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Details of Filing

Document Lodged: Statement of Claim - Form 17 - Rule 8.06(1)(a)
File Number: NSD331/2022
File Title: PFIZER IRELAND PHARMACEUTICALS & ANOR v SAMSUNG
BIOEPIS CO., LTD & ORS
Registry: NEW SOUTH WALES REGISTRY - FEDERAL COURT OF
AUSTRALIA



Sia Lagos

Dated: 6/05/2022 5:00:10 PM 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.

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Statement of Claim

No. NSD

of 2022

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

Pfizer Ireland Pharmaceuticals

Pfizer Australia Pty Ltd (ACN 008 422 348)

Applicants

Samsung Bioepis Co., Ltd

Samsung Bioepis AU Pty Ltd (ACN 611 890 094)

Merck, Sharp & Dohme Corp.

Merck Sharp & Dohme (Australia) Pty Ltd (ACN 000 173 508)

Organon LLC

Organon Pharma Pty Ltd (ACN 637 107 512)

Arrow Pharmaceuticals Pty Ltd (ACN 605 909 911)

Arrow Pharma Pty Ltd (ACN 605 909 920)

Respondents

A. THE PARTIES

1. The First Applicant, Pfizer Ireland Pharmaceuticals (**Pfizer Ireland**), is and has been at all material times:
 - i. a company duly formed according to the laws of Ireland;
 - ii. able to sue in its corporate name; and
 - iii. the developer of etanercept products, which are marketed in Australia under the ENBREL® brand (**Enbrel Products**).
2. The Second Applicant, Pfizer Australia Pty Ltd (**Pfizer Australia**), is and has been at all material times:
 - i. a company duly formed according to the laws of Australia;

Filed on behalf of (name & role of party) Pfizer Ireland Pharmaceuticals and Pfizer Australia Pty Ltd, Applicants
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- ii. able to sue in its corporate name;
- iii. the exclusive supplier in Australia of the Enbrel Products;
- iv. the sponsor on the Australian Register of Therapeutic Goods (**ARTG**) of the following registrations for the Enbrel Products (**Enbrel Registrations**):
 - a) ARTG Registration No. 90456 for ENBREL etanercept (rch) 25 mg powder for injection vial and diluent syringe composite pack;
 - b) ARTG Registration No. 157622 for ENBREL etanercept (rch) 50 mg solution for injection auto-injector;
 - c) ARTG Registration No. 124421 for ENBREL etanercept (rch) 25 mg solution for injection pre-filled syringe;
 - d) ARTG Registration No. 124422 for ENBREL etanercept (rch) 50 mg solution for injection pre-filled syringe;
 - e) ARTG Registration No. 352090 for ENBREL etanercept (rch) 25 mg solution for injection cartridge; and
 - f) ARTG Registration No. 352091 for ENBREL etanercept (rch) 50 mg solution for injection cartridge; and
- v. the responsible person with respect to the Enbrel Products listed on the Schedule of Pharmaceutical Benefits (**PBS**).

Particulars

The public summaries for the Enbrel Registrations are published online by the Australian Therapeutic Goods Administration (**TGA**) and can be viewed at <https://www.ebs.tga.gov.au/>.

3. Pfizer Ireland and Pfizer Australia are both related entities of Pfizer, Inc., a pharmaceutical and biotechnology corporation headquartered in New York City.
4. The First Respondent, Samsung Bioepis Co Ltd (**SBK**), is and has been since about February 2012:
 - i. a company duly formed according to the laws of Korea;
 - ii. able to be sued in its corporate name; and
 - iii. the developer, either itself or through its servants, agents, related entities, joint venturers, or contractors (the **Samsung Group**), of biosimilar etanercept products known by the names SB4, BRENZYS and BENEPALI (**Brenzys Products**).

