embryo culture medium for in vitro fertilization,* PNAS 2016, (Juanjuan Xua, Rui Fang, Li Chena, Daozhen Chenb, Jian-Ping Xiao, Weimin Yang, Honghua Wang, Xiaoqing Song, Ting Ma, Shiping Bo, Chong Shi, Jun Ren, Lei Huang, Li-Yi Cai, Bing Yaoa, X. Sunney Xie and Sijia Lu.);

(vi) *Noninvasive chromosome screening of human embryos by genome sequencing of embryo culture medium for in vitro fertilization,* Annals of Medicine 2017;49:319–328, Liu et al. (2017);

(vii) *Non-invasive preimplantation genetic screening using array comparative genomic hybridization on spent culture media: a proof-of-concept pilot study,* Reproductive biomedicine Online, 2017 (Michael Feichtinger, Enrico Vaccari, Luca Carli, Elisabeth Wallner, Ulrike Mädel, Katharina Figl, Simone Palini, Wilfried Feichtinger);

(viii) *Origin and composition of cell-free DNA in spent medium from human*

embryo culture during preimplantation development, Obstet Gynecol Surv 2018;33:745–756, Vera- Rodriguez et al. (2018);

(ix) *Pushing the limits of detection: investigation of cell-free DNA for aneuploidy screening in embryos,* Fertil Steril 2018;110:467–475.e2, Ho et al. (2018);

(x) *Origin and composition of cell-free DNA in spent medium from human embryo culture during preimplantation development,* Human Reproduction, 2018 (M. Vera-Rodriguez, A. Diez-Juan, J. Jimenez-Almazan, S. Martinez, R. Navarro, V. Peinado, A. Mercader, M. Meseguer, D. Blesa, I. Moreno, D. Valbuena, C. Rubio, and C. Simon);

(xi) *Non-invasive preimplantation genetic testing (niPGT): the next revolution in reproductive genetics?,* Human Reproduction Update, 2019 (Megan Leaver, and DaganWells);

(xii) *Embryonic cell-free DNA versus trophectoderm biopsy for aneuploidy testing: concordance rate and clinical implications,* Fertil Steril 2019;112:510–519, Rubio et al. (2019);

(xiii) *Noninvasive preimplantation genetic testing may provide the solution to the problem of embryo mosaicism,* PNAS, 2019 (Lei Huanga, Sijia Lub, Catherine Racowskya, and X. Sunney Xiec);

(xiv) *Cell-free genetic testing of embryos,* Fertility & Sterility, 2020 (Lynsey Cree, Cynthia Farquhar).

No other known provider of fertility treatment for commercial reward in Australia or elsewhere throughout the world utilised niPGT-A in the relevant period as the sole basis of determining embryo viability (euploid status).

The plaintiffs also refer to and rely on paragraphs 14-16A below and the particulars joined to those paragraphs.

14. By reason of the matters alleged in the preceding paragraph, at all relevant times clinical application of niPGT-A as a substitute for embryo biopsy was ~~unsafe~~ unsuitable.

Particulars

Clinical application of niPGT-A as a substitute for embryo biopsy was ~~unsafe~~ unsuitable in that it cannot be relied upon to determine the aneuploid status of embryos without an increased risk of false-positives and false-negative results when compared with embryo biopsy.

14A. From about April 2017 to July 2017, a pilot study of niPGT-A was conducted by Repromed (**pilot study**).

Particulars

The plaintiffs refer to and rely on *NEST4E: A pilot study into the clinical effectiveness of Non-invasive Preimplantation Genetic Screening (PGS) method for Embryo ploidy status among patients undergoing IVF treatment* registered 6 April 2017, ACTRN 12617000500358, application 2016-12-891 submitted by Professor Lane on or around 24 January 2017 to Bellberry Limited and subsequent amendments and/or updates to that application on 20 December 2017; and information submitted by Professor Lane and/or Dr Bell to ANZCTR for registration of ACTRN 12617000500358.

14B. The pilot study:

(a) was conducted for the purpose of testing a method of Pre-implantation Genetic Screening (PGS) for human embryos developed by the investigators for amplifying cell-free DNA from human embryo culture medium using Next Generation Sequencing (NGS);

(b) was sponsored by Repromed;

(c) had as its principal investigator, Professor Lane;

(d) had as its co-investigators: Dr Bell, Dr Henshaw, and Dr Hamilton;

(e) had as its nominated contact person for public and scientific queries, Dr Bell;

(f) was granted Human Research Ethics (**HREC**) approval by Bellberry Limited on 9 March 2017 for the period 9 March 2017 to 31 December 2019;

(g) was granted HREC approval based on information submitted to Bellberry by Professor Lane;

(h) on 24 January 2017, was reported by Professor Lane to Bellberry Limited to be a Phase I trial;

(i) at no stage between its HREC approval on 9 March 2017 and 20 October 2020, included the aim of evaluating the implementation of niPGT-A for aneuploidy screening for embryos that were able to be screened by standard biopsy and PGS technology.

Particulars

The plaintiffs refer to and rely on the particulars to paragraph 14A above.

15. From on or about 2 July 2018 to 4 March 2019, a clinical trial of a method of niPGT-A was conducted by or on behalf of the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ (**clinical trial**).

Particulars

73 patients were recruited to participate in the trial to determine, inter alia, for aneuploid embryos the percentage of embryos tested using non-invasive pre-implantation genetic screening for aneuploidy with concordance to confirmatory biopsy and standard pre-implantation genetic screening. The plaintiff relies on clinical trial ACTRN 12618001064291.

The clinical trial followed the pilot study ~~*NEST4E: A pilot study into the clinical effectiveness of Non-invasive Preimplantation Genetic Screening (PGS)*~~

~~*method for Embryo ploidy status among patients undergoing IVF treatment* registered 6 April 2017, ACTRN 12617000500358.~~

~~Further particulars may be provided following discovery.~~

15A. The clinical trial:

(a) was conducted for the primary objective of evaluating implementation of niPGT-A for aneuploidy screening of Grade 3 embryos that were unable to be screened by standard biopsy and PGS technology;

(b) had as its main aims:

(i) For euploid embryos - determine the percentage concordance of media sample to 1st trimester screening;

(ii) For aneuploid embryos determine the percentage of embryos with concordance to a modified confirmatory biopsy and screening;

(iii) Determine clinical pregnancy rates and live birth outcomes of transferred embryos.

(c) was funded by Repromed;

(d) was sponsored by Repromed;

(e) had as its principal investigator, Professor Lane;

(f) had as its co-investigators, Dr Bell, Professor Tremellen, Dr Zander-Fox and Dr Pacella-Ince;

(g) had as its nominated contact person for public and scientific queries, Dr Bell;

(h) was granted HREC approval by Bellberry Limited on 8 June 2018 for the period 8 June 2018 to 31 December 2021;

(i) was granted HREC approval based on information submitted to Bellberry Limited by Professor Lane;

(j) from at least 8 June 2018, recruited patients from Repromed at 180 Fullarton Road, Dulwich, South Australia 5065;

(k) from about January 2019, recruited patients from:

(i) Monash IVF Parramatta (Level 2 1 Fennell Street Parramatta 2151);

(ii) Monash IVF Hawthorn (Epworth Hawthorn 50 Burwood Road Hawthorn 3122);

(iii) Monash IVF Clayton (Monash Surgical Private Hospital Suite 1 252-256 Clayton Road Clayton 3168);

(iv) Monash IVF Gold Coast (Level 3 2 Short St Southport 4215);

(l) from at least 8 June 2018, used niPGT-A testing on surplus media of human embryos collected from the recruited patients at Repromed at 180 Fullarton Road, Dulwich, South Australia 5065;

(m) on 14 March 2018 and 25 January 2019, was reported by Professor Lane to Bellberry Limited to be a Phase I trial;

(n) at no stage between its HREC approval on 8 June 2018 and 20 October 2020, included the aim of evaluating the implementation of niPGT-A for aneuploidy screening for embryos that were able to be screened by standard biopsy and PGS technology;

Particulars

The plaintiffs refer to and rely on Protocol Version 2 for *NEST4E Non-invasive Preimplantation Genetic Screening (PGS) testing for blastocysts that are not suitable for standard biopsy and PGS*, clinical trial registration ACTRN 12618001064291, application 2018-02-082 submitted by Professor Lane on or around 14 March 2018 to Bellberry Limited and subsequent amendments and/or updates to that application on 25 January 2019; and information submitted by Professor Lane and/or Dr Bell to ANZCTR for registration of ACTRN 12618001064291.

15B. From at least November 2018, Monash IVF Group, on behalf of Repromed, sought accreditation from NATA for accreditation of an In-Vitro Diagnostic Device (**IVD**), being niPGT-A.

Particulars

On 23 November 2018, Dr Zander-Fox wrote to NATA by email requesting accreditation of niPGT-A testing (PGT-A using cell free DNA in culture media rather than biopsied cells).

On or about 8 March 2019 NATA visited Repromed in South Australia for the purpose of conducting an audit in response to the request on 23 November 2018.

On 8 March 2019 NATA issued an interim report granting provisional approval of niPGT-A.

15C. In support of its request for accreditation, Monash IVF Group, on behalf of Repromed, made a written submission to NATA describing the results and validation process of the results of its niPGT-A testing and research (**NATA validation study**).

Particulars

The plaintiffs refer to and rely on *In house IVD Validation- Next generation sequencing- cell free DNA* and *Summary of Non Invasive PGS Validation.*

The validation study relied on data obtained from the pilot study and/or clinical trial.

The plaintiffs rely on the following representations made to NATA in the NATA validation study:

(a) Its validation process was performed on 114 media samples;

(b) Patients with euploid, aneuploid or inconclusive embryos were used for testing to validate NGS-cell free;

(c) 121 chromosomes were called as aneuploid with culture media compared with 114 chromosomes determined to be aneuploid with biopsied cells and niPGT-A had a concordance rate of 94.7% (109/115) compared to cell biopsy using PGT-A which is quoted as 98%;

(d) The sensitivity of the test for chromosomes was calculated based on the No of true positives (aneuploid)/(no of true positives + No. of false negatives) = 99.4%;

(e) The specificity of the test was calculated based on the no of true negatives (euploid)/ (No of true negatives + no of false positives) = 99.6%;

(f) The results were reviewed by medical specialists of the laboratory who have deemed this to be an accepted accuracy for the implementation of this test;

(g) A concordance rate of 98.2% (111/113) was achieved when compared with the biopsy cell result from the same embryo for all samples. A chromosome concordance rate of 99.9% (5175/5177) was achieved when compared with the biopsy cell results;

(h) The sensitivity of the test was calculated based on the No of true positives (aneuploid)/(no of true positives + No. of false negatives) = 100%;

(i) The specificity of the test was calculated based on the no of true negatives (euploid)/ (No of true negatives + no of false positives) = 95.3%.

