IN THE SUPREME COURT OF VICTORIA **No. S ECI 2020**
AT MELBOURNE
COMMON LAW DIVISION
GROUP PROCEEDINGS LIST

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

DEFENCE
(Filed pursuant to the Orders of the Honourable Justice John Dixon made on 11 August 2023 and 23 October 2023)

Date of document:	27 October 2023
Filed on behalf of:	**Defendants**
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To the Second Amended Statement of Claim dated 17 August 2023 (**SASOC**), the defendants adopt the definitions used in the SASOC for convenience only and say as follows:

A. Preliminary

1. As to paragraph 1 of the SASOC, the defendants do not plead to it as it contains no allegations against them.

2. As to paragraph 2 of the SASOC, the defendants do not plead to it as it contains no allegations against them save that insofar as paragraph 2 contains allegations of fact against the defendants by implication they deny the paragraph.

3. As to paragraph 3 of the SASOC, the defendants:

   (a) admit that between about July 2017 and about January 2020 the first plaintiff engaged the eighth defendant as trustee for Fertility Australia Trust (**Fertility Australia**) operating a clinic at Bondi Junction in New South Wales for IVF treatment;

   (b) deny paragraph 3(b).

4. As to paragraph 4 of the SASOC, the defendants:

   (a) admit that between about March 2020 and about March 2021 the second plaintiff engaged the second defendant operating a clinic in Darwin in the Northern Territory for IVF treatment;

   (b) deny paragraph 4(b).

5. The defendants do not plead to paragraph 5 of the SASOC as it contains no allegations against them.

The defendants

6. As to paragraph 6 of the SASOC, the defendants:

   (a) admit paragraph 6(a);

   (b) say that Monash IVF provided IVF treatment and related medical services to patients referred to it in Victoria and Queensland;

   (c) otherwise deny the paragraph.

7. As to paragraph 7 of the SASOC, the defendants:

   (a) admit paragraph 7(a);

   (b) say that Repromed provided IVF treatment and related medical services to patients referred to it in South Australia and the Northern Territory;

(c) otherwise deny the paragraph.

8. As to paragraph 8 of the SASOC, the defendants:

(a) admit paragraph 8(a);

(b) say that, in the relevant period, the first, second, fourth, fifth and eighth defendants were subsidiaries of Monash IVF Group;

(c) say that, in the relevant period, Monash IVF Group:

(i) until August 2019, owned 47.3% of the shares in the sixth defendant;

(ii) from August 2019, owned 57.4% of the shares in the sixth defendant, which thereby became a subsidiary of Monash IVF Group;

(d) say that, in the relevant period, Monash IVF Group owned 25% of the shares in the seventh defendant;

(e) otherwise deny the paragraph.

8A. As to paragraph 8A of the SASOC, the defendants:

(a) admit paragraph 8A(a);

(b) say that Monash IVF Auchenflower provided IVF treatment and related medical services to patients referred to it in Queensland;

(c) otherwise deny the paragraph.

8B. As to paragraph 8B of the SASOC, the defendants:

(a) admit paragraph 8B(a);

(b) say that Palantrou provided IVF treatment and related medical services to patients referred to it in New South Wales;

(c) otherwise deny the paragraph.

8C. As to paragraph 8C of the SASOC, the defendants:

(a) admit paragraph 8C(a);

(b) say that Hobart IVF provided IVF treatment and related medical services to patients referred to it in Tasmania;

(c) otherwise deny the paragraph.

8D. As to paragraph 8D of the SASOC, the defendants:

(a) admit paragraph 8D(a);

(b) say that Compass Fertility provided IVF treatment and related medical services to patients referred to it in the Australian Capital Territory;

(c) otherwise deny the paragraph.

8E. As to paragraph 8E of the SASOC, the defendants:

(a) admit paragraph 8E(a);

(b) say that Fertility Australia Pty Ltd provided IVF treatment and related medical services to patients referred to it in New South Wales*;*

(c) otherwise deny the paragraph.

9. [There is no paragraph 9 in the SASOC.]

10. As to paragraph 10 of the SASOC, the defendants:

(a) repeat paragraphs 3, 4, 6,7, 8, 8A, 8B, 8C, 8D and 8E herein;

(b) say they provided their services to patients during the relevant period;

(c) admit that the services provided to the plaintiffs and patients during the relevant period were provided in trade or commerce within the meaning of section 2 of the Australian Consumer Law;

(d) otherwise deny the paragraph.

10A. As to paragraph 10A of the SASOC, the defendants:

(a) deny the paragraph;

(b) repeat paragraphs 3, 4, 6, 7, 8, 8A, 8B, 8C, 8D and 8E herein.

10B. As to paragraph 10B of the SASOC, the defendants say:

(a) between 2015 and 4 February 2020, Professor Michelle Lane was employed by Monash IVF Group;

(b) during the said period Professor Lane was also employed and held the position of Research Fellow with the University of Adelaide;

(c) between about 2015 and 2017, Professor Lane undertook pre-clinical research relating to niPGT-A while employed in the capacities identified above;

(d) Professor Lane undertook pre-clinical research relating to niPGT-A in collaboration with RHS Ltd;

(e) Professor Lane received funding for pre-clinical research through the University of Adelaide;

(f) Professor Lane was the principal investigator in two clinical trials relating to niPGT-A undertaken by Repromed, namely, a pilot study and subsequently, a borderline embryo study;

(g) between 2016 and September 2020, Dr Francesca Bell was employed by Repromed;

(h) Dr Bell assisted Professor Lane with her pre-clinical research;

(i) Dr Bell was a co-investigator in the two clinical trials relating to niPGT-A conducted by Repromed;

(j) during 2018 and 2019, Dr Leanne Pacella-Ince was an employee of Repromed;

(k) during the period alleged in sub-paragraph (j) above, Dr Pacella-Ince in her capacity as an embryologist performed modified biopsies on a small number of embryos that were utilised in the borderline embryo study;

(l) a decision that niPGT-A should be made available to patients undergoing IVF treatment was made in or about April 2019 by a Steering Committee which included Professor Michelle Lane, Michael Knaap, Tedd Fuell, Brett Comer, Dr Hamish Hamilton and Malik Jainudeen;

(m) the persons identified in subparagraph (l) were employed by Monash IVF Group at the time of the said decision save for Dr Hamilton who was an employee of Repromed;

(n) otherwise deny the paragraph.

