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File Title:	REGENERON PHARMACEUTICALS, INC. & ORS v SANDOZ PTY LTD (ACN 075 449 553)
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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 position statement on validity

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

Sandoz Pty Ltd (ACN 075 449 553)
Cross-claimant

Regeneron Pharmaceuticals, Inc and another
Cross-respondents

1. Unless otherwise stated, the terms used in this position statement on validity are as defined in the Cross-claimant's Statement of Cross-claim.

2. Each of the Asserted AU'599 Claims (i.e., claims 1, 3, 4, 5 and 12) is alleged to be invalid based on:

   (a) Lack of novelty (see paragraph [5] of the Statement of Cross-claim).

   (b) Lack of inventive step (see paragraph [6] of the Statement of Cross-claim).

   (c) Failure to comply with section 40(2)(a) of the *Patents Act* (disclosure) (see paragraph [7] of the Statement of Cross-claim).

   (d) Failure to comply with section 40(3) of the *Patents Act* (support) (see paragraph [8] of the Statement of Cross-claim).

Filed on behalf of (name & role of party) Sandoz Pty Ltd, the Cross-Claimant and Respondent
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3. The grounds and particulars which will be raised by the Cross-claimant for the purpose of the Applicants' application for interlocutory injunctive relief are as follows:

   (a) Lack of novelty, limited to the Earliest Asserted Priority Date and Dixon, the 2009 Press Release and Adis.

   (b) Lack of inventive step, limited to: (i) the Earliest Asserted Priority Date; (ii) the common general knowledge when considered together with each of Dixon, the 2009 Press Release and Adis; and (iii) any features of the Asserted Claims, which the Applicants/Cross-Respondents assert are not disclosed in each of those documents.

   (c) Failure to comply with section 40(3) of the *Patents Act* (support) but limited to the question of disclosure/technical contribution, not enablement.

4. With respect to the integers of the Asserted Claims disclosed in:

   (a) Adis, see **Table 1**, below, from page [3].

   (b) the December 2010 Press Release, see **Table 2**, below, from page [11].

   (c) the November 2010 Press Release, see **Table 3**, below, from page [18].

   (d) the 2009 Press Release, see **Table 4**, below, from page [25].

   (e) Dixon, see **Table 5**, below, from page [31].

5. The Cross-claimant reserves the right to supplement or amend this position statement on validity, including after the preparation of its evidence and in light of the manner in which the Applicants seek to prosecute their infringement case, including by way of construing the Asserted AU'599 Claims.

26 June 2025

Solicitors for the Respondent

TABLE 1 - ADIS

Integer	Feature	Cross-claimant's position on disclosure of feature in Adis	Cross-respondents' response to Cross-claimant's position
Claim 1			
1.1	A method of treating an angiogenic eye disorder in a patient, comprising:	1. Present; see page 263 of Adis: *A second phase III trial (VIEW 2) in wet AMD began with the first patient dosed in May 2008. The VIEW 2 trial will enrol approximately 1200 patients from the EU, Asia Pacific, Japan and Latin America. This study will evaluate the safety and efficacy of aflibercept at 0.5 mg and 2.0 mg administered at 4-week intervals and 2.0 mg at an 8-week dosing interval, including one additional 2.0 mg dose at week 4. Patients randomized to the ranibizumab arm of the trial will receive a 0.5 mg dose every 4 weeks. The primary endpoint will be the proportion of patients treated with aflibercept who maintain vision at the end of 1 year compared with ranibizumab patients.* (a) The quote above discloses a method of treatment of wet AMD, which is an angiogenic eye disorder, in patients, where the treatment seeks to bring about maintenance of vision at the end of one year of treatment as compared to a ranibizumab treatment for the same condition.	

Integer	Feature	Cross-claimant's position on disclosure of feature in Adis	Cross-respondents' response to Cross-claimant's position
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;	2. Present; refer to the quote at [1], above: (a) "*aflibercept*" referred to in the quote is a VEGF antagonist. (b) The treatments included "*2.0 mg at an 8-week dosing interval, including one additional 2.0 mg dose at week 4*". That is, 2.0 mg doses of aflibercept were administered at week 0, week 4, week 8, then every 8 weeks after that. (i) The dose at week 0 is a "*single initial dose*" within the meaning of this feature. (ii) The doses at week 4 and week 8 are "*one or more secondary doses*" within the meaning of this feature. (iii) The doses from week 16 are "*one or more tertiary doses*" within the meaning of this feature.	
1.3	wherein each secondary dose is administered 2 to 4 weeks after the immediately preceding dose; and	3. Present; refer to the quote at [1], above: (a) Each of the secondary doses identified in [2(b)(ii)] above is administered 4 weeks after the immediately preceding dose.	
1.4	wherein each tertiary dose is administered 8 weeks after the immediately preceding dose	4. Present; refer to the quote at [1], above: (a) Each of the tertiary doses identified in [2(b)(iii)] above is administered 8 weeks after the immediately preceding dose.	