5. The Second Respondent, Samsung Bioepis AU Pty Ltd (**SBA**), is and has been since about 15 April 2016:
 - i. a company duly formed according to the laws of Australia;
 - ii. able to be sued in its corporate name; and
 - iii. a wholly owned subsidiary of SBK.
6. The Third Respondent, Merck, Sharp & Dohme Corp. (**MSD**), is and has been at all material times:
 - i. a company duly formed according to the laws of the United States; and
 - ii. able to be sued in its corporate name.
7. The Fourth Respondent, Merck Sharp & Dohme (Australia) Pty Ltd (**MSD AU**), is and has been at all material times:
 - i. a company duly formed according to the laws of Australia;
 - ii. able to be sued in its corporate name; and
 - iii. a wholly owned subsidiary of MSD.
8. The Fifth Respondent, Organon LLC (**Organon**), is and has been since in or about 2020, on a date the Applicants are unable more particularly to specify:
 - i. a company duly formed according to the laws of the United States; and
 - ii. able to be sued in its corporate name.
9. The Sixth Respondent, Organon Pharma Pty Ltd (**Organon AU**), formerly known as OBS Pharma Pty Ltd, is and has been since on or about 29 October 2019:
 - i. a company duly formed according to the laws of Australia;
 - ii. able to be sued in its corporate name; and
 - iii. a wholly owned subsidiary of Organon.
10. The Seventh Respondent, Arrow Pharmaceuticals Pty Ltd (**Arrow**), formerly known as Strides (Australia) Pharma Pty Ltd, is and has been since about 19 May 2015:
 - i. a company duly formed according to the laws of Australia;
 - ii. able to be sued in its corporate name; and
 - iii. a wholly owned subsidiary of Arrotex Pharmaceuticals Pty Ltd (ACN 605 552 234) (**Arrotex**), formerly known as Strides Arcolab (Australia) Pty Ltd.

11. The Eighth Respondent, Arrow Pharma Pty Ltd (**Arrow Pharma**), formerly known as Strides (Australia) IP Pty Ltd, is and has been since about 19 May 2015:
- i. a company duly formed according to the laws of Australia;
 - ii. able to be sued in its corporate name; and
 - iii. a wholly-owned subsidiary of Arrotex.

B. THE PATENT

12. The First Applicant is, and has been at all material times, registered pursuant to the *Patents Act 1990* (Cth) (the **Act**) as the proprietor of Australian Patent No. 2005280034 for an invention titled "*Production of polypeptides*" (the **034 Patent**).
13. The Second Applicant is, and has been at all material times, the exclusive licensee of the 034 Patent.

Particulars

- A. Licence Deed dated 23 January 2017 between the First Applicant and the Second Applicant, which formalised the exclusive licence of the 034 Patent to the Second Applicant.
 - B. On 23 March 2017, the Second Applicant was recorded in the Australian Official Journal of Patents as the registered licensee of the 034 Patent.
 - C. The Second Applicant is registered on the Australian Register of Patents as the exclusive licensee of the 034 Patent.
14. The 034 Patent is, and has at all material times been, valid, subsisting and in full force and effect.

Particulars

The 034 Patent:

- A. has an earliest priority date of 27 August 2004;
 - B. was published and became open for public inspection on 9 March 2006;
 - C. was granted on 4 October 2012; and
 - D. is due to expire on 26 August 2025.
15. The Applicants will seek orders in this proceeding that claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent be amended pursuant to s 105 of the Act in accordance with the proposed amendments set out in Schedule A to this Statement of Claim (the **Proposed Amended Claims**).

16. Each of the proposed amendments is allowable pursuant to s 102 of the Act.

C. THE RESPONDENTS' CONDUCT

17. From a date unknown to the Applicants, but sometime before 21 July 2014, SBK and MSD entered into a common design (**Common Design**) to:

- i. participate; and/or
- ii. authorise, induce or procure:
 - a) members of the Samsung Group, whether then existing or subsequently caused to be created; and
 - b) servants or agents of MSD and bodies corporate related to MSD, including servants, agents, contractors, and sub-licensees of MSD and those related bodies corporate (the **MSD Group**), whether then existing or subsequently caused to be created,

to engage, and/or authorise, induce or procure others to engage,

in acts of exploitation, within the meaning of the Act (**acts of exploitation**), in relation to the Brenzys Products in the "patent area" as that term is defined in the Act (**Patent Area**).