10C. As to paragraph 10C of the SASOC, the defendants:

(a) repeat paragraph 10B hereof;

(b) say that paragraphs 16A and 62 of the SASOC do not plead as material facts any acts and omissions;

(c) otherwise deny the paragraph.

10D. As to paragraph 10D of the SASOC, the defendants:

(a) repeat paragraphs 10B and 10C hereof;

(b) otherwise deny the paragraph.

10E. As to paragraph 10E of the SASOC, the defendants:

(a) repeat paragraphs 10B and 10C hereof;

(b) otherwise deny the paragraph.

10F. As to paragraph 10F of the SASOC, the defendants:

(a) repeat paragraphs 10B and 10E hereof;

(b) otherwise deny the paragraph.

IVF research and treatment

11. As to paragraph 11 of the SASOC, the defendants:

(a) admit that the first IVF pregnancy in the world was achieved in 1973;

(b) say that IVF is a medical procedure whereby an egg is fertilised by sperm outside the body;

(c) otherwise deny the paragraph.

12. As to paragraph 12 of the SASOC, the defendants:

    (a) admit that during the relevant period Adelaide Fertility tested samples supplied to it for the correct number of chromosomes;

    (b) otherwise deny the paragraph.

13. The defendants deny the allegations in paragraph 13 of the SASOC and say further that National Association of Testing Authorities (**NATA**) accreditation was obtained by Adelaide Fertility.

14. The defendants deny paragraph 14 of the SASOC.

14A. As to paragraph 14A of the SASOC, the defendants:

    (a) say that between about April 2017 to April 2018 a pilot study was conducted by Repromed;

    (b) otherwise deny the paragraph.

14B. As to paragraph 14B of the SASOC, the defendants say:

    (a) the purpose of the pilot study was to perform a pilot trial on embryos of fifteen Repromed patients to evaluate the clinical effectiveness of determining embryo ploidy status by amplifying cell free DNA from human embryo culture medium and using Next Generation Sequencing;

    (b) the study applied to embryos that were able to be screened for aneuploidy by biopsy;

    (c) the study received ethics approval from Bellberry Human Research Ethics Committee on 9 March 2017 following the submission of an application by Professor Michelle Lane;

    (d) the study was instigated, designed, supervised and run by Professor Lane as principal investigator;

    (e) Dr Francesca Bell assisted Professor Lane with the study as a co-investigator;

    (f) they admit sub-paragraphs (b), (c), and (f);

    (g) they otherwise deny the paragraph.

15. As to paragraph 15 of the SASOC, the defendants:

(a) say that the clinical trial was sponsored by Adelaide Fertility;

(b) say that the clinical trial was instigated, designed, supervised and run by Professor Michelle Lane;

(c) say that the clinical trial was in respect of niPGT-A;

(d) otherwise deny the paragraph.

15A. As to paragraph 15A of the SASOC, the defendants say:

(a) the purpose of the borderline embryo trial was to evaluate the clinical implementation of niPGT-A in determining the ploidy status of Grade 3 embryos that were not suitable for PGS using standard biopsy and PGS technology;

(b) the trial received ethics approval from Bellberry Human Research Ethics Committee on 8 June 2018, following an application by Professor Michelle Lane;

(c) the trial was initially conducted on embryos of patients of Repromed. Following, approval from Bellberry Human Research Ethics Committee granted on 6 February 2019, the trial was extended to embryos of patients from Monash IVF Paramatta, Monash IVF Hawthorn, Monash IVF Clayton and Monash IVF Gold Coast;

(d) the trial was instigated, designed, supervised and run by Professor Michelle Lane as principal investigator;

(e) Dr Francesca Bell assisted Professor Lane with the trial as co-investigator;

(f) Dr Pacella-Ince in her capacity as an embryologist performed modified biopsies on a small number of embryos that were the subject of the borderline embryo trial;

(g) they admit sub-paragraphs (b), (c), (d), (e), (g), (h), (j) and (l);

(h) they otherwise deny the paragraph.

15B. As to paragraph 15B of the SASOC, the defendants say:

(a) from about 21 November 2018, enquiries were made to NATA on behalf of Repromed about the process for obtaining accreditation of niPGT-A;

Particulars

The enquiries were in writing and evidenced by emails exchanged between Dr Deirdre Zander-Fox and Milana Ranieri and Wendy Harris (of NATA) between 21 November 2018 and 10 December 2018.

(b) on 8 February 2019, documents were submitted to NATA on behalf of Repromed for the purpose of obtaining accreditation of niPGT-A;

Particulars

The documents were submitted by way of email from Dr Deirdre Zander-Fox to Wendy Harris dated 8 February 2019 and are listed in that email. The documents may be inspected upon reasonable notice.

(c) on 8 March 2019, NATA conducted an on site audit at Repromed for the purpose of considering accreditation of niPGT-A;

(d) they otherwise deny the paragraph.

15C. As to paragraph 15C of the SASOC, the defendants:

(a) repeat paragraph 15B hereof;

(b) say one of the documents submitted to NATA on 8 February 2019 was a document titled "Summary of Non Invasive PGS Validation" which included, inter alia, a summary and table of the results of a validation study;

(c) otherwise deny the paragraph.