Integer	Feature	Cross-claimant's position on disclosure of feature in Adis	Cross-respondents' response to Cross-claimant's position
1.5	wherein the VEGF antagonist is a VEGF receptor-based chimeric molecule comprising:	5. Present; refer to the quote at [1], above: (a) "*aflibercept*" referred to in the quote is inherently a VEGF receptor-based chimeric molecule. 6. See also the abstract on page 261 of Adis, first paragraph: *Aflibercept is a fully human recombinant fusion protein composed of the second Ig domain of VEGFR1 and the third Ig domain of VEGFR2, fused to the Fc region of human IgG1*	
1.5.1	(1) a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2;	7. Present; refer to the quote at [1], above: (a) "*aflibercept*" referred to in the quote inherently has a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2. 8. See also the abstract at [6], above: (a) The "*second domain of VEGFR1*" referred to in the abstract inherently comprises 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	9. Present; refer to the quote at [1], above: (a) "*aflibercept*" referred to in the quote inherently has a VEGFR2 component comprising amino acids 130-231 of SEQ ID NO:2. 10. See also the abstract at [6], above: (a) The "*third Ig domain of VEGFR2*" referred to in the abstract inherently comprises amino acids 130-231 of SEQ IS NO:2.	

Integer	Feature	Cross-claimant's position on disclosure of feature in Adis	Cross-respondents' response to Cross-claimant's position
1.5.3	(3) a multimerization component comprising amino acids 232-457 of SEQ ID NO:2.	11. Present; refer to the quote at [1], above: (a) "*aflibercept*" referred to in the quote inherently has a multimerization component comprising amino acids 232-457 of SEQ ID NO:2. 12. See also the abstract at [6], above: (a) the "*Fc region of human IgG1*" referred to in the abstract is a multimerization component comprising amino acids 232-457 of SEQ ID NO:2.	
Claim 3			
3.1	The method of claim 1,	13. Present; refer to [1] to [12], above.	
3.2	wherein only two secondary doses are administered to the patient,	14. Present; refer to [2(b)(ii)] above.	
3.3	and wherein each secondary dose is administered 4 weeks after the immediately preceding dose.	15. Present; refer to [3(a)] above.	
Claim 4			
4.1	The method of claim 1,	16. Present; refer to [1] to [12], above.	

Integer	Feature	Cross-claimant's position on disclosure of feature in Adis	Cross-respondents' response to Cross-claimant's 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.	17. Present; refer to [1(a)], above: (a) Wet AMD is a form of "*age related macular degeneration*" within the meaning of this feature.	
Claim 5			
5.1	The method of claim 4,	18. Present; refer to [16] and [17], above.	
5.2	wherein the angiogenic eye disorder is age related macular degeneration.	19. Present; refer to [17], above.	
Claim 7			
7.1	The method of claim 1,	20. Present; refer to [1] to [12], above.	

Integer	Feature	Cross-claimant's position on disclosure of feature in Adis	Cross-respondents' response to Cross-claimant's position
7.2	wherein all doses of the VEGF antagonist are administered to the patient by topical administration or by intraocular administration.	21. Present; refer to the quote at [1], above and the statement at page 264 of Adis: "*Additionally, Regeneron chose to pursue intravitreal injection as a route of administration, instead of systemic delivery*" supported by an endnote to a media release from 2005 (prior to the commencement of the trial referred to in the quote at [1], above) and the disclosure in Adis that the trial referred to in the quote at [1], above was run by Bayer and Regeneron as disclosed by the last line of the table on page 266 of Adis and the endnotes to the paragraph quoted at [1] above, namely endnotes 12 and 13. 22. Further or alternatively inferred from the matters in [21] above in conjunction with the paragraph before and after the quote at [1] where: (i) the preceding paragraph on page 263 of Adis describes the VIEW 1 wet AMD trial as involving intravitreal administration. (ii) the following paragraph on page 263 of Adis describes a phase II trial evaluating intravitreal aflibercept for wet AMD. 23. Intravitreal injection is a form of intraocular administration.	
Claim 8			
8.1	The method of claim 7,	24. Present; refer to [20] to [23], above.	

