NOTICE OF FILING AND HEARING

This document was lodged electronically in the FEDERAL COURT OF AUSTRALIA (FCA) on 17/07/2019 12:09:27 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:	VID774/2019
File Title:	SAMSUNG BIOEPIS AU PTY LIMITED 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**:** 23/07/2019 10:35:44 AM AEST Registrar

Important Information

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

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

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

Form 15
Rules 8.01; 8.04(1)

Originating application

of 2019

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**
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Address for service	Level 50, Bourke Place, 600 Bourke Street, Melbourne VIC 3000
Ref:	MS/DLP: 603-0042240

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 15 (inclusive) of Australian patent number no. 2015263246 entitled *Liquid pharmaceutical composition* (**246 Patent**) is invalid.

2 An order that the 246 Patent be revoked, either wholly or so far as it relates to each and any of the claims referred to in that paragraph.

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 50, Bourke Place
600 Bourke Street
MELBOURNE VIC 3000

Email: matthew.swinn@au.kwm.com
(Ref: MS/DLP: 603-0042240)

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.

It is also intended to serve this application on the Commissioner of Patents.

Date: 17 July 2019

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Matthew Swinn
Lawyer for the Applicant
King & Wood Mallesons

Form 17
Rules 8.05(1)(a)

Statement of claim

of 2019

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 2015263246 entitled *Liquid pharmaceutical composition* (**246 Patent**).

4 Each of claims 1 to 15 (inclusive) of the 246 Patent is invalid and liable to be revoked on the grounds set out in the following sub-paragraphs.

C. Lack of Novelty

4.1 The alleged invention so far as claimed in each of claims 1 to 15 (inclusive) of the 246 Patent 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.

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 50, Bourke Place, 600 Bourke Street, Melbourne VIC 3000
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Particulars

(a) The Applicant relies on information made publicly available before the priority date of the claims of the 246 Patent in the following documents:

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

(ii) International Patent publication no. WO 2014/039903 A2 (**Manning**), published on 13 March 2014.

D. Lack of inventive step

4.2 The alleged invention so far as claimed in each of claims 1 to 15 (inclusive) of the 246 Patent 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 such 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).

(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) Mannitol, 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.

(c) The Applicant additionally relies on the common general knowledge referred to in paragraph 4.2(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; and

(v) Manning.

Date: 17 July 2019

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Matthew Swinn
Lawyer for the Applicants
King & Wood Mallesons

This pleading was prepared by Matthew Swinn of King & Wood Mallesons.