15D. As to paragraph 15D of the SASOC, the defendants:

(a) repeat paragraphs 15B and 15C hereof;

(b) say Professor Rombauts did not review the NATA validation study alleged or the document referred to in paragraph 15C(b) hereof prior to its submission to NATA and did not convey any concerns in respect of that document as alleged;

(c) say Michael Knaap and Professor Tremellen did not hold the concerns alleged, engaged in communications about steps to be taken before launch and in the clinical implementation of niPGT-A, and supported the implementation of niPGT-A;

Particulars

The defendants refer to emails between Professor Tremellen and Michael Knaap dated 20 February 2019, an email from Tedd Fuell to inter alia Professor Tremellen and Michael Knaap dated 27 February 2019, a subsequent exchange of emails between Professor Tremellen and Michael Knaap dated 28 February 2019, NIPGT GMAC update dated 15 May 2019, and emails from Professor Tremellen to Deirdre Zander Fox dated 17 May 2019.

(d) otherwise deny the paragraph.

15E. As to paragraph 15E of the SASOC, the defendants:

(a) repeat paragraphs 15B(b) and 15C(b) hereof;

(b) admit the table in the document titled "Summary of Non Invasive PGS Validation" purported to identify 121 samples of which 16 were duplicates of others identified in the table and a further 5 were triplicates of others identified in the table;

(c) otherwise deny the paragraph.

15F. As to paragraph 15F of the SASOC, the defendants:

(a) deny that the table in the document titled "Summary of Non Invasive PGS Validation" was based upon and purported to represent the results achieved in the pilot study and the borderline clinical trial as alleged;

(b) otherwise deny the paragraph.

15G. As to paragraph 15G of the SASOC, the defendants:

(a) say GMAC proposed a protocol that embryos not suitable for biopsy be tested using niPGT-A and a possible change to this protocol post the introduction of niPGT-A based upon the independent request of clinicians;

(b) otherwise deny the paragraph.

15H. As to paragraph 15H of the SASOC, the defendants:

(a) say that on 20 May 2019, Sloane Karlson of Monash IVF Group confirmed that the protocol for the implementation of niPGT-A was that it was to be offered as an adjunct to biopsy whereby embryos that were suitable for biopsy were to be tested using biopsy and embryos not suitable for biopsy were to be tested using niPGT-A and that as doctors became comfortable with the new test they might choose to select it only for a subset of patients and that some doctors who were involved in the verification and trials might choose to move to this step straight away;

(b) otherwise deny the paragraph.

15I. As to paragraph 15I of the SASOC, defendants say:

(a) on 30 April 2019, NATA informed Repromed that a recommendation to grant accreditation would be made by its Accreditation Advisory Committee;

(b) otherwise admit the paragraph.

15J. As to paragraph 15J of the SASOC, the defendants:

(a) admit that neither Monash IVF Group or Repromed told NATA of the matters alleged in sub-paragraphs (a) to (i) inclusive prior to 10 July 2019 or before October 2020;

(b) deny the factual matters alleged in sub-paragraphs (a), (c), (d), (e), (f), (g), and (i) and repeat paragraphs 15A, 15H, 15D and 15E hereof in response to the matters alleged in subparagraphs (a) to (i) inclusive;

(c) say that neither Monash IVF Group or Repromed had any obligation to tell NATA of the matters alleged in sub-paragraphs (a), (d), (e), (f) (g) and (i) because they were not true and further, and in any event, because they were not relevant;

(d) in respect of the matters alleged in sub-paragraph (h) refer to paragraph 15E(b) hereof and say that Monash IVF Group and Repromed did not become aware of the duplicate and triplicate samples in the table included in the "Summary of Non Invasive PGS Validation" until September 2020 upon discovery of which they subsequently informed NATA;

(e) say that a NATA representative attended Repromed on 8 March 2019 to conduct an audit of the niPGT-A at which Repromed made available to NATA access to any information NATA required concerning the pre clinical research and clinical trials relating to niPGT-A including any validation data, and made available to NATA Professor Michelle Lane to answer any questions or provide any information NATA required about the pre-clinical research, clinical trials, validation data and niPGTA generally including, its proposed roll out;

(f) otherwise deny the paragraph.

15K. As to paragraph 15K of the SASOC, the defendants:

(a) admit that Professor Tremellen expressed views to the effect alleged in subparagraphs (a) and (b) to the persons identified by email dated 29 July 2020;

(b) otherwise deny the paragraph and inter alia refer to sub-paragraphs (c) to (e) inclusive below;

(c) by 30 July 2020, the General Science and Advisory Committee (**GSAC**) of Monash IVF Group had considered the initial clinical data and concluded that:

a. the euploid rate in high quality embryos from young women undergoing niPGT-A testing was significantly lower when compared to biopsy but that the reason for this was not known and that the niPGT-A result might have been a true reflection of the embryo given that niPGT-A sampled a higher number of cells from the embryo than biopsy;

b. patients having niPGT-A with embryos that on day 5 were good quality and would have been suitable for biopsy and freezing (good quality day 5 embryos) but were cultured for an extra day to facilitate niPGT-A had lower pregnancy rates compared to their matched invasive cohort;

c. the reason for the pregnancy rate disparity referred to in b. above was not known but could be due to one or more factors including that good quality day 5 embryos that were cultured for an extra day to facilitate niPGT-A:

   i. were true day 6 embryos and were not being transferred on their optimal day during the FET cycle;

   ii. were advanced with a very large blastocoel cavity and were possibly experiencing damage at freezing which in turn decreased their viability post thaw;

   iii. were not receiving required nutrients on day 6 thus impacting upon embryo viability.

d. the pregnancy rate was similar for embryos which on day 5 were delayed and not suitable for biopsy and freezing but were suitable for freezing on day 6 and underwent either biopsy or niPGT-A;

e. the pregnancy rate for embryos unsuitable for biopsy and freezing but found to be euploid after niPGT-A testing on day 6 was superior to untested embryos;

f. the concordance rate for embryos classified as euploid using niPGT-A was high;

g. niPGT-A continued to have utility as a ranking measure for embryos not suitable for genetic screening by biopsy.

