# NOTICE OF FILING AND HEARING

## Filing and Hearing Details

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| Document Lodged**:** | Originating Application - Form 15 - Rule 8.01(1) |
| Court of Filing: | FEDERAL COURT OF AUSTRALIA (FCA) |
| Date of Lodgment: | 5/09/2024 12:50:00 PM AEST |
| Date Accepted for Filing: | 5/09/2024 1:05:58 PM AEST |
| File Number: | NSD1224/2024 |
| File Title: | SIMON HARROLD v EXACTECH AUSTRALIA PTY LTD ACN 146 150 754 & 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 |


Registrar

## Important Information

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 date of the filing of the document is determined pursuant to the Court's Rules.

Form 15
Rules 8.01(1); 8.04(1)

# Originating application

No. NSD of 2024

Federal Court of Australia

District Registry: New South Wales

Division: General

**SIMON HARROLD**

Applicant

**EXACTECH AUSTRALIA PTY LTD ACN 146 150 754** and another named in schedule 1.

Respondents

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**: 184 Phillip Street Sydney NSW 2000

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


Filed on behalf of (name & role of party) Simon Harrold, the Applicant
Prepared by (name of person/lawyer) David Cossalter
Law firm (if applicable) Gerard Malouf and Partners
Tel 1800 004 878 Fax Not applicable
Email diane.chapman@gmp.net.au
**Address for service** (include state and postcode) Level 5, 109 Pitt Street, Sydney, NSW 2000

**Details of claim**

On the grounds stated in the accompanying Statement of Claim, the Applicant claims the following relief on his own behalf and on behalf of the Group Members:

1. an order or orders that the First Respondent pay damages to the Applicant and/or the Group Members, or at least one or some of them, pursuant to section 236 or compensation pursuant to section 237 of the Australian Consumer Law in schedule 2 of the *Competition and Consumer Act* 2010 (Cth) (or the **ACL**) for any loss and damage caused by the First Respondent's contraventions of sections 18, 29 and/or 33 of the ACL; and/or

2. an order or orders that the First Respondent pay damages to the Applicant and/or the Group Members, or at least one or some of them, pursuant to sections 82 and/or 87 of the *Trade Practices Act* 1974 (Cth) (or the **TPA**) for any loss and damage caused by the First Respondent's contraventions of sections 52 and/or 55 of the TPA; and/or

3. an order or orders that the First Respondent and/or the Second Respondent pay damages to the Applicant and/or the Group Members, or at least one or some of them, pursuant to sections 271 and 272 (1) of the ACL for any loss and damage caused by the Respondents' failure to comply with the guarantee as to 'acceptable quality' in section 54 of the ACL; and/or

4. an order or orders that the First Respondent and/or the Second Respondent pay damages to the Applicant and/or the Group Members, or at least one or some of them, pursuant to section 74D of the TPA for any loss and damage caused by the Respondents' liability arising under the same provision in relation to the supply of unmerchantable goods; and/or

5. an order or orders that the First Respondent and/or the Second Respondent pay damages to the Applicant and/or the Group Members, or at least one or some of them, pursuant to section 259(4) of the ACL for any loss and damage caused by the Respondents' failure to comply with the guarantee of 'fitness for any disclosed purpose' in section 55 of the ACL; and/or

6. an order or orders that the First Respondent and/or the Second Respondent pay damages to the Applicant and/or the Group Members, or at least one or some of them, pursuant to section 74B of the TPA for any loss and damage caused by reason of the Respondents' liability for the supply of unsuitable goods; and/or

7. an order or orders that the First Respondent and/or the Second Respondent pay damages to the Applicant and/or the Group Members, or at least one or some of them, pursuant to

section 138 of the ACL for any loss and damage caused by reason of the Respondents' liability arising for the supply of goods with a 'safety defect'; and/or

8. an order or orders that the First Respondent and/or the Second Respondent pay damages to the Applicant and/or the Group Members, or at least one or some of them, pursuant to section 75AD of the TPA for any loss and damage caused by reason of the Respondents' liability, arising under section 75AC, for the supply of goods with a 'defect'; and/or

9. an order or orders that the First Respondent and/or the Second Respondent pay common law damages to the Applicant and/or the Group Members, or at least one or some of them, as modified by statute, such as the *Civil Liability Act* 2002 (NSW) and/or cognate legislation in other States and Territories of Australia, for any loss and damage caused by the Respondents' liability in negligence;

