

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALVOTECH USA INC. and ALVOTECH HF,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

Case PGR2025-00085
U.S. Patent No. 12,168,036

REPLY DECLARATION OF ROBERT J. FALCONER, Ph.D

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I, Robert John Falconer, Ph.D., declare as follows:

I. INTRODUCTION

1. I previously submitted a declaration in this proceeding, relating to U.S. Patent No. 12,168,036 (the “’036 patent”), on behalf of Petitioners Alvotech USA Inc. and Alvotech hf. (“Alvotech”) against Regeneron Pharmaceuticals, Inc. (“Regeneron”), dated September 17, 2025. EX1004. I provided a description of my professional experience, qualifications, compensation, the person of ordinary skill in the art, and my understanding of the applicable legal standards in my initial Declaration, all of which remain accurate.

2. I understand that the Board has instituted a post grant review for the ’036 patent, and that Patent Owner has submitted a Patent Owner’s Response, dated June 19, 2026. Paper 28.

3. I understand that this Reply Declaration is being submitted in support of Alvotech’s Reply to Patent Owner’s Response in the post grant review involving the ’036 patent.

4. I further understand that Dr. Bernhardt L. Trout, Ph.D. has submitted a declaration relating to the ’036 patent in support of Regeneron’s Patent Owner’s Response. EX2051.

5. In this Reply Declaration, I respond to arguments made in Patent Owner’s Response and the opinions Dr. Trout expresses in his declaration. Dr. Trout

repeats his opinions several times throughout his declaration. To the extent I do not address each section in which he repeats his opinion, my opinions are intended to respond to those sections. Further, to the extent I do not address any of Dr. Trout's opinions expressly, it should not be taken as an agreement with that opinion.

6. I confirm that the opinions offered in my initial Declaration remain true to the best of my knowledge. The opinions detailed in my initial Declaration regarding the patentability of the challenged claims of the '036 patent remain unchanged and are incorporated into this Reply Declaration.

II. MATERIALS CONSIDERED

7. In addition to the materials I reviewed while preparing my initial Declaration, I have also reviewed and considered the materials referenced herein.

III. PREPARATION OF MY INITIAL DECLARATION

8. In my deposition, I testified that I did not recall the timing and circumstances regarding when I prepared my initial Declaration. EX2046 (Falconer Tr.) at 22:4–24:14. I started working on my initial Declaration in July 2025 and I spent over 30 hours between July and September 2025 preparing the opinions set forth therein.

IV. RESPONSES TO DR. TROUT AND REGENERON'S COMMENTS REGARDING OBVIOUSNESS

A. High Concentration Protein Formulations and Intravitreal Administration

9. Intravitreal formulations of therapeutic proteins were well-known in the art by 2018. Dr. Trout agreed in his deposition that “[t]here were certainly products before 2018 that were administered intravitreally.” EX1081 (Trout Tr.) at 114:21–115:4.

10. The specific formulation tools and strategies for making therapeutic protein formulations that were suitable for intravitreal administration were also known and readily identifiable, and a skilled formulator seeking to make an intravitreal therapeutic protein formulation would have understood how to use those tools and strategies. Dr. Trout agreed that a skilled formulator seeking to formulate an intravitreal product would be able to find which excipients or additives had been used in intravitreal administration before 2018. EX1081 (Trout Tr.) at 115:5–14. The Chang 2002 article cited by Dr. Trout explains that “[g]enerally, it is preferred to select excipients that have been used in marketed products with a relevant route of delivery. Further, it is preferable if these excipients have been used with similar frequency of dosing, history of chronic use and similar patient populations.” EX2061 (Chang 2002) at 14; EX1081 (Trout Tr.) at 115:15–116:19.

11. Aflibercept, in particular, was a well-known and thoroughly characterized therapeutic protein by 2018. Eylea[®] (aflibercept) was approved by FDA in 2011. EX2064 (Eylea[®] 2011 Label) at 1; EX2051 (Trout Decl.) ¶ 78; EX1081 (Trout Tr.) at 121:16–21. Dr. Trout agreed that, having gone through FDA approval, Eylea[®] “in terms of stability ... met the threshold of safe and effective.” EX1081 (Trout Tr.) at 121:22–122:11. Dr. Trout agreed that by 2018, aflibercept and its primary structure were known in the art. EX1081 (Trout Tr.) at 116:21–117:2, 122:13–123:11. He further agreed that by that time, Regeneron had been working with aflibercept “for more than a decade” and that Regeneron had “a lot of experience” with aflibercept. EX1081 (Trout Tr.) at 119:4–120:2. Consistent with this background, Regeneron’s own prior-art disclosures, including Furfine, Vitti, and Dix,¹ collectively teach aqueous aflibercept formulations that are suitable for intravitreal administration, including at 100 mg/mL. EX1004 (Falconer Decl.) ¶¶ 114–118, 120–122, 125, 190–193, 195, 243. A skilled formulator in 2018 seeking to

