

## NOTICE OF FILING

### Details of Filing

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File Title:	SIMON HARROLD v EXACTECH AUSTRALIA PTY LTD ACN 146 150 754 & ANOR
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA



A handwritten signature in blue ink that reads "Sia Lagos".

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.



## Defence

No. NSD1224 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

Respondents

#### A. THE PARTIES

##### A1. The Group Members and the Applicant

1. In respect of paragraph 1 of the Statement of Claim (**Claim**), the Respondents:
  - (a) admit that the proceeding was commenced as a representative proceeding under Part IVA of the *Federal Court of Australia Act 1976* (Cth) (**FCA Act**) by the Applicant on his own behalf and on behalf of the Group Members who are alleged to be persons of the kind as described in paragraph 1 of the Statement of Claim (**Group Members**);
  - (b) in respect of the definition of Affected Devices in sub-paragraph (a), say that, during the Relevant Period:
    - (i) some, but not all of the Inserts for the Hip Joint Devices were made from moderately cross-linked ultra-high molecular weight polyethylene; and
    - (ii) the Inserts for the Hip Joint Devices (other than those referred to in paragraph 1(b)(i) above), the Knee Joint Devices and the Shoulder Joint Devices were made from ultra-high molecular weight polyethylene, and not from moderately cross-linked ultra-high molecular weight polyethylene; and
  - (c) otherwise do not admit the allegations in paragraph 1 of the Claim.

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Filed on behalf of (name & role of party)	The Respondents		
Prepared by (name of person/lawyer)	Amanda Beattie		
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2. In respect of paragraph 2 of the Claim, the Respondents:
  - (a) refer to and repeat sub-paragraph 1(b) above; and
  - (b) otherwise do not admit the allegations in paragraph 2 of the Claim.
3. In respect of paragraph 3 of the Claim, the Respondents:
  - (a) refer to and repeat sub-paragraph 1(b) above; and
  - (b) otherwise do not admit the allegations in paragraph 3 of the Claim.
4. In respect of paragraph 4 of the Claim, the Respondents:
  - (a) refer to and repeat sub-paragraph 1(b) above; and
  - (b) otherwise do not admit the allegations in paragraph 4 of the Claim.
5. In respect of paragraph 5 of the Claim, the Respondents:
  - (a) refer to and repeat sub-paragraph 1(b) above; and
  - (b) otherwise do not admit the allegations in paragraph 5 of the Claim.
6. In respect of paragraph 6 of the Claim, the Respondents:
  - (a) refer to and repeat sub-paragraph 1(b) above; and
  - (b) otherwise do not admit the allegations in paragraph 6 of the Claim.
7. In respect of paragraph 7 of the Claim, the Respondents:
  - (a) refer to and repeat sub-paragraph 1(b) above; and
  - (b) otherwise do not admit the allegations in paragraph 7 of the Claim.
8. In respect of paragraph 8 of the Claim, the Respondents:
  - (a) admit that, at the date of the commencement of the proceeding, there were seven or more Group Members;
  - (b) refer to and repeat sections F, G, H, I and J below; and
  - (c) otherwise deny the allegations in paragraph 8 of the Claim.
9. The Respondents do not know and cannot admit the allegations in paragraph 9 of the Claim.
10. The Respondents do not know and cannot admit the allegations in paragraph 10 of the Claim.
11. In respect of paragraph 11 of the Claim, the Respondents:
  - (a) refer to and repeat paragraphs 49, 54 and 59 below; and