Integer	Feature	Cross-claimant's position on disclosure of feature in Adis	Cross-respondents' response to Cross-claimant's position
8.2	wherein all doses of the VEGF antagonist are administered to the patient by intraocular administration.	25. Present; refer to [21] and/or [22] and [23], above.	
Claim 9			
9.1	The method of claim 8,	26. Present; refer to [24] and [25], above.	
9.2	wherein the intraocular administration is intravitreal administration.	27. Present; refer to [21] and/or [22] and [23], above.	
Claim 10			
10.1	The method of claim 9,	28. Present; refer to [26] and [27], above.	
10.2	wherein all doses of the VEGF antagonist comprise from about 0.5 mg to about 2 mg of the VEGF antagonist.	29. Present; refer to [2(b)], above.	
Claim 12			
12.1	The method of claim 10,	30. Present; refer to [28] and [29], above.	

Integer	Feature	Cross-claimant’s position on disclosure of feature in Adis	Cross-respondents' response to Cross-claimant’s position
12.2	wherein all doses of the VEGF antagonist comprise 2 mg of the VEGF antagonist.	31. Present; refer to [2(b)], above.	

TABLE 2 – THE DECEMBER 2010 PRESS RELEASE

Integer	Feature	Cross-claimant's position on disclosure of feature in the December 2010 Press Release	Cross-respondents' response to Cross-claimant's position
Claim 1			
1.1	A method of treating an angiogenic eye disorder in a patient, comprising:	32. Present; see pages 1-2 of the December 2010 Press Release: *Regeneron and Bayer HealthCare also reported 52 week follow-up results from the Phase 2 DA VINCI study in patients with diabetic macular edema (DME). In this study, the previously reported visual acuity gains achieved with VEGF Trap-Eye treatment over 24 weeks … were maintained or numerically improved up to completion of the study at week 52 in all VEGF Trap-Eye study groups, including 2 mg dosed every other month … Two groups received three initial monthly doses of 2.0mg of VEGF Trap-Eye (at baseline and weeks 4 and 8), followed through week 52 by either every two months dosing or PRN (as needed) dosing with very strict repeat dosing criteria* [following which a table of "*Mean gains in visual acuity versus baseline*" shows efficacy, following which there is a positive discussion as to safety] (a) The quote above discloses a method of treatment of "*diabetic macular edema (DME)*", which is an angiogenic eye disorder, in patients.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the December 2010 Press Release	Cross-respondents' response to Cross-claimant's position
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;	33. Present; refer to the quote at [32], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept (see first main paragraph "*results for VEGF Trap-Eye (aflibercept ophthalmic solution)*", which is a VEGF antagonist. (b) The treatments included "*2.0mg of VEGF Trap-Eye (at baseline and weeks 4 and 8), followed through week 52 by … every two months dosing*". That is, 2.0 mg doses of aflibercept were administered at week 0, week 4, week 8, then every two months after that up to week 52. (i) The dose at week 0 is a "*single initial dose*" within the meaning of this feature. (ii) The doses at week 4 and week 8 are "*one or more secondary doses*" within the meaning of this feature. (iii) The doses "*every two months*" up to week 52 are "*one or more tertiary doses*" within the meaning of this feature.	
1.3	wherein each secondary dose is administered 2 to 4 weeks after the immediately preceding dose; and	34. Present; refer to the quote at [32], above: (a) Each of the secondary doses identified in [33(b)(ii)] above is administered 4 weeks after the immediately preceding dose.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the December 2010 Press Release	Cross-respondents' response to Cross-claimant's position