15D. Prior to submitting the NATA validation study to NATA:

(a) the proposed NATA validation study was reviewed by Professor Rombauts;

(b) Professor Rombauts identified a number of concerns with the proposed NATA validation study;

(c) Professor Rombauts conveyed his concerns in writing to Professor Lane, Tedd Fuell, Michael Knapp and Brett Comer.

Particulars

(i) On or before 23 February 2019, Professor Rombauts reviewed a folder of documents containing the proposed NATA validation study.

(ii) The concerns identified by Professor Rombauts included:

(A) the number of embryos purported to have been tested for the validation study varied across the data between 47 and 130 or >300;

(B) the set of data from which metrics were calculated was not made clear;

(C) it was not clear to GMAC how many embryos the validation study started with and which ones were included in which studies;

(D) GMAC did not understand which data was sourced from the preclinical study, validation and verification studies and two small clinical trials;

(E) the accuracy of niPGT-A disclosed in the Patient Consent Form did not match the "Clinician Communication";

(F) patient fact sheets and consent forms failed to disclose the following, *inter alia*: that longer embryo culturing periods, such as that used in niPGT-A, tend to cause embryos to succumb; the likelihood of inconclusive results; and the rate of false positives.

(iii) On 23 February 2019. Professor Rombauts conveyed his concerns in writing to Professor Lane, Tedd Fuell, Michael Knapp and Brett Comer by email.

(d) Michael Knapp had concerns about the readiness of niPGT-A for commercial use, which he conveyed in writing to Professor Tremellen;

(e) Professor Tremellen had concerns about potential damage that might arise from implementing niPGT-A, which he conveyed to Michel Knapp in writing.

Particulars

(i) On or before 27 February 2019, Michael Knapp had a conversation with Professor Rombauts about the readiness of niPGT-A which led to postponement of the GMAC meeting scheduled for 28 February 2019 at which the commercial launch of niPGT-A was to be discussed;

(ii) On 28 February 2019 Michael Knapp conveyed his concern and the fact of postponement of the GMAC meeting to Professor Tremellen in writing by email;

(iii) On 28 February 2019, and in response to Michael Knapp, Professor Tremellen in writing by email:

(A) conveyed his concern to Michael Knapp that "*Unless we get this right this new test has the potential to damage more than its potential to boost. The more I delve into the detail the more concerned I get.*"

(B) advised Michael Knapp that a single scientist was involved in all steps of analysis of the trial of niPGT-A and the normal clinical 2 scientist double check for the type of research being conducted had not been used; there was no pregnancy data supporting a potential point of difference between invasive PGT-A and non-invasive testing; the pregnancy rate in the NEST4E embryos was pretty poor for euploid embryos; and that in Professor Tremellen's opinion, Professor Lane needed to let go of the project and give others input.

(f) Professor Rombauts had concerns that Monash IVF and/or Repromed had not published the results of the pilot study and/or the clinical trial, which he conveyed to Professor Lane in writing.

Particulars

The existence of the concerns and conveying to Professor Lane are inferred from correspondence between Professor Rombauts and Professor Tremellen on 29 July 2020 and from Professor Rombauts to Professor Lane dated 23 February 2019. Further particulars may be provided.

15E. The NATA validation study submitted to NATA contained the following material errors:

(a) 16 of the 121 samples were duplicates of other samples in the cohort;

(b) 5 of the 121 samples were triplicates of other samples in the cohort;

(c) 6 samples that formed part of the NATA validation study had been omitted from the cohort of 121 samples of which 4 were dis-concordant with their paired embryo biopsy sample;

Particulars

The plaintiffs refer to and rely on the review conducted by Tod Fullston dated 18 September 2020; and the *Review of the Non-Invasive PGT Outcomes and Validation interim report* dated 22 September 2020 and *Draft Report* dated 25 September 2020; and Report of Professor Alan Handyside and Tristan Hardy dated about 8 April 2021.

15F. The result of the material errors in the NATA validation study was that the concordance rate between the results of niPGT-A testing and confirmatory biopsy was represented to NATA to be higher than what was achieved in the pilot study and clinical trial.

Particulars

The plaintiffs refer to and rely on the review conducted by Tod Fullston dated 18 September 2020; and the *Review of the Non-Invasive PGT Outcomes and Validation interim report* dated 22 September 2020 and *Draft Report* dated 25 September 2020; and the review of Professor Alan Handyside dated about 2 February 2021; and Report of Professor Alan Handyside and Trisan Hardy dated about 8 April 2021.

15G. On or about 16 May 2019. the GMAC of Monash IVF Group approved the use of niPGT-A on a commercial basis for all embryos, including embryos that were able to be screened by standard biopsy and PGS technology.

Particulars

The plaintiffs refer to the minutes of the GMAC meeting dated 16 May 2019; the email from Sloane Karlson of Monash IVF Group to Professor Lane, Michael Knapp, Brett Comer, Malik Jainudeen; Dr Zander-Fox, Dr Hamilton and Tedd Fuell (and others) dated 17 May 2019; and the email from Sloane Karlson of Monash IVF Group to Dr Hamilton, Dr Pacella-Ince, Jayne Mullen, Dr Zander-Fox, Professor Lane, Michael Knapp, Brett Comer, Malik Jainudeen; and Tedd Fuell (and others) dated 20 May 2019.

15H. As of 20 May 2019, Monash IVF Group intended;

(a) niPGT-A would be offered as an adjunct to the existing PGS for embryos that are suitable for biopsy; and

(b) niPGT-A would be offered for embryos that are not suitable for biopsy.

Particulars

The plaintiffs rely on the email from Sloane Karlson of Monash IVF Group to Dr Hamilton, Dr Pacella-Ince, Jayne Mullen, Dr Zander-Fox, Professor Lane, Michael Knapp, Brett Comer, Malik Jainudeen; and Tedd Fuell (and others) dated 20 May 2019.

15I. On 10 July 2019, NATA granted the accreditation request referred to in paragraph 15B above (**accreditation**).

Particulars

On 10 July 2019, NATA granted accreditation to Repromed for *Pre-implantation genetic testing Aneuploidy screening of amplified cfDNA*.

15J. At no time prior to 10 July 2019 or at all before October 2020 did Monash IVF Group or Repromed tell NATA:

(a) the HREC approval it obtained from Bellberry Limited for the clinical trial was for a clinical trial of niPGT-A for the purpose of evaluating implementation of niPGT-A for aneuploidy screening of Grade 3 embryos that were unable to be screened by standard biopsy and PGS technology;

(c) the clinical trial was a Phase I clinical trial;

(d) that as of 20 May 2019 it intended to offer niPGT-A on a commercial basis as stand-alone test for aneuploidy for embryos that were suitable for standard biopsy and PGS technology;

(e) about the concerns of Professor Rombauts referred to in the particulars joined to paragraph 15D(b), (c) and (f) above;

(f) about the concerns of Michael Knapp and Professor Tremellen referred to in the particulars joined to paragraph 15D(d) above;

(g) about the concerns of Michael Knapp and Professor Tremellen referred to in the particulars joined to paragraph 15D(e) above;

(h) about the material errors in the NATA validation study pleaded at paragraph 15E above;

(i) that the concordance rate reported in the NATA validation study was likely to be incorrect in that it was higher in the NATA validation study than the results obtained from the pilot study and/or clinical trial.

15K. From 29 July 2020, by way Professor Tremellen, Rebecca Redden, Dr Pacella-Ince, Dr Hamilton, Dr Zander-Fox, and Professor Rombauts, Monash IVF Group and Repromed knew:

(a) The pregnancy rate for embryos screened using niPGT-A and determined to be euploid was significantly less than embryos screened using biopsy and determined to be euploid;

(b) The rate of high quality embryos from young women determined to be euploid after niPGT-A testing was significantly lower than biopsy;

(c) The matters in (a) and (b) above required:

(i) immediate suspension of niPGT-A; and

(ii) retaining and not discarding embryos that had been determined to be aneuploid after niPGT-A testing.

Particulars

The plaintiffs refer to and rely on correspondence between Professor Tremellen, Rebecca Redden, Dr Pacella-Ince, Dr Hamilton, Dr Zander-Fox and Professor Rombauts on 29 July 2020.

15L. Despite the knowledge in 15K, Monash IVF Group and Repromed:

(a) did not immediately suspend niPGT-A testing;

(b) did not inform the Subsidiary Providers to immediately suspend niPGT-A testing;

(c) did not immediately inform NATA of the matters pleaded in 15K above or (a) and (b) of this paragraph.

15M. The failure of Monash IVF Group and/or Repromed to disclose the matters pleaded in paragraphs 15J above to NATA until October 2020 permitted Repromed to:

(a) obtain accreditation on 10 July 2019;

(b) retain accreditation until October 2020.

Particulars

Particulars will be provided after delivery of expert evidence.

15N. The failure of Monash IVF Group and/or Repromed to disclose the matters pleaded in paragraphs 15K and 15L(a) and (b) above to NATA until October 2020 permitted Repromed to retain accreditation until October 2020.

Particulars

Particulars will be provided after delivery of expert evidence.

15O. Without accreditation from NATA, neither Monash IVF nor Repromed would have been permitted to offer niPGT-A testing on a commercial basis.

Particulars

Any “in-house” testing conducted on human samples that assists in clinical diagnosis or used to make decisions concerning patient treatment or management, and which had not been assessed and accredited by NATA and notified/registered with the TGA by 1 July 2017 could not be legally offered from that date.

Any commercial IVD sold for “Diagnostic Use” in Australia must be registered on the Australian Register for Therapeutic Goods (ARTG) by 1 July 2016. After that date any commercial IVD not registered on the ARTG could not be legally offered.

Further, it was a condition of ongoing accreditation that Repromed adhered to NATA Rules and NATA General Accreditation Criteria, which included ISO 15189 and the NATA Specific Accreditation Criteria. The plaintiffs refer to and rely on the notice of grant of accreditation from NATA to Dr Zander-Fox of Repromed, dated 10 July 2019.

Further particulars will be provided after delivery of expert evidence.

16. Following the clinical trial, the defendants:

(a) did not publish the results of the clinical trial for evaluation by peers in accordance with good Australian IVF treatment industry practice;

(b) did not conduct further alternatively conduct sufficient testing or evaluation of their niPGT-A method to determine the aneuploid status of embryos;

(c) from in or about May 2019, commenced commercial marketing of niPGT-A testing within Australia;

(d) from in or about May 2019 to October 2020, provided the service of niPGT-A testing as a diagnostic test to determine aneuploid status of embryos without confirmatory biopsy and standard pre-implantation genetic screening.

Particulars

The plaintiffs ~~relies~~ rely upon the Fact Sheet (defined in paragraph 63 below) and the provision of the Services including niPGT-A testing to the plaintiffs and group members.

Further particulars may be provided following discovery.