- (b) otherwise do not know and cannot admit the allegations in paragraph 11 of the Claim.
- 12. The Respondents do not know and cannot admit the allegations in paragraph 12 of the Claim.
- 13. In respect of paragraph 13 of the Claim, the Respondents:
  - (a) insofar as the paragraph concerns the Optetrak Brochure Representations:
    - (i) refer to and repeat paragraphs 11 above and 49, 54 and 59 below; and
    - (ii) deny the allegations in paragraph 13 of the Claim; and
  - (b) otherwise do not know and cannot admit the allegations in paragraph 13 of the Claim.
- 14. In respect of paragraph 14 of the Claim, the Respondents:
  - (a) refer to and repeat paragraph 13 above; and
  - (b) do not know and cannot admit the allegations in paragraph 14 of the Claim.
- 15. The Respondents do not know and cannot admit the allegations in paragraph 15 of the Claim.
- 16. The Respondents do not know and cannot admit the allegations in paragraph 16 of the Claim.
- 17. In respect of paragraph 17 of the Claim, the Respondents:
  - (a) say that the price of any particular device is determined with reference to the particular contract pursuant to which it is sold, and varies from contract to contract;
  - (b) say that the average price in Australian private hospitals in the period from 2019 to 2024 was:
    - (i) \$7,072 for total hip replacement devices;
    - (ii) \$6,209 for total knee replacement devices; and
    - (iii) \$9,763 for total shoulder replacement devices;
  - (c) say that they have no involvement in, and do not know, what fees are charged by treating physicians and/or hospitals to any particular patient who undergoes a joint replacement surgery; and
  - (d) otherwise do not know and cannot admit the allegations in paragraph 17 of the Claim.

## **A2. The Respondents**

18. In respect of paragraph 18 of the Claim, the Respondents:
  - (a) say that Exactech Australia was incorporated on 3 September 2010;
  - (b) refer to and repeat sub-paragraph 1(b) above;
  - (c) admit the allegations in sub-paragraphs (a) and (b) of paragraph 18 of the Claim;
  - (d) say that Exactech Australia, through referrals from sales agents, sold the devices directly to surgeons or hospitals, who in turn re-supplied those devices to consumers, including the Group Members; and
  - (e) in those premises, otherwise deny the allegations in paragraph 18 of the Claim.
19. In respect of paragraph 19 of the Claim, the Respondents:
  - (a) refer to and repeat sub-paragraph 1(b) above; and
  - (b) otherwise admit the allegations in paragraph 19 of the Claim.
20. In respect of paragraph 20 of the Claim, the Respondents:
  - (a) refer to and repeat sub-paragraph 1(b) above;
  - (b) say that Exactech US outsourced the manufacturing of the packaging for the devices to a third party supplier;
  - (c) in those premises, deny the allegation in sub-paragraph 20(b);
  - (d) say that Exactech Australia has been the only sponsor of the Joint Devices and/or the Affected Devices in Australia in the period since 3 September 2010; and
  - (e) otherwise admit the allegations in paragraph 20 of the Claim.
21. In respect of paragraph 21 of the Claim, the Respondents:
  - (a) refer to and repeat sub-paragraphs 1(b) and 20(b) above; and
  - (b) otherwise admit the allegations in paragraph 21 of the Claim.

## **B. THE JOINT DEVICES**

### **B1. What is a Total Knee Arthroplasty?**

22. In respect of paragraph 22 of the Claim, the Respondents:
  - (a) say that not all Inserts are made from polymers such as MXPLE or HXPLE; and
  - (b) otherwise do not admit the allegations in paragraph 22 of the Claim.
23. In respect of paragraph 23 of the Claim, the Respondents:

- (a) refer to and repeat sub-paragraph 22(a) above; and
- (b) otherwise do not admit the allegations in paragraph 23 of the Claim.

**B2. What is a Total Hip Arthroplasty?**

24. In respect of paragraph 24 of the Claim, the Respondents:

- (a) refer to and repeat sub-paragraph 22(a) above; and
- (b) otherwise do not admit the allegations in paragraph 24 of the Claim.

25. In respect of paragraph 25 of the Claim, the Respondents:

- (a) refer to and repeat sub-paragraph 22(a) above; and
- (b) otherwise do not admit the allegations in paragraph 25 of the Claim.

**B3. What is Anatomic Total Shoulder Arthroplasty?**

26. In respect of paragraph 26 of the Claim, the Respondents:

- (a) refer to and repeat sub-paragraph 22(a) above; and
- (b) otherwise do not admit the allegations in paragraph 26 of the Claim.