1.4	wherein each tertiary dose is administered 8 weeks after the immediately preceding dose	35. Present; refer to the quote at [32], above: (a) Each of the tertiary doses identified in [33(b)(iii)] above is administered two months after the immediately preceding dose up to week 52. (b) By saying "*up to week 52*" and by equating "*initial monthly doses"* with doses "*at baseline and weeks 4 and 8"* administration "*every two months*" is equated to every 8 weeks. (c) Further or in the alternative to [(b)] above, the skilled addressee would understand administration "*every two months*" to require administration every 8 weeks.	
1.5	wherein the VEGF antagonist is a VEGF receptor-based chimeric molecule comprising:	36. Present; refer to the quote at [32], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and is inherently a VEGF receptor-based chimeric molecule.	
1.5.1	(1) a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2;	37. Present; refer to the quote at [32], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and inherently has 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	38. Present; refer to the quote at [32], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and inherently has a VEGFR2 component comprising amino acids 130-231 of SEQ ID NO:2.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the December 2010 Press Release	Cross-respondents' response to Cross-claimant's position
1.5.3	(3) a multimerization component comprising amino acids 232-457 of SEQ ID NO:2.	39. Present; refer to the quote at [32], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and inherently has a multimerization component comprising amino acids 232-457 of SEQ ID NO:2.	
Claim 3			
3.1	The method of claim 1,	40. Present; refer to [32] to [39], above.	
3.2	wherein only two secondary doses are administered to the patient,	41. Present; refer to [33(b)(ii)] above.	
3.3	and wherein each secondary dose is administered 4 weeks after the immediately preceding dose.	42. Present; refer to [34(a)] above.	
Claim 4			
4.1	The method of claim 1,	43. Present; refer to [32] to [39], above.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the December 2010 Press Release	Cross-respondents' response to Cross-claimant's 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.	4. Present; refer to [32(a)], above.	
Claim 5			
5.1	The method of claim 4,	45. Present; refer to [43] and [44], above.	
5.2	wherein the angiogenic eye disorder is age related macular degeneration.	46. Not present.	
Claim 7			
7.1	The method of claim 1,	47. Present; refer to [32] to [39], above.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the December 2010 Press Release	Cross-respondents' response to Cross-claimant's position
7.2	wherein all doses of the VEGF antagonist are administered to the patient by topical administration or by intraocular administration.	48. Present; refer to the quote at [32], above and in the discussion about the treatment disclosed in that quote regarding safety (following the table of results on page 2 of the December 2010 Press Release): "*The most common adverse events reported were those typically associated with intravitreal injections or the underlying disease*". 49. Intravitreal injection is a form of intraocular administration.	
Claim 8			
8.1	The method of claim 7,	50. Present; refer to [47] to [49], above.	
8.2	wherein all doses of the VEGF antagonist are administered to the patient by intraocular administration.	51. Present; refer to [48] and [49], above.	
Claim 9			
9.1	The method of claim 8,	52. Present; refer to [50] and [51], above.	
9.2	wherein the intraocular administration is intravitreal administration.	53. Present; refer to [48] and [49], above.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the December 2010 Press Release	Cross-respondents' response to Cross-claimant's position
Claim 10			
10.1	The method of claim 9,	54. Present; refer to [52] and [53], above.	
10.2	wherein all doses of the VEGF antagonist comprise from about 0.5 mg to about 2 mg of the VEGF antagonist.	55. Present; refer to [33(b)], above.	
Claim 12			
12.1	The method of claim 10,	56. Present; refer to [54] and [55], above.	
12.2	wherein all doses of the VEGF antagonist comprise 2 mg of the VEGF antagonist.	57. Present; refer to [33(b)], above.	

