



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

No. S ECI 2020

Case: S ECI 2020 04761

Filed on: 28/05/2021 04:40 PM

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 19 April 2021)

Date of document:	28 May 2021
Filed on behalf of:	Defendants
	Solicitors' code: 108866
Prepared by:	
Colin Biggers & Paisley	Tel: +61 2 8281 4443
Level 42, 2 Park Street	Ref: DLK:JKL:2005698
SYDNEY NSW 2000	Att: Debbie Kaminskas
	Email: Debbie.Kaminskas@cbp.com.au

To the Statement of Claim dated 23 April 2021 (**SOC**) the defendants adopt the definitions used in the Amended Statement of Claim for convenience only and say as follows:

A. Preliminary

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

2. As to paragraph 2 of the SOC 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 it denies those paragraph.
3. As to paragraph 3 of the SOC the defendants:
 - (a) deny paragraph 3(a);
 - (b) say that the first plaintiff engaged Fertility Australia Pty Ltd as trustee for Fertility Australia Trust (**Fertility Australia**) operating a clinic at Bondi Junction in New South Wales for IVF treatment;
 - (c) deny paragraph 3(b).
4. As to paragraph 4 of the SOC the defendants:
 - (a) deny paragraph 4(a);
 - (b) say that the second plaintiff engaged Adelaide Fertility Centre Pty Ltd (**Adelaide Fertility**) operating a clinic in the Northern Territory for IVF treatment;
 - (c) deny paragraph 4(b).
5. The defendants do not plead to paragraph 5 of the SOC as it contains no allegations against them.

The defendants

6. As to paragraph 6 of the SOC 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 SOC 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 SOC the defendants:
- (a) admit paragraph 8(a);
 - (b) say that Monash IVF and Repromed were subsidiaries of Monash IVF Group;
 - (c) otherwise deny the paragraph.
9. As to paragraph 9 of the SOC the defendants:
- (a) say the entities in paragraph 9 were subsidiaries of Monash IVF Group;
 - (b) say that the entities provided IVF treatment and/or related medical services to patients referred to them as the case may be;
 - (c) otherwise deny the paragraph.
10. As to paragraph 10 of the SOC the defendants:
- (a) repeat paragraphs 3,4, 6,7 and 8 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.

IVF research and treatment

11. As to paragraph 11 of the SOC 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 fertilized by sperm outside the body;

- (c) otherwise deny the paragraph.
12. As to paragraph 12 of the SOC the defendants:
- (a) admit that during the relevant period Adelaide Fertility tested embryos 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 SOC and say further that National Association of Testing Authorities (**NATA**) accreditation was obtained by Adelaide Fertility.
14. The defendants deny paragraph 14 of the SOC.
15. As to paragraph 15 of the SOC 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.
16. As to paragraph 16 of the SOC the defendants:
- (a) admit that the results of the clinical trial were not published;
 - (b) say that from in or about May 2019, Monash IVF informed patients seeking IVF treatment about the availability of niPGTA;
 - (c) say that from in or about May 2019, Fertility Australia and Adelaide Fertility informed patients seeking IVF treatment about the availability of niPGTA;
 - (d) say that from about May 2019 to October 2020, niPGT-A was arranged 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.
 - (e) otherwise deny the paragraph.

Particulars

Adelaide Fertility funded an almost four-year long process of research and validation in respect of ni-PGTA. 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.

17. As to paragraph 17 of the SOC the defendants:

- (a) admit that niPGT-A was suspended in or about October 2020;
- (b) admit that patients of Fertility Australia and Adelaide Fertility 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 SOC the defendants:

- (a) say niPGT-A was suspended in or about October 2020;
- (b) say Monash IVF and Repromed 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 SOC.
20. The defendants deny paragraph 20 of the SOC.

Informed consent

21. As to paragraph 21 of the SOC 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 (f), (g), (h) 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 Ms Bopping's embryo could not undergo biopsy testing for aneuploidy due to the risks associated with such testing;
- (f) say that Ms Pedersen'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) otherwise deny the paragraph.

22. The defendants deny paragraph 22 of the SOC.

B. Contracts

The first plaintiff's treatment

23. The defendants deny paragraph 23 of the SOC and repeat paragraph 3(b) hereof.

24. As to paragraph 24 of the SOC the defendants:

- (a) repeat paragraph 23 hereof;
- (b) admit the plaintiff received IVF treatment during the period alleged;
- (c) otherwise deny the allegations.

25. The defendants deny paragraph 25 of the SOC and repeat paragraph 23 hereof.

The second plaintiff's treatment

26. The defendants deny paragraph 26 of the SOC and repeat paragraph 4(b) hereof.

27. As to paragraph 27 of the SOC the defendants:

- (a) repeat paragraph 26 hereof;
- (b) admit the plaintiff received IVF treatment during the period alleged;
- (c) otherwise deny the allegations.