27. In respect of paragraph 27 of the Claim, the Respondents:

- (a) refer to and repeat sub-paragraph 22(a) above; and
- (b) otherwise do not admit the allegations in paragraph 27 of the Claim.

**B4. What is the purpose of an Insert?**

28. In respect of paragraph 28 of the Claim, the Respondents:

- (a) say, in respect of sub-paragraph (c), that any joint insert has an estimated lifespan, after which it will need to be replaced;
- (b) in those premises, deny that the purpose of a joint insert is to ease pain and restore function for as long as possible; and
- (c) otherwise do not admit the allegations in paragraph 28 of the Claim.

**C. THE DEVICE DEFECTS AND THE DEFECT CONSEQUENCES**

**C1. Production Defect Background**

29. In respect of paragraph 29 of the Claim, the Respondents:

- (a) say that, throughout the Relevant Period, Exactech US has manufactured Inserts for the Joint Devices;
- (b) say that, prior to the Relevant Period, Exactech US did not always manufacture Inserts for the Joint Devices; and

(c) otherwise deny the allegations in paragraph 29 of the Claim.

30. In respect of paragraph 30 of the Claim, the Respondents:

- (a) deny that the process alleged in the paragraph was widely accepted as a manufacturing standard in the industry;
- (b) say that there are multiple accepted and practised ways of manufacturing Inserts in the industry; and
- (c) otherwise deny the allegations in paragraph 30 of the Claim.

**C2. The Production Defect**

31. In respect of paragraph 31 of the Claim, the Respondents:

- (a) deny the allegations in paragraph 31 of the Claim;
- (b) further, say that the 'Frequently Asked Questions' document dated 24 June 2021 referred to in particular (A) to paragraph 31 of the Claim does not support the propositions advanced by the Applicant therein; and
- (c) further or alternatively, say that the fact that a later-in-time product has better performance characteristics does not necessarily mean that the earlier-in-time product is unsafe or defective.

**C3. The Background to the Packaging Defects**

32. The Respondents deny the allegations in paragraph 32 of the Claim.

**C4. The Packaging Defects**

33. The Respondents deny the allegations in paragraph 33 of the Claim.

34. The Respondents deny the allegations in paragraph 34 of the Claim.

35. The Respondents deny the allegations in paragraph 35 of the Claim.

36. The Respondents deny the allegations in paragraph 36 of the Claim.

**C5. The Defects' Consequences**

37. In respect of paragraph 37 of the Claim, the Respondents:

- (a) say that, to the extent that the consequences pleaded in paragraph 37 flow from joint replacement surgery, they are potential risks of any joint replacement surgery; and
- (b) otherwise deny the allegations in paragraph 37 of the Claim.

**C6. The Applicant's Facts, Matters and Circumstances**

- 38. The Respondents do not know and cannot admit the allegations in paragraph 38 of the Claim.
- 39. The Respondents do not know and cannot admit the allegations in paragraph 39 of the Claim.
- 40. The Respondents do not know and cannot admit the allegations in paragraph 40 of the Claim.
- 41. The Respondents do not know and cannot admit the allegations in paragraph 41 of the Claim.
- 42. The Respondents do not know and cannot admit the allegations in paragraph 42 of the Claim.
- 43. The Respondents do not know and cannot admit the allegations in paragraph 43 of the Claim.
- 44. The Respondents do not know and cannot admit the allegations in paragraph 44 of the Claim.
- 45. In respect of paragraph 45 of the Claim, the Respondents:
  - (a) refer to and repeat paragraphs 31 and 36 above; and
  - (b) otherwise deny the allegations in paragraph 45 of the Claim.
- 46. The Respondents do not know and cannot admit the allegations in paragraph 46 of the Claim.