TABLE 3 – THE NOVEMBER 2010 PRESS RELEASE

Integer	Feature	Cross-claimant's position on disclosure of feature in the November 2010 Press Release	Cross-respondents' response to Cross-claimant's position
Claim 1			
1.1	A method of treating an angiogenic eye disorder in a patient, comprising:	58. Present; see page 2 of the November 2010 Press Release: *The VIEW (VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD) program consists of two randomized, double masked, Phase 3 clinical trials evaluating VEGF Trap-Eye in the treatment of then neovascular form of age-related macular degeneration (wet AMD). ... The primary endpoint evaluation was conducted at 52 weeks. ... In each of the studies, VEGF Trap-Eye was evaluated for its effect on maintaining and improving vision when dosed as an intravitreal injection on a schedule of ... 2mg every two months (following three monthly loading doses), as compared with intravitreal ranibizumab ... during the first year of the studies.* [following which positive efficacy results are set out]. (a) The quote above discloses a method of treatment of "*wet AMD*", which is an angiogenic eye disorder, in patients.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the November 2010 Press Release	Cross-respondents' response to Cross-claimant's position
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;	59. Present; refer to the quote at [58], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept (see first main paragraph "*all regimens of VEGF Trap-Eye (aflibercept ophthalmic solution)*", which is a VEGF antagonist. (b) The treatments included "*2mg every two months (following three monthly loading doses)*". That is, 2.0 mg doses of aflibercept were administered at month 0, month 1, and month 2, then every two months after that up to week 52. (i) The dose at month 0 is a "*single initial dose*" within the meaning of this feature. (ii) The doses at month 1 and month 2 are "*one or more secondary doses*" within the meaning of this feature. (iii) The doses "*every two months*" up to week 52 are "*one or more tertiary doses*" within the meaning of this feature.	
1.3	wherein each secondary dose is administered 2 to 4 weeks after the immediately preceding dose; and	60. Present; refer to the quote at [58], above: (a) Each of the secondary doses identified in [59(b)(ii)] above is administered 1 month after the immediately preceding dose. (b) The skilled addressee would understand "*monthly loading doses*" to require administration every 4 weeks.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the November 2010 Press Release	Cross-respondents' response to Cross-claimant's position
1.4	wherein each tertiary dose is administered 8 weeks after the immediately preceding dose	61. Present; refer to the quote at [58], above: (a) Each of the tertiary doses identified in [59(b)(iii)] above is administered two months after the immediately preceding dose over 52 weeks (including the initial dose and secondary doses). (b) By saying "*over 52 weeks*", administration "*every two months*" is equated to every 8 weeks. (c) Further or in the alternative to [(b)] above, the skilled addressee would understand "*every two months*" to require administration every 8 weeks.	
1.5	wherein the VEGF antagonist is a VEGF receptor-based chimeric molecule comprising:	62. Present; refer to the quote at [58], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and is inherently a VEGF receptor-based chimeric molecule.	
1.5.1	(1) a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2;	63. Present; refer to the quote at [58], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and inherently has 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	64. Present; refer to the quote at [58], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and inherently has a VEGFR2 component comprising amino acids 130-231 of SEQ ID NO:2.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the November 2010 Press Release	Cross-respondents' response to Cross-claimant's position
1.5.3	(3) a multimerization component comprising amino acids 232-457 of SEQ ID NO:2.	65. Present; refer to the quote at [58], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and inherently has a multimerization component comprising amino acids 232-457 of SEQ ID NO:2.	
Claim 3			
3.1	The method of claim 1,	66. Present; refer to [58] to [65], above.	
3.2	wherein only two secondary doses are administered to the patient,	67. Present; refer to [59(b)(ii)] above.	
3.3	and wherein each secondary dose is administered 4 weeks after the immediately preceding dose.	68. Present; refer to [60(a)] above.	
Claim 4			
4.1	The method of claim 1,	69. Present; refer to [58] to [65], above.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the November 2010 Press Release	Cross-respondents' response to Cross-claimant's 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.	70. Present; refer to [58(a)], above.	
Claim 5			
5.1	The method of claim 4,	71. Present; refer to [69] and [70], above.	
5.2	wherein the angiogenic eye disorder is age related macular degeneration.	72. Present; "*wet AMD*", as disclosed in the quote at [58] above, is a form of age related macular degeneration.	
Claim 7			
7.1	The method of claim 1,	73. Present; refer to [58] to [65], above.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the November 2010 Press Release	Cross-respondents' response to Cross-claimant's position
7.2	wherein all doses of the VEGF antagonist are administered to the patient by topical administration or by intraocular administration.	74. Present; refer to the quote at [58], above in particular "*when dosed as an intravitreal injection".* 75. Intravitreal injection is a form of intraocular administration.	
Claim 8			
8.1	The method of claim 7,	76. Present; refer to [73] to [75], above.	
8.2	wherein all doses of the VEGF antagonist are administered to the patient by intraocular administration.	77. Present; refer to [74] and [75], above.	
Claim 9			
9.1	The method of claim 8,	78. Present; refer to [76] and [77], above.	
9.2	wherein the intraocular administration is intravitreal administration.	79. Present; refer to [74] and [75], above.	
Claim 10			
10.1	The method of claim 9,	80. Present; refer to [78] and [79], above.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the November 2010 Press Release	Cross-respondents' response to Cross-claimant's position
10.2	wherein all doses of the VEGF antagonist comprise from about 0.5 mg to about 2 mg of the VEGF antagonist.	81. Present; refer to [59(b)], above.	
Claim 12			
12.1	The method of claim 10,	82. Present; refer to [80] and [81], above.	
12.2	wherein all doses of the VEGF antagonist comprise 2 mg of the VEGF antagonist.	83. Present; refer to [59(b)], above.	