10. an order or orders that the First Respondent pay:

    a. pursuant to section 33Z(1)(e) of the *Federal Court Act of Australia* 1976 (Cth) (the **FCA Act**), an award, or awards of damages for the Group Members, being damages consisting of specified amounts or amounts worked out in such manner as the Court specifies, in respect of some or all of the damages sought in paragraphs 1 and/or 2 (above) to which the Group Members are entitled, being in respect of those head of damages that are amenable to determination on a common basis;

    b. in the alternative to the order sought in paragraph 10(a), pursuant to section 33Z(1)(f) of the FCA Act, an award of damages in an aggregate amount without specifying the amounts awarded in respect of individual Group Members, in respect of some or all of the damages sought by the orders in paragraphs 1 and/or 2 to which the Group Members are entitled, being in respect of those heads of damages that are amenable to determination on a common basis;

11. an order or orders that the First Respondent and/or the Second Respondent pay:

    a. pursuant to section 33Z(1)(e) of the *Federal Court Act of Australia* 1976 (Cth) (the **FCA Act**), an award, or awards of damages for the Group Members, being damages consisting of specified amounts or amounts worked out in such manner as the Court specifies, in respect of some or all of the damages sought in paragraphs 3, and/or 4, and/or 5, and/or 6, and/or 7, and/or 8 (above) to which the Group Members are entitled, being in respect of those head of damages that are amenable to determination on a common basis;

    b. in the alternative to the order sought in paragraph 11(a), pursuant to section 33Z(1)(f) of the FCA Act, an award of damages in an aggregate amount without specifying the amounts awarded in respect of individual Group Members, in respect

of some or all of the damages sought in paragraphs 3, and/or 4, and/or 5, and/or 6, and/or 7, and/or 8 (above) to which the Group Members are entitled, being in respect of those heads of damages that are amenable to determination on a common basis;

12. interest pursuant to section 51A of the FCA Act;

13. costs; and

14. such further or other order as the Court thinks fit.

**Questions common to the claims of the Group Members**

The questions of law or fact common to the claims of the Group Members (defined below) are set out in the second schedule of this document (**Schedule 2**).

**Claim for interlocutory relief**

The Applicant claims the following interlocutory relief:

1. pursuant to rule 10.43(2) of the *Federal Court Rules* 2011, a grant of leave to serve this originating application dated [INSERT] on the Second Respondent in the United States of America in accordance with the requirements of the 'Convention of 15 November 1965 on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters'; and

2. any further order the Court deems fit including costs.

**Representative action**

The Applicant brings this application as a representative party under Part IVA of the FCA Act.

The Group Members to whom this proceeding relates are described in paragraph 1 of the accompanying Statement of Claim being persons who:

1. in Australia, at any time in the period commencing 1 January 2003 and the date of filing of this Originating Application (the **Filing Date**) inclusive (the **Relevant Period**) purchased, and were implanted, with one or more joint replacement devices for knees (the **TKAs** or **TKA**) and/or hips (the **THAs** and **THA**) and/or shoulders (anatomic) (the **TSAs** or **TSA**) (collectively, the **Joint Devices**) which included an orthopaedic impact bearing component (known as a liner or **Insert**) made with 'moderately cross linked ultra-high molecular weight polyethylene' pursuant to the Exactech Standard Process, as defined in the Statement of Claim, (the **Affected Devices**); and

**Particulars**

A. See the first schedule of the Statement of Claim which identifies the Affected Devices by reference to the details recorded with the Australian Register of Therapeutic Goods (the ARTG), such as their 'Summary for ARTG Entry' and their registration number (**Schedule 1**).

B. The 'Relevant Period' will be amended following completion of discovery processes to include joint devices and their Inserts exported to Australia prior to the incorporation of Exactech Australia, and made with 'moderately cross linked ultra-high molecular weight polyethylene' (or **MXPLE**) pursuant to the Exactech Standard Process.