16A. At all times prior to offering, or making available niPGT-A testing on a commercial clinical basis, including to the patients of the Subsidiary Providers, and during the relevant period (as defined in paragraph 2(a) above) Monash IVF Group and Repromed (including by way of the employees and agents set out at paragraph 10B, who are identified in the particulars to this paragraph) knew clinical application of niPGT-A was unsuitable (as pleaded in paragraph 14 above) because:

(a) concordance between results of niPGT-A and standard pre-implantation genetic screening by embryo biopsy did not support clinical application of niPGT-A;

(b) niPGT-A was unsuitable for use as a diagnostic test to determine ploidy status of embryos; and

(c) niPGT-A was unsuitable to be offered or provided as a commercial clinical service.

Particulars of knowledge

Monash IVF Group and Repromed knew:

(i) by July 2016, by way of Professor Lane, Dr Bell, Dr Henshaw and Dr Hamilton, the matters pleaded in paragraphs 14A and 14B above;

(ii) by way of Professor Lane, Dr Henshaw, Dr Hamilton and Dr Bell, from at least 8 February 2017 that the experimental niPGT-A technology could produce false negatives.

(iii) by way of Professor Lane, Professor Tremellen, Dr Zander-Fox, Dr Pacella-Ince and Dr Bell (the investigators for the clinical trial referred to in paragraph 15 above) from at least 23 April 2018 that (before undertaking the clinical trial pleaded in paragraph 15 above) the main risk of niPGT-A was false positives for aneuploidy when using niPGT-A compared to the standard biopsy test, and that a modified biopsy procedure would be necessary to confirm positive results for aneuploidy from niPGT-A to avoid the risk of an embryo being incorrectly discarded;

(iv) by way of Professor Lane, Professor Tremellen, Dr Zander-Fox, Dr Pacella-Ince and Dr Bell knew from at least 28 May 2018 that niPGT-A was substantially less accurate than biopsy (90% compared to >98%), and that a modified biopsy procedure would be necessary to confirm positive results.

(v) by way of Dr Bell knew from at least 19 June 2018 that false positives were the highest risk of niPGT-A, and that Repromed declared that a standard confirmatory biopsy of embryos would be used in the NEST4E trial to confirm embryos classified as aneuploid by niPGT-A. These

embryos would be only those which were unsuitable for standard biopsy at the time of niPGT-A.

(vi) at least by 2 July 2018 and before 4 March 2019, by way of Professor Lane, Dr Bell, Professor Tremellen, Dr Zander-Fox and Dr Pacella-Ince, the matters pleaded in paragraphs 15 and 15A above;

(vii) at least by 23 November 2018 and before 8 March 2019, by way of Dr Zander-Fox, the matter pleaded at paragraph 15B above;

(viii) by way of Professor Lane, Professor Tremellen, Dr Zander-Fox, Dr Pacella-Ince and Dr Bell knew from at least 3 December 2018 that:

(A) in the NATA validation study of n=121 embryos tested with both niPGT-A and biopsy, 111/113 samples with conclusive results were reported as sharing concordance between both types of test (98.2%). 2/113 samples with conclusive results were reported as being discordant due to false positive niPGT-A results (1.8%); and

(B) of the 111 results reported as concordant, 5/111 expressed different chromosomal profiles (i.e. different types of aneuploidy) even where both final results were still aneuploid.

(x) by way of Professor Lane, from at least 12 December 2018, that data from the NATA validation study was to be used in a submission by Monash IVF Group, on behalf of Repromed, to NATA for the purpose of obtaining accreditation of niPGT-A from NATA as an IVD.

(xi) from at least 19 February 2019, by way of Professor Luk Rombauts, Professor Lane, Michael Knapp and Professor Tremellen that Professor Rombauts had advised on 19 February 2019 that the majority of clinicians at a MAC meeting the previous night agreed that niPGT-A should be offered only on embryos not suitable for C-PGT-A because it

was easy and quick to explain, removes the risk to a large extent that niPGT-A does not live up to the hype, that untested embryos will always carry a higher risk of an abnormality than one that is tested no matter the accuracy of the test, but if niPGT-A was offered as an alternative to C-PGT-A the story could be different, and standalone use of niPGT-A would be a risk if problems emerged with the test.

(xii) from at least 20 February 2019, by way of Professor Tremellen, Professor Rombauts, Tedd Fuell, Professor Lane and Michael Knapp that Professor Tremellen advised Professor Rombauts, Tedd Fuell, Professor Lane, Michael Knapp and Brett Comer that:

(A) the Adelaide group of doctors and scientists have years of experience with niPGT-A and are in a better position to make comment on the issues raised by Professor Rombauts on 19 February 2019;

(B) the research phase was limited to embryos otherwise not testable;

(xv) by 23 February 2019, by way of Professor Lane, Professor Rombauts, Tedd Fuell, Michael Knapp, Brett Comer, the matters pleaded in paragraphs 15C and 15D(a)(c) and (f) above;

(xvi) by 27 February 2019, by way of Michael Knapp and Professor Tremellen, the matters pleaded in paragraph 15C and 15D(d) and (e) above;

(xvii) by way of Professor Lane, Professor Tremellen, Dr Zander-Fox, Dr Pacella-Ince and Dr Bell from at least 18 March 2019, that Repromed NEST4E trial results (n=40 embryos) indicated a 10.5% false positive rate of niPGT-A and that the false positive rate for PGT-A according to NATA validation documentation was less than 2%.

(xviii) by way of Professor Lane ~~knew~~ from at least 10 April 2019 that many embryos failed to secrete sufficient amounts of DNA to produce conclusive niPGT-A results. Culturing embryos past day 5 greatly increased the conclusiveness of niPGT-A, but also increased the risk that embryos would hatch due to the hole produced by laser drilling of the zona pellucida.

(xix) by way of Dr Sameer Jatkar, Professor Lane, Professor Rombauts, Jayne Mullen, Brett Comer, Tedd Fuell from at least 15 April 2019 that:

(A) clinicians had expressed concern in Victorian Medical Advisory Committee (VMAC) meetings about the readiness for commercial use of niPGT-A, specifically the need for the trial data to be published for peer review; and

(B) the VMAC had agreed that niPGT-A should be used as a selection tool only, and not as a basis to discard embryos classified as aneuploid.

(xx) by way of Michael Knapp, Professor Lane, Brett Comer, Sloane Karlson, Malik Kainudeen and Dr Zander-Fox from at least 7 May 2019 that the intended policy at launch was for niPGT-A use to be restricted to only embryos unsuitable for biopsy.

(xxi) by way of Jayne Mullen and Dr Bell from at least 7 May 2019 that concerns had been raised with Jayne Mullen about consent forms provided by Dr Bell on 6 May 2019 appearing to have suspicious handwritten signatures and signatures attributed to different patients appeared to have been written in the same hand, and instances of signatures attributed to the same patient appeared to have been written in different handwriting.

(xxii) by way of Michael Knapp, Professor Lane, Brett Comer, Malik Jainudeen, Dr Zander-Fox from at least 7 May 2019 that those embryos unsuitable for biopsy and tested using niPGT-A had seen lower pregnancy rates at Repromed to that point in time.

(xxiii) by way of Dr Pacella-Ince, Professor Lane, Dr Bell and Dr Zander-Fox from at least 13 May 2019 that personal enmities and suspicious conduct was reported to Repromed for HR purposes among embryology staff responsible for niPGT-A culturing and culture media collection, including:

(A) disagreements and acrimony between Dr Todd Fullston and the pair of Professor Michelle Lane and Dr Francesca Bell;

(B) allegations of bullying and imperious behaviour by Professor Lane, with Dr Bell complicit;

(C) an allegation by Dr Leanne Pacella-Ince that Professor Lane interfered in a situation where the former had discovered that a discordant niPGT-A result was due to improper labelling of paperwork;

(D) an allegation that Professor Lane was keeping tabs on the behaviour of others; and

(E) an allegation that a former staff member had previously left Repromed after an altercation with Professor Lane.

(xxiv) by way of Dr Zander-Fox, Professor Lane and Dr Bell from 1 October 2019, that Dr Zander-Fox represented to clinicians in a presentation that:

(A) an n=80 embryos trial of niPGT-A produced a 7.5% inconclusive and a 5.5% false positive rate;

(B) niPGT-A's efficacy was highly dependent on embryology processes in the laboratory, especially due to contamination by

maternal DNA and between embryos, and the fact that some embryos fail to secrete enough DNA by day 5;

(C) embryos prepared for and tested with niPGT-A were unsuitable for thaw, biopsy, and refreeze (TARFO);

(D) 15% of clinical use cases involved niPGT-A being used as a standalone test due to clinician or patient preference; and

(E) apoptosis of cells (the natural programmed death of cells) was a likely source of false positives.

(xxv) by way of Dr Liu and Dr Bell, from at least 17 April 2020 that laboratory practice and culture were contributing to inconclusive rates, including:

(A) personal practices;

(B) how busy the laboratory was at times;

(C) a reduced volume of culture media in B samples;

(D) failure to wash embryos and exchange media properly; and

(E) contamination by the oil used to cover the petri dish.

(xxvii) by 29 July 2020, by way of Professor Tremellen, Rebecca Redden, Dr Pacella-Ince, Dr Hamilton, Dr Zander-Fox, and Professor Rombauts, the matters pleaded at paragraph 15K above;

(xxviii) by at least 18 September 2020, by way of Tod Fullston, the matters pleaded in paragraph 15E and 15F above;

(xxix) By way of Rebecca Redden and Dr Bell, from 21 September 2020, that on 21 September 2020 Dr Bell alleged in a meeting with Rebecca Redden that:

(A) after Professor Michelle Lane's death, Dr Leanne Pacella-Ince interrogated Dr Bell about her knowledge of issues with the validation trial data;

(B) Dr Hamilton was aware of the reason that said data was missing;

(C) Dr Bell feared possible criminal consequences of her actions;

(D) Professor Lane would, during the validation trial, provide Dr Bell with whole embryo marked to be discarded and instruct her to amplify them (presumably of media samples obtained from biopsied embryos for the purpose of obtaining concordant results);

(E) Dr Bell destroyed data from the trial in the form of a spreadsheet after Professor Lane's death, fearing that Professor Lane could no longer protect her;

(F) Dr Bell had confirmed that the destroyed/deleted data could be recovered;

(G) Dr Bell also burnt paper evidence (amplified data sheets), having removed it the day after Professor Lane passed away [this being in February 2020];

(H) Dr Bell intended, if data were recovered, to delete specific items that could incriminate her;

(I) Dr Bell was the only person who could "decode" the spreadsheet; and

(xxx) On 1 October 2020 by way of Professor Tremellen; Dr Hamilton; Dr Pacella-Ince; Dr Henshaw from attendance at a meeting of the Repromed Medical Advisory Committee (MAC):

(A) MAC members discussed issues with the NATA validation study data, including the duplication of samples and poor record keeping;

(B) that an attendee at the meeting, Professor Tremellen raised whether Repromed should continue collecting cell media in case niPGT-A were to be resumed in future;

(C) that an attendee at the meeting, Dr Koch and other MAC doctors questioned strongly whether cell media collection should cease;

(D) that an attendee at the meeting, Dr Hamilton stated that a validation study on new samples would take approximately three months to deliver results;

(E) a unanimous decision from all attendees was made for Repromed to completely hold niPGT-A;

(F) interstate clinics were continuing to offer niPGT-A;

(G) Repromed was concerned it would be liable if it tested samples obtained from interstate clinics;

(H) Dr Hamilton believed the "overall biggest exposure is potential loss child";

(I) a remediation package for affected patients would be offered;

16B. Despite the knowledge of Monash IVF and Repromed pleaded in paragraph 16A above, Monash IVF and Repromed did not suspend or withdraw niPGT-A testing until October 2020.