**D. EVALUATION AND WARNINGS**

- 47. In respect of paragraph 47 of the Claim, the Respondents:
  - (a) say that the paragraph is defective in that it fails to plead the respect or respects in which the respective processes are alleged to be effective; and
  - (b) deny the allegations in paragraph 47 of the Claim.
- 48. In respect of paragraph 48 of the Claim, the Respondents:
  - (a) refer to and repeat paragraphs 31, 36, 37 and 47 above;
  - (b) say that the pleading is defective insofar as it repeats the allegations in paragraph 47; and
  - (c) otherwise deny the allegations in paragraph 48 of the Claim.

**E. EXACTECH AUSTRALIA'S REPRESENTATIONS**



**E1. The Device Representations**

49. In respect of paragraph 49 of the Claim, the Respondents:

- (a) say that, from time to time, Exactech US published brochures directed at hospitals and/or surgeons, which were technical in nature and not intended to be read by a lay audience (**Technical Brochures**);
- (b) say that, from time to time, Exactech US published brochures to and for hospitals and/or surgeons which were able to be provided to patients, and which contained general information about joint replacements (**Patient Education Materials**);
- (c) say that the Patient Education Materials were for educational purposes only, and were intended to be read by a patient only in conjunction with specialist advice from their treating surgeon;
- (d) say that, from time to time, Exactech Australia made the Patient Education Materials available for download on its website;
- (e) subject to (d) above, say that Exactech Australia did not distribute Patient Education Materials directly to patients;
- (f) say that the Applicant has not identified any particular representations made in any particular publications by the Respondents upon which it relies in support of the allegations in paragraph 49;
- (g) say that the Technical Brochures and the Patient Educational Materials do not contain any language that would expressly or impliedly support the representations alleged in the paragraph; and
- (h) otherwise deny the allegations in paragraph 49 of the Claim.

50. In respect of paragraph 50 of the Claim, the Respondents:

- (a) refer to and repeat paragraph 49 above; and
- (b) otherwise deny the allegations in paragraph 50 of the Claim.

51. In respect of paragraph 51 of the Claim, the Respondents:

- (a) refer to and repeat paragraph 49 above; and
- (b) otherwise deny the allegations in paragraph 51 of the Claim.

52. In respect of paragraph 52 of the Claim, the Respondents:

- (a) refer to and repeat paragraph 49 above; and
- (b) otherwise deny the allegations in paragraph 52 of the Claim.

53. In respect of paragraph 53 of the Claim, the Respondents:

- (a) refer to and repeat paragraph 49 above; and
- (b) otherwise deny the allegations in paragraph 53 of the Claim.

## **E2. The Future Device Representations**

54. In respect of paragraph 54 of the Claim, the Respondents:

- (a) refer to and repeat paragraph 49 above; and
- (b) otherwise deny the allegations in paragraph 54 of the Claim.

55. In respect of paragraph 55 of the Claim, the Respondents:

- (a) refer to and repeat paragraphs 49 and 54 above; and
- (b) otherwise deny the allegations in paragraph 55 of the Claim.

56. In respect of paragraph 56 of the Claim, the Respondents:

- (a) refer to and repeat paragraphs 49 and 54 above; and
- (b) otherwise deny the allegations in paragraph 56 of the Claim.

57. In respect of paragraph 57 of the Claim, the Respondents:

- (a) refer to and repeat paragraphs 49 and 54 above; and
- (b) otherwise deny the allegations in paragraph 57 of the Claim.

58. In respect of paragraph 58 of the Claim, the Respondents:

- (a) refer to and repeat paragraphs 49 and 54 to 57 above;
- (b) say that, alternatively, if the Future Device Representations were made (which is denied), the Second Respondent had a reasonable basis for making those representations at the time they were made; and
- (c) otherwise deny the allegations in paragraph 58 of the Claim.

59. In respect of paragraph 59 of the Claim, the Respondents:

- (a) refer to and repeat paragraphs 49 and 54 above; and
- (b) otherwise deny the allegations in paragraph 59 of the Claim.

