NOTICE OF FILING AND HEARING

This document was lodged electronically in the FEDERAL COURT OF AUSTRALIA (FCA) on 7/06/2022 9:28:01 AM AEST and has been accepted for filing under the Court's Rules. Filing and hearing details follow and important additional information about these are set out below.

Filing and Hearing Details

Document Lodged:	Originating Application Starting a Representative Proceeding under Part IVA Federal Court of Australia Act 1976 - Form 19 - Rule 9.32
File Number:	NSD244/2021
File Title:	DEBRA FOWKES v BOSTON SCIENTIFIC CORPORATION & ANOR
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA
Reason for Listing:	To Be Advised
Time and date for hearing:	To Be Advised
Place:	To Be Advised

Dated: 7/06/2022 10:42:22 AM AEST Registrar

Important Information

As required by the Court's Rules, this Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

The Reason for Listing shown above is descriptive and does not limit the issues that might be dealt with, or the orders that might be made, at the hearing.

The date and time of lodgment also shown above are the date and time that the document was received by the Court. Under the Court's Rules the date of filing of the document is the day it was lodged (if that is a business day for the Registry which accepts it and the document was received by 4.30 pm local time at that Registry) or otherwise the next working day for that Registry.

Form 19
Rule 9.32

Amended Originating application starting a representative proceeding under Part IVA of the Federal Court of Australia Act 1976

Amended on 7 June 2022 and filed pursuant to an order made on 1 June 2022

No. NSD 244 of 2021

Federal Court of Australia

District Registry: New South Wales

Division: General

Debra Fowkes
Applicant

Boston Scientific Corporation
First Respondent

Boston Scientific Pty Limited
Second Respondent

To the Respondents

The Applicant applies for the relief set out in this application.

The Court will hear this application, or make orders for the conduct of the proceeding, at the time and place stated below. If you or your lawyer do not attend, then the Court may make orders in your absence.

You must file a notice of address for service (Form 10) in the Registry before attending Court or taking any other steps in the proceeding.

Time and date for hearing:

Place: Law Courts Building, Queens Square, Sydney

Filed on behalf of (name & role of party) Debra Fowkes (Applicant)
Prepared by (name of person/lawyer) Rebecca Jancauskas, Shine Lawyers
Law firm (if applicable) Shine Lawyers
Tel (07) 3006 6051 Fax (07) 3229 1999
Email rjancauskas@shine.com.au
Address for service (include state and postcode) Level 13, 160 Ann Street, Brisbane QLD 4000

The Court ordered that the time for serving this application be abridged to

Date:

.....

Signed by an officer acting with the authority
of the District Registrar

Details of claim

On the grounds stated in the accompanying Amended Statement of Claim, the Applicant claims that the Respondents each contravened sections 74D and 75AD of the *Trade Practices Act 1974* (Cth) (**TPA**) and additionally, or alternatively, sections 138 (having regard to section 9 and otherwise) and 54 of schedule 2 of the *Competition and Consumer Act 2010 (*Cth) (**ACL**) and were negligent. The Applicant claims relief as follows :

Statutory Claims

1. Declarations that:

   (a) The safety of the **Implants** (as defined in the Amended Statement of Claim) was not such as persons generally were entitled to expect and had a defect for the purposes of section 75AC(1) and 75AD(1) of the TPA and a safety defect for the purposes of sections 9 and 138 of the ACL;

   (b) The Implants acquired by each of the Group Members were not of merchantable quality, or acceptable quality, within the meaning of section 74D of the TPA and section 54 of Schedule 2 of the ACL;

2. Compensation or damages from the Respondents for the Group Members on the following bases:

   (a) pursuant to section 75AD of the TPA or, as the case may be, compensation pursuant to section 138 of the ACL;

   (b) pursuant to sections 74D(1) of the TPA or, as the case may be, damages pursuant to sections 54, 271 and 272 of Schedule 2 of the ACL.

3. Interest on the amounts referred to in proposed order 2 above.

Claims in Negligence

4. Declarations that:

   (a) The First Respondent breached its duty of care to each of the Group Members by designing and manufacturing each of the Implants in such a way that they had:

      (i) The characteristics pleaded in paragraph 8 of the Amended Statement of Claim; and in addition, or alternatively,

(ii) a risk of and in addition, or alternatively, were susceptible to, causing the **Implant Complications** (as defined in the Amended Statement of Claim) and in addition, or alternatively, the **Implant Treatment and Removal Complications** (as defined in the Amended Statement of Claim);

(b) The Second Respondent breached its duty of care to each of the Group Members by continuing to design, manufacture, market and, in addition or alternatively, supply the Implants notwithstanding the matters referred to in subparagraph (a) above;

(c) The First Respondent breached its duty of care to the Group Members by failing to conduct any, or any adequate, pre- market evaluation of the safety and effectiveness of the Implants;

(d) The First Respondent breached its duty of care to the Group Members by failing to conduct any, or any adequate, post market evaluation of the safety and effectiveness of the Implants;

(e) The First Respondent breached its duty of care to each of the Group Members by failing to inform them, Boston Australia, or the treating hospitals and/or treating doctors:

(i) that the Implants had the characteristics pleaded at paragraph 8 of the Amended Statement of Claim;

(ii) that the Implants had a risk of and, or alternatively were susceptible to, causing the Implant Complications and, or alternatively, the Implant Treatment and Removal Complications; and in addition, or alternatively;

(iii) of the **Implant Warning Matters** (as that term is defined in the Amended Statement of Claim);

(f) The Second Respondent breached its duty of care to each of the Group Members by failing to inform them, or the treating hospitals and/or treating doctors:

(i) that the Implants had the characteristics pleaded at paragraph 8 of the Amended Statement of Claim;

(ii) that the Implants had a risk of and, or alternatively were susceptible to, causing the Implant Complications and, or alternatively, the Implant Treatment and Removal Complications; and in addition, or alternatively;

(iii) of the Implant Warning Matters.