(d) by 30 July 2020, Monash IVF Group and Repromed proceeded upon the basis that:

a. further investigation of niPGT-A should be undertaken;

b. good quality embryos which were suitable for biopsy on day 5 would only be screened for ranking purposes using biopsy;

c. niPGT-A would only be available as a screening measure for embryos that were delayed in development and not suitable for biopsy;

d. any embryos which were screened using niPGT-A would not be discarded;

e. patient information sheets would be amended to include further information about the use of niPGT-A as a screening and ranking measure.

(e) by reason of the matters alleged above, neither Monash IVF Group nor Repromed had the knowledge alleged.

15L. As to paragraph 15L of the SASOC, the defendants:

(a) refer to paragraph 15K hereof;

(b) admit Monash IVF Group and Repromed did not take the steps alleged in sub-paragraphs (a) to (c).

(c) deny that Monash IVF Group and Repromed had the knowledge alleged and should have taken the steps alleged;

(d) otherwise denies the paragraph.

15M. As to paragraph 15M of the SASOC, the defendants:

(a) refer to paragraph 15J hereof;

(b) otherwise deny the paragraph.

15N. As to paragraph 15N of the SASOC, the defendants:

(a) refer to paragraphs 15K and 15L hereof;

(b) otherwise deny the paragraph.

15O. As to paragraph 15O of the SASOC, the defendants deny the paragraph.

16. As to paragraph 16 of the SASOC, the defendants:

(a) admit that the results of the clinical trial were not published;

(b) say that from in or about May 2019, the first, second, fourth, fifth, sixth, seventh and eighth defendants informed patients seeking IVF treatment about the availability of niPGT-A;

(c) say that from about May 2019 to October 2020, niPGT-A was arranged by the first, second, fourth, fifth, sixth, seventh and eighth defendants to be provided by Repromed for persons seeking IVF treatment as a screening test to determine the aneuploid status of embryos in circumstances where a biopsy test was not available to the patient, or where niPGT-A was specifically requested;

(d) otherwise deny the paragraph.

Particulars

Adelaide Fertility funded an almost four-year long process of research and validation in respect of niPGT-A. The Monash IVF niPGT-A was approved by the Group Medical Advisory Committee (**GMAC**) and human ethical trials were approved by Bellberry Limited (an accredited Human Research Ethics Committee (**HREC**)). Pre-clinical studies, a prospective pilot study, a trial on slower embryos (that cannot be tested using embryo biopsy) and NATA validation studies were conducted. A NATA accreditation audit, with technical expert and review of validation data, occurred in or around early 2019. Further particulars will be provided prior to trial.

16A. As to paragraph 16A of the SASOC, the defendants say:

(a) the absence of total concordance between biopsy and niPGT-A in determining the ploidy status of embryos did not render the introduction and use of niPGT-A by Monash IVF Group during the relevant period unsuitable as alleged;

(b) the suitability of introducing and using niPGT-A as a clinical ranking measure during the period alleged was affected by a range of relevant considerations including:

a. that biopsy of embryos as a screening measure was not itself foolproof and was capable of producing false positives and false negatives;

b. that biopsy of embryos required dedicated equipment and personnel with highly trained technical expertise;

c. the increased cost associated with biopsy of embryos and its non-availability in the absence dedicated equipment and sufficiently qualified and trained personnel;

d. the disadvantages associated with biopsy of embryos as a screening measure including that:

i. it was a highly invasive procedure which interfered with the embryo's cell make up with the consequence that a potentially good embryo might not otherwise be available for transfer;

ii. it was a highly invasive procedure that when performed had the potential to cause damage to the embryo with the consequence that a potentially good embryo might not otherwise be available for transfer;

iii. the invasiveness of biopsy created increased difficulties with freezing of embryos with the consequence that a potentially good embryo might not otherwise be available for transfer;

iv. because of its invasive nature, biopsy was only suitable for high quality embryos which were vastly more capable of surviving the biopsy process and the freeze and thaw process;

v. many older women were not able to have their embryos screened by biopsy because they did not produce embryos of sufficiently high quality to be biopsied with the consequence that biopsy was often unavailable to the IVF patients who stood to benefit most from PGT-A;

vi. because of its invasive nature some IVF clinicians did not favour recommending biopsy to patients particularly in circumstances where there was ongoing debate as to whether it benefited IVF outcomes in younger women undergoing IVF treatment and particularly, older women (who usually produced fewer good quality embryos) undergoing IVF treatment;

vii. studies associated biopsy with a significant increase in pre-eclampsia and hypertensive disorders;

viii. studies associated biopsy not being of benefit in patients aged < 38 years.

e. the potential advantages of niPGT-A as a screening measure including that:

i. it did not subject the embryo to the invasive risks associated with biopsy;

ii. it could be utilised for embryos of poor quality that could not undergo biopsy and therefore would be available to older IVF patients;

iii. it could provide some screening information for patients not wishing to have their embryo biopsied in circumstances where no screening information would otherwise be available.

f. the social utility of making available a ranking measure to IVF patients who would otherwise not be open to biopsy;

g. the fact that niPGT-A was offered only as a screening test to rank embryos for transfer with a view to shortening the time to pregnancy and avoiding miscarriages;

h. the fact there had been international studies conducted some of which demonstrated high concordance between niPGT-A and biopsy;

i. the fact that clinicians and their patients were informed that niPGT-A as a screening test was:

a. a screening test only and not a diagnostic test;

b. a new screening test;

c. not wholly concordant with biopsy;

d. was not one hundred percent accurate and there was a risk of misdiagnosis.

j. the fact that IVF clinicians and patients alike who were able to access niPGT-A had total autonomy and discretion as to the use of biopsy and niPGT-A and whether to discard or preserve embryos tested using niPGT-A;

k. the fact Monash IVF Group proposed to and did in fact review and monitor clinical performance of the test.