¹ Dr. Trout suggests that Dix should be disregarded because it “is directed to cancer treatment, not ophthalmic use, and expressly teaches formulations for subcutaneous or intravenous delivery—not intravitreal injection.” EX2051 (Trout Decl.) ¶ 196. I disagree with Dr. Trout’s assertion that because Dix describes non-intravitreal formulations for cancer treatment it is not pertinent. While Dr. Trout recognizes that Avastin[®] (bevacizumab) was a known intravenous anti-VEGF therapeutic protein formulation approved for cancer treatment in 2004, EX2051 (Trout Decl.) ¶ 74, he fails to acknowledge that Avastin[®] was also successfully administered intravitreally. EX1020 (Das 2015) at 1382.

make an aqueous formulation of aflibercept would therefore have understood that aflibercept was a well-characterized therapeutic protein that had been successfully formulated for intravitreal administration and deemed sufficiently stable, safe, and effective to obtain FDA approval, not a molecule of unknown chemical and physical properties that would render any attempts to make such a formulation, including at higher concentrations of 100 mg/mL or greater, uniquely and inherently more challenging than formulating any other well-characterized therapeutic protein.

12. A skilled formulator in 2018 faced an established field of intravitreal protein formulation, a known and available set of tools for creating such formulations at high concentrations, and a specific molecule—aflibercept—that was approved, marketed, stable, and well-characterized, and for which Dr. Trout identified no particular stability or viscosity problem. For the reasons explained above and in my initial Declaration, a skilled formulator would have reasonably expected in light of this background knowledge that aflibercept formulations with concentrations of 100 mg/mL or more suitable for intravitreal administration could be prepared successfully.

B. Stability

13. None of challenged claims 1–38 of the '036 patent recites a stability limitation. Independent claims 1 and 35 recite:

1. A method for treating an angiogenic eye disorder in a human subject in need thereof comprising administering, intravitreally into an eye of the subject, in a volume of about 100 microliters or less, at least about 8 mg of a VEGF receptor fusion protein comprising two polypeptides that comprise an immunoglobulin-like (Ig) domain 2 of VEGFR1, an Ig domain 3 of a VEGFR2, and a multimerizing component; wherein the VEGF receptor fusion protein is in an aqueous pharmaceutical formulation comprising at least 100 mg/ml of the VEGF receptor fusion protein and having a viscosity of about 5-15 centiPoise (cP) at 20° C.

35. A method for treating an angiogenic eye disorder in a human subject in need thereof comprising administering, intravitreally into an eye of the subject, about 70 microliters of an aqueous pharmaceutical formulation comprising about 103-126 mg/ml of aflibercept and having a viscosity of about 5-15 cP at 20° C.

EX1001 ('036 patent) at claims 1, 35. None of independent claims 1 and 35, or dependent claims 2-34 and 36-38 includes a reference to “stable” or “stability,” recites any limitation in degree or type of modification to the claimed VEGF receptor fusion protein or aflibercept’s function, or specifies any storage period or storage conditions under which that modification should be assessed.

14. Dr. Trout agreed during his deposition that the challenged claims do not include a stability limitation:

Q. And you’re saying that administering intravitreally into the eye of a subject relates to stability?

...

A. No. ... all these things are related in terms of formulation. What I'm saying here is there's not a stability limitation here per se. But we talked about the term "suitable." ... it has to be able to be administered intravitreally into the eye of the subject. There's no stability limitation in terms of time here or anything, but it has to be suitable or the doctor has to be able to administer it at the time.

EX1081 (Trout Tr.) at 162:5–163:6. Dr. Trout also testified in his deposition that, "[i]f you can't inject it intravitreally into the eye of a subject, then it's not part of the claim," but "[i]f you make it and you can inject it ... and it meets all the limitations, then it falls under the claim." EX1081 (Trout Tr.) at 164:8–165:10.