TABLE 4 – THE 2009 PRESS RELEASE

Integer	Feature	Cross-claimant's position on disclosure of feature in the 2009 Press Release	Cross-respondents' response to Cross-claimant's position
Claim 1			
1.1	A method of treating an angiogenic eye disorder in a patient, comprising:	84. Present; see page 1 of the 2009 Press Release: *Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced the completion of patient enrollment in two randomized, double-masked, Phase 3 clinical trials evaluating VEGF Trap-Eye in the treatment of the neovascular form of age-related macular degeneration (wet AMD). In each study of the VIEW (VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD) program, VEGF Trap-Eye is being evaluated for its effect on maintaining and improving vision when dosed as an intravitreal injection on a schedule of ... 2.0 mg every eight weeks (following three monthly doses), as compared with intravitreal ranibizumab ... during the first year of the studies. ...* *The primary endpoint of these non-inferiority studies is the proportion of patients treated with VEGF Trap-Eye who maintain vision at the end of one year, compared to ranibizumab patients.* (a) The quote above discloses a method of treatment of "*wet AMD*", which is an angiogenic eye disorder, in patients.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the 2009 Press Release	Cross-respondents' response to Cross-claimant's position
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;	85. Present; refer to the quote at [84], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept, which is a VEGF antagonist. (b) The treatments included "*2.0 mg every eight weeks (following three monthly doses)*". The 2009 Press Release later explains that dosing schedule to be "*2.0 mg at an eight-week dosing interval following one additional 2.0 mg dose at week four*". That is, 2.0 mg doses of aflibercept were administered at week 0, week 4, week 8, then every 8 weeks after that during the first year. (i) The dose at week 0 is a "*single initial dose*" within the meaning of this feature. (ii) The doses at week 4 and week 8 are "*one or more secondary doses*" within the meaning of this feature. (iii) The doses "*every 8 weeks*" up to the end of a year are "*one or more tertiary doses*" within the meaning of this feature.	
1.3	wherein each secondary dose is administered 2 to 4 weeks after the immediately preceding dose; and	86. Present; refer to the quotes at [84] and [85(b)], above: (a) Each of the secondary doses identified in [85(b)(ii)] above is administered 4 weeks after the immediately preceding dose.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the 2009 Press Release	Cross-respondents' response to Cross-claimant's position
1.4	wherein each tertiary dose is administered 8 weeks after the immediately preceding dose	87. Present; refer to the quote at [84], above: (a) Each of the tertiary doses identified in [85(b)(iii)] above is administered 8 weeks after the immediately preceding dose up to the end of a year.	
1.5	wherein the VEGF antagonist is a VEGF receptor-based chimeric molecule comprising:	88. Present; refer to the quote at [84], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and is inherently a VEGF receptor-based chimeric molecule.	
1.5.1	(1) a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2;	89. Present; refer to the quote at [84], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and inherently has 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	90. Present; refer to the quote at [84], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and inherently has a VEGFR2 component comprising amino acids 130-231 of SEQ ID NO:2.	
1.5.3	(3) a multimerization component comprising amino acids 232-457 of SEQ ID NO:2.	91. Present; refer to the quote at [84], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and inherently has a multimerization component comprising amino acids 232-457 of SEQ ID NO:2.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the 2009 Press Release	Cross-respondents' response to Cross-claimant's position
Claim 3			
3.1	The method of claim 1,	92. Present; refer to [84] to [91], above.	
3.2	wherein only two secondary doses are administered to the patient,	93. Present; refer to [85(b)(ii)] above.	
3.3	and wherein each secondary dose is administered 4 weeks after the immediately preceding dose.	94. Present; refer to [86(a)] above.	
Claim 4			
4.1	The method of claim 1,	95. Present; refer to [84] to [91], 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.	96. Present; refer to [84(a)], above.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the 2009 Press Release	Cross-respondents' response to Cross-claimant's position
Claim 5			
5.1	The method of claim 4,	97. Present; refer to [95] and [96], above.	
5.2	wherein the angiogenic eye disorder is age related macular degeneration.	98. Present; "*wet AMD*", as disclosed in the quote at [84] above, is a form of age related macular degeneration.	
Claim 7			
7.1	The method of claim 1,	99. Present; refer to [84] to [91], above.	
7.2	wherein all doses of the VEGF antagonist are administered to the patient by topical administration or by intraocular administration.	100. Present; refer to the quote at [84], above in particular "*when dosed as an intravitreal injection".* 101. Intravitreal injection is a form of intraocular administration.	
Claim 8			
8.1	The method of claim 7,	102. Present; refer to [99] to [101], above.	
8.2	wherein all doses of the VEGF antagonist are administered to the patient by intraocular administration.	103. Present; refer to [100] and [101], above.	