28. The defendants deny paragraph 28 of the SOC and repeat paragraph 26 hereof.

Testing and destruction of embryos

29. As to paragraph 29 of the SOC the defendants:

- (a) say that Adelaide Fertility carried out niPGT-A testing on Ms Bopping's embryo;

- (b) otherwise deny the paragraph.
30. As to paragraph 30 of the SOC 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 SOC the defendants:
- (a) say that Ms Bopping's embryo has not been discarded but remains in storage;
 - (b) deny the allegations.
32. As to paragraph 32 of the SOC the defendants:
- (a) say that Adelaide Fertility performed the niPGT-A testing on Ms Pedersen's embryos;
 - (b) say that three embryos were screened by embryo biopsy testing and four embryos were screened by niPGT-A testing;
 - (c) otherwise deny the paragraph.
33. As to paragraph 33 of the SOC the defendants:
- (a) say that in or about June and September 2020 Ms Pedersen was informed by Adelaide Fertility that one embryo had been identified as aneuploidy following ni PGT-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 SOC 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 SOC 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) otherwise deny the paragraph.

Breach of agreements

36. The defendants deny paragraph 36 of the SOC.

C. Breach of guarantees under the Australian Consumer Law

37. The defendants deny paragraph 37 of the SOC.
38. The defendants deny paragraph 38 of the SOC.
39. The defendants deny paragraph 39 of the SOC.
40. The defendants deny paragraph 40 of the SOC.
41. The defendants deny paragraph 41 of the SOC.
42. As to paragraph 42 of the SOC 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 SOC 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;

- (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 Australian Consumer Law 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 SOC 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 ni PGT-A.

44. As to paragraph 44 of the SOC 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 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;
- (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 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.;
- (p) deny paragraph 44(p);
- (q) as to paragraph 44(q) the defendants say: (i) they did not use niPGT-A testing as a basis for discarding embryos; (ii) they do not know what fertility programs were offered worldwide; (c) 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).

45. As to paragraph 45 of the SOC 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) otherwise deny the paragraph.
46. The defendants deny paragraph 46 of the SOC.
 47. The defendants deny paragraph 47 of the SOC and repeat paragraphs 13, 14, 15 and 16 hereof.
 48. The defendants deny paragraph 48 of the SOC and repeat paragraph 21 hereof.
 49. The defendants deny paragraph 49 of the SOC.
 50. As to paragraph 50 of the SOC 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) otherwise deny the paragraph.
 51. The defendants deny paragraph 51 of the SOC.
 52. The defendants deny paragraph 52 of the SOC.
 53. The defendants deny paragraph 53 of the SOC.
 54. The defendants deny paragraph 54 of the SOC.
 55. The defendants deny paragraph 55 of the SOC.
 56. The defendants deny paragraph 56 of the SOC.
 57. The defendants deny paragraph 57 of the SOC.

Precautions and breach

58. As to paragraph 58 of the SOC the defendants:
 - (a) deny paragraph 58(a);
 - (b) deny paragraph 58(b) and refer to paragraph 21 hereof;
 - (c) deny paragraph 58(c);

- (d) deny paragraph 58(d) and refer to 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 refer to paragraph 21 hereof;
 - (h) deny paragraph 58(h).
59. The defendants deny paragraph 59 of the SOC 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 SOC.
61. As to paragraph 61 of the SOC 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 SOC 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 was provided to the second plaintiff and patients seeking IVF treatment from Adelaide Fertility;
- (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 SOC 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) and (h);
- (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) otherwise deny the paragraph.

64. As to paragraph 64:

- (a) the defendants refer to 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 SOC.

66. The defendants deny paragraph 66 of the SOC.

67. The defendants deny paragraph 67 of the SOC.

68. The defendants deny paragraph 68 of the SOC and repeat paragraph 63 hereof, and say further and alternatively that they had reasonable grounds for making the alleged representations.
69. The defendants deny paragraph 69 and repeat paragraph 63 hereof.
70. The defendants deny paragraph 70 of the SOC.
71. The defendants deny paragraph 71 of the SOC and say further that Ms Bopping'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 SOC the defendants:
 - (a) repeat paragraphs 21, 28 to 34 inclusive and 43 hereof;
 - (b) say further that Ms Bopping'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 SOC 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 SOC and repeat paragraphs 21 and 73 hereof.
75. The defendants deny the allegations in paragraph 75 of the SOC 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.

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, 16, 27 to 33 inclusive and cognate legislation in other States and Territories as the case may be for each group member.

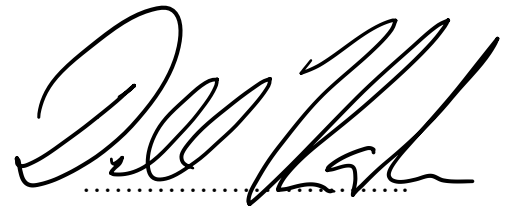
G. Common questions

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 QC

N. C. Dour

Counsel for the defendants

A handwritten signature in black ink, appearing to be 'Colin Biggers & Paisley', written over a dotted line.

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