Particulars

(a) Despite the knowledge particularised in subparagraphs 16A(i) to 16A(xxiii) Monash IVF and Repromed offered niPGT-A testing as a commercial service from May 2019.

(b) Despite the knowledge particularised in subparagraphs 16A(i) to 16A(xxx), Monash IVF and Repromed did not suspend or withdraw niPGT-A testing until 19 October 2020.

17. In or about October 2020, the defendants ~~Monash IVF, Repromed and the Monash IVF Group~~:

    (a) determined that the proportion of abnormal embryos classified aneuploid by niPGT-A testing was higher than what was observed in the clinical trial;

    (b) suspended niPGT-A testing; and

    (c) notified patients including the plaintiffs and group members that niPGT-A testing had been suspended (**notice**)~~;~~.

Particulars

The notice was in writing sent by email:

(i) from Monash IVF to the first plaintiff in or about October 2020;

(ii) from Repromed to the second plaintiff on or about 10 October 2020~~.~~;

In the notice, Monash IVF Group and/or Repromed informed the first and second plaintiffs that the ni-PGT-A testing preliminary investigations showed the proportion of abnormal embryos classified (aneuploid) appeared to be marginally higher than what was observed in the clinical trial.

~~Further particulars shall be provided at or prior to trial.~~

Particulars of the notice to group members shall be provided following the trial of the common questions.

18. From October 2020, the defendants ~~Monash IVF, Repromed and the Monash IVF Group~~ offered only the service of embryo biopsy for the purposes of preimplantation genetic testing to determine the aneuploid status of embryos.

19. By reason of the matters alleged in paragraphs 11 to 18 above, prior to October 2020, the defendants ~~Monash IVF~~ did not undertake testing or evaluation, sufficient testing or evaluation and/or further testing or evaluation in relation to whether niPGT-A testing:

    (a) was appropriate for clinical application as a diagnostic test to determine aneuploid status of embryos without confirmatory biopsy and standard pre-implantation genetic screening;

(b) results were concordant with embryo biopsy;

(c) results were appropriate for use as the sole basis to determine embryo viability (euploid status).

20. In the premises, the defendants' use of niPGT-A testing instead of embryo biopsy to determine the aneuploid status of embryos increased an individual's risk of developing psychiatric injury, loss and damage if:

(a) the nature and risks of niPGT-A testing was not disclosed to patients;

Particulars

The plaintiffs ~~relies~~ rely upon paragraph 21 below.

(b) a viable euploid embryo was or may have been destroyed or not transferred based upon results of niPGT-A testing.

Informed consent

21. During the relevant period, the defendants ~~Monash IVF, Repromed and the Monash IVF Group~~ did not inform any of the plaintiffs or ~~any of the~~ group members:

(a) adequately or at all as to the nature of niPGT-A, and in particular the risk that niPGT-A might produce false-positive results and therefore an erroneous determination that an embryo was aneuploidy and not suitable for transfer;

(b) that embryo biopsy was a more reliable pre-implantation genetic test to detect aneuploidy than niPGT-A;

(c) that clinical application of niPGT-A was not appropriate to determine embryos that were aneuploidy, and therefore not suitable for transfer, without confirmatory embryo biopsy;

(d) that niPGT-A was appropriate for use in prioritising embryos for transfer once the viability (euploid status) of the embryo had been determined by embryo biopsy;

(e) that whilst other providers of IVF medical services in Australia use niPGT-A including to prioritise embryos for transfer, it is not used by other providers of

IVF medical services as the sole basis to determine the euploid status of the embryo;

(f) that it is good professional practice in the IVF treatment industry in Australia to publish results of clinical trials, thereby exposing the results to peer review so that new technologies do not compromise safety and/or increase the already considerable financial burden to patients;

(g) that the results of the clinical trial conducted by or on behalf of the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ had not been published or otherwise made available for peer review in accordance with good professional industry practice;

(h) that the clinical trial was not a proper basis for clinical application of niPGT-A to determine viability of embryos in the course of treatment of patients by the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~;

(i) that the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ conducted the only fertility treatment program in Australia, further and in the alternative in the world, using niPGT-A testing results as the sole basis to:

(i) determine the aneuploid status of embryos;

(ii) discard or not proceed to transfer embryos.

Particulars

The plaintiffs ~~relies~~ rely upon the particulars sub-joined to paragraph 13-15L and at 16A(i) to 16A(xxx) above.

Further particulars shall be provided after discovery and delivery of expert evidence.

22. In the premises of paragraph 21 above, the defendants ~~Monash IVF and/or Repromed~~ did not obtain informed consent from the plaintiffs or group members prior to conducting the niPGT-A testing of their embryos.

B. CONTRACTS

The first plaintiff's treatment

23. On or about 7 July 2017, the first plaintiff consulted ~~Monash IVF~~ Fertility Australia in Bondi, NSW.

Particulars

The plaintiff consulted Dr Devine, a fertility specialist with ~~Monash IVF~~ Fertility Australia, in Bondi, NSW, in relation to undergoing IVF treatment including egg retrieval using donor sperm in circumstances including that she was then aged 39 years (having been born on 11 September 1977), did not have a partner and did not have any children.

24. ~~Monash IVF~~ Fertility Australia provided IVF treatment to and for the benefit of the first plaintiff during the period from about 7 July 2017 to 15 January 2020.

Particulars

The treatment included:

(i) IVF specialist consultations on, but not limited to, about 7 July 2017, 17 August 2017, 27 September 2018, 1 March 2019 and 15 January 2020;

(ii) initial counsellor screening on 2 August 2017;

(iii) placing an order with California Cryobank (US) on 24 September 2018 (California Cryobank Invoice 13-781337 for donor subscription; and sales order No. 11-677434) for donor sperm;

(iv) a nurse orientation on 27 September 2018;

(v) oocyte Recovery on or about 14 November 2018 (Eastern Suburbs Endoscopy Clinic Tax Invoice/Receipt 36154) and on or about 25 November 2019 (Bondi Junction Private Hospital Informed Financial Consent 25 November 2019);

(vi) IVF treatment on or about 3 November 2018 (~~Monash IVF~~ tax invoice

456123) and early November 2019 (see Bondi Junction Treatment Summary dated 26 November 2019) including a treatment cycle using the donor sperm and related services; and

(vii) frozen embryo transfer on or about 2 February 2019; on or about 6 April 2019; on or about 19 July 2019 (invoice 471854); and on or about 14 August 2019.

Further particulars are known to Fertility Australia ~~Monash IVF~~, and shall be provided following discovery and interrogation.

25. In the premises, in or about July alternatively December 2017, the first plaintiff and ~~Monash IVF~~ Fertility Australia entered into an agreement (**Bopping agreement**) whereby ~~Monash IVF~~ Fertility Australia agreed to provide medical services including IVF treatment to the first plaintiff for the purposes of the fertility treatment of the first plaintiff.

Particulars

The Bopping agreement was in writing, oral and to be implied. Insofar as it was in writing, the first plaintiff refers to invoices referred to in the particulars to the previous paragraph; and to the quotation from ~~Monash IVF~~ Fertility Australia to the first plaintiff dated 6 December 2017 (RMU 1659) signed by the first plaintiff.

Insofar as it was oral it is comprised by conversations between the first plaintiff and Dr Devine, a fertility specialist with ~~Monash IVF~~ Fertility Australia in or about July 2017, the substance of which is to the effect alleged.

Insofar as it was implied, the first plaintiff refers to the treatment provided to her by ~~Monash IVF~~ Fertility Australia.

Further particulars shall be provided at or prior to trial.

Particulars of contracts between Fertility Australia ~~Monash IVF~~ and individual

group members will be provided following the trial of common questions.

The second plaintiff's treatment

26. On or about 24 March 2020, the second plaintiff consulted Repromed in Darwin, Northern Territory.

Particulars

The second plaintiff consulted Reprome~~nd~~ fertility specialist Dr Stephanie Girle (by telephone) in relation to undergoing IVF treatment including egg retrieval and fertilization using her husband's sperm in circumstances including that she was then aged 35 years (having been born on 12 February 1985), and her diagnosis of endometriosis and adenomyosis.

27. Repromed provided IVF treatment to and for the benefit of the second plaintiff during the period from 24 March 2020 to March 2021 (inclusive).

Particulars

The treatment included

(i) IVF specialist consultations with Dr Girle on, but not limited to, about:

A. 24 March 2020 (by phone), 24 April 2020 and 26 May 2020 (by phone);

B. 15 June 2020 at Repromed Darwin Private Hospital clinic;

C. 24 August 2020 at Repromed clinic;

(ii) 11 May 2020 – Egg retrieval, with all eggs frozen (Repromed IVF/ICSI quote; Financial Information 441107 dated 27 April 2020; and receipt 78578 dated 7 May 2020);

(iii) 18 May 2020 – Zoladex inserted at Repromed Darwin Private Hospital clinic;

(iv) 15 June 2020 – Zoladex inserted at Repromed Darwin Private Hospital clinic;

(v) 22 July 2020 – Single embryo transfer (Repromed Financial Information 442920 dated 21 May 2020; and receipt 79551 dated 22 July 2020);

(vi) 21 September 2020 - Zoladex inserted at Repromed Darwin Private Hospital clinic;

(vii) 28 October 2020 – Single embryo transfer (provided at no cost to the second plaintiff);

(viii) 16 December 2020 - Zoladex inserted at Repromed Darwin Private Hospital clinic;

(ix) 13 January 2021 - Zoladex inserted at Repromed Darwin Private Hospital clinic;

(x) 2 March 2021 – Double embryo transfer (Repromed Financial Information 468977 dated 4 February 2021 and 469517 dated 10 February 2021; and receipt 79551 dated 22 July 2020)(provided at no cost to the second plaintiff).

Further particulars are known to Repromed and shall be provided following discovery and interrogation.

28. In the premises, on or about 24 March 2020, the second plaintiff and Repromed entered into an agreement (**Pedersen agreement**) whereby Repromed agreed to provide medical services including IVF treatment to the second plaintiff for the purposes of the fertility treatment of the second plaintiff.

Particulars

The Pedersen agreement was in writing, oral and to be implied. Insofar as it was in writing, the second plaintiff refers to invoices and other documentation referred to in the particulars to the previous paragraph; Consent Form F dated and IVF treatment summary signed by her on 24 April 2020.

