

NOTICE OF FILING

Details of Filing

Document Lodged:	Particulars (including Further and Better Particulars)
Court of Filing	FEDERAL COURT OF AUSTRALIA (FCA)
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File Number:	NSD65/2024
File Title:	SAMSUNG BIOEPIS AU PTY LTD v JANSSEN BIOTECH, INC.
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.



Particulars of Invalidity

No. NSD of 2024

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

Samsung Bioepis AU Pty Ltd

Applicant

Janssen Biotech, Inc.

Respondent

I. GENERAL

A. Introduction

1. The following are the Applicant's Particulars of Invalidity in respect of the 041 Patent and the 042 Patent.

B. Definitions

2. In these Particulars of Invalidity:
 - (a) **041 Patent** means Australian Innovation Patent No. 2023100041.
 - (b) **042 Patent** means Australian Innovation Patent No. 2023100042.
 - (c) **Patents Act** means the *Patents Act 1990* (Cth) (as it applies to the 041 Patent and the 042 Patent, being the Patents Act after the commencement of the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth) in respect of, and in force at, the filing dates of the 041 Patent and the 042 Patent).

Filed on behalf of (name & role of party) Samsung Bioepis AU Pty Ltd (Applicant)
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II. THE 041 PATENT

A. Lack of novelty

3. The alleged invention as claimed in each of the claims of the 041 Patent is not a patentable invention within the meaning of section 18(1A)(b)(i) of the Patents Act in that it was not novel when compared with the prior art base as it existed before 24 September 2018.

Particulars

- (a) The Applicant relies on the information made publicly available in each of the following documents:
- (i) clinical trial record of the clinical trial titled "*A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Participants With Moderately to Severely Active Ulcerative Colitis (UNIFI)*" and identifiable by ClinicalTrials.gov identifier NCT02407236 published on the ClinicalTrials.gov website on 13 August 2018 (**CTR 236**);
 - (ii) Ochsenkühn et al (2018) "*P759 Ustekinumab as rescue treatment in therapy-refractory or -intolerant ulcerative colitis*" 12(S1) Journal of Crohn's and Colitis S495 published on 16 January 2018 (**Abstract P759**);
 - (iii) Poster titled "*Tu1713: Clinical outcomes with ustekinumab as rescue treatment in therapy-refractory or -intolerant ulcerative colitis: real world experience in a large single center cohort*" presented at the American Gastroenterological Association's annual conference, Digestive Disease Week, on 5 June 2018 (the **DDW Poster**); and
 - (iv) Ochsenkühn et al (2018) "*Tu1713 Clinical outcomes with ustekinumab as recue [sic] treatment in therapy-refractory or -intolerant ulcerative colitis: real worl [sic] experience in a large single center cohort*" 154(6;S1) *Gastroenterology* S-997 published in May 2018 (**Abstract Tu1713**).
- (b) Further or in the alternative, the Applicant relies on information made publicly available in each of the following combinations of prior art documents, the relationship between them in each case being such that the person skilled in the art would treat them as a single source of information:
- (i) CTR 236 and the Product Information for Stelara® (ustekinumab) dated 27 February 2017 (the **Stelara 2017 PI**);
 - (ii) Abstract P759 and the Stelara 2017 PI;

- (iii) the DDW Poster and the Stelara 2017 PI; and
 - (iv) Abstract Tu1713 and the Stelara 2017 PI.
- (c) Further particulars may be provided.

B. Lack of innovative step

4. Further or in the alternative to paragraph 3 above, the alleged invention as claimed in each of the claims of the 041 Patent is not a patentable invention within the meaning of section 18(1A)(b)(ii) of the Patents Act in that it did not involve an innovative step when compared with the prior art base as it existed before 24 September 2018.

Particulars

- (a) The alleged invention as claimed in each of the claims would, to a person skilled in the relevant art, in the light of the common general knowledge as it existed (whether in or out of the patent area) before 24 September 2018 only vary from the information set out in each of the following pieces of prior art information (each considered separately) in ways that make no substantial contribution to the working of the alleged invention:
- (i) CTR 236;
 - (ii) Abstract P759;
 - (iii) the DDW Poster; and
 - (iv) Abstract Tu1713.
- (b) Further or in the alternative, the Applicant relies on information made publicly available in each of the following combinations of prior art documents, the relationship between them in each case being such that the person skilled in the art would treat them as a single source of information:
- (i) CTR 236 and the Stelara 2017 PI;
 - (ii) Abstract P759 and the Stelara 2017 PI;
 - (iii) the DDW Poster and the Stelara 2017 PI; and
 - (iv) Abstract Tu1713 and the Stelara 2017 PI.
- (c) Further particulars may be provided.

III. THE 042 PATENT

A. Lack of novelty

5. The alleged invention as claimed in each of the claims of the 042 Patent is not a patentable invention within the meaning of section 18(1A)(b)(i) of the Patents Act in that it was not novel when compared with the prior art base as it existed before 24 September 2018.

Particulars

- (a) The Applicant repeats particulars (a) and (b) to paragraph 3 above.
(b) Further particulars may be provided.

B. Lack of innovative step

6. Further or in the alternative to paragraph 5 above, the alleged invention as claimed in each of the claims of the 042 Patent is not a patentable invention within the meaning of section 18(1A)(b)(ii) of the Patents Act in that it did not involve an innovative step when compared with the prior art base as it existed before 24 September 2018.

Particulars

- (a) The Applicant repeats particulars (a) and (b) to paragraph 4 above.
(b) Further particulars may be provided.

Date: 23 January 2024



Signed by Ben Miller
Lawyer for the Applicant