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Important Information

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Applicants' position statement on infringement

No. VID 715 of 2025

Federal Court of Australia

District Registry: Victoria

Division: General

Regeneron Pharmaceuticals, Inc. and others

Applicants

Sandoz Pty Ltd (ACN 075 449 553)

Respondent

1. The Applicants' position statement on the infringement of each of claims 1, 3, 4, 5 and 12 of Australian Patent No. 2012205599 (**the 599 Patent**) with respect to the Sandoz Aflibercept Products (as those terms are defined in the Applicants' Statement of Claim) are outlined in the table below.

2. The Applicants say that the Sandoz Aflibercept Products are relevantly identical in respect of the integers outlined in Table 1.

3. The Applicants refer to extracts of the Australian Product Information sheets for the AFQLIR product (**AFQLIR Product Information**) and ENZEEVU product (**ENZEEVU Product Information**), which are annexed to the Applicants' Statement of Claim.

4. The Applicants say that the AFQLIR Product Information and ENZEEVU Product Information are relevantly identical in respect of the integers outlined in Table 1.

Filed on behalf of (name & role of party)	The Applicants	
Prepared by (name of person/lawyer)	Aaron Yates, Lawyer; Grant Fisher, Lawyer	
Law firm (if applicable)	Davies Collison Cave Law Pty Ltd; Corrs Chambers Westgarth	
Tel	(03) 9254 2888 (03) 9672 3000	Fax
Email	AYates@dcc.com; IPascarl@dcc.com; Grant.Fisher@corrs.com.au; David.Fixler@corrs.com.au; Kate.Donald@corrs.com.au	
Address for service (include state and postcode)	Davies Collison Cave Law Level 15, 1 Nicholson Street Melbourne, VIC, 3000	Corrs Chambers Westgarth 567 Collins Street Melbourne, VIC, 3000

TABLE 1

Integer	Feature	Sandoz Aflibercept Products
Claim 1		
1.1	A method of treating an angiogenic eye disorder in a patient, comprising:	Neovascular (wet) age related macular degeneration (**wet AMD**) and diabetic macular oedema (**DME**) are each an angiogenic eye disorder. Each of AFQLIR and ENZEEVU are indicated for the treatment of wet AMD and DME in a patient (see section 4.1 and section 4.2 under the headings *Treatment of neovascular (wet) age-related macular degeneration (wet AMD)* and *Treatment of diabetic macular oedema (DME)* of each of the AFLIQR Product Information and ENZEEVU Product Information).
1.2	sequentially administering to the patient a single initial dose of a VEGF antagonist, followed by one or more secondary doses of the VEGF antagonist, followed by one of more tertiary doses of the VEGF antagonist;	As to "a VEGF antagonist", see integer 1.5 et seq below. Each of the AFQLIR Product Information and ENZEEVU Product Information provides the following dosage regimen for the treatment of wet AMD (see section 4.2 under the heading *Treatment of neovascular (wet) age-related macular degeneration (wet AMD)*): [AFQLIR / ENZEEVU] *2 mg treatment is initiated with one* [AFQLIR / ENZEEVU] *2 mg injection per month for three consecutive months, followed by one injection every two months.* This dosage regimen for treatment of wet AMD provides for 3 doses administered at monthly intervals, that is, a single initial dose in the first month followed by a secondary dose per month for the subsequent two months, followed by one or more tertiary doses at two monthly intervals. Each of the AFQLIR Product Information and ENZEEVU Product Information provides the following dosage regimen for the treatment of DME (see section 4.2 under the heading *Treatment of diabetic macular oedema (DME)*): [AFQLIR / ENZEEVU] *2mg treatment is initiated with one* [AFQLIR / ENZEEVU] *2mg injection per month for five consecutive months.* *Following the initiation period and based on the ophthalmologist's judgment of visual and/or anatomic outcomes, the treatment interval may then be maintained at an injection every two months or further individualised…* This dosage regimen for treatment of DME provides for 5 doses administered at monthly intervals, that is, a single initial dose in the first month, followed by a

Integer	Feature	Sandoz Aflibercept Products
		secondary dose per month for the subsequent four months, which can be followed by one or more tertiary doses at two monthly intervals.
1.3	wherein each secondary dose is administered 2 to 4 weeks after the immediately preceding dose; and	The Applicants refer to and repeat the analysis in relation to integer 1.2 above. For the treatment of wet AMD, each of the AFQLIR Product Information and ENZEEVU Product Information instructs that a secondary dose is to be administered one month after the initial dose, and the next secondary dose is to be administered one month after the first secondary dose. That is, each secondary dose is to be administered 4 weeks after the immediately preceding dose. For the treatment of DME, each of the AFQLIR Product Information and ENZEEVU Product Information instructs the first secondary dose is to be administered one month after the initial dose, and each of the next 3 secondary doses are to be administered one month after the previous secondary dose. That is, each secondary dose is instructed to be administered 4 weeks after the immediately preceding dose.
1.4	wherein each tertiary dose is administered 8 weeks after the immediately preceding dose	The Applicants refer to and repeat the analysis in relation to integer 1.2 above. For the treatment of wet AMD, each of the AFQLIR Product Information and ENZEEVU Product Information instructs that following the second secondary dose, tertiary doses are to be administered every two months. That is, each of the AFQLIR Product Information and ENZEEVU Product Information instructs that each tertiary dose is to be administered 8 weeks after the immediately preceding dose. For the treatment of DME, each of the AFQLIR Product Information and ENZEEVU Product Information instructs that following the fourth secondary dose, tertiary doses can be administered every two months. That is, each of the AFQLIR Product Information and ENZEEVU Product Information instructs that each tertiary dose is to be administered 8 weeks after the immediately preceding dose.
1.5	wherein the VEGF antagonist is a VEGF receptor-based chimeric molecule comprising:	Integers 1.5, 1.5.1, 1.5.2, 1.5.3 collectively provide for a VEGF antagonist according to the amino acid sequence of aflibercept. The Sandoz Aflibercept Products have the amino acid sequence of aflibercept, as set out in Figure 7 on page 42 of
1.5.1	(1) a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2;	