Integer	Feature	Cross-claimant's position on disclosure of feature in the 2009 Press Release	Cross-respondents' response to Cross-claimant's position
Claim 9			
9.1	The method of claim 8,	104. Present; refer to [102] and [103], above.	
9.2	wherein the intraocular administration is intravitreal administration.	105. Present; refer to [100] and [101], above.	
Claim 10			
10.1	The method of claim 9,	106. Present; refer to [104] and [105], above.	
10.2	wherein all doses of the VEGF antagonist comprise from about 0.5 mg to about 2 mg of the VEGF antagonist.	107. Present; refer to [85(b)], above.	
Claim 12			
12.1	The method of claim 10,	108. Present; refer to [106] and [107], above.	
12.2	wherein all doses of the VEGF antagonist comprise 2 mg of the VEGF antagonist.	109. Present; refer to [85(b)], above.	

TABLE 5 – DIXON

Integer	Feature	Cross-claimant's position on disclosure of feature in Dixon	Cross-respondents' response to Cross-claimant's position
Claim 1			
1.1	A method of treating an angiogenic eye disorder in a patient, comprising:	110. Present; see page 1576 of Dixon: *A two part Phase III trial of VEGF Trap-Eye was initiated in August of 2007. The first part, VIEW 1 (VEGF Trap: Investigation of Efficacy and safety in Wet age-related macular degeneration) [46] will enroll ~ 1200 patients with neovascular AMD in the US and Canada. This non-inferiority study will evaluate the safety and efficacy of intravitreal VEGF Trap-Eye at doses of 0.5 and 2.0 mg administered at 4-week dosing intervals and 2.0 mg at an 8 week dosing interval (following three monthly doses), compared with 0.5 mg of ranibizumab administered every 4 weeks. After the first year of the study, patients will enter a second year of p.r.n. dosing evaluation. The VIEW 2 [47] study has a similar study design and is currently enrolling patients in Europe, Asia Pacific, Japan and Latin America. In both trials, the primary out- come will be the proportion of patients who maintain vision at week 52 (defined as a loss of < 15 ETDRS letters).* (a) The quote above discloses a method of treatment of "*Wet age-related macular degeneration*" (wet AMD), which is an angiogenic eye disorder, in patients, where the treatment seeks to bring about maintenance of vision at the end of one year (52 weeks) of treatment and not be inferior to a ranibizumab treatment for the same condition.	

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;	111. Present; refer to the quote at [110], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept (see section 2.3 on page 1575 "*VEGF Trap-Eye and aflibercept ... have the same molecular structure"*), which is a VEGF antagonist. (b) The treatments included "*2.0 mg at an 8 week dosing interval (following three monthly doses)*". Given the other arms were administered at 4-week dosing intervals throughout, and this arm includes 8 week dosing, it would be inferred that the initial three monthly doses would be administered every 4 weeks. That is, 2.0 mg doses of aflibercept were administered at week 0, week 4, week 8, then every 8 weeks after that up to week 52. (i) The dose at week 0 is a "*single initial dose*" within the meaning of this feature. (ii) The doses at week 4 and week 8 are "*one or more secondary doses*" within the meaning of this feature. (iii) The doses from week 16 to week 52 are "*one or more tertiary doses*" within the meaning of this feature. 112. Furthermore, in the United States District Court for the Northern District of West Virginia proceeding Civil No. 1:22-CV-61 before Justice Kleeh (the **Kleeh Proceeding**), the Cross-respondent (who was the plaintiff in that proceeding) admitted or otherwise did not dispute that Dixon discloses the regimen in claim 6 of the Cross-respondent's US Patent No. 11,253,572 (the **US'572 Patent**), which regimen required, *inter alia* "*sequentially administering to the patient by intravitreal injection a single initial dose of 2 mg of aflibercept, followed by one or more*	

Integer	Feature	Cross-claimant's position on disclosure of feature in Dixon	Cross-respondents' response to Cross-claimant's position
		secondary doses of 2 mg of aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept". The Cross-Respondent ought not be permitted to adopt a different position in this proceeding.	
1.3	wherein each secondary dose is administered 2 to 4 weeks after the immediately preceding dose; and	113. Present; refer to the quote at [110], above: (a) Each of the secondary doses identified in [111(b)(ii)] above is administered 4 weeks after the immediately preceding dose. 114. Furthermore, in the Kleeh Proceeding, the Cross-respondent admitted or otherwise did not dispute that Dixon discloses the regimen in claim 6 of the US'572 Patent which regimen required, in addition to the matters set out in [112] above, that "*each secondary dose is administered approximately 4 weeks following the immediately preceding dose; and wherein each tertiary dose is administered approximately 8 weeks following the immediately preceding dose".* The Cross-Respondent ought not be permitted to adopt a different position in this proceeding.	
1.4	wherein each tertiary dose is administered 8 weeks after the immediately preceding dose	115. Present; refer to the quote at [110], above: (a) Each of the tertiary doses identified in [111(b)(iii)] above is administered 8 weeks after the immediately preceding dose. 116. Furthermore, the Cross-claimant repeats [114], above.	