Insofar as it was oral it is comprised by conversations between the second

plaintiff and Dr Girle, a fertility specialist with Repromed on or about 24 March and 24 April 2020, the substance of which is to the effect alleged.

Insofar as it was implied, the first plaintiff refers to the treatment provided to her by Repromed.

Further particulars shall be provided at or prior to trial.

Particulars of contracts between Repromed and individual group members will be provided following the trial of common questions.

28A. Each of the Subsidiary Providers entered into agreements with group members to provide them with medical services including IVF treatment.

Particulars

Particulars of contracts between the Subsidiary and individual group members will be provided following the trial of common questions.

Testing and destruction of embryos

29. On or about 30 November 2019, ~~Monash IVF, Repromed and/or the~~ Monash IVF Group, either directly or by its agents the Subsidiary Providers, ~~its servants or agents~~ performed niPGT-A testing on an embryo produced from donor sperm and an egg of the first plaintiff (**Ms Bopping's embryo**).

Particulars

Monash IVF Treatment Summary dated 26 November 2019.

The first plaintiff does not presently know who conducted the testing. Further particulars shall be provided once discovery and interrogation is complete.

30. In or about December 2019, Fertility Australia ~~Monash IVF~~ notified the first plaintiff that the embryo had an abnormal niPGT-A test result having been identified as aneuploidy (**Bopping test results**).

Particulars

The Bopping test results were in writing. Further particulars are known to Fertility Australia ~~Monash IVF~~.

31. Following notification of the Bopping test results, ~~Monash IVF, Repromed and/or the~~ Monash IVF Group, either directly or by its agents, ~~it/their servants or agents~~ discarded Ms Bopping's embryo.

Particulars

The first plaintiff was notified verbally by an unknown agent or representative of Monash IVF Group, shortly after notification of the Bopping test results, that the embryo had been discarded.

Further particulars are known to Fertility Australia, alternatively Monash IVF Group ~~Monash IVF~~, and shall be provided after discovery and interrogation.

32. In or about:

(a) May 2020; and

(b) September 2020,

~~Monash IVF, Repromed and/or the~~ Monash IVF Group, either directly or by its agents the Subsidiary Providers, ~~its servants or agents~~ performed niPGT-A testing on a total of seven (7) embryos produced from the second plaintiff's husband, Damien Pedersen's sperm and the second plaintiff's eggs (**Ms Pedersen's embryos**).

Particulars

4 of Ms Pedersen's embryos were tested on or about 29 May 2020 (Repromed invoice 623483 dated 2 June 2020).

3 further of Ms Pedersen's embryos were tested on or about 2 September 2020 Repromed invoice 635627 dated 17 September 2020).

The second plaintiff does not presently know who conducted the testing. Further particulars are known to one or more of the defendants, and shall be provided once discovery and interrogation is complete.

33. In separate notifications sent in or about:

    (a) June 2020; and

    (b) September 2020,

    Repromed, alternatively Monash IVF Group, notified the second plaintiff that two of her embryos had abnormal niPGT-A test results having been identified as aneuploidy (**Pedersen test results**).

Particulars

The Pedersen test results were in writing. Further particulars are known to Repromed, alternatively Monash IVF Group, and shall be provided after discovery and interrogation.

34. Following notification of and in reliance upon the Pedersen test results, the second plaintiff donated her two embryos which had returned abnormal niPGT-A test results to research.

Particulars

The second plaintiff refers to emails from the Repromed Embryology Laboratory dated 9 July 2020 and 4 September 2020.

Further particulars are known to Repromed, further Monash IVF Group, and shall be provided after discovery and interrogation.

Terms of the agreements

35. It was an implied term of the Bopping agreement and the Pedersen agreement, and each of the other agreements in paragraph 28A, that ~~Monash IVF and Repromed~~ and the particular Subsidiary Provider as the case may be, ~~respectively,~~ would exercise the care and skill of a reasonably competent provider of infertility treatment to the plaintiffs (**Due Care Term**).

Particulars

The term is implied in order to give the agreements the business efficacy which the parties intended.

Breach of agreements

36. The Subsidiary Providers ~~Monash IVF and Repromed~~ each breached the Due Care Term.

Particulars

The plaintiffs refer to the particulars of the breach of the Duty at paragraph 62 below.

C. BREACH OF GUARANTEES UNDER THE AUSTRALIAN CONSUMER LAW

37. In providing the niPGT-A testing, the defendants supplied services to the plaintiffs and group members, in trade or commerce, within the meaning of s 2 of the Australian Consumer Law.

38. Pursuant to section 60 of the Australian Consumer Law, the defendants ~~Monash IVF and Repromed~~ guaranteed to the plaintiffs and group members that the supply of the niPGT-A testing would be rendered with due care and skill (**Due Care Guarantee**).

39. Each of the plaintiffs and group members impliedly made known to the defendants ~~Monash IVF or Repromed~~, by engaging them to provide IVF treatment and niPGT-A testing, that they were acquiring the niPGT-A testing for the purpose of safely determining the viability of their embryos (**embryo viability purpose**).

40. Pursuant to section 61 of the Australian Consumer Law, the defendants:

~~(a) Monash IVF guaranteed to the first plaintiff; and~~

~~(b) Repromed guaranteed to the second plaintiff; and~~

~~(c) Monash IVF and/or Repromed guaranteed to the group members;~~

guaranteed to the plaintiffs and the group members that the supply of the niPGT-A testing would be fit for the embryo viability purpose (**Fitness for Purpose Guarantee**).

40A. At all material times, it was reasonably foreseeable to each of the defendants that if they breached the Due Care Guarantee or Fitness for Purpose Guarantee the plaintiffs and each of the group members would suffer loss or damage of the kind alleged in paragraph 45(f) and (g) below.

Particulars

The plaintiffs refer to and rely on the matters referred to in paragraphs 43-53 below and the particulars joined to those paragraphs.

41. ~~If the allegations in paragraphs 13 and 14 are proved, then the~~ At all material times, niPGT-A testing was not:

(a) rendered by the defendants with due care and skill ~~safe to use to determine embryo viability~~; or

(b) fit for the purpose of determining embryo viability.

Particulars

The plaintiffs repeat the particulars to paragraphs 13-16A above ~~and 14~~.

42. In the premises, the defendants ~~Monash IVF and Repromed~~ breached the:

(a) Due Care Guarantee; and/or

(b) Fitness for Purpose Guarantee; and

thereby caused the plaintiffs and group members loss and damage of the kinds alleged in paragraph 45.

D. NEGLIGENCE

Duty

43. At all relevant times from in or about May 2019, the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~:

(a) had control over:

(i) clinical or other evaluation of whether niPGT-A was appropriate for clinical application to determine the euploid status of the embryo;

(ii) their commercial marketing of niPGT-A for clinical application to determine the euploid status of the embryo;

(iii) the conduct of PGT-A testing on patient embryos; and

(iv) information given to patients, employees, contractors, agents including IVF specialists as to the risks of the use of niPGT-A to determine the aneuploid status of an embryo;

(b) exercised the control referred to in (a) above; and

(c) in the premises, had control over use by the defendants of niPGT-A testing to determine the aneuploid status of patient embryos within their IVF treatment programs.

44. At all relevant times:

(a) aneuploidy is the principal genetic factor causing reproductive failure during both natural and IVF cycles;

(b) IVF treatment programs conducted by the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ for their commercial benefit offer pre-implantation genetic testing of embryos for aneuploidy (PGT-A) in order to facilitate transfer of euploid embryos and thereby improve clinical outcomes (pregnancy and live birth) for persons undergoing IVF treatment;

(c) the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ tested embryos of patients within their IVF treatment programs to determine aneuploid status prior to transfer;

(d) the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ destroyed or did not transfer embryos classified as aneuploid;

(e) providing IVF treatment carries an increased risk of incorrect classification of embryos as aneuploid if embryo biopsy is not conducted;

(f) the destruction or non-transfer of viable euploid embryos incorrectly classified

as aneuploid was capable of causing psychiatric injury, physical inconvenience and financial loss to patients;

(g) during 2019 and 2020, clinical application of niPGT-A was a new technology;

(h) patients of the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ were entitled to receive sufficient information as to the nature and risks of the niPGT-A testing to ensure the patients provided informed consent to such testing;

(i) the nature of niPGT-A included the risk that the niPGT-A testing might produce false positive results and therefore an erroneous determination that an embryo was aneuploidy and not suitable for transfer;

(j) embryo biopsy was a more reliable pre-implantation genetic test to detect aneuploidy than niPGT-A testing;

(k) a niPGT-A test result indicating aneuploid status without confirmatory embryo biopsy was not an appropriate basis to determine that embryos were not suitable for transfer;

(l) niPGT-A test results are appropriate for prioritising embryos classified as euploid for transfer;

(m) during the relevant period, it was good IVF treatment industry practice in Australia to use niPGT-A test results to prioritise embryos for transfer, but not as a basis to discard embryos;

(n) reliance upon clinical medical trials without peer review of results and without conducting further and more comprehensive trials carries with it a risk of unintended outcomes inconsistent with trial results in practice;

(o) the clinical trial referred to in paragraph 15 above had not been peer reviewed or followed by further and more comprehensive trials of niPGT-A. The plaintiffs refer to and rely on the matters referred to in paragraphs 15A, 15D,

16 and 16A and the particulars joined to those paragraphs;

(p) having regard to the state of scientific knowledge in 2019 and 2020, the clinical trial was not a proper basis for treatment of patients by the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ using niPGT-A testing to determine aneuploid status of embryos. The plaintiffs refer to and rely on the matters referred to in paragraphs 13-16A and the particulars joined to those paragraphs;

(q) the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ conducted the only fertility treatment program in the world using niPGT-A testing as the sole basis to discard live embryos;

(r) results of niPGT-A are not concordant with embryo biopsy;

(s) niPGT-A is not as accurate or reliable as embryo biopsy; and

(t) the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ as providers of the Services, through their officers, employees or agents knew, or ought reasonably to have known from no later than May 2019 the matters set out in (a) to (s) inclusive above. In respect of Monash IVF Group and Repromed, the plaintiffs refer to and rely on the matters referred to in paragraphs 10B-10F, 15A-15F, and 16A and the particulars joined to those paragraphs.