Integer	Feature	Sandoz Aflibercept Products
1.5.2	(2) a VEGFR2 component comprising amino acids 130-231 of SEQ ID NO:2; and	AFQLIR Product Information and Figure 7 on page 42 of ENZEEVU Product Information. Aflibercept is a VEGF-receptor-based chimeric molecule (see Figure 6 on page 41 AFQLIR Product Information and Figure 6 on page 42 ENZEEVU Product Information).
1.5.3	(3) a multimerization component comprising amino acids 232-457 of SEQ ID NO:2.	
Claim 3 (wet AMD only)		
3.1	The method of claim 1,	The Applicants refer to and repeat the analysis in relation to claim 1 above.
3.2	wherein only two secondary doses are administered to the patient,	The Applicants refer to and repeat the analysis in relation to integer 1.2 above in relation to the dosage regimen for the treatment of wet AMD.
3.3	and wherein each secondary dose is administered 4 weeks after the immediately preceding dose.	The Applicants refer to and repeat the analysis in relation to integer 1.3 above in relation to the dosage regimen for the treatment of wet AMD.
Claim 4		
4.1	The method of claim 1,	The Applicants refer to and repeat the analysis in relation to claim 1 above.
4.2	wherein the angiogenic eye disorder is selected from the group consisting of: age related macular degeneration, diabetic retinopathy, diabetic macular edema, central retinal vein occlusion and corneal neovascularization.	The Applicants refer to and repeat the analysis in relation to integer 1.1 above.
Claim 5 (wet AMD only)		
5.1	The method of claim 4,	The Applicants refer to and repeat the analysis in relation to claim 4 above.
5.2	wherein the angiogenic eye disorder is age related macular degeneration.	The Applicants refer to and repeat the analysis in relation to integer 1.1 above in relation to wet AMD.
Claim 7		
7.1	The method of claim 1,	The Applicants refer to and repeat the analysis in relation to claim 1 above.
7.2	wherein all doses of the VEGF antagonist are administered to the patient by topical administration or by intraocular administration.	Each of the AFQLIR Product Information and ENZEEVU Product Information provide that AFQLIR and ENZEEVU are to be administered by intravitreal injection (see section 4.2, first sentence under the heading *DOSE AND METHOD OF ADMINISTRATION* and the paragraphs under the heading *Method of Administration* of the AFLIQR Product Information and ENZEEVU Product Information).

Integer	Feature	Sandoz Aflibercept Products
		Intravitreal injection is a type of intraocular administration.
Claim 8		
8.1	The method of claim 7,	The Applicants refer to and repeat the analysis in relation to claim 7 above.
8.2	wherein all doses of the VEGF antagonist are administered to the patient by intraocular administration.	The Applicants refer to and repeat the analysis in relation to integer 7.2 above.
Claim 9		
9.1	The method of claim 8,	The Applicants refer to and repeat the analysis in relation to claim 8 above.
9.2	wherein the intraocular administration is intravitreal administration.	The Applicants refer to and repeat the analysis in relation to integer 7.2 above.
Claim 10		
10.1	The method of claim 9,	The Applicants refer to and repeat the analysis in relation to claim 9 above.
10.2	wherein all doses of the VEGF antagonist comprise from about 0.5 mg to about 2 mg of the VEGF antagonist.	The Applicants refer to and repeat the analysis in relation to integer 1.5 above. The VEGF antagonist is aflibercept. The AFQLIR Product Information and ENZEEVU Product Information provide that the recommended dose for AFQLIR and ENZEEVU is 2 mg of aflibercept (see section 4.2 first sentence under the heading *Dosage).*
Claim 12		
12.1	The method of claim 10,	The Applicants refer to and repeat the analysis in relation to claim 10 above.
12.2	wherein all doses of the VEGF antagonist comprise 2 mg of the VEGF antagonist.	The Applicants refer to and repeat the analysis in relation to integer 10.2 above.

CORRS CHAMBERS WESTGARTH

Lawyers for the First Applicant

DAVIES COLLISON CAVE LAW

Lawyers for the Second and Third Applicants

Date: 5 June 2025