15. The claims of the '036 patent do not include any limitations that require "stability" as that term is used in the art and would be understood by a skilled formulator. They do not require that the formulation retain any particular degree of the protein's chemical structure or biological function, identify any specific physical or chemical stability property of the protein, specify any storage period, or specify any storage conditions. As Dr. Trout testified, "stability is not an explicit limitation" and "there doesn't have to have stability per se per the claim." EX1081 (Trout Tr.) at 153:10–154:20. Rather, what the claims require is that the formulation must be "suitable" such that one is "able to administer it intravitreally." EX1081 (Trout Tr.) at 153:10–154:20. In other words, "at the time of administration ... it can't have particulates and these sort of things that would not be desired." EX1081 (Trout Tr.)

at 153:10–154:20. That is a property of the formulation as prepared, not a measure of the physical and chemical properties of the formulation over time in storage. I therefore agree with Dr. Trout that a skilled formulator would understand that a formulation that can be injected intravitreally at the time of administration is suitable for intravitreal use, regardless of whether it would maintain a certain degree of physical or chemical stability after weeks or months of storage.

16. Accordingly, Dr. Trout’s arguments grounded in the purported difficulty in developing a “stable” high-concentration intravitreal formulation, including his assertion that a skilled formulator would not have been motivated or had a reasonable expectation of success in making such a formulation, *see, e.g.*, EX2051 (Trout Decl.) ¶¶ 103–105, 121–122, 133, 137–139, 143, 151–153, 155, 161, 167–168, 174, 177, 192–193, 200–201, 204–206, 209, 211–212, 221–222, 227, 230, 234, are directed to a property that the claims do not require.

17. In any event, as I explained in my initial Declaration, the prior art teaches that aflibercept formulations at 100 mg/mL are stable and suitable for intravitreal injection. *See, e.g.*, EX1004 (Falconer Decl.) at ¶¶ 85–89, 97–112, 114–121, 172, 177, 184, 190–193, 195, 243. Additionally, Dr. Trout confirmed that Furfine teaches ophthalmic formulations of up to 100 mg/mL of aflibercept that are suitable for intravitreal injection:

Q. Okay. ... so Furfine is teaching aflibercept formulations of up to 100 mgs per mL of aflibercept, correct?

A. I mean, I think that's correct. I mean, there are other limitations, but if we're talking about Claim 1, but yes, it's 1 to 100 mgs per mL, correct.

Q. Okay. ... that formulation is suitable for intravitreal injection, correct?

A. I mean, given the terminology, it's an ophthalmic formulation, so it can be injected into the eye, I would say, intravitreally.

EX1081 (Trout Tr.) at 199:7–21.

Q. ... you agree then that Furfine is teaching a range of formulations from 1 to 100 mgs per mL of aflibercept suitable for ophthalmic use in intravitreal injection, correct?

A. I mean, we were talking about the claims ... but I agree. In Column 2, as you correctly read, it comprises 1 to 100 milligrams per milliliter of the VEGF specific fusion protein, other components, it teaches. And I agree it's a liquid ophthalmic formulation that can be injected intravitreally.

EX1081 (Trout Tr.) at 202:1–16. Dr. Trout also agreed that “a person of ordinary skill ... looking at Claim 1 of Furfine would understand that Furfine's inventors were in possession of Claim 1's 100 mg per mL formulation of aflibercept.” EX1081 (Trout Tr.) at 207:12–208:7. Claim 1 of Furfine is shown below:

1. An ophthalmic formulation of a vascular endothelial growth factor (VEGF) antagonist, comprising

- a) 1-100 mg/ml of a VEGF antagonist comprising the amino acid sequence of SEQ ID NO:4;
- b) 0.01-5% of one or more organic co-solvent(s) which is one or more of polysorbate, polyethylene glycol (PEG), and propylene glycol;
- c) 30-150 mM of a tonicity agent selected from sodium chloride or potassium chloride; and,
- d) 5-40 mM of sodium phosphate buffer.

EX1005 (Furfine) at claim 1.

C. Viscosity

18. Regarding viscosity, Dr. Trout asserts that because each protein's concentration-viscosity curve is protein-specific and cannot be predicted from concentration alone, and there was no viscosity data for high-concentration aflibercept formulations in the prior art, a skilled formulator would not have been motivated to combine the prior art references with a reasonable expectation of success in making a high-concentration aflibercept formulation with the claimed viscosity without an understanding of the specific concentration-viscosity relationship for aflibercept. *See, e.g.,* EX2051 (Trout Decl.) ¶¶ 92–96, 126–130, 137–139. I disagree with Dr. Trout.

19. A skilled formulator did not need to know the precise viscosity of a high-concentration aflibercept formulation or its concentration-viscosity curve in advance of making it to have a reasonable expectation of success in achieving the claimed viscosity. I understand that a reasonable expectation of success requires only

a reasonable probability of success, not absolute predictability, conclusive proof, data, or a guarantee of success in determining a property's precise value before the formulation is made.

20. A skilled formulator seeking to obtain