45. At all relevant times it was reasonably foreseeable to each of the defendants ~~Monash IVF, Repromed and the Monash IVF Group~~ that:

(a) if they ~~Monash IVF and Repromed~~ agreed to provide IVF treatment to the plaintiffs and group members, each would pay substantial sums of money to receive such treatment;

(b) the plaintiffs and group members were patients in IVF fertility programs in order to achieve, inter alia, pregnancy and live birth;

(c) the plaintiffs and group members as patients in IVF fertility programs were each in a vulnerable position to the defendants by reason of their or their sexual partner's age, infertility or other medical condition;

(d) the plaintiffs and group members would rely upon advice provided to them by one or more of the defendants as to:

(i) the viability of live embryos;

(ii) the accuracy of the niPGT-A testing;

(iii) the efficacy of the niPGT-A testing; and

(e) if the results of niPGT-A testing were positive for aneuploidy:

(i) live embryos would be discarded or donated for research; or

(ii) otherwise not be transferred;

(f) if an embryo was discarded or not transferred on the basis of the niPGT-A testing results, there was a risk of psychiatric injury or physical inconvenience and financial loss to patients;

(g) persons with a close relationship with a patient whose live embryo had been destroyed or not transferred on the basis of niPGT-A testing might suffer psychiatric injury and physical inconvenience and/or financial loss.

46. At all relevant times, the probability of the risks identified in paragraphs 45(f) and (g) (**Risk of Harm**) materialising was not insignificant by reason of the nature of IVF treatment.

Particulars

The plaintiffs refers to the previous paragraph 45 above.

47. Prior to the commercial marketing and supply of niPGT-A testing, none of the defendants undertook any, or in the alternative any adequate, clinical or other evaluation of the risks, associated with the use of the niPGT-A testing, including:

(a) the risk or susceptibility of the niPGT-A testing incorrectly classifying embryos

as aneuploidy;

(b) destruction or non-transfer of viable euploid embryos.

48. At all material times, the defendants failed to give any, or any sufficient, information or warning to the plaintiffs and group members of:

(a) the risk or susceptibility of the niPGT-A testing incorrectly classifying embryos as aneuploidy;

(b) the risk of destruction or non-transfer of viable euploid embryos.

49. Further, at all material times during the period, the defendants knew or ought to have known about the matters alleged in paragraphs 43 to 48, further the Risk of Harm.

Particulars

The plaintiffs refers ~~to the particulars to~~ paragraph 13 and, in respect of Monash IVF Group and Repromed refers to paragraph 16A above, and the particulars joined to those paragraphs.

Further particulars may be provided following discovery

50. The Services were provided by the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ to the plaintiffs and group members in order to *inter alia* achieve pregnancy and live birth.

51. The Services thereby included the mitigation of risks of erroneous discarding or non-use of live viable euploid embryos, including the Risk of Harm.

52. By recommending and providing alternatively procuring the niPGT-A testing, the defendants ~~Monash IVF, Repromed and the Monash IVF Group~~ had responsibility for and control over the Risk of Harm.

53. At all relevant times, the plaintiffs and group members ~~patients of Monash IVF, Repromed and the Monash IVF Group~~ (**Class**):

(a) had no ability, or no practical and effective ability, to prevent or minimize the Risk of Harm; and

(b) were vulnerable to the impact of live viable euploid embryos being destroyed or not being transferred; consequently;

(c) were to a relevant degree dependent, for the protection of their persons, upon the defendants ~~Monash IVF, Repromed and the Monash IVF Group~~:

(i) ensuring that the PGT-A testing performed on live embryos was appropriate to be used as a basis for discarding or not proceeding to transfer live embryos;

(ii) exercising reasonable care in carrying out the Services;

(iii) exercising reasonable care to ensure medical services including the PGT-A testing were appropriate to determine the aneuploidy status of live embryos;

(iv) informing patients of all relevant matters in relation to the niPGT-A testing in order to obtain their informed consent to the testing of embryos.

Particulars

niPGT-A testing was not appropriate for determining the aneuploidy status of live embryos and was suspended by the defendants in October 2020.

54. In the premises, at all relevant times, each of the defendants ~~Monash IVF, Repromed and the Monash IVF Group, its servants and agents~~ owed the plaintiffs and group members ~~Class~~ a duty of care (**Duty**) to provide adequate medical treatment to the plaintiffs using reasonable care during the course of providing IVF treatment.

55. In the premises, the defendants ~~Monash IVF, Repromed and the Monash IVF Group,~~ owed a further duty (**Further Duty**) of care to the plaintiffs and group members ~~Class~~ to take reasonable care to avoid psychiatric injury to the plaintiffs by reason of the reliance upon the niPGT-A testing to determine the aneuploidy status of embryos generated by the IVF treatment of the plaintiffs and group members ~~Class~~ resulting

in the increased likelihood of the needless non-transfer and/or destruction of viable euploid embryos.

56. ~~At all material times, the plaintiffs and group members were persons within, or the personal representatives of deceased persons who, during the relevant period were within, the Class.~~

57. In addition to paragraphs 54 and 55 ~~the premises set out in the preceding paragraph~~, at all material times ~~Monash IVF, Repromed and~~ by reason of the matters set out in paragraph 10A above, the Monash IVF Group owed the Duty and the Further Duty to the plaintiffs and the group members in respect of the Services provided by the Subsidiary Providers.

57A. Repromed:

(a) was the sponsor and funder of the following trials registered with Australian New Zealand Clinical Trials Registry:

(i) NEST4E: A pilot study into the clinical effectiveness of Non-invasive Preimplantation Genetic Screening (PGS) method for Embryo ploidy status among patients undergoing IVF treatment registered 6 April 2017, ACTRN 12617000500358;

(ii) NEST4E Non-invasive Preimplantation Genetic Screening (PGS) testing for IVF patient embryos that are not suitable for standard biopsy to determine the proportion of embryos that are unable to be screened using standard PGS that can be conclusively screened for aneuploidy using NEST4E by analysing cell-free DNA in the embryo culture media, ACTRN 12618001064291;

(b) submitted an application to Bellberry Limited for Human Research Ethics Approval (HREC) (**ethics approval**) of ACTRN 12617000500358 and ACTRN 12618001064291;

(c) was responsible for complying with the conditions of ethics approval granted by Bellberry Limited of ACTRN 12617000500358 and ACTRN 12618001064291;

(d) via Professor Lane, Professor Tremellen, Dr Zander-Fox, Dr Pacella-Ince, Dr Bell, Dr Hamilton and Michael Knapp assisted Monash IVF Group to obtain NATA accreditation of niPGT-A by authoring, alternatively, approving the NATA validation study;

(e) before October 2020, was aware of the matters pleaded in paragraphs:

(i) 14A;

(ii) 15A;

(iii) 15B;

(iv) 15C;

(v) 15D;

(vi) 15E;

(vii) 15F;

(viii) 15G;

(ix) 15H;

(x) 15I;

(xi) 15J;

(xii) 15K;

(xiii) 15L;

Particulars

The plaintiffs refer to the matters pleaded and particulars joined to paragraphs 14A-15L above.

57B. By reason of the matters pleaded in paragraphs 16A, 16B and 57A above, in addition to paragraphs 54 and 55, Repromed owed the Duty and the Further Duty

to the plaintiffs and the group members in respect of the Services provided by the Subsidiary Providers other than themselves.

Precautions and Breach

58. At all relevant times, it was the case that the risk of false-positive diagnosis of aneuploidy was likely to be materially reduced if the defendants ~~each of Monash IVF, Repromed and the Monash IVF Group, by its servants, agents and contractors~~:

(a) conducted or relied upon adequate testing and research of niPGT-A prior to its clinical application that is,

(i) validating test results by using blind samples;

(ii) ensuring staff analysing the results of the niPGT-A were adequately trained, alternatively, experienced;

(iii) ensuring the results of niPGT-A were confirmed by two or more adequately trained, alternatively, experienced staff;

(iv) ensuring a system of record keeping was in place that enabled the methodology of testing and research and the results of testing to be interpreted by people not involved in the testing and research;

(v) ensuring data obtained from research and testing was interpreted accurately when used in reporting results of the research and testing internally and to regulatory authorities responsible for the accreditation of niPGT-A;

(vi) ensuring data obtained from external sources was interpreted accurately when used in reporting results of the research and testing internally and to regulatory authorities responsible for the accreditation of niPGT-A;

(vii) ensuring reporting of data and results of research and testing was reviewed and confirmed by adequately trained alternatively, experienced staff not involved in the research and testing;

(viii) complying with any conditions of ethics approval;

(b) obtained informed consent from patients;

PARTICULARS

The plaintiffs refer to and rely upon paragraph 21 above.

In respect of Monash IVF Group and Repromed, informed consent included medical practitioners providing IVF treatment and medical services to patients:

(A) being informed by Monash IVF Group and Repromed:

(1) of the knowledge set out in paragraph 16A and its particulars, as those matters became known to Monash IVF Group and Repromed;

(2) that embryos that had been cultured from day 5 to day 6 specifically to allow the niPGT-A testing to be performed were exhibiting lower pregnancy rates than expected. The plaintiffs refer to and rely on the answer to question 3 of Professor William Ledger's report dated 6 June 2024 to the extent the answer provides an opinion about this particular (**Ledger Report**);

(3) in the document 'Cell Free PGS (PGT-A)' [MON.001.008.8446], or by other means, that the 2017 paper by Liu *et al* '*Non-invasive pre-implantation aneuploidy screening and diagnosis of beta thalassemia IVSII654 mutation using spent embryo culture medium*' cited in MON.001.008.8446 recorded a concordance rate between biopsied cells and niPGT-A testing of 64.52%. The plaintiffs refer to and rely on the 2017 paper by Liu *et al*, MON.001.008.8446 and the answers to question 1 of the Ledger

Report to the extent the answer provides an opinion on those documents and this particular;

(B) not being informed by Monash IVF Group or Repromed that:

(1) niPGT-A testing had shown a concordance to the embryo biopsy of approximately 95% or words to that effect, as this was false, as detailed in the Interim Report of Review of niPGT-A Validation dated 22 September 2020 and Draft Report of Review of niPGT-A Validation dated 25 September 2020 (set out at paragraphs 15E and 15F above). The plaintiffs further refer to and rely on MON.001.009.1937, MON.001.009.1946, MON.001.065.7053, MON.001.008.8446, MON.001.008.8409, MON.001.009.1939, MON.001.009.1943 and the answers to questions 1-3 of the Ledger Report to the extent those answers provide opinions on those documents and this particular;

(2) doctors have the option of offering niPGT-A without biopsy. The plaintiffs refer to and rely on MON.001.009.1937 and the answer to question 1 of the Ledger Report to the extent the answer provides an opinion on that document and this particular;

(3) niPGT-A testing was “a world first genetic test” without providing any caveats about concordance with embryo biopsy and possible inaccuracies in niPGT-A, those caveats being the matters set out in paragraph 58(b)(A) immediately above. The plaintiffs rely on MON.002.065.2738 and the answer to question 1 of the Ledger report to the extent the answer provides an opinion on that document and this particular;

(4) via the Fact Sheet [MON.001.016.4571], namely that:

- "Published studies and our own results have demonstrated that cf-PGT results are identical to the cell biopsy PGT results in between 75-85% of the cases"
- False Positive (Chromosomally normal embryo incorrectly classified as abnormal) results for biopsy PGTA as 0.5%-10.9% and for niPGTA 6.2%.
- False Negative (Chromosomally abnormal embryo incorrectly classified as normal) results for biopsy PGTA as 1.9%-3.2% and for niPGTA 9.4%.
- The plaintiffs refer to and rely on MON.001.016.4571, MON.001.071.5869, MON.002.053.5180 and the answers to question 2 of the Ledger report to the extent those answers provide opinions on those documents and this particular,

as matters relevant to their consideration to recommending and obtaining informed consent for niPGT-A testing to patients.

