NOTICE OF FILING

Details of Filing

Document Lodged:	Non-Prescribed Notice/Request
Court of Filing	FEDERAL COURT OF AUSTRALIA (FCA)
Date of Lodgment:	26/06/2025 2:41:13 PM AEST
Date Accepted for Filing:	26/06/2025 2:41:19 PM AEST
File Number:	VID715/2025
File Title:	REGENERON PHARMACEUTICALS, INC. & ORS v SANDOZ PTY LTD (ACN 075 449 553)
Registry:	VICTORIA REGISTRY - FEDERAL COURT OF AUSTRALIA

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.

Respondent's response to 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 Respondent's response to the **Applicants' position statement on infringement** dated 5 June 2025 regarding each of claims 1, 3, 4, 5 and 12 of the **599 Patent** with respect to the **Sandoz Aflibercept Products** (as those terms are defined in the Applicants' Amended Statement of Claim) are outlined in Table 1 below, in the column titled "*Respondent's response to Applicants' position*".

2. The text in the column titled "*Applicants' position as to Sandoz Aflibercept Products*" in Table 1 below is copied from Table 1 of the Applicants' position statement on infringement.

3. The Respondent refers 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' Amended Statement of Claim.

4. The Respondent accepts that the two Sandoz Aflibercept Products and the Product

Filed on behalf of (name & role of party) Sandoz Pty Ltd, the Respondent
Prepared by (name of person/lawyer) Robert Cooper
Law firm (if applicable) MinterEllison
Tel +61 3 8608 2625 Fax +61 3 8608 1000
Email robert.cooper@minterellison.com
Address for service (include state and postcode) Level 20, Collins Arch, 447 Collins Street MELBOURNE VIC 3000

Information for each of them are relevantly the same for the purposes of this proceeding and are referred to below, collectively, as the **Sandoz Product Information**.

5. On the basis that the Applicants' position statement on infringement is silent on allegations of accessorial liability, this responsive position statement on infringement is limited to the Respondent's position as to infringement as alleged by the Applicants under section 117 of the *Patents Act 1990* (Cth) and is without prejudice to its position with respect to any allegations of accessorial liability including authorisation or joint tortfeasorship.

6. With respect to each reference to s 117(2)(c) in Table 1 below, the Respondent denies that s 117(2)(c) applies additionally because the Sandoz Product Information is not "given" by the Respondent to any person to whom the Sandoz Aflibercept Products will be, or are, supplied, and who will use them, unless requested by that person (such requests being rarely, if ever, made), and so cannot constitute an instruction or inducement within the meaning of section 117(2)(c) of the Act (see paragraph [31] of the Respondent's Defence). Any admissions in Table 1 below are subject to this qualification.

7. The Respondent reserves the right to supplement or amend this responsive position statement on infringement, including after the preparation of its evidence.

26 June 2025

Solicitors for the Respondent

TABLE 1

Integer	Feature	Applicants' position as to Sandoz Aflibercept Products	Respondent's response to Applicants' position
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. Section 117(2)(b) – This feature is present in the sense that: (a) Sandoz has reason to believe each Sandoz Aflibercept Product will be used to treat wet AMD and DME among other conditions which the Applicants do not assert will infringe the 599 Patent, including visual impairment due to macular oedema secondary to central retinal vein occlusion (**CRVO**), visual impairment due to macular oedema secondary to branch retinal vein occlusion (**BRVO**), and visual impairment due to myopic choroidal neovascularization (**myopic CNV**). 2. Section 117(2)(c) – This feature is present in the sense that: (a) The Sandoz Product Information contains instructions to use each Sandoz Aflibercept Product to treat wet AMD and DME among other conditions which the Applicants do not assert will infringe the 599 Patent, namely CRVO, BRVO and myopic CNV.
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	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*	3. Section 117(2)(b) – This feature is present in the sense that: (a) Sandoz has reason to believe that each Sandoz Aflibercept Product will be administered for the treatment of wet AMD and DME in a temporal sequence of administration of three or more doses. 4. Section 117(2)(c) - This feature is present in the sense that: (a) The Sandoz Product Information contains instructions to

Integer	Feature	Applicants' position as to Sandoz Aflibercept Products	Respondent's response to Applicants' position
	one of more tertiary doses of the VEGF antagonist;	*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	administer each Sandoz Aflibercept Product for the treatment of wet AMD and DME in a temporal sequence of administration of three or more doses.