Particulars

- A. Under a Development and Commercialization Agreement (the **DCA**) between SBK and MSD dated 28 February 2013 (as amended from 21 July 2014 and further amended as particularised in paragraph B, below), SBK granted MSD the exclusive right (Article 3.1) in the territory, which included Australia, to:
 - (i) Commercialize Compounds, as defined in the DCA (the compounds including the Brenzys Products from the date of the First Amendment to the DCA – Article 1.14.6); and
 - (ii) use, import and export any and all compounds and products for the purposes of Commercialization in the Territory;
 - (iii) Commercialization was defined in Article 1.11 of the DCA to include: promote, market, distribute, sell, and provide product support for SBK's Brenzys Products in Australia (see also, Letter dated 22 April 2022 from Ashurst to DLA Piper).
- B. The DCA was amended on the following dates:
 - (i) 21 July 2014;

- (ii) 11 July 2017;
 - (iii) 1 October 2017;
 - (iv) 1 September 2018;
 - (v) 15 October 2018;
 - (vi) 19 December 2018; and
 - (vii) 15 May 2020.
- C. On about 15 April 2016, SBA, a wholly-owned subsidiary of SBK, was incorporated in Australia.
- D. SBK says that the Brenzys Products have at all times been delivered by SBK or persons authorised or approved by SBK, and title in the products has passed as hereafter described, outside the Patent Area, including to or for the benefit of MSD or members of the MSD Group to enable or facilitate the performance by MSD, either by itself or members of the MSD Group, of MSD's obligations pursuant to the DCA (see letter dated 22 April 2022 from Ashurst to DLA Piper).
- E. The Applicants refer to and repeat the matters in paragraphs 19 to 25, below.
- F. Further particulars may be provided following discovery or similar processes of the Court.
18. Further, or in the alternative, from a date unknown to the Applicants, but sometime before 21 July 2014, SBK, whether by itself or through members of the Samsung Group:
- i. in furtherance of the Common Design; or, alternatively,
 - ii. independently of the Common Design,
- authorised, induced or procured MSD and/or members of the MSD Group, ultimately including MSD AU, to:
- iii. participate; and/or
 - iv. authorise, induce or procure another person or persons to engage,
- in acts of exploitation in relation to the Brenzys Products in Australia.

Particulars

The Applicants refer to and repeat the particulars to paragraph 17, above.

19. On a date unknown to the Applicants, SBK and/or one or more members of the Samsung Group, and/or MSD and/or one or more members of the MSD Group, one or more of them acting:

- i. in furtherance of the Common Design; or, alternatively,
- ii. as authorised, induced or procured by SBK,

caused ERA Consulting (Australia) Pty Ltd (**ERA Consulting**) to apply to the TGA for registration on the ARTG of the following etanercept products marketed in Australia under or by reference to the brand BRENZYS (the **AU Brenzys Products**):

- iii. ARTG Registration No. 245253 for BRENZYS etanercept (rch) 50 mg solution for injection auto-injector; and
- iv. ARTG Registration No. 245252 for BRENZYS etanercept (rch) 50 mg solution for injection pre-filled syringe.

Particulars

- A. The ARTG Public Summaries for the AU Brenzys Products (**AU Brenzys Public Summaries**) are published online by the TGA and can be viewed at <https://www.ebs.tga.gov.au/>.
- B. Under the DCA, SBK and MSD have regulatory responsibility (Articles [3.5] and [3.6]).

20. On 22 July 2016, the AU Brenzys Products were entered on the ARTG.

Particulars

The AU Brenzys Public Summaries provide that the 'ARTG Start Date' for each of the AU Brenzys Products is 22 July 2016.

21. On or about 16 August 2016, SBK, and/or one or more members of the Samsung Group, and/or MSD and/or one or more members of the MSD Group, one or more of them acting:

- i. in furtherance of the Common Design; or, further or alternatively,
- ii. authorised, induced or procured by SBK,

caused:

- iii. ERA Consulting to transfer the ARTG registrations for the AU Brenzys Products to SBA;
- iv. SBA to become the sponsor of the AU Brenzys Products, to be registered on the ARTG as such and to thereafter fulfil its statutory obligations as the sponsor; and
- v. SBA, since at least that time, to:
 - a) join in the Common Design; or, in the alternative,

- b) be authorised, induced or procured by SBK, and/or members of the SBK Group, to:
1. participate and/or engage; or
 2. authorise, induce or procure another person or persons to engage,
- in acts of exploitation in relation to the AU Brenzys Products in Australia.