## **F. FAILURE TO COMPLY WITH THE CONSUMER GUARANTEE OF ACCEPTABLE QUALITY – LIABILITY FOR THE SUPPLY OF UNMERCHANTABLE GOODS**

60. The Respondents admit the allegations in paragraph 60 of the Claim.

61. In respect of paragraph 61 of the Claim, the Respondents:

- (a) refer to and repeat sub-paragraphs 1(b), 18(d), and 20(d) above; and
- (b) otherwise admit the allegations in paragraph 61 of the Claim.

- 62. The Respondents admit the allegations in paragraph 62 of the Claim.
- 63. The Respondents admit the allegations in paragraph 63 of the Claim.
- 64. In respect of paragraph 64 of the Claim, the Respondents:
  - (a) refer to and repeat paragraph 17 above; and
  - (b) otherwise admit the allegations in paragraph 64 of the Claim.
- 65. The Respondents admit the allegations in paragraph 65 of the Claim.
- 66. In respect of paragraph 66 of the Claim, the Respondents:
  - (a) refer to and repeat paragraph 28 above; and
  - (b) otherwise do not admit the allegations in paragraph 66 of the Claim.
- 67. In respect of paragraph 67 of the Claim, the Respondents:
  - (a) refer to and repeat paragraphs 28, 31, 36, 37, 49 and 54 above; and
  - (b) otherwise deny the allegations in paragraph 67 of the Claim.
- 68. In respect of paragraph 68 of the Claim, the Respondents:
  - (a) refer to and repeat paragraph 67 above; and
  - (b) otherwise deny the allegations in paragraph 68 of the Claim.
- 69. In respect of paragraph 69 of the Claim, the Respondents:
  - (a) refer to and repeat paragraphs 67 and 68 above; and
  - (b) otherwise deny the allegations in paragraph 69 of the Claim.
- 70. In respect of paragraph 70 of the Claim, the Respondents:
  - (a) refer to and repeat paragraphs 66 to 69 above; and
  - (b) otherwise deny the allegations in paragraph 70 of the Claim.

**G. FAILURE TO COMPLY WITH THE CONSUMER GUARANTEE OF FITNESS FOR ANY DISCLOSED PURPOSE – LIABILITY IN RESPECT OF UNSUITABLE GOODS**

- 71. The Respondents admit the allegations in paragraph 71 of the Claim.
- 72. In respect of paragraph 72 of the Claim, the Respondents:
  - (a) refer to and repeat sub-paragraph 1(b) above; and
  - (b) otherwise admit the allegations in paragraph 72 of the Claim.
- 73. In respect of paragraph 73 of the Claim, the Respondents:
  - (a) refer to and repeat paragraph 28 above; and

(b) otherwise do not admit the allegations in paragraph 73 of the Claim.

74. In respect of paragraph 74 of the Claim, the Respondents:

(a) refer to and repeat paragraph 73 above; and

(b) otherwise do not admit the allegations in paragraph 74 of the Claim.

75. In respect of paragraph 75 of the Claim, the Respondents:

(a) refer to and repeat paragraphs 31, 36 and 37 above; and

(b) otherwise deny the allegations in paragraph 75 of the Claim.

76. In respect of paragraph 76 of the Claim, the Respondents:

(a) refer to and repeat paragraph 75 above; and

(b) otherwise deny the allegations in paragraph 76 of the Claim.

77. In respect of paragraph 77 of the Claim, the Respondents:

(a) refer to and repeat paragraphs 73 to 76 above; and

(b) otherwise deny the allegations in paragraph 77 of the Claim.

#### **H. MISLEADING AND DECEPTIVE CONDUCT**

78. In respect of paragraph 78 of the Claim, the Respondents:

(a) refer to and repeat paragraphs 49 and 54 above; and

(b) on that basis, deny the allegations in paragraph 78 of the Claim.

79. In respect of paragraph 79 of the Claim, the Respondents:

(a) refer to and repeat paragraphs 31, 36, 37 and 67 above; and

(b) otherwise deny the allegations in paragraph 79 of the Claim.