Integer	Feature	Applicants' position as to Sandoz Aflibercept Products	Respondent's response to Applicants' position
		month, followed by a 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.	5. Section 117(2)(b) - Feature is present in the sense that: (a) Sandoz has reason to believe that, for the treatment of wet AMD and DME, some patients will be administered each Sandoz Aflibercept Product 4 weeks after the immediately preceding dose. 6. Section 117(2)(c) - Feature is **not** present in the sense that: (a) The Sandoz Product Information states that for each Sandoz Aflibercept Product administration is to be initiated with: (i) for the treatment of wet AMD: "*one* [AFQLIR / ENZEEVU] *2 mg injection per **month** for three consecutive **months**"* (emphasis added); and (ii) for the treatment of DME "*one [AFQLIR / ENZEEVU] 2mg injection per **month** for five consecutive **months***" (emphasis added). (b) The above concerns administration of each Sandoz Aflibercept Product one **month** after the immediately preceding dose, not [**2 to**] **4 weeks** after the immediately preceding dose as required by this feature.
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	7. Section 117(2)(b) - Feature is **not** present in the sense that: (a) Sandoz does not have reason to believe that each tertiary dose will be administered 8 weeks after the immediately preceding dose, because:

Integer	Feature	Applicants' position as to Sandoz Aflibercept Products	Respondent's response to Applicants' position
		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.	(i) the treat-and-extend regimen involves doses being administered at intervals other than 8 weeks; and (ii) patient and health care professional availability, preferences and logistics inevitably result in doses being administered at intervals other than 8 weeks even where there is an intention to administer at 8 weekly intervals (e.g., at 7.5 weeks, 8.5 weeks, 8 weeks and 2 days, 7 weeks and 5 days etc). 8. Section 117(2)(c) - Feature is **not** present in the sense that: (a) The Sandoz Product Information states for each Sandoz Aflibercept Product that: (i) For all treatments (including wet AMD and DME), at 4.2 under "*Dosage*": "*Once optimal visual acuity is achieved and/or there are no signs of disease activity, treatment may then be continued with a treat-and-extend regimen with gradually increased treatment intervals to maintain stable visual and/or anatomic outcomes. If disease activity persists or recurs, the treatment interval may be shortened accordingly. Monitoring should be done at injection visits. The monitoring and treatment schedule should be determined by the treating ophthalmologist based on the individual patient's response. If visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment, AFQLIR should be discontinued."* (ii) For the treatment of wet AMD (emphasis added): "[AFQLIR / ENZEEVU] *2 mg treatment is initiated with one* [AFQLIR / ENZEEVU] *2 mg injection per month for three consecutive months, followed by one*

Integer	Feature	Applicants' position as to Sandoz Aflibercept Products	Respondent's response to Applicants' position
			injection every two months. *Based on the physician's judgement of visual and/or anatomic outcomes, the treatment interval* ***may be maintained at two months or further extended using a treat-and-extend dosing regimen****, by increasing injection intervals in 2- or 4-weekly increments while maintaining stable visual and/or anatomic outcomes. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened to a minimum of four weeks based on anatomical and/or visual outcomes. Generally, once optimal visual acuity is achieved and/or there are no signs of disease activity, the treatment interval may be adjusted based on visual and/or anatomic outcomes."* (iii) For the treatment of 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 individualized such as with a treat-and-extend dosing regimen, by increasing injection intervals in 2- or 4-weekly increments while maintaining stable visual and/or anatomic outcomes. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly. Treatment intervals shorter than 4 weeks or longer than 4 months have not been studied (see Section 5.1 Pharmacodynamic properties, Clinical trials).* (b) In the premises, the Sandoz Product Information states that each Sandoz Aflibercept Product can be administered **2 months** after the immediately preceding dose, not **8 weeks**

