NOTICE OF FILING AND HEARING

This document was lodged electronically in the FEDERAL COURT OF AUSTRALIA (FCA) on 29/07/2022 2:21:59 PM 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 - Form 15 - Rule 8.01(1)
File Number:	VID422/2022
File Title:	SAMSUNG BIOEPIS AU PTY LTD v FRESENIUS KABI DEUTSCHLAND GMBH
Registry:	VICTORIA REGISTRY - FEDERAL COURT OF AUSTRALIA
Reason for Listing:	To Be Advised
Time and date for hearing:	To Be Advised
Place:	To Be Advised

Dated**:** 29/07/2022 4:07:21 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.

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 15
Rules 8.01; 8.04(1)

Originating application

of 2022

Federal Court of Australia
District Registry: Victoria
Division: General

Samsung Bioepis AU Pty Ltd ACN 611 890 094
Applicant

Fresenius Kabi Deutschland GmbH
Respondent

To the Respondent

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: Commonwealth Law Courts, 305 William Street, Melbourne

Date:

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

Filed on behalf of Samsung Bioepis AU Pty Ltd, the Applicant
Prepared by Matthew Swinn
Law firm **KING & WOOD MALLESONS**
Tel +61 3 9643 4389 Fax +61 3 9643 5999
Email matthew.swinn@au.kwm.com
Address for service: Level 27, Collins Arch, 447 Collins Street, Melbourne VIC 3000
Ref: MGS:6030042240

Details of claim

On the grounds stated in the accompanying statement of claim, the Applicant claims:

1 A declaration that each of claims 1 to 21 (inclusive) of Australian patent number 2020204269 titled *Liquid pharmaceutical composition* (**269 Patent**) is invalid.

2 An order that the 269 Patent be revoked.

3 Costs.

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

Applicant's address

The Applicant's address for service is:

Lawyer:	Matthew Swinn King & Wood Mallesons
Place:	Level 27, Collins Arch 447 Collins Street MELBOURNE VIC 3000
Email:	matthew.swinn@au.kwm.com (Ref: MGS:6030042240)

The Applicant's address is Level 16, 201 Elizabeth Street, SYDNEY NSW 2000.

Service on the Respondent

It is intended to serve this application on the Respondent.

Date: 29 July 2022

.....
Matthew Swinn
Lawyer for the Applicant
King & Wood Mallesons

NOTICE OF FILING

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Details of Filing

Document Lodged:	Statement of Claim - Form 17 - Rule 8.06(1)(a)
File Number:	VID422/2022
File Title:	SAMSUNG BIOEPIS AU PTY LTD v FRESENIUS KABI DEUTSCHLAND GMBH
Registry:	VICTORIA REGISTRY - FEDERAL COURT OF AUSTRALIA

Dated: 29/07/2022 4:07:24 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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Form 17
Rules 8.05(1)(a)

Statement of claim

of 2022

Federal Court of Australia
District Registry: Victoria
Division: General

Samsung Bioepis AU Pty Ltd ACN 611 890 094
Applicant

Fresenius Kabi Deutschland GmbH
Respondent

A. Parties

1 The Applicant is duly incorporated in the Commonwealth of Australia under the *Corporations Act 2001* (Cth) and able to sue in its corporate name.

2 The Respondent is a company incorporated under the laws of the Federal Republic of Germany and is able to be sued in its corporate name.

B. Respondent's patent

3 The Respondent is the registered owner of Australian patent number 2020204269 entitled *Liquid pharmaceutical composition* (**269 Patent**).

4 Each of claims 1 to 21 (inclusive) of the 269 Patent (**Disputed Claims**) is invalid and liable to be revoked on the grounds set out in the following paragraphs.

C. Priority date

5 The Disputed Claims of the 269 Patent are not entitled to a priority date earlier than 26 June 2020, being the filing date of the 269 Patent.

Filed on behalf of Samsung Bioepis AU Pty Ltd, the Applicant
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Address for service: Level 27, Collins Arch, 447 Collins Street, Melbourne VIC 3000
Ref: MGS:6030042240

Particulars

(a) The Disputed Claims are not for an invention disclosed in the specification filed in relation to Australian Patent Application no. 2015263247, as required under section 79B(1) of the Act, and are not entitled to priority calculated in accordance with section 43(2)(a) of the Act and regulation 3.13D of the *Patents Regulations 1991* (Cth).

D. Lack of novelty

6 The alleged invention so far as claimed in each of the Disputed Claims is not a patentable invention within the meaning of section 18(1)(b)(i) of the *Patents Act 1990* (Cth) (the **Act**) in that the alleged invention was not novel when compared with the prior art base as it existed before the priority date of each such claim.