80. In respect of paragraph 80 of the Claim, the Respondents:

(a) refer to and repeat paragraphs 78 and 79 above; and

(b) otherwise deny the allegations in paragraph 80 of the Claim.

81. In respect of paragraph 81 of the Claim, the Respondents:

(a) refer to and repeat paragraphs 78 to 80 above; and

(b) otherwise deny the allegations in paragraph 81 of the Claim.

#### **I. LIABILITY FOR A SAFETY DEFECT**

82. The Respondents admit the allegations in paragraph 82 of the Claim.

83. In respect of paragraph 83 of the Claim, the Respondents:

- (a) refer to and repeat paragraphs 31, 36 and 37 above;
- (b) further and alternatively, say that the state of scientific or technical knowledge at the time when the goods were supplied was not such as to enable any safety defect to be discovered, and in those premises, rely on the defence in section 142(c) of the Australian Consumer Law; and
- (c) otherwise deny the allegations in paragraph 83 of the Claim.

84. In respect of paragraph 84 of the Claim, the Respondents:

- (a) refer to and repeat paragraph 83 above; and
- (b) otherwise deny the allegations in paragraph 84 of the Claim.

#### **J. NEGLIGENCE**

85. In respect of paragraph 85 of the Claim, the Respondents:

- (a) refer to and repeat sub-paragraphs 1(b) and 20(b) above; and
- (b) otherwise admit the allegations in paragraph 85 of the Claim.

86. In respect of paragraph 86 of the Claim, the Respondents:

- (a) say that the Personal Injury Consequences were potential risks of any joint replacement surgery; and
- (b) otherwise do not admit the allegations in paragraph 86 of the Claim.

87. In respect of paragraph 87 of the Claim, the Respondents

- (a) refer to and repeat paragraphs 31, 36, 47, 48 and 86 above; and
- (b) otherwise deny the allegations in paragraph 87 of the Claim.

88. The Respondents deny the allegations in paragraph 88 of the Claim.

#### **K. CAUSATION**

89. The Respondents deny the allegations in paragraph 89 of the Claim.

90. The Respondents deny the allegations in paragraph 90 of the Claim.

91. The Respondents deny the allegations in paragraph 91 of the Claim.

92. The Respondents deny the allegations in paragraph 92 of the Claim.

#### **L. LOSS AND DAMAGE**

93. The Respondents deny the allegations in paragraph 93 of the Claim.

94. The Respondents deny the allegations in paragraph 94 of the Claim.

95. The Respondents deny the allegations in paragraph 95 of the Claim.

**M. RELIEF**

96. The Respondents deny that the Applicant and/or the Group Members are entitled to the relief referred to in paragraph 96 of the Claim.

**N. LIMITATION PERIODS AND RELATED ISSUES**

97. In answer to the Applicant and Group Members' claims in respect of the Misleading Device Conduct (as defined in the Claim):
- (a) the Applicant and/or the Group Members are not entitled to recover an amount of loss or damage for contraventions of sections 19, 29 or 33 of the *Australian Consumer Law* to the extent that loss or damage is, or results from, personal injury; and

**Particulars**

*Competition and Consumer Act 2010* (Cth), sections 137C(1) and 137E(1).

- (b) the Applicant and/or the Group Members are not entitled to recover an amount of loss or damage for contravention of section 52 of the *Trade Practices Act 1974* (Cth) to the extent that loss or damage is, or results from, personal injury, unless the injury occurred on or prior to 19 April 2006.

**Particulars**

*Trade Practices Act 1974* (Cth), section 82(1AAA).

98. In further answer to the Applicant and/or the Group Members' claims arising from the Misleading Device Conduct (as defined in the Claim), at least some of those claims in the period prior to 5 September 2018 are out of time, where prior to that date the cause of action had accrued.

**Particulars**

- (i) *Australian Consumer Law*, sections 236(2) and 237(3).
- (ii) *Trade Practices Act 1974* (Cth), sections 82(2) and 87(1CA).

