



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

Case: S ECI 2020 04761  
No. S ECI 2020 04761  
Filed on: 02/06/2022 02:07 PM

B E T W E E N:

**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

**AMENDED STATEMENT OF CLAIM**

(Filed pursuant to the Orders of the Honourable Justice John Dixon  
made 11 May 2022)

Date of Document:	<u>2 June 2022</u> <del>23 April 2024</del>	Solicitors Code:	113394
Filed on behalf of:	The Plaintiff	Telephone:	(03) 9133 0288
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**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)(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 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(~~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 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:

- (i) fertility health check;
- (ii) ovulation induction;
- (iii) egg timer test;
- (iv) in vitro fertilisation;
- (v) ICSI - intracytoplasmic sperm injection;
- (vi) IUI - assisted insemination;
- (vii) egg freezing;
- (viii) supply of donor eggs;
- (ix) sperm retrieval;
- (x) semen analysis;
- (xi) sperm health test;

- (xii) sperm freezing;
- (xiii) supply of donor sperm;
- (xiv) surrogacy;
- (xv) preimplantation genetic testing/preconception genetic screening;
- (xvi) preimplantation genetic testing for aneuploidy screening.

The plaintiffs refers 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.

### ***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:-

- (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 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 LiYing, Wei Yuan, Huang Jin, Zhu XiaoHui, Shi XiaoDan, Xia Xi, Yan Jie, Lu CuiLing, 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 trophoctoderm 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 Huang, Sijia Lub, Catherine Racowsky, and X. Sunney Xie);
- (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).

Further particulars may be provided following discovery and expert evidence.

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.

### **Particulars**

Clinical application of niPGT-A as a substitute for embryo biopsy was unsafe 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.

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 *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.

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.

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 s 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.

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 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 Repromed fertility specialist Dr Stephanie Gidle (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, its 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**).
41. If the allegations in paragraphs 13 and 14 are proved, then the niPGT-A testing was not safe to use to determine embryo viability.

### Particulars

The plaintiffs repeat the particulars to paragraphs 13 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 had not been peer reviewed or followed by further and more comprehensive trials of niPGT-A;
- (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;
- (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.

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 above.

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 the premises set out in the preceding paragraph, at all material times Monash IVF, Repromed and the Monash IVF Group owed the Duty and the Further Duty to the plaintiffs and the group members.

### **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;
  - (b) obtained informed consent from patients;

- (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 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 appropriate and peer reviewed clinical trials of niPGT-A testing before providing the Services.
- (ii) Failing to obtain informed consent to the niPGT-A testing.
- (iii) Failing to advise the plaintiff and group members that embryo biopsy was more accurate and reliable.
- (iv) Failing to warn the plaintiff and group members of the risks of using niPGT-A testing as the sole basis for discarding live embryos.
- (v) 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.

**(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**).

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) were implied. 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 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;
- (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 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.

### 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.
- 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.

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