Particulars

(a) In respect of each of claims 1 to 19 (inclusive) of the 269 Patent, the Applicant relies on information made publicly available before the priority date of the claims of the 269 Patent in the following documents:

(i) Priority Application no. 1606/MUM/2012 (**Cadila**), published on 7 November 2013

(ii) International Patent publication no. WO 2014/039903 (**Manning**), published on 13 March 2014.

(b) In respect of each of claims 1 to 21 (inclusive) of the 269 Patent, the Applicant relies on information made publicly available before the priority date of the claims of the 269 Patent in the following documents:

(i) Australian Patent Application no. 2015263247, published on 1 December 2016 (**247 Patent**).

E. Lack of inventive step

7 The alleged invention so far as claimed in each of the Disputed Claims is not a patentable invention within the meaning of section 18(1)(b)(ii) of the Act in that, the invention so far as claimed in each of the said claims, does not involve an inventive step when compared with the prior art base as it existed before the priority date of each such claim.

Particulars

(a) The alleged invention so far as claimed in each of the said claims would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed before the priority date of each claim.

(b) The common general knowledge of a person skilled in the art included, without limitation, the following information:

(i) Maintaining the stability of therapeutic proteins was a key objective of formulation development.

(ii) The formulation of HUMIRA (adalimumab) and its indications.

(iii) Antibodies were susceptible to different degradation pathways at different pH values.

(iv) One or more buffers were commonly included as part of an antibody formulation to maintain the formulation at or near the desired pH to preserve antibody stability.

(v) Histidine and citrate were buffers commonly used in the manner described in (iv).

(vi) One or more sugars were commonly included as part of an antibody formulation to enhance the stability of a formulation, including but not limited to thermal stability.

(vii) Trehalose and sorbitol were sugars commonly used in the manner described in (vi).

(viii) Surfactants were commonly included as part of an antibody formulation to reduce the surface tension between different liquids and solutes within a formulation.

(ix) Polysorbate 20 and Polysorbate 80 were commonly used in the manner described in (viii) and were generally considered to be interchangeable with limited overall impact on formulations.

(x) Tonicifiers were commonly included as part of an antibody formulation to adjust the osmolality and osmolarity of the formulation to make it isotonic with physiologic fluids.

(xi) Sugars were commonly used in the manner described in (x).

(xii) Amino acids were commonly used as stabilisers, but could also have a destabilising effect.

(xiii) It was desirable for a formulation to include as few constituents as feasible to provide the desired stability.

(c) The Applicant additionally relies on the common general knowledge referred to in paragraph 7(b) considered separately or together with the information made publicly available in each of the following documents (insofar as they were not part of the common general knowledge), each of which constituted prior art information:

(i) the FDA approved Prescribing Information for Humira (the **Humira Prescribing Information**), which was made available to the public before the priority date, including on the FDA website from December 2002 when Humira was granted a marketing authorisation in the US

(ii) the FDA approved Prescribing Information for Simponi (the **Simponi Prescribing Information**), which was made available to the public before the priority date, including on the FDA website from April 2009 when SIMPONI (golimumab) was granted a marketing authorisation in the US

(iii) Bender A., *Alternative buffers for pharmaceutical anti-TNFα monoclonal antibody formulations* (**Bender**) published on 6 February 2013 on priorartregister.com

(iv) Cadila

(v) Manning

(vi) International Patent publication no. WO 2010/129469 (**Fraunhofer**), published on 11 November 2010

(vii) the 247 Patent.

(d) In the alternative to paragraph 7(c), the Applicant relies on the common general knowledge referred to in paragraph 7(b) considered separately or together with the information made publicly available in two or more of the following documents (insofar as they were not part of the common general knowledge), each of which constituted prior art information that the skilled person could, before the priority date of the relevant claim, be reasonably expected to have combined:

(i) the Humira Prescribing Information

(ii) the Simponi Prescribing Information

(iii) Bender

(iv) Cadila

(v) Manning

(vi) Fraunhofer

(vii) the 247 Patent.

F. Lack of utility

8 The alleged invention so far as claimed in each of the Disputed Claims of the 269 Patent is not a patentable invention in that it is not useful as required by subsection 18(1)(c) of the Act.

Particulars

(a) The 269 Patent includes the promise that the claimed invention provides "alternative and improved liquid pharmaceutical compositions, which generally exhibit comparable or better stability and viability than those of the prior art… achieved using less complex formulations with fewer excipients" (the **Promise**).

(b) Insofar as each of the claims of the 269 Patent encompass compositions that:

(i) may contain additional components not specifically identified in the claims; or

(ii) contain or permit a further buffer system; or

(iii) in the case of claims 12, 16 to 18 (inclusive) and their dependent claims, require the presence of histidine buffer,

the claimed composition does not achieve the Promise.