Particulars

- A. The Applicants refer to and repeat the particulars to paragraph 19.
 - B. Letter dated 26 August 2016 from ERA Consulting to DLA Piper.
 - C. The AU Brenzys Public Summaries identify SBA as the sponsor of the AU Brenzys Products.
 - D. The Product Information for the AU Brenzys Products (**Brenzys PI**) (revised most recently in 2022) identifies SBA as the sponsor of the AU Brenzys Products.
 - E. The Consumer Medicine Information for the AU Brenzys Products (**Brenzys CMI**) (revised most recently in 2022) identifies SBA as the sponsor of the AU Brenzys Products.
 - F. Further particulars may be provided following discovery or similar processes of the Court.
22. On a date unknown to the Applicants but in or before July 2016:
- i. in furtherance of the Common Design; or, alternatively,
 - ii. authorised, procured or induced by SBK, and/or members of the Samsung Group, and/or MSD, and/or members of MSD Group,

MSD AU made a submission to the Pharmaceutical Benefits Advisory Committee (**PBAC**) seeking a positive recommendation to list the AU Brenzys Products on the PBS.

Particulars

July 2016 PBAC Summary Document.

23. In July 2016, the PBAC recommended the listing of the AU Brenzys Products on the PBS.

Particulars

July 2016 PBAC Summary Document.

24. On 1 April 2017, the AU Brenzys Products were listed on the PBS in MSD AU's name.

25. From dates presently unknown to the Applicants, but from at least about 1 April 2017 to in or about June 2021:

- i. in furtherance of the Common Design; or, alternatively,
- ii. authorised, procured or induced by SBK, and/or members of the Samsung Group, and/or MSD, and/or members of the MSD Group,

MSD AU, through its servants, agents or otherwise:

- iii. engaged in acts of exploitation of the AU Brenzys Products in Australia; and
- iv. entered into an agreement with one or more of Arrow or Arrow Pharma, jointly or severally, (the **Arrow Group**) in or about August 2019 (**Arrow Agreement**), authorising, procuring or inducing the Arrow Group to promote, keep for sale, offer for sale, and sell the AU Brenzys Products in Australia.

Particulars

- A. The Applicants refer to and repeat paragraph A of the particulars to paragraph 17, above.
- B. The Brenzys PI.
- C. The Brenzys CMI.
- D. The Arrow Agreement is to be inferred from the fact that:
 - (i) in or about August 2019, by agreement with MSD AU and subsequently with Organon AU (as described in paragraphs 26 to 29 below), Arrow has offered for sale and sold the AU Brenzys Products in Australia (see Letter dated 1 May 2022 from Corrs Chambers Westgarth to DLA Piper); and
 - (ii) as at the date of this pleading, Arrow Pharma is the only entity identified on the PBS with respect to the AU Brenzys Products and has been listed as the manufacturer/supplier since on or about 1 January 2021.
- E. Further particulars may be provided following discovery or similar processes of the Court.

26. By an Agreement dated as of June 2021 (**Separation and Distribution Agreement**), to the full terms and effect of which the Applicants will refer at the trial herein, MSD separated out from its business that business conducted by Organon.

Particulars

The Separation and Distribution Agreement is published online by the U.S. Securities and Exchange Commission (**SEC**) and can be viewed at <https://www.sec.gov/Archives/edgar/data/1821825/000119312521116316/d56612dex21.htm>.

27. By an amendment identified as Amendment No. 7, dated May 15, 2020 (**Amendment No. 7**), to the full terms and effect of which the Applicants will refer at the trial herein, SBK and MSD agreed that the DCA be varied to entitle MSD to assign to its affiliate Organon and Organon's Affiliates (which included Organon AU) MSD's rights and obligations under the DCA (which included the AU Brenzys Products).