For the first plaintiff, particulars identifying the medical practitioners are set out at paragraphs 23 and 24.

For the second plaintiff, equivalent particulars are given at paragraphs 26 and 27.

(c) advised the plaintiffs and group members that embryo biopsy ~~to determine~~ was more accurate and reliable than niPGT-A to diagnose aneuploid embryos;

(d) warned patients of the relative risks of PGT-A by niPGT-A or embryo biopsy to diagnose aneuploid embryos;

(e) had and implemented systems complying with good IVF medical treatment industry practice in Australia, alternatively appropriate practice, for minimising the risk of false diagnosis of aneuploidy;

(f) did not use niPGT-A to diagnose aneuploid embryos;

(g) warned the plaintiffs and group members of the risks of using niPGT-A testing as the sole basis to:

(i) diagnose aneuploid embryos;

(ii) not transfer embryos;

(iii) discard live embryos;

(h) did not:

(i) fail to transfer;

(ii) discard;

a live embryo (blastocyst) on the sole or primary basis of the results of niPGT-A testing.

(**Precautions**).

59. The financial costs and logistical burdens of taking the Precautions were not disproportionate, having regard to:

(a) their likely effect in reducing the probability of:

(i) misdiagnosis of aneuploid status of embryos;

(ii) destruction or non-transfer of viable euploid embryos;

(iii) injury loss and damage to patients of the kinds referred to in paragraph 45 above;

(b) the gravity of harm if a risk described in sub-paragraph (a) above eventuated;

(c) the positive social utility in providing IVF treatment including PGT-A with the Precautions having been taken;

(d) the negligible impact on the social utility providing IVF treatment, with the Precautions having been taken, compared to the social utility of providing IVF treatment if the Services were provided without the Precautions having been taken;

(e) the social detriment in having IVF treatment provided without the Precautions having been taken.

Particulars

So far as the defendants ~~Monash IVF and/or the Repromed~~ performing obligations under the agreements are concerned, no additional burden would have arisen in undertaking them with due skill and care.

As to social utility and social detriment, the social utility in providing IVF treatment is supported by the safe use of PGT-A methods.

The social detriments of unsafe PGT-A methods, including the costs of live embryos not being transferred or of injury to persons from nervous shock and the costs of IVF treatment are so significant that use of unsafe PGT-A methods, in the premises of the existence of reasonable and available precautions set out at paragraph 58, is not acceptable or authorised at law.

There was no social utility in permitting viable euploid embryos to be destroyed or not transferred.

60. In the premises of the preceding two paragraphs, a reasonable person would have taken the Precautions.

61. Each of the defendants had the capacity to exercise control of the use of niPGT-A testing so as to take the Precautions which a reasonable person in its position would have taken against the Risk of Harm, by:

(a) not doing the following acts at all:

(i) using niPGT-A testing without confirmatory biopsy and standard pre-implantation genetic screening;

(b) doing the following things,

(i) investigating and assessing the risks associated with the use of niPGT-A testing before using, or continuing to use it (and not using it at all);

(ii) using PGT-A by embryo biopsy and standard pre-implantation genetic screening;

(iii) warning the plaintiff and group members as to the nature and risks of niPGT-A testing.

62. The defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ breached the Duty and/or the Further Duty.

Particulars of breach

(i) Failing to conduct or rely upon adequate testing and research of niPGT-A prior to its clinical application by failing to:

(A) validate test results by using blind samples;

(B) ensure staff analysing the results of the niPGT-A were adequately trained, alternatively, experienced;

(C) ensure the results of niPGT-A were confirmed by two or more adequately trained alternatively, experienced staff;

(D) ensure a system of record keeping was in place that enabled the methodology of testing and research and the results of

testing to be interpreted by people not involved in the testing and research;

(E) ensure data obtained from research and testing was interpreted accurately when used in reporting results of the research and testing internally and to regulatory authorities responsible for the accreditation of niPGT-A;

(F) ensure data obtained from external sources was interpreted accurately when used in reporting results of the research and testing internally and to regulatory authorities responsible for the accreditation of niPGT-A;

(G) ensure reporting of data and results of research and testing was reviewed and confirmed by adequately trained alternatively, experienced staff not involved in the research and testing;

(H) comply with the conditions of ethics approval.

The plaintiffs rely on the reports of Dr Leeanda Wilton dated 4 May 2023 and Professor Alison Murdoch dated 4 May 2023. Further particulars may be provided after delivery of expert evidence.

(ii) Failing to conduct or rely upon appropriate and peer reviewed clinical trials of niPGT-A testing before providing the Services. The plaintiffs refer to and rely on the matters referred to in paragraphs 10B-10F, 13-16A above and the particulars joined to those paragraphs.

(iii) Failing to obtain informed consent to the niPGT-A testing. The plaintiffs refer to and rely on the matters referred to in paragraphs 21 and 22 above and the particulars joined to those paragraphs. The plaintiffs further refer to and rely on the matters referred to in paragraph 58(b) above and say further:

(A) failing to obtain informed consent by Monash IVF Group and

Repromed occurred by Monash IVF Group and Repromed not informing medical practitioners providing IVF treatment and medical services to patients:

(1) of the knowledge set out in paragraph 16A and its particulars, as those matters became known to Monash IVF Group and Repromed;

(2) that embryos that had been cultured from day 5 to day 6 specifically to allow the niPGT-A testing to be performed were exhibiting lower pregnancy rates than expected. The plaintiffs refer to and rely on the answer to question 3 of the Ledger report to the extent the answer provides an opinion about this particular;

(3) in the document 'Cell Free PGS (PGT-A)' [MON.001.008.8446], or by other means, that the 2017 paper by Liu *et al* '*Non-invasive pre-implantation aneuploidy screening and diagnosis of beta thalassemia IVSII654 mutation using spent embryo culture medium*' cited in MON.001.008.8446 recorded a concordance rate between biopsied cells and niPGT-A testing of 64.52%. The plaintiffs refer to and rely on the 2017 paper by Liu *et al*, MON.001.008.8446 and the answers to question 1 of the Ledger Report to the extent the answer provides an opinion on those documents and this particular;

(B) failing to obtain informed consent by Monash IVF Group and Repromed by informing medical practitioners providing IVF treatment and medical services to patients that:

(1) niPGT-A testing had shown a concordance to the embryo

biopsy of approximately 95% or words to that effect, which was false as detailed in the Interim Report of Review of niPGT-A Validation dated 22 September 2020 and Draft Report of Review of niPGT-A Validation dated 25 September 2020 (set out at paragraphs 15E and 15F above). The plaintiffs refer to and rely on MON.001.009.1937, MON.001.009.1946, MON.001.065.7053, MON.001.008.8446, MON.001.008.8409, MON.001.009.1939, MON.001.009.1943 and the answers to questions 1-3 of the Ledger Report to the extent those answers provide opinions on those documents and this particular;

(2) doctors have the option of offering niPGT-A without biopsy. The plaintiffs refer to and rely on MON.001.009.1937 and the answer to question 1 of the Ledger Report to the extent the answer provides an opinion on that document and this particular;

(3) niPGT-A testing was "a world first genetic test", without providing any caveats about concordance with embryo biopsy and possible inaccuracies in niPGT-A, those caveats being those matters set out in 62(iii)(A) immediately above. The plaintiffs rely on MON.002.065.2738 and the answer to question 1 of the Ledger report to the extent the answer provides an opinion on that document and this particular;

(4) via the Fact Sheet [MON.001.016.4571], namely that:

- "Published studies and our own results have demonstrated that cf-PGT results are identical to the cell biopsy PGT results in between 75-85% of the cases"
- False Positive (Chromosomally normal embryo incorrectly

classified as abnormal) results for biopsy PGTA as 0.5%-10.9% and for niPGTA 6.2%.

- False Negative (Chromosomally abnormal embryo incorrectly classified as normal) results for biopsy PGTA as 1.9%-3.2% and for niPGTA 9.4%.
- The plaintiffs refer to and rely on MON.001.016.4571, MON.001.071.5869, MON.002.053.5180 and the answers to question 2 of the Ledger report to the extent those answers provide opinions on those documents and this particular,

as matters relevant to their consideration to recommending and obtaining informed consent for niPGT-A testing to patients.

(iv) Failing to advise the plaintiffs and group members that embryo biopsy

was more accurate and reliable. The plaintiffs further rely on:

(A) the knowledge set out in paragraph 16A and its particulars, as those matters became known to Monash IVF Group and Repromed;

(B) that embryos that had been cultured from day 5 to day 6 specifically to allow the niPGT-A testing to be performed were exhibiting lower pregnancy rates than expected. The plaintiffs refer to and rely on the answer to question 3 of the Ledger report to the extent the answer provides an opinion about this particular;

(C) in the document 'Cell Free PGS (PGT-A)' [MON.001.008.8446], or by other means, that the 2017 paper by Liu *et al* '*Non-invasive pre-implantation aneuploidy screening and diagnosis of beta thalassemia IVSII654 mutation using spent embryo culture medium*' cited in MON.001.008.8446 recorded a concordance rate between biopsied cells and niPGT-A testing of 64.52%. The plaintiffs refer to and rely on the 2017 paper by Liu *et al*, MON.001.008.8446 and the answers to question 1 of the Ledger Report to the extent the answer provides an opinion on those documents and this particular;

(v) Failing to warn the plaintiffs and group members of the risks of using niPGT- A testing as the sole or primary basis for discarding live embryos. The plaintiffs refer to and rely upon paragraph 62(iii) above.

(vi) Discarding and/or not transferring a live embryo (blastocyst) on the basis of the results of niPGT-A testing.

~~Further particulars shall be provided upon receipt of expert evidence.~~

E. MISLEADING AND DECEPTIVE CONDUCT; MISREPRESENTATION

63. At all relevant times from May 2019, Monash IVF Group represented to patients including the plaintiffs and group members that:

(a) "*in-house studies have demonstrated that non-invasive PGT results are identical to the embryo biopsy PGT results in 95% of the cases. Therefore, it is important to note that this method is not 100% accurate*";

(b) niPGT-A is "95%" accurate; and

(c) "*while every effort is made to ensure that the PGT-A test offered has the highest possible accuracy using the currently available technology, results are not 100% accurate*";

(d) niPGT-A testing would be appropriate to detect aneuploid status of embryos without confirmatory biopsy;

(e) niPGT-A testing results would be identical to embryo biopsy PGT results in 95% of the cases;

(f) niPGT-A testing conducted by or on behalf of the defendants would be 95% accurate;

(g) niPGT-A being non-invasive would be better for an embryo than an invasive biopsy PGT-A because after embryo biopsy some embryos may be damaged;

(h) the Services would be provided exercising the care and skill of a reasonably competent provider of infertility treatment;

(j) the research and testing involved in the in-house studies had been conducted according to accepted scientific standards, being those set out in paragraph 58(a) above.