Integer	Feature	Applicants' position as to Sandoz Aflibercept Products	Respondent's response to Applicants' position
			after the immediately preceding dose. (c) Further, in the context of the overarching statement extracted at [(a)(i)] above, when read in the context of the statements extracted at [(a)(ii)] or [(a)(iii)] above, there is no instruction to administer **each** (and every) dose of each Sandoz Aflibercept Product at 8 weeks. Instead, once optimal visual acuity is achieved and/or there are no signs of disease activity treatment, if treatment is to be continued, it is to be with a treat-and-extend regime.
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 AFQLIR Product Information and Figure 7 on page 42 of ENZEEVU Product Information.	9. This feature is present in the sense that it is inherent that aflibercept has the feature and each of the Sandoz Aflibercept Products contains aflibercept.
1.5.1	(1) a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2;		
1.5.2	(2) a VEGFR2 component comprising amino acids 130-231 of SEQ ID NO:2; and	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).	10. This feature is present in the sense that it is inherent that aflibercept has the feature and each of the Sandoz Aflibercept Products contains aflibercept.
1.5.3	(3) a multimerization component comprising amino acids 232-457 of SEQ ID NO:2.		

Integer	Feature	Applicants' position as to Sandoz Aflibercept Products	Respondent's response to Applicants' position
Claim 3			
3.1	The method of claim 1,	The Applicants refer to and repeat the analysis in relation to claim 1 above.	11. Feature not present for the reasons identified above for claim 1.
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.	12. Section 117(2)(b) - Feature is present in the sense that: (a) Sandoz has reason to believe that some patients will receive only two secondary doses. 13. Section 117(2)(c) - Feature is present with respect to wet AMD only in the sense that: (a) The Sandoz Product Information instructs that only two secondary doses be administered.
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.	14. The Respondent repeats paragraphs [5] and [6], above.
Claim 4			
4.1	The method of claim 1,	The Applicants refer to and repeat the analysis in relation to claim 1 above.	15. Feature not present for the reasons identified above for claim 1.

Integer	Feature	Applicants' position as to Sandoz Aflibercept Products	Respondent's response to Applicants' position
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.	16. Section 117(2)(b) – This feature is present in the sense that: (a) Sandoz has reason to believe each Sandoz Aflibercept Product will be used to treat wet AMD and DME. 17. Section 117(2)(c) – This feature is present in the sense that: (a) The Sandoz Product Information contains instructions to use each Sandoz Aflibercept Product to treat wet AMD and DME.
Claim 5			
5.1	The method of claim 4,	The Applicants refer to and repeat the analysis in relation to claim 4 above.	18. Feature not present for the reasons identified above for claim 1.
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.	19. Section 117(2)(b) – This feature is present in the sense that: (a) Sandoz has reason to believe each Sandoz Aflibercept Product will be used to treat wet AMD. 20. Section 117(2)(c) – This feature is present in the sense that: (a) The Sandoz Product Information contains instructions to use each Sandoz Aflibercept Product to treat 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.	21. Claim not asserted.

Integer	Feature	Applicants' position as to Sandoz Aflibercept Products	Respondent's response to Applicants' position
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. Intravitreal injection is a type of intraocular administration.	22. Section 117(2)(b) – This feature is present in the sense that: (a) Sandoz has reason to believe each Sandoz Aflibercept Product will be used with intravitreal administration to treat wet AMD and DME with doses of 2mg of aflibercept. 23. Section 117(2)(c) – This feature is present in the sense that: (a) The Sandoz Product Information contains instructions to use each Sandoz Aflibercept Product with intravitreal administration to treat wet AMD and DME with doses of 2mg of aflibercept.
Claim 8			
8.1	The method of claim 7,	The Applicants refer to and repeat the analysis in relation to claim 7 above.	24. Claim not asserted.
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.	25. See [22] and [23], above.
Claim 9			
9.1	The method of claim 8,	The Applicants refer to and repeat the analysis in relation to claim 8 above.	26. Claim not asserted.

Integer	Feature	Applicants' position as to Sandoz Aflibercept Products	Respondent's response to Applicants' position
9.2	wherein the intraocular administration is intravitreal administration.	The Applicants refer to and repeat the analysis in relation to integer 7.2 above.	27. See [22] and [23], above.
Claim 10			
10.1	The method of claim 9,	The Applicants refer to and repeat the analysis in relation to claim 9 above.	28. Claim not asserted.
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).*	29. See [22] and [23], above.
Claim 12			
12.1	The method of claim 10,	The Applicants refer to and repeat the analysis in relation to claim 10 above.	30. Feature not present for the reasons identified above for claim 1.
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.	31. See [22] and [23], above.