Particulars

Amendment No. 7 is published online by the SEC and can be viewed at <https://www.sec.gov/Archives/edgar/data/1821825/000119312521116316/d56612dex1011.htm>.

28. Amendment No. 7 expressly referred to and redefined the Territory for the purposes of the DCA, insofar as it related to the Brenzys Products, in terms that encompass the Patent Area.

Particulars

Section II, Article 2.23 of Amendment No. 7.

29. Organon and Organon AU thereupon joined and engaged in the acts formerly undertaken by MSD and MSD AU, as transferred and/or assigned to them, or each of them, by MSD and/or MSD AU, including MSD and/or MSD AU assigning to Organon and/or Organon AU all the rights and obligations under the Arrow Agreement, further or alternatively causing the Arrow Agreement to be novated with Organon and Organon AU:
- i. in furtherance of the Common Design; or, alternatively,
 - ii. pursuant to the authorisation, procurement or inducement described in paragraph 25,

to engage henceforth in the acts described in paragraph 25 above.

Particulars

- A. Organon and Organon AU engaged in Commercialization of the AU Brenzys Products and the use, importation and exportation of any and all compounds and products for the purposes of Commercialization of the AU Brenzys Products in the Territory, as defined in the DCA, described in the particulars to paragraph 17, above.

- B. SBK has stated by way of admission that:
- (i) it understands that MSD's rights and obligations under the DCA between SBK and MSD have been transferred to Organon and, by reason of the terms of Amendment 7 defined in paragraph 27 above, to the DCA, it is to be inferred that the rights and obligations under the DCA have also been transferred to members of the Organon group, including Organon AU; and
 - (ii) it has confidentiality arrangements in place with the Organon group, including Organon AU, encompassing, inter alia, the Prospective Respondent Confidential Material disclosed to the Applicants prior to the commencement of this proceeding, (see Letter dated 22 April 2022 from Ashurst to DLA Piper).
- C. Letter dated 1 May 2022 from Corrs Chambers Westgarth to DLA Piper.
- D. The Applicants refer to and rely on paragraphs 25 to 28 above.
- E. Further particulars may be provided following discovery or similar processes of the Court.
30. From a date unknown to the Applicants, but since on or about 1 January 2021, the listing on the PBS for the AU Brenzys Products was transferred from MSD AU to Arrow Pharma.
31. From a date or dates unknown to the Applicants, but since in or about 15 May 2020, Organon AU, through its servants, agents or otherwise:
- i. engaged in acts of exploitation of the AU Brenzys Products in Australia; and/or
 - ii. authorised, procured or induced the Arrow Group to promote, keep for sale, offer for sale and sell the AU Brenzys Products in Australia.

Particulars

- A. The Applicants refer to and repeat paragraphs 25 to 30, above including the particulars thereto.
 - B. Brenzys PI.
 - C. Brenzys CMI.
 - D. Further particulars may be provided following discovery or similar processes of the Court.
32. Each of the acts of exploitation described in paragraph 31, above, was undertaken:
- i. in furtherance of the Common Design; or, alternatively,

- ii. pursuant to the authorisation, inducement or procurement of SBK, and/or members of the Samsung Group, further or alternatively MSD and/or members of the MSD Group, or further or alternatively Organon.
33. In the premises of paragraphs 17 to 32, above, from a date or dates unknown to the Applicants, each of SBA, MSD AU and Organon AU, or one or more of them, either alone or jointly or severally:
- i. in furtherance of the Common Design; or, alternatively,
 - ii. pursuant to the authorisation, inducement or procurement of SBK and/or members of the Samsung group, further or alternatively MSD and/or members of the MSD Group, or further or alternatively Organon,
- has engaged in acts of exploitation in relation to the AU Brenzys Products in Australia by, inter alia, importing, offering for sale, and supplying, the AU Brenzys Products in Australia.
34. Pursuant to the Arrow Agreement and, further or alternatively, the Arrow Agreement as transferred to, or novated with, Organon and/or Organon AU, the Arrow Group has engaged in acts of exploitation in relation to the AU Brenzys Products in Australia by, inter alia, importing, offering for sale, and selling, the AU Brenzys Products in Australia.