(**Representations**).

Particulars

The representations in (a) to (c) were in writing. The plaintiffs refers to Monash IVF Group's *Fact Sheet – Preimplantation Genetic Testing For Aneuploidy (PGT-A)* dated May 2019 (**Fact Sheet**) and the *Consent Form (M) Preimplantation Genetic Testing For Aneuploidy (PGT-A)* dated 7 November 2019 signed by the first plaintiff.

The Fact Sheet was prepared by the Monash IVF Group with the intention of it being provided to patients of the Subsidiary Providers entities it owned and controlled, including Monash IVF and Repromed.

The Fact Sheet was provided to the first plaintiff by email from Dr Tucker on 16 August 2019.

The Fact Sheet was provided to the second plaintiff by Dr Girle on or about 18 May 2020.

Further particulars in relation to group members shall be provided following the trial of the common questions.

The representations in (d) to (g) were implied by:

(i) the Fact Sheet; and

(ii) the defendants or any of them offering the service of niPGT-A testing without embryo biopsy to determine the aneuploid status of patient embryos.

The representations in (h) wasere implied.

The representation in (j) above was implied by:

(i) the express reference in the Fact Sheet and consent form for niPGT-A testing to the existence of the in-house studies and the accuracy of niPGT-A testing resulting from the studies from which the ordinary person reading the Fact Sheet and/or consent form would infer:

(B) the in-house studies had been conducted in accordance with accepted scientific standards.

(ii) the defendants or any of them offering the service of niPGT-A testing without embryo biopsy to determine the aneuploid status of patient embryos.

The Representations include the implied terms alleged in paragraph 35 above, and the plaintiffs repeat the particulars to paragraph 35.

64. The representations were made in trade or commerce within the meaning of section 2 of the Australian Consumer Law.

65. Fertility Australia Monash IVF, alternatively Monash IVF Group, repeated the Representations to the first plaintiff.

Particulars

Fertility Australia or Monash IVF Group servants and/or agents provided the Fact Sheet to the first plaintiff by email on or about 16 August 2019, and provided IVF treatment services to her including niPGT-A testing.

66. Repromed, alternatively Monash IVF Group, repeated the Representations to the second plaintiff.

Particulars

Repromed or Monash IVF Group servants and/or agents provided the Fact Sheet to the second plaintiff on or about 18 May 2020 at the Repromed Clinic

at Darwin Hospital, and provided IVF treatment services to her including niPGT-A testing.

67. Further, the Subsidiary Providers, alternatively Monash IVF Group, ~~Monash IVF and/or Repromed~~ repeated the Representations to the group members.

Particulars

Particulars in relation to group members shall be provided following the trial of the common questions.

68. The Representations in sub-paragraphs 63(d) to (h) (inclusive) above were each, when they were made, representations as to future matters.

Particulars

The plaintiffs ~~relies~~ rely upon section 4, Australian Consumer Law

69. In the premises:

(a) each of the Representations were false, misleading ~~and~~ or deceptive in that niPGT-A testing:

(i) results were not identical to (concordant with) embryo biopsy PGT-A results in 95% of the cases;

(ii) was not 95% accurate;

(iii) did not have the highest possible accuracy using the currently available technology;

(iv) was not appropriate to detect euploid status of embryos without confirmatory biopsy;

(vi) the testing and research involved in the in-house studies were not conducted in accordance with accepted scientific standards.

Particulars

The plaintiffs refer to and rely on the particulars at paragraph 62(i) above.

(b) the defendants did not have reasonable grounds for making or repeating the Representations in sub-paragraphs 63(d) to (h) (inclusive) above.

Particulars

The plaintiffs ~~relies~~ rely upon paragraph 13 above.

Further particulars may be provided following discovery, interrogation and receipt of expert evidence.

70. In the circumstances in paragraphs 63 to 69, the Representations were misleading or deceptive or likely to mislead or deceive.

Particulars

In addition to any remedies at general law, the plaintiffs rely on section 18 of the Australian Consumer Law.

71. The plaintiffs and group members each relied on the Representations in engaging the defendants ~~Monash IVF or Repromed~~ to provide IVF treatment, including:

(a) niPGT-A testing of their embryos without confirmatory embryo biopsy;

(b) not proceeding to transfer embryos classified aneuploid based on the results of niPGT-A testing.

Particulars

The first plaintiff engaged and received the treatment from Fertility Australia ~~Monash IVF~~ on the assumption that the Representations were correct.

The second plaintiff engaged and received the treatment from Repromed on the assumption that the Representations were correct.

Particulars in relation to the group members will be provided after the trial of the common questions.

F. CAUSATION, LOSS AND DAMAGE

72. By reason of the breaches of the Duty and/or the Further Duty ~~by Monash IVF, Repromed and/or the Monash IVF Group~~ alleged above:

(a) Ms Bopping's embryo was:

(i) tested for aneuploid status by niPGT-A;

(ii) not tested for aneuploid status by embryo biopsy PGT-A;

(iii) not transferred to her uterus;

(iv) discarded by Monash IVF;

(b) Ms Pedersen's embryos were:

(i) tested for aneuploid status by niPGT-A;

(ii) not tested for aneuploid status by embryo biopsy PGT-A;

(iii) not transferred to her uterus;

(iv) donated to Repromed for research.

73. But for the breaches of the duty alleged:

(a) niPGT-A testing would not have been used as the diagnostic test to determine aneuploid status of embryos;

(b) the plaintiffs' embryos would have been tested for aneuploid status by embryo biopsy PGT-A;

(c) the plaintiffs would not have failed to transfer embryos based upon the results of niPGT-A;

(d) the plaintiffs' embryos would not have been discarded, donated and or deselected for transfer based upon the results of niPGT-A;

(e) the plaintiffs would not have been exposed to the risk that a viable embryo may have been discarded or not transferred based upon the results of niPGT-A.

74. But for the breaches of the further duty, the plaintiffs:

(a) would have been informed by the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ of the matters in sub-paragraphs 21(a) to (i) above;

(b) would not have subjected their embryos to the niPGT-A testing at all or without confirmatory embryo biopsy to determine viability;

(c) refer to and repeat the allegations in sub-paragraphs 73(a) to (e) inclusive above.

75. As a result of the:

(a) breach of the Due Care Term;

(b) breach of the Due Care Guarantee;

(c) breach of the Fitness for Purpose Guarantee;

(d) breach of the Duty;

(e) breach of the Further Duty; and/or

(f) the misleading or deceptive Representations,

the plaintiffs and each of the group members have suffered loss and damage of the kinds referred to in paragraph 45 above.

Particulars of loss and damage

The plaintiffs suffered psychiatric injury, loss and damage, including:

(i) Pain and suffering;

(ii) Loss of chance of pregnancy;

(iii) Further and in the alternative, loss of opportunity to have genetically related children;

(iv) Cost of niPGT-A testing and IVF treatment;

(v) Medical and like expenses, particulars of which will be provided prior to trial;

(vi) Loss of earnings and loss of earning capacity, particulars of which will be provided prior to trial;

(vii) Physical inconvenience;

(viii) Loss or damage suffered because of the conduct of the defendants in contravention of sections 18, 60 and/or 61 of the Australian Consumer Law.

Particulars of the plaintiffs' loss and damage will be provided prior to trial. Particulars relating to individual group members will be provided following the trial of common questions.

75A. By reason of the matters pleaded in paragraphs 15-16, 17 and 47; and/or 21-22; and/or 40-41; and/or 43-45, 48-53, and 57A-62; and/or 63 and 69 in the circumstances pleaded in paragraphs 10B-10F and 12-16B the plaintiffs and group members are entitled to, from Monash IVF Group and/or Repromed:

(a) aggravated damages; and/or

(b) exemplary damages.

Particulars

(i) The deliberate, highhanded and wrongful conduct of Monash IVF Group and/or Repromed, including the continued failure to provide to the plaintiffs full disclosure regarding the wrongdoing of Monash IVF Group and/or Repromed has worsened and prolonged the plaintiffs' anguish and suffering, including by informing, as set out in paragraph 17 above, the plaintiffs and group members in the notice that the ni-PGT-A testing preliminary investigations showed the proportion of abnormal embryos classified (aneuploid) appeared to be marginally higher than what was observed in the clinical trial, when:

(A) in fact the investigations, being the Interim Report of Review of niPGT-A Validation dated 22 September 2020 and Draft Report of Review of niPGT-A Validation dated 25 September 2020 (set out at paragraphs 15E and 15F above), showed a 35% false positive rate;

(B) the defendants had opted not to disclose such a false positive rate on the basis that to do so would (in the words of Chief Marketing Officer Fiona Allen in an email chain with Malik Janudeen dated 5 October 2020) be "suicidal" [MON.002.048.1491],

(C) and the plaintiffs further rely on the Ledger report and his answer to question 4 to the extent that the answer provides an opinion on this particular;

(ii) The deliberate and reckless misconduct of Monash IVF Group and/or Repromed in the conduct of the clinical trial, the commercial implementation of the niPGT-A testing, and the failure to withdraw the testing at the earliest possible date, is demonstrative of a contumelious disregard of the rights of the plaintiffs with the intent of pursuing commercial and reputational gain.

(iii) The conduct of Monash IVF Group and/or Repromed is deserving of the Court's disapprobation and condign punishment with an award of exemplary damages commensurate to the resources of the defendants.

G. COMMON QUESTIONS

76. The questions of law or fact common to the claims of the plaintiffs and each of the group members are:

(a) whether the facts concerning the niPGT-A testing and fertility treatment including IVF treatment provided by the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ to patients in the relevant period are as alleged above;

(b) whether the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ owed a common law duty of care to the plaintiffs and group members, and if so the content of the duty;

(c) if the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ owed such a common law duty of care, whether the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ breached that duty;

(d) whether the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ breached the implied terms of any agreement with the plaintiffs and group

members;

(e) if the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ breached a common law duty or the agreement, was such breach a cause of any losses sustained by any claimants and/or class of claimants;

(f) whether the defendants ~~Monash IVF, Repromed and/or the Monash IVF Group~~ made the representations;

(g) whether the representations were false, misleading and deceptive;

(h) whether there was any failure to comply with the Australian Consumer Law;

(i) what are the principles for identifying and measuring compensable losses suffered by the claimants resulting from the breaches alleged.

AND THE PLAINTIFFS CLAIM on their own behalf and on behalf of the group members:

A. Damages including aggravated and exemplary damages.

B. Damages pursuant to sections 236 and 267(3)(b) and 267(4) of the *Australian Consumer Law* (Victoria).

C. Interest.

D. Costs.

Timothy P. Tobin S.C.

~~Andrew Fraatz~~

~~Stella Gold~~

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