99. In answer to the Applicant and/or the Group Members' claims arising from the Acceptable Quality Contraventions (as defined in the Claim), at least some of the Group Members' claims in the period prior to 5 September 2021 are out of time, where prior to that date the Group Member was aware, or ought reasonably to have become aware, that the guarantee to which the claim relates had not been complied with.

**Particulars**

*Australian Consumer Law, section 273.*

100. In answer to the Applicant and Group Members' claims arising from the Respondents' Liability for Safety Defects (as defined in the Claim):

- (a) any of the Group Members' claims under section 138 of the *Australian Consumer Law* where supply occurred prior to 5 September 2014 are out of time; and

**Particulars**

- (i) *Australian Consumer Law, section 143(2).*
  - (ii) *Trade Practices Act 1974 (Cth), section 74J(3).*
- (b) further, at least some of the Group Members' claims under section 138 of the *Australian Consumer Law* in the period prior to 5 September 2021 are out of time, where prior to that date the Group Member was aware, or ought reasonably to have become aware, of the alleged loss or damage, the safety defect of the goods, and the identity of the person who manufactured the goods.

**Particulars**

*Australian Consumer Law, section 143(1).*

101. In answer to the Applicant and Group Members' claims for Personal Injury Damage and Loss resulting from negligence:

- (a) at least some of the Group Members' claims where supply occurred prior to 5 September 2012 are out of time; and

**Particulars**

- (i) The State laws on limitation periods for negligence claims are applicable: *Judiciary Act 1903 (Cth) s 79.*
  - (ii) *Limitation Act 1969 (NSW), section 50C(1)(b).*
  - (iii) *Limitation of Actions Act 1958 (Vic), section 27D(1)(b).*
- (b) further, at least some of the Group Members' claims in the period prior to 5 September 2021 are out of time, where prior to that date the cause of action was discoverable by the Group Member.

**Particulars**

- (i) The State laws on limitation periods for negligence claims are applicable: *Judiciary Act 1903 (Cth) s 79.*
  - (ii) *Limitation Act 1969 (NSW), section 50C(1)(a).*
  - (iii) *Limitation of Actions Act 1958 (Vic), section 27D(1)(a).*

- (iv) *Limitation of Actions Act 1974* (QLD), section 11(1).
- (v) *Limitation Act 2005* (WA), sections 14(1) and 55(1).
- (vi) *Limitation Act 1985* (ACT), section 16B(2).
- (vii) *Limitation Act 1974* (TAS), section 5(1).
- (viii) *Limitations of Actions Act 1936* (SA), section 36(1).
- (ix) *Limitation Act 1981* (NT), section 12(1).

102. In further answer to all of the Applicant and Group Members' claims, Exactech Australia cannot bear any liability for claims made in these proceedings in the period prior to its incorporation on 3 September 2010.
103. In further answer to all of the Applicant and Group Members' claims, insofar as paragraph 1 of the Claim pleads that the Relevant Period commences on 1 January 2003:
- (a) the Respondents deny any liability for the period prior to the period alleged in paragraph 31 of the Claim; and
  - (b) the Respondents deny any liability in respect of that proportion of TKAs, TSAs and THAs that were not placed in 'out of specification' packaging since, at the least, 2004, as alleged in paragraph 32 of the Claim.

Date: 11 December 2024



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Signed by Amanda Beattie  
Lawyer for the Respondents

This pleading was prepared by Catherine Gleeson and Emily Hall of counsel




**Certificate of lawyer**

I Amanda Beattie certify to the Court that, in relation to the defence filed on behalf of the Respondent, the factual and legal material available to me at present provides a proper basis for:

- (a) each allegation in the pleading; and
- (b) each denial in the pleading; and
- (c) each non admission in the pleading.

Date: 11 December 2024

A handwritten signature in dark ink, appearing to read 'A Beattie', is written over a light grey rectangular background.

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Signed by Amanda Beattie  
Lawyer for the Respondents