(c) they otherwise deny the paragraph.

16B. As to paragraph 16B of the SASOC, the defendants:

(a) say niPGT-A testing ceased on or about 25 September 2020;

(b) refer to paragraphs 15K and 16A hereof;

(c) otherwise deny the paragraph.

17. As to paragraph 17 of the SASOC, the defendants:

(a) admit that niPGT-A was suspended by the defendants in or about October 2020;

(b) admit that patients of the defendants, including the plaintiffs, were notified of the suspension of niPGT-A;

(c) otherwise deny the paragraph.

Particulars

The first plaintiff was notified by telephone on or about 16 October 2020 and subsequently by letter.

The second plaintiff was notified by telephone on or about 10 October 2020 by phone and subsequently by letter.

18. As to paragraph 18 of the SASOC, the defendants:

(a) say niPGT-A was suspended in or about October 2020;

(b) say the defendants continued to provide embryo biopsy testing to some patients for the purpose of determining the aneuploid status of embryos;

(c) otherwise deny the paragraph.

19. The defendants deny paragraph 19 of the SASOC and repeat paragraphs 15 and 16 hereof.

20. The defendants deny paragraph 20 of the SASOC.

Informed consent

21. As to paragraph 21 of the SASOC, the defendants:

(a) deny the underlying factual premise of the matters alleged in sub-paragraphs (b), (c), (d), (f), (g) and (h) and therefore that they were required to disclose such matters to the plaintiffs or patients seeking IVF treatment;

(b) deny that the matters in sub-paragraphs (e), (f), (g), (h) and (i) were matters of the kind that were required to be disclosed to the plaintiffs and patients seeking IVF treatment;

(c) say further that biopsy testing by reason of its invasive nature may not be as safe as niPGT-A and may not be available for use by all patients requesting testing for aneuploidy;

(d) say that biopsy testing is in any event not 100 percent accurate as a test for determining the aneuploidy status of embryos and has limitations in relation to its use.

Particulars

(i) Embryos that are too advanced or less advanced may not be able to be biopsied;

(ii) After embryo biopsy embryos may be damaged or not develop to a stage to be suitable for transfer;

(iii) The cells taken at biopsy are assumed to represent the whole embryo even though this may not in fact be the case;

(e) say that the first plaintiff's embryo could not undergo biopsy testing for aneuploidy due to the risks associated with such testing;

(f) say that the second plaintiff's embryo could not undergo biopsy testing for aneuploidy due to the risks associated with such testing;

(g) say that the plaintiffs and patients seeking IVF treatment were made aware of risks associated with the accuracy of pre-implantation testing including niPGT-A in the fact sheet, consent forms, in a video and by the patient’s treating physician;

(h) cannot know and do not admit paragraph 21(i);

(i) refer to paragraph 16A hereof;

(j) otherwise deny the paragraph.

22. The defendants deny paragraph 22 of the SASOC.

B. Contracts

The first plaintiff's treatment

23. As to paragraph 23 of the SASOC, the defendants:

(a) repeat paragraph 3 hereof;

(b) admit that on or about 6 July 2017, the first plaintiff consulted Fertility Australia;

(c) say that the first plaintiff consulted Dr Justin Tucker and Dr Bronwyn Devine who were independent clinicians;

(d) otherwise do not admit the paragraph.

24. As to paragraph 24 of the SASOC, the defendants:

(a) repeat paragraph 23 hereof;

(b) admit the first plaintiff received IVF treatment from Fertility Australia during the period alleged;

(c) otherwise deny the paragraph.

25. As to paragraph 25 of the SASOC, the defendants:

(a) repeat paragraphs 3, 23 and 24 hereof;

(b) admit that Ms Bopping entered into an agreement for the provision of IVF services with Fertility Australia;

(c) otherwise deny the paragraph and repeat paragraphs 23 and 24 hereof.

The second plaintiff's treatment

26. As to paragraph 26 of the SASOC, the defendants:

(a) repeat paragraph 4 hereof;

(b) admit that on or about 24 March 2020, the second plaintiff consulted Repromed;

(c) say that the second plaintiff consulted Dr Stephanie Girle who was an independent clinician;

(d) otherwise do not admit the paragraph.

27. As to paragraph 27 of the SASOC, the defendants:

(a) repeat paragraph 26 hereof;

(b) admit the second plaintiff received IVF treatment from Repromed during the period alleged;

(c) otherwise deny the paragraph.

28. The defendants deny paragraph 28 of the SASOC and repeat paragraphs 25 and 26 hereof.

28A. The defendants are unable to plead to paragraph 28A of the SASOC in the absence of any particulars of individual group members' claims and under cover of that objection deny the paragraph.

Testing and destruction of embryos

29. As to paragraph 29 of the SASOC, the defendants:

(a) repeat paragraph 10A hereof;

(b) say that in December 2019, Repromed carried out niPGT-A testing on Ms Bopping's embryo;

(c) otherwise deny the paragraph.

30. As to paragraph 30 of the SASOC, the defendants:

(a) say that Ms Bopping was informed by Fertility Australia in or about December 2019 that her embryo had been identified as aneuploidy following niPGT-A testing;

(b) otherwise deny the paragraph.

31. As to paragraph 31 of the SASOC, the defendants:

    (a) say that Ms Bopping's embryo has not been discarded but remain in storage;

    (b) deny the allegations.

32. As to paragraph 32 of the SASOC, the defendants:

    (a) say that in September 2020 Repromed performed niPGT-A testing on four of Ms Pedersen's embryos;

    (b) say that in May 2020 three of Ms Pedersen's embryos were screened by embryo biopsy testing;

    (c) repeat paragraph 10A hereof;

    (d) otherwise deny the paragraph.