Integer	Feature	Cross-claimant's position on disclosure of feature in Dixon	Cross-respondents' response to Cross-claimant's position
1.5	wherein the VEGF antagonist is a VEGF receptor-based chimeric molecule comprising:	117. Present; refer to the quote at [110], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and is inherently a VEGF receptor-based chimeric molecule. 118. See also Figure 1 of Dixon on page 1576.	
1.5.1	(1) a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2;	119. Present; refer to the quote at [110], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and inherently has a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2. 120. See also Figure 1 of Dixon on page 1576.	
1.5.2	(2) a VEGFR2 component comprising amino acids 130-231 of SEQ ID NO:2; and	121. Present; refer to the quote at [110], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and inherently has a VEGFR2 component comprising amino acids 130-231 of SEQ ID NO:2. 122. See also Figure 1 of Dixon on page 1576.	
1.5.3	(3) a multimerization component comprising amino acids 232-457 of SEQ ID NO:2.	123. Present; refer to the quote at [110], above: (a) "*VEGF Trap-Eye*" referred to in the quote is aflibercept and inherently has a multimerization component comprising amino acids 232-457 of SEQ ID NO:2. 124. See also Figure 1 of Dixon on page 1576.	

Integer	Feature	Cross-claimant's position on disclosure of feature in Dixon	Cross-respondents' response to Cross-claimant's position
Claim 3			
3.1	The method of claim 1,	125. Present; refer to [110] to [124], above.	
3.2	wherein only two secondary doses are administered to the patient,	126. Present; refer to [111(b)(ii)] above.	
3.3	and wherein each secondary dose is administered 4 weeks after the immediately preceding dose.	127. Present; refer to [113(a)] above.	
Claim 4			
4.1	The method of claim 1,	128. Present; refer to [110] to [124], 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.	129. Present; refer to [110(a)], above: (a) Wet AMD is a form of "*age related macular degeneration*" within the meaning of this feature.	

Integer	Feature	Cross-claimant's position on disclosure of feature in Dixon	Cross-respondents' response to Cross-claimant's position
Claim 5			
5.1	The method of claim 4,	130. Present; refer to [128] and [129], above.	
5.2	wherein the angiogenic eye disorder is age related macular degeneration.	131. Present; refer to [129], above.	
Claim 7			
7.1	The method of claim 1,	132. Present; refer to [110] to [124], above.	
7.2	wherein all doses of the VEGF antagonist are administered to the patient by topical administration or by intraocular administration.	133. Present; refer to the quote at [110], above and the word "*intravitreal"* therein. 134. Intravitreal is intraocular administration. 135. See also page 1574 of Dixon: *"Accordingly, all anti-VEGF agents for neovascular AMD are administered only by intravitreal injection.*" 136. Furthermore, the Cross-claimant repeats [112], above.	
Claim 8			
8.1	The method of claim 7,	137. Present; refer to [132] to [136], above.	

Integer	Feature	Cross-claimant's position on disclosure of feature in Dixon	Cross-respondents' response to Cross-claimant's position
8.2	wherein all doses of the VEGF antagonist are administered to the patient by intraocular administration.	138. Present; refer to [133] to [136], above.	
Claim 9			
9.1	The method of claim 8,	139. Present; refer to [137] and [138], above.	
9.2	wherein the intraocular administration is intravitreal administration.	140. Present; refer to [133] to [136], above.	
Claim 10			
10.1	The method of claim 9,	141. Present; refer to [139] and [140], above.	
10.2	wherein all doses of the VEGF antagonist comprise from about 0.5 mg to about 2 mg of the VEGF antagonist.	142. Present; refer to [111(b)], above.	
Claim 12			
12.1	The method of claim 10,	143. Present; refer to [141] and [142], above.	

Integer	Feature	Cross-claimant’s position on disclosure of feature in Dixon	Cross-respondents' response to Cross-claimant’s position
12.2	wherein all doses of the VEGF antagonist comprise 2 mg of the VEGF antagonist.	144. Present; refer to [111(b)], above.	