2. are not:

   a. a director or an officer or a close associate of a director or officer (as defined in section 9 of the *Corporations Act 2001* (Cth) (**the Corporations Act**)) of Exactech Australia or Exactech US; or

   b. a related party (as defined in section 228 of the Corporations Act) of Exactech Australia or Exactech US; or

   c. a related body corporate (as defined in section 50 of the Corporations Act) of the Exactech Australia or Exactech US; or

   d. an associate entity (as defined in section 50AAA of the Corporations Act) of the Exactech Australia or Exactech US; or

   e. an Authorised Dealer (a term defined below); or

   f. a person described in section 33E(2) of the FCA Act; or

   g. a Chief Justice, Justice, District Registrar or Deputy District Registrar of the Federal Court of Australia or the High Court of Australia.

3. Such of those Group Members that were implanted with a TKA with an Affected Device before 1 January 2011 are **Sub-Group A Members**.

4. Such of those Group Members that were implanted with a THA with an Affected Device before 1 January 2011 are **Sub-Group B Members**.

5. Such of those Group Members that were implanted with a TSA with an Affected Device before 1 January 2011 are **Sub-Group C Members**.

6. Such of those Group Members that were implanted with a TKA with an Affected Device on or after 1 January 2011 are **Sub-Group D Members**.

7. Such of those Group Members that were implanted with a THA with an Affected Device on or after 1 January 2011 are **Sub-Group E Members**.

8. Such of those Group Members that were implanted with a TSA with an Affected Device on or after 1 January 2011 are **Sub-Group F Members**.

**Applicant's address**

The Applicant's address for service is:

Place: Gerard Malouf and Partners, Level 5, 109 Pitt Street, Sydney NSW

Email: diane.chapman@gmp.net.au

The Applicant's address is C/- Gerard Malouf & Partners Level 5, 109 Pitt Street, Sydney NSW

**Service on the Respondent**

It is intended to serve this application on all Respondents.

Date: 5 September 2024

Signed by David Cossalter

Solicitor for the Applicant

**Schedule 1**

No. NSD of 2024

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

**Respondents**

Second Respondent: Exactech Incorporated

Date: August 2024

## Schedule 2

### Questions common to the claims of the Group Members

[the wording for the common questions adopts the terms defined in the Statement of Claim]

1. With respect to factual matters:

   a. was the First Respondent a manufacturer of the Affected Devices within the meaning of sections 7, 138 and 271 of the ACL and section 74A(3) of the TPA?

   b. was the Second Respondent a manufacturer of the Affected Devices within the meaning of sections 7, 138 and 271 of the ACL and section 74A(3) of the TPA?

   c. was the First Respondent a supplier of the Affected Devices within the meaning of sections 7, 55 and 259(4) of the ACL?

   d. do the Affected Devices possess the Production Defect?

   e. do the Affected Devices possess the Oxidising Defect?

   f. by reason of the Production Defect and/or the Oxidising Defect, do the Affected Devices shed, or possess the propensity to shed, materially greater volumes of particle debris *in vivo* than Inserts made with HXPLE manufactured and treated pursuant to the Predominant Industry Process?

   g. by reason of the Production Defect and/or the Oxidising Defect, do the Affected Devices carry an abnormal and/or superadded risk of earlier and/or more frequent revision surgery post index surgery when compared to the revision rates of comparable joint devices using Inserts made with HXPLE manufactured and treated pursuant to the Predominant Industry Process for the same period? If the answer is 'Yes', what is the magnitude of this risk?

   h. are Inserts manufactured with MXPLE in accordance with the Exactech Standard Process, and used as orthopaedic impact bearing components in TKAs, as effective in treating Knee Pathologies, or in the alternative not materially less effective in treating Knee Pathologies, as Inserts made with HXPLE in accordance with the Predominant Industry Process?

   i. are Inserts manufactured with MXPLE in accordance with the Exactech Standard Process, and used as orthopaedic impact bearing components in THAs, as effective in treating Hip Pathologies, or in the alternative not materially less effective in treating Hip Pathologies, as Inserts made with HXPLE in accordance with the Predominant Industry Process?

j. are Inserts manufactured with MXPLE in accordance with the Exactech Standard Process, and used as orthopaedic impact bearing components in TSAs, as effective in treating Shoulder Pathologies, or in the alternative not materially less effective in treating Shoulder Pathologies, as Inserts made with HXPLE in accordance with the Predominant Industry Process?

k. with respect to the Personal Injury Consequences:

i. do the Affected Devices cause or have the propensity to cause the following:

A. an adverse reaction to particle debris (**ARPD**);

B. chronic inflammation of periprosthetic tissue;

C. osteolysis;

D. chronic swelling in the affected joint;

E. loss of movement in the affected joint;

F. mental harm;

G. damage to modular components of the Joint Devices;

H. re-operation;

I. one or more revision surgeries;

J. infections;

K. scarring; and

L. severe pain

ii. is the answer to the foregoing question affected by factors such as individual patient presenting symptoms, clinical presentation, medical history, the type of Joint Device or surgical technique used in the implant surgery?

l. do Inserts manufactured with HXPLE in accordance with the Predominant Industry Process bear a greater, or lesser, propensity, than Inserts manufactured with MXPLE in accordance with the Exactech Standard Process, to cause one or more of the Personal Injury Consequences?

m. did the First Respondent make any of the Device Representations?

n. did the First Respondent make any of the Future Device Representations? If the answer is 'Yes', did the First Respondent have a reasonable basis for making any of those representations?

2. With respect to the Acceptable Quality Contraventions:

a. at the time of supply, were the Affected Devices:

i. fit for all purposes for which goods of that kind are commonly supplied?

ii. free from defects?

iii. safe?

iv. durable?

b. At the time of supply, did the Affected Devices satisfy the statutory guarantee as to 'acceptable quality' set out in section 54 of the ACL?

3. With respect to the Respondents' Liability for Unmerchantable Goods:

a. at the time of supply, were the Affected Devices of unmerchantable quality?

4. With respect to the Fitness for Purpose Contraventions:

a. did any of the Group Members make known, expressly or impliedly, the Insert Purpose to either:

i. one or more of the Suppliers? And/or

ii. one or more of the Respondents by or through any one of the Suppliers?

b. at the time of supply, were the Affected Devices reasonably fit for the Insert Purpose?

c. At the time of supply, did the Affected Devices satisfy the statutory guarantee as to 'fitness for any disclosed purpose set out in section 55 of the ACL?

5. With respect to the Respondents' Liability for Unsuitable Goods:

a. at the time of supply, were the Affected Devices fit for the Insert Purpose?

6. With respect to the Misleading Device Conduct:

a. did the First Respondent fail to correct or qualify any of the Device Representations?

b. did the First Respondent fail to correct or qualify any of the Future Device Representations?

c. in respect of the Device Representations and/or the Future Device Representations, did the First Respondent:

i. engage in misleading and/or deceptive conduct in contravention of section 18 of the ACL or 52 of the TPA?

ii. make false or misleading representations that the Affected Devices were of a particular standard, quality or composition in contravention of section 29(1)(a) of the ACL?

iii. make false or misleading representations that the Affected Devices have or had performance characteristics, uses or benefits in contravention of section 29(1)(g) of the ACL?

iv. engage in conduct that was liable to mislead the public as to the nature, characteristics, and/or suitability for their purpose, in contravention of section 33 of the ACL and/or section 55 of the TPA?

7. With respect to the Respondents' Liability for Safety Defects:

a. was the safety of any one of the Affected Devices beneath the standard persons were generally entitled to expect from Inserts?

b. do the Affected Devices possess a 'safety defect' within the meaning of section 9 of the ACL and/or a 'defect' within the meaning of section 75AC of the TPA?

c. was the state of scientific or technical knowledge regarding the manufacturing process of Inserts insufficient to enable the Respondents to discover the 'safety defect' and/or 'defect'?

8. With respect to the Common Law Breach Matters:

a. did the First Respondent and/or the Second Respondent owe the Group Members a duty to exercise reasonable care and skill in the design, evaluation, manufacture, packaging and supply of the Affected Devices?

b. would a reasonable manufacturer and/or supplier in the position of the Respondents have taken one or more of the Device Precautions to protect against the occurrence of one or more of the Personal Injury Consequences?

c. did the First Respondent and/or the Second Respondent breach their duty of care to the Group Members by failing to implement one or more of the Device Precautions?

d. did the First Respondent and/or the Second Respondent fail to give any, or any adequate, information or warning as to any one or more of the Device Evaluation Matters and/or any one or more of the Device Warning Matters?

e. did the First Respondent and/or the Second Respondent fail to conduct any, or any adequate, evaluation of the safety and efficacy of the Affected Devices before supplying, distributing, marketing or promoting them in Australia?