33. As to paragraph 33 of the SASOC, the defendants:

    (a) say that in or about June and September 2020, Ms Pedersen was informed by Repromed that one embryo had been identified as aneuploidy following niPGT-A testing, one embryo had been identified as aneuploidy following embryo biopsy testing, and one embryo had been identified as inconclusive following niPGT-A testing;

    (b) otherwise deny the paragraph.

34. The defendants deny paragraph 34 of the SASOC and say further that the two embryos identified as aneuploidy and the single embryo identified as inconclusive remain in storage.

Terms of the agreements

35. As to paragraph 35 of the SASOC, the defendants:

    (a) admit that it was an implied term of Ms Bopping's agreement with Fertility Australia that it would exercise reasonable care and skill in providing the medical services the subject of the agreement with Ms Bopping;

(b) admit that it was an implied term of Ms Pedersen's agreement with Adelaide Fertility that it would exercise reasonable care and skill in providing the medical services the subject of the agreement with Ms Pedersen;

(c) repeats paragraph 28A hereof;

(d) otherwise deny the paragraph.

Breach of agreements

36. The defendants deny paragraph 36 of the SASOC.

36A. The defendants say the first plaintiff entered into an agreement with Repromed prior to undertaking niPGT-A, a condition of which was that Repromed and its agents were absolved from all liability for injury, damage or loss howsoever caused arising from niPGT-A including for negligence and breach of contract.

C. Breach of guarantees under the Australian Consumer Law

37. The defendants deny paragraph 37 of the SASOC.

38. The defendants deny paragraph 38 of the SASOC.

39. The defendants deny paragraph 39 of the SASOC.

40. The defendants deny paragraph 40 of the SASOC.

40A. The defendants deny paragraph 40A of the SASOC.

41. The defendants deny paragraph 41 of the SASOC.

42. As to paragraph 42 of the SASOC, the defendants:

(a) deny they owed or breached the Due Care Guarantee or the Fitness for Purpose Guarantee;

(b) further and alternatively deny that any alleged breach of the alleged guarantees caused the plaintiffs or the group members loss and damage of the kinds alleged in paragraph 45 of the SASOC or at all;

(c) further and alternatively say that any remedy available to the plaintiffs and group members in respect of any alleged loss or damage suffered by reason of the alleged

breaches is limited to the cost of doing the work again or refunding the amount paid pursuant to ss 64A(2) and (3) of the Australian Consumer Law (**ACL**);

(d) further and alternatively say that any alleged loss or damage suffered by the plaintiffs and group members as a result of the alleged breaches was not reasonably foreseeable within the meaning of s 267(4) of the ACL such that the plaintiffs and group members are not entitled to recover damages by reason of the alleged breaches;

(e) further and alternatively say that any alleged loss or damage suffered by the plaintiffs and group members as a result of the alleged breaches is limited by a law of a State or a Territory as the proper law of the contract that applies to limit or preclude liability for the failure, and recovery of that liability (if any), in the same way as it applies to limit or preclude liability, and recovery of any liability, for a breach of a term of the contract for the supply of the services.

Particulars

The defendants rely on s 275 of the ACL and the *Civil Liability Act 2002 (NSW)*, including, without limitation, ss 5A, 11A , 12, 13, 14 and 16, and cognate legislation in other States and Territories as the case may be for each group member.

(f) otherwise deny the paragraph.

D. Negligence

43. The defendants deny paragraph 43 of the SASOC and say further:

(a) PGT-A testing on embryos was requested by only a minority of patients undergoing IVF treatment;

(b) the type of PGT-A on embryos was affected by the nature of the embryo and whether it was suitable to undergo a biopsy;

(c) whether or not embryos underwent PGT-A and the type of testing undertaken was affected by the wishes and instructions of patients;

(d) patients had the opportunity to discuss PGT-A with their treating physicians and referring general practitioners and obtain information as to the advantages, risks and accuracy of outcomes;

(e) IVF specialists and general practitioners and others had access to publicly available information via journal articles and through other entities providing IVF treatment as to the use and risks associated with PGT-A including niPGT-A.

44. As to paragraph 44 of the SASOC, the defendants:

(a) deny the allegations in paragraph 44(a) and say further that the principal causes of reproductive failure vary having regard to the age and personal physiological circumstances of patients;

(b) deny the allegations in paragraph 44(b) save that PGT-A was used in order to facilitate the transfer of euploid embryos so as to reduce time to pregnancy;

(c) admit PGT-A was undertaken for patients of the defendants requesting it so as to determine the likely aneuploid status of embryos prior to transfer but otherwise deny the allegations in paragraph 44(c);

(d) admit embryos classified as aneuploidy were not transferred but otherwise deny the allegations in paragraph 44(d);

(e) deny paragraph 44(e);

(f) deny paragraph 44(f);

(g) admit that during 2019 and 2020 clinical use of niPGT-A was new in Australia but otherwise deny the allegations in paragraph 44(g);

(h) deny paragraph 44(h);

(i) as to paragraph 44(i) admit that niPGT-A included a risk of the kind alleged but say further that the risk of erroneous determination that an embryo was aneuploidy also inheres in embryo biopsy testing;

(j) deny paragraph 44(j);

(k) deny paragraph 44(k) and say further that some embryos are not suitable for biopsy testing;

(l) admit paragraph 44(l);

(m) deny paragraph 44(m);

(n) deny paragraph 44(n);

(o) admit that the clinical trial referred to in paragraph 15 had not been peer reviewed but otherwise deny the allegations in paragraph 44(o) and say further that Adelaide Fertility had obtained NATA accreditation following NATA validation and further, repeat paragraphs 15A, 15D, 15J, 16 and 16A hereof;

(p) deny paragraph 44(p) and further repeat paragraphs 13-16A hereof;

(q) as to paragraph 44(q) say: (i) they did not use niPGT-A testing as a basis for discarding embryos; (ii) they do not know the details of fertility programs which were offered by all providers of fertility programs worldwide; (iii) otherwise deny the allegations;

(r) deny paragraph 44(r) and say that the clinical trial referred to in paragraph 16 hereof indicated concordance with embryo biopsy testing;

(s) deny paragraph 44(s) and say further that some embryos are not suitable for embryo biopsy testing;

(t) deny paragraph 44(t) and further repeat paragraphs 10B-10F, 15A-15F and 16A hereof.