(c) Insofar as the claims encompass compositions with a pH of 5.0, 5.1, 5.2 and 5.3, the specification discloses no credible use within the meaning of section 7A of the Act in that the specification does not disclose, and a person skilled in the relevant art would not appreciate, that such compositions would be adequately stable.

G. Failure to disclose best method

9 The specification of the 269 Patent does not comply with section 40(2)(aa) of the Act as it does not disclose the best method of performing the invention that was known to the patentee at the filing date.

Particulars

(a) Each of the Disputed Claims either encompass or require sorbitol as a component of the aqueous pharmaceutical composition of the claimed invention,

whereas the specification does not disclose any method of performing the invention in which sorbitol is a component of the said composition.

(b) Each of the Disputed Claims either encompass or require Polysorbate 20 as a component of the claimed aqueous pharmaceutical composition of the claimed invention, whereas the specification does not disclose any method of performing the invention in which Polysorbate 20 is a component of the said composition.

(c) At least claims 4 and 5 and their dependent claims either encompass or require the sugar stabiliser as a tonicifier component of the aqueous pharmaceutical composition of the claimed invention, whereas the specification does not disclose any method of performing the invention in which the sugar stabiliser is a tonicifier component of the said composition.

H. Lack of clarity

10 Claims 1 and 11 and their dependent claims and claim 21 of the 269 Patent do not comply with subsection 40(3) of the Act in that they are not clear.

Particulars

(a) The meaning of the phrase 'free of' in claims 1, 11 and 21 is not clear in that the person skilled in the relevant art is unable to determine whether each of these references is directed to a formulation that is 'substantially free' or 'entirely free' of the relevant substance.

(b) The meaning of the phrase "free of amino acids selected from the group consisting of arginine, lysine, and aspartic acid" in claims 1 and 21 is unclear. It is not clear whether the claimed composition is free of all three amino acids, or free of one or more of the listed amino acids.

I. Claims not supported

11 The Disputed Claims do not comply with section 40(3) of the Act in that they are not supported by matter disclosed in the specification.

Particulars

(a) Insofar as the Disputed Claims require sorbitol as the sugar stabiliser in the claimed composition, the claims are not supported by matter disclosed in the specification. The claimed technical contribution to the art does not provide adequate support for a claim comprising sorbitol as a sugar stabiliser or any other component of the composition.

(b) Insofar as the Disputed Claims require a sugar stabiliser as the tonicifier in the claimed composition, the claims are not supported by matter disclosed in the

specification. The claimed technical contribution to the art does not provide adequate support for a claim comprising a sugar stabiliser as a tonicifier component of the composition.

(c) Insofar as the Disputed Claims require a surfactant in the claimed composition, the claims are not supported by matter disclosed in the specification. The claimed technical contribution to the art does not provide adequate support for a claim comprising a surfactant as a component of the composition.

(d) Insofar as the Disputed Claims require Polysorbate 20 in the claimed composition, the claims are not supported by matter disclosed in the specification. The claimed technical contribution to the art does not provide adequate support for a claim comprising Polysorbate 20 as a component of the composition.

(e) Insofar as the Disputed Claims require the claimed composition to have a pH between 5.0 and 6.0 or between 5.0 and 5.4, the claims are not supported by matter disclosed in the specification. The claimed technical contribution to the art does not provide adequate support for a claim to compositions with a pH less than 5.4 or greater than 5.8.

(f) Insofar as the claims permit the inclusion of arginine in the composition, the claims are not supported by matter disclosed in the specification. The claimed technical contribution to the art does not provide adequate support for a claim to compositions comprising arginine as a component of the invention.

(g) Insofar as the Disputed Claims permit the inclusion of histidine or other amino acids in the composition, the claims are not supported by matter disclosed in the specification. The claimed technical contribution to the art does not provide adequate support for a claim to compositions comprising histidine or other amino acids as a component of the invention.

(h) The specification does not support a composition comprising at most one sugar stabiliser as claimed or encompassed in claims 1 and 21 and their dependent claims. The claimed technical contribution to the art does not provide adequate support for limiting the number of sugar stabilisers in the composition in this way.

(i) The specification does not support a composition comprising a histidine buffer or further buffer system in addition to a citrate buffering agent or citrate buffer system as claimed or encompassed in claims 11 to 18 (inclusive) and their dependent claims. The claimed technical contribution to the art does not provide

adequate support for a claim comprising a citrate buffering agent or citrate buffer system with a further buffering agent as a component of the composition.

Date: 29 July 2022

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Matthew Swinn
Lawyer for the Applicant
King & Wood Mallesons

This pleading was prepared by Matthew Swinn, lawyer.

Certificate of lawyer

I, Matthew Swinn, certify to the Court that, in relation to the statement of claim filed on behalf of the Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 29 July 2022

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Matthew Swinn
Lawyer for the Applicant
King & Wood Mallesons