Particulars

- A. The Applicants refer to and repeat the particulars to paragraph 25, above.
 - B. Further particulars may be provided following discovery or similar processes of the Court.
35. Each of the acts of exploitation described in paragraph 34, above, was undertaken:
- i. in furtherance of the Common Design; or, further or alternatively,
 - ii. pursuant to the authorisation, procurement or inducement of one or more of SBA, MSD, MSD AU, Organon or Organon AU, acting jointly or severally.

D. THE AU BRENZYS PRODUCTS

36. Each of the AU Brenzys Products contains etanercept, being a dimeric fusion protein consisting of the extracellular ligand-binding portion of the human tumor necrosis factor receptor 2 (TNFR-2) linked to the Fc portion of IgG1.

Particulars

- A. AU Brenzys Public Summaries.

- B. Australian Public Assessment Report in relation to the Brenzys Products (**Brenzys AusPAR**), dated June 2017 (Updated July 2017).
 - C. Brenzys PI.
 - D. Brenzys CMI.
37. The etanercept in each of the AU Brenzys Products is, and has been at all material times, manufactured using processes each of which fall within each of claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent in their form as granted and in the form of the Proposed Amended Claims (see paragraph 15, above, and Schedule A).

Particulars

- A. SBK says that the etanercept manufactured for the AU Brenzys Products supplied by SBK to MSD and Organon (or their respective servants or agents or related entities) has been produced for the Australian commercial market using two different cell culture processes, which are referred to as Process A and Process B (see Letter from Ashurst to DLA Piper dated 22 April 2022, citing *Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd (No 3)* [2021] FCA 1428 at [32]-[34]).
 - B. Process A and Process B each fall within each of claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent in their form as granted and in the form of the Proposed Amended Claims.
 - C. Further particulars may be provided following discovery or similar processes of the Court.
- E. PATENT INFRINGEMENT**
38. The Applicants have not authorised the Respondents, or any of them, to engage by themselves, or to authorise, induce, procure, or act in a common design for and/or with, others to engage, in any acts of exploitation in relation to the AU Brenzys Products in Australia.
39. Unless restrained by this Court, each of SBK, SBA, Organon, Organon AU, and the Arrow Group, will continue to engage, or authorise, induce, procure, or act in a common design for and/or with others to engage, in acts of exploitation in relation to the AU Brenzys Products in Australia.

Direct infringement

40. By reason of the matters aforesaid, SBA, by engaging in the conduct described in paragraph 21, 33 and 36 to 39 above, has infringed, and, unless restrained by this Court, will continue to infringe each of claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent in their form as granted and in the form of the Proposed Amended Claims.
41. By reason of the matters aforesaid in paragraphs 22, 25, 33 and 36 to 39, above, MSD AU has infringed each of claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent in their form as granted and in the form of the Proposed Amended Claims.
42. By reason of the matters aforesaid in paragraphs 29, 31, 33 and 36 to 39, above, Organon AU has infringed, and, unless restrained by this Court, will continue to infringe each of claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent in their form as granted and in the form of the Proposed Amended Claims.
43. By reason of the matters aforesaid in paragraphs 30, 34 and 36 to 39, above, the Arrow Group, has infringed, and, unless restrained by this Court, will continue to infringe each of claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent in their form as granted and in the form of the Proposed Amended Claims.

Indirect infringement

44. By reason of the matters aforesaid:
 - i. each of the First to Sixth Respondents jointly or, further or alternatively, severally has, by engaging in acts in furtherance of the Common Design, engaged in acts of exploitation in relation to the AU Brenzys Products in the Patent Area;
 - ii. each of the First to Sixth Respondents has thereby infringed as joint tortfeasors each of claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent in their form as granted and in the form of the Proposed Amended Claims.
45. By reason of the matters aforesaid in paragraphs 17, 18, 21, 22, 25, 27 to 29, and 31 to 39, above, SBK has infringed, and, unless restrained by this Court, will continue to infringe, indirectly, each of claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent in their form as granted and in the form of the Proposed Amended Claims by:
 - i. engaging in acts in furtherance of the Common Design; or, alternatively,
 - ii. authorising, inducing or procuring, whether by itself or members of the Samsung Group, one or more of the Second to Sixth Respondents to engage, or authorise, induce or procure others to engage, in acts of exploitation in relation to the AU Brenzys Products in the Patent Area.
46. By reason of the matters aforesaid in paragraphs 21, 22, 25, and 29 to 39, above, SBA has infringed, and, unless restrained by this Court, will continue to infringe, indirectly, each

of claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent in their form as granted and in the form of the Proposed Amended Claims by:

- i. engaging in acts in furtherance of the Common Design; or, alternatively,
 - ii. authorising, inducing or procuring one or more of Third to Sixth Respondents, the Arrow Group or others to engage, or authorise, induce or procure others to engage, in acts of exploitation in relation to the AU Brenzys Products in the Patent Area.
47. By reason of the matters aforesaid in paragraphs 17, 18, 21, 22, 25, and 33 to 39, above, MSD has infringed indirectly each of claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent in their form as granted and in the form of the Proposed Amended Claims by:
- i. engaging in acts in furtherance of the Common Design; or, alternatively,
 - ii. authorising, inducing or procuring MSD AU, the Arrow Group or others to engage, or authorise, induce or procure others to engage, in acts of exploitation in relation to the AU Brenzys Products in the Patent Area.
48. By reason of the matters aforesaid in paragraphs 25, 30, and 33 to 39, MSD AU has infringed indirectly each of claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent in their form as granted and in the form of the Proposed Amended Claims by:
- i. engaging in acts in furtherance of the Common Design; or, alternatively,
 - ii. authorising, inducing or procuring the Arrow Group or others to engage, or authorise, induce or procure others to engage, in acts of exploitation in relation to the AU Brenzys Products in the Patent Area.
49. By reason of the matters aforesaid in paragraphs 26 to 29, and 31 to 39, above, Organon has infringed, and, unless restrained by this Court, will continue to infringe, indirectly, each of claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent in their form as granted and in the form of the Proposed Amended Claims by:
- i. engaging in acts in furtherance of the Common Design; or, alternatively,
 - ii. authorising, inducing or procuring Organon AU, the Arrow Group or others to engage, or authorise, induce or procure others to engage, in acts of exploitation in relation to the AU Brenzys Products in the Patent Area.
50. By reason of the matters aforesaid in paragraphs 29, and 31 to 39, Organon AU has infringed and, unless restrained by this Court, will continue to infringe, indirectly, each of claims 1, 2, 7, 33, 37, 38, and 42 of the 034 Patent in their form as granted and in the form of the Proposed Amended Claims by:
- i. engaging in acts in furtherance of the Common Design; or, alternatively,
 - ii. authorising, inducing or procuring the Arrow Group or others to engage, or authorise, induce or procure others to engage, in acts of exploitation in relation to the AU Brenzys Products in the Patent Area.

F. RELIEF

51. Each of SBK, SBA, Organon, Organon AU and the Arrow Group will, unless restrained, continue to engage in the conduct pleaded above.
52. The Applicants have suffered, and will continue to suffer, substantial loss and damage by reason of the Respondents' conduct pleaded above.

Particulars

- A. The Applicants claim loss and damage in respect of the sale of the AU Brenzys Products.
 - B. Further loss and damage may be particularised.
53. By reason of the Respondents' conduct pleaded above, each of the Respondents has earned, and will continue to earn, substantial profits.
 54. The Applicants seek the relief specified in the accompanying originating application.

Applicants' address

The Applicants' address for service is:

Place: DLA Piper Australia, No. 1 Martin Place, Sydney NSW 2000

Email: Nicholas.Tyacke@dlapiper.com

Date: 6 May 2022



Nicholas Tyacke
DLA Piper Australia
Solicitors for the Applicants

This pleading was prepared by DLA Piper Australia and settled by David Shavin QC and Cynthia Cochrane SC.

Certificate of lawyer

I, **NICHOLAS TYACKE** of DLA Piper Australia, certify to the Court that, in relation to the statement of claim filed on behalf of the Applicants, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 6 May 2022



Nicholas Tyacke
DLA Piper Australia
Solicitors for the Applicants