45. As to paragraph 45 of the SASOC, the defendants:

(a) say that it was reasonably foreseeable that the plaintiffs and other patients who agreed to undergo IVF treatment would pay a monetary fee in exchange for that treatment;

(b) say that it was reasonably foreseeable that the plaintiffs and other patients who sought IVF treatment did so in order to achieve pregnancy and live birth;

(c) say that it was reasonably foreseeable that if the results of niPGT-A testing were positive for aneuploidy the embryo the subject of those results would not be transferred;

(d) refer to paragraph 16A hereof;

(e) otherwise deny the paragraph.

46. The defendants deny paragraph 46 of the SASOC.

47. The defendants deny paragraph 47 of the SASOC and repeat paragraphs 13, 14, 15 and 16 hereof.

48. The defendants deny paragraph 48 of the SASOC and repeat paragraph 21 hereof.

49. The defendants deny paragraph 49 of the SASOC.

50. As to paragraph 50 of the SASOC, the defendants:

(a) admit IVF treatment was provided by Fertility Australia to the first plaintiff and other patients in order to achieve pregnancy and live birth;

(b) admit IVF treatment was provided by Adelaide Fertility to the second plaintiff and other patients in order to achieve pregnancy and live birth;

(c) say that they are unable to plead further in relation to group members in the absence of any particulars of individual group members' claims and under cover of that objection otherwise deny the paragraph.

51. The defendants deny paragraph 51 of the SASOC.

52. The defendants deny paragraph 52 of the SASOC.

53. The defendants deny paragraph 53 of the SASOC.

54. The defendants deny paragraph 54 of the SASOC.

55. The defendants deny paragraph 55 of the SASOC.

56. [There is no paragraph 56 in the SASOC.]

57. The defendants deny paragraph 57 of the SASOC.

57A. As to paragraph 57A of the SASOC, the defendants:

(a) admit sub-paragraphs (a), (b);

(b) admit approval was granted by Bellberry for the trials subject to the conditions mentioned in the letter of approval;

(c) deny sub-paragraph (d) and say that NATA accreditation for niPGT-A was obtained by Repromed;

(d) repeat paragraphs 14A-15L hereof and otherwise deny sub-paragraph (e);

(e) otherwise deny the paragraph.

57B. As to paragraph 57B of the SASOC, the defendants:

(a) repeat paragraphs 16A, 16B, 54, 55 and 57A hereof.

(b) otherwise deny the paragraph.

Precautions and breach

58. As to paragraph 58 of the SASOC, the defendants:

(a) deny paragraph 58(a);

(b) deny paragraph 58(b) and repeat paragraph 21 hereof;

(c) deny paragraph 58(c);

(d) deny paragraph 58(d) and repeat paragraph 21 hereof;

(e) do not know what "systems" are to be implemented as alleged or the "appropriate practice" as alleged and therefore cannot plead to the allegations in paragraph 58(e). Under cover of that objection, the defendants deny the allegations in paragraph 58(e);

(f) deny paragraph 58(f);

(g) deny paragraph 58(g) and repeat paragraph 21 hereof;

(h) deny paragraph 58(h).

59. The defendants deny paragraph 59 of the SASOC and say further that niPGT-A had social utility in the provision of IVF treatment.

Particulars

The defendants refer to the social utility of: (i) testing embryos by niPGT-A which could not have been tested by embryo biopsy; (ii) testing delayed embryos which might not be suitable for embryo biopsy; (iii) avoiding or minimising the risk of harm or damage to an embryo by biopsy testing.

Further particulars may be provided following receipt of expert evidence.

60. The defendants deny paragraph 60 of the SASOC.

61. As to paragraph 61 of the SASOC, the defendants:

(a) deny paragraph 61(a);

(b) as to paragraph 61(b):

(i) deny paragraph 61(b)(i) and repeat paragraphs 13, 15 and 16 hereof;

(ii) deny paragraph 61(b)(ii) and repeat paragraph 21 hereof;

(iii) deny paragraph 61(b)(iii), and repeat paragraph 21 hereof.

62. The defendants deny paragraph 62.

E. Misleading and deceptive conduct; misrepresentation

63. As to paragraph 63 of the SASOC, the defendants:

(a) admit a fact sheet was made available to the first plaintiff and patients seeking IVF treatment from Fertility Australia via the Monash IVF website and a fact sheet and was provided to the second plaintiff and patients seeking IVF treatment from Repromed;

(b) say that the fact sheet was made available to the plaintiffs and patients together with other information concerning PGT-A and repeat paragraph 21 hereof;

(c) admit the fact sheet contained, inter alia, the statements alleged in paragraphs 63(a) and (c) of the SASOC and will rely upon the fact sheet at trial for its full terms and effect;

(d) deny that the fact sheet contained the representations alleged in paragraphs 63(b), (d), (e), (f), (g), (h) and (j);

(e) say further and alternatively that any representations contained in the fact sheet as to the accuracy of niPGT-A or as alleged were in the nature of opinions which were reasonably held;

(f) repeat paragraphs 23(c) and 26(c) hereof;

(g) otherwise deny the paragraph.

64. As to paragraph 64 of the SASOC, the defendants:

(a) repeat paragraph 63 hereof;

(b) admit the statements referred to in paragraph 63(c) hereof were made in trade or commerce;

(c) otherwise deny the paragraph.