5. Damages from each of the Respondents at common law for each of the Group Members.

6. Interest on the amounts referred to in proposed order 5 above.

7. Costs.

8. Such further or other orders as the Court thinks fit.

Questions common to claims of group members

THE IMPLANTS, THEIR RISKS AND COMPLICATIONS

Q1. Can the Implants cause the following complications or any of them:

(a) pain, which may be chronic and, or alternatively, severe and may be refractory to treatment;

(b) entrapment of nerves in the scar tissue surrounding the Implant resulting in pain which may be chronic and, or, severe and may not remain localised and may be refractory to treatment;

(c) de novo dyspareunia which may be severe, worsened dyspareunia and in addition, or alternatively, apareunia;

(d) erosion or extrusion of the Implant into the vaginal canal resulting in:

(i) infection of the tissue surrounding the non-exposed part of the Implant which may be difficult to treat effectively and may result in offensive vaginal discharge;

(ii) pain including during sexual intercourse;

(e) erosion or extrusion of the Implant into surrounding organs such as the bladder, urethra or rectum with the risk of damage to those organs, infection and, or alternatively, pain;

(f) difficulty voiding or defecating;

(g) de novo urge incontinence and/or urge incontinence;

(h) de novo stress urinary incontinence in the case of the POP Implants; and

(i) psychiatric injury as a consequence of the development of one or more of the complications referred to at paragraphs (a) to (h) above?

Q2. If the answer to question 1 is 'yes', can treatment of the complications referred to in question 1 require one or more surgical procedures to remove the Implants or those parts of the Implants that are reasonably capable of being removed?

Q3. If the answer to question 2 is 'yes', were the Implants difficult or impossible to safely remove from patients?

Q4. Can treatment of the complications referred to in question 1 be difficult or impossible, and/or carry with it the risk of new or aggravated complications?

Q5. If any of questions 2, 3 and/or 4 is answered 'yes', can patients suffer psychiatric injury as a consequence?

MECHANISM OF THE COMPLICATIONS

Q6. Is it necessary for Group Members to prove the mechanism by which the Implants caused the complications which they suffered as a result of their Implant?

Q7. If the answer to question 6 is 'yes' were the complications, or any of them caused by reason that the Implants were:

(a) made, at least partly, from polypropylene;

(b) implanted transvaginally, abdominally or laparoscopically;

(c) brought into contact with the vagina and, in the case of the SUI Implants, the urethra during implantation;

(d) intended to, and do, elicit a chronic inflammatory reaction of the tissues and, or alternatively, the surrounding tissues, in which they are implanted; and, or alternatively

(e) catalysts for the continuous regeneration of scar tissue within and surrounding the Implant for so long as it remains in the body, which can cause the Implant (separately or in conjunction with surrounding tissue) to contract.

DEFECTIVE GOODS

Q8. Did the Implants, or any of them, have a defect within the meaning of section 75AC of the TPA and did they have a safety defect within the meaning of section 9 of the ACL?

Q9. Are either or both of the Respondents liable if the Applicant or any Group Member proves that they have suffered injury because of the defect, or safety defect, in an Implant?

NOT OF MERCHANTABLE QUALITY OR ACCEPTABLE QUALITY

Q10. Were the Implants, or any of them, not of merchantable quality or acceptable quality within the meaning of section 74D(3) of the TPA, or acceptable quality within the meaning of section 54 of Schedule 2 of the CCA?

Q11. Are either or both of the Respondents liable if the Applicant or any Group Member proves that they have suffered injury because of the defect, or safety defect, in an Implant?

NEGLIGENCE

Duty of Care

Q12. Did the Respondents, or either of them, owe a duty of care to group members?

Q13. Did the First Respondent owe the Group Members a duty to take reasonable care in the design, testing, evaluation, supply and marketing of the Implants?

Q14. Did the Second Respondent owe the Group Members a duty to take reasonable care in the supply and marketing of the Implants?

Q15. What was the scope or content of the Respondents' duty of care in relation to the supply and marketing of the Implants?

Breach

Pre-market Evaluation

Q16. Did the First Respondent breach its duty of care by failing to undertake adequate pre-market evaluations of the safety and effectiveness of the Implants?

Post-market Evaluation

Q17. Did the First Respondent breach its duty of care by failing to undertake adequate post-market evaluations of the safety and effectiveness of the Implants?

Information

Q18. For the period from the date of first supply of any the Implants in Australia, did the Respondents breach their duty of care to Group Members by failing to provide adequate information, advice or warnings as to the complications and the absence of any adequate clinical or other evaluation of the risks associated with the use of the Implants?

Q19. In what respects was the information, advice or warnings provided by the Respondents about the complications inadequate?

Representative action

9. The Applicant brings this application as a representative party under Part IVA of the *Federal Court of Australia Act 1976*.

Applicant's address

The Applicant's address for service is:

Place: Shine Lawyers

Email: rjancauskas@shine.com.au

The Applicant's address is Level 13, 160 Ann Street, Brisbane QLD 4000.

Service on the Respondents

It is intended to serve this application on the Respondents.

Date: 7 June 2022

Signed by Rebecca Jancauskas
Lawyer for the Applicant

Schedule

No. NSD244 of 2021

Federal Court of Australia
District Registry: New South Wales
Division: General

Applicant

Applicant: Debra Fowkes

Respondents

First Respondent: Boston Scientific Corporation

Second Respondent: Boston Scientific Pty Ltd (ACN 071 676 063)

Date: 7 June 2022