65. The defendants deny paragraph 65 of the SASOC.

66. The defendants deny paragraph 66 of the SASOC.

67. As to paragraph 67 of the SASOC, the defendants:

(a) repeat paragraphs 10A, 63 and 65 hereof;

(b) say that they are unable to plead further in relation to group members in the absence of any particulars of individual group members' claims;

(c) deny the paragraph.

68. The defendants deny paragraph 68 of the SASOC and repeat paragraph 63 hereof, and say further and alternatively that they had reasonable grounds for making the alleged representations and repeat paragraphs 13, 15, 16, 16A and 21 hereof.

69. The defendants deny paragraph 69 and repeat paragraph 63 hereof.

70. The defendants deny paragraph 70 of the SASOC.

71. The defendants deny paragraph 71 of the SASOC and say further that Ms Bopping's embryo and Ms Pedersen's embryo could not undergo biopsy testing due to the risks associated with such testing.

F. Causation, loss and damage

72. As to paragraph 72 of the SASOC, the defendants:

    (a) repeat paragraphs 21, 28 to 34 inclusive and 43 hereof;

    (b) say further that Ms Bopping's embryo and Ms Pedersen's embryo could not undergo biopsy testing due to the risks associated with such testing;

    (c) deny the paragraph.

73. As to paragraph 73 of the SASOC, the defendants:

    (a) repeat paragraph 72 hereof;

    (b) say that the risk of a viable embryo being discarded or not transferred is a risk inherent in all forms of aneuploidy testing;

    (c) otherwise deny the paragraph.

74. The defendants deny paragraph 74 of the SASOC and repeat paragraphs 21 and 73 hereof.

75. The defendants deny the allegations in paragraph 75 of the SASOC and without limiting the generality of the denial, the defendants say further that:

    (a) a single non-invasively screened embryo of the first plaintiff remains in storage at the Bondi Clinic;

    (b) a single non-invasively screened embryo, a single biopsy screened embryo and a single non-invasively screened inconclusive embryo of the second plaintiff remain in storage at the Northern Territory Clinic;

    (c) the second plaintiff had other viable embryos available for transfer.

75A. As to paragraph 75A of the SASOC, the defendants:

(a) repeat paragraphs 10B-10F, 12-16B, 21, 22, 40, 41, 43, 45, 47, 48-53, 57A-62, 63 and 69 hereof.

(b) refer to and rely upon statutory provisions.

Particulars

Personal Injuries (Liabilities and Damages) Act 2003 (NT), section 19.

Civil Liability Act 2003 (Qld), section 52.

Civil Liability Act 2002 (NSW), section 21.

(c) otherwise deny the allegations.

76. The defendants say further and alternatively that recovery of any alleged loss or damage suffered by the plaintiffs and group members as a result of the alleged breaches is limited by the *Civil Liability Act 2002 (NSW)*, including, without limitation, ss 5A, 11, 11A, 12, 13, 14, 15, 16, 18, 27 to 33 inclusive and cognate legislation in other States and Territories including:

(a) ss 32 to 36, 41, 93, 98 to 100 of the *Civil Law (Wrongs Act) 2002* (ACT);

(b) ss 4, 18, 20 to 30 of the *Personal Injuries (Liabilities and Damages) Act 2003* (NT);

(c) ss 4, 7, 50, 51, 53 to 62 of the *Civil Liability Act 2003* (Qld);

(d) ss 4, 33, 52 to 58 of the *Civil Liability Act 1936* (SA);

(e) ss 4, 24 to 28BA, 29 to 35 of the *Civil Liability Act 2002* (Tas); and/or

(f) Part VB of the *Wrongs Act 1958* (Vic), and ss 28A, 67 to 75 of that Act, including the need for the person allegedly injured to establish that they have suffered 'significant injury', as required by Part VBA of that Act;

as the case may be for each group member.

76A. The defendants say further that, in answer to the claims made against them by each of the plaintiffs and group members, they rely upon the provisions of:

(a) Part 1A, Divisions 1, 2 and 3, and Part 3 of the *Civil Liability Act* 2002 (NSW);

(b) Part 3.2, and Chapter 3, Parts 4.1, 4.2 and 4.3 and/or Chapter 5 of the *Civil Law (Wrongs Act)* 2002 (ACT);

(c) Chapter 2, Part 1, Divisions 1 and 2 of the *Civil Liability Act* 2003 (Qld) and Chapter 2, Part 1 of the *Personal Injuries Proceedings Act* 2002 (Qld);

(d) Part 6, Divisions 1 and 2 of the *Civil Liability Act* 1936 (SA);

(e) Part 6, Divisions 1, 2 and 3, and Part 8 of the *Civil Liability Act* 2002 (Tas); and/or

(f) Part X, Divisions 1, 2 and 3, and Part XI of the *Wrongs Act* 1958 (Vic);

as may be applicable to each of the plaintiffs and for each of the group members.

G. Common questions

77. The defendants deny the alleged common questions arise and say that any appropriate common questions that arise ought to be formulated prior to trial.

P Zappia KC

L Barrett

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Colin Biggers & Paisley Lawyers

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Colin Biggers & Paisley

Solicitors for the defendants

SCHEDULE OF PARTIES

DANIELLE BOPPING

First plaintiff

MICHELLE LOUISE PEDERSEN

Second plaintiff

MONASH IVF PTY LTD (ACN 006 942 990)

First defendant

ADELAIDE FERTILITY CENTRE PTY LTD
trading as Repromed (ACN 116 453 126)

Second defendant

MONASH IVF GROUP LIMITED (ACN 169 302 309)

Third defendant

MONASH IVF AUCHENFLOWER PTY LTD (ACN 111 370 891)

Fourth defendant

PALANTROU PTY LIMITED (ACN 111 795 692)

Fifth defendant

HOBART IVF PTY LTD (ACN 610 573 889)

Sixth defendant

COMPASS FERTILITY PTY LTD (ACN 130 793 583)

Seventh defendant

FERTILITY AUSTRALIA PTY LTD (ACN 117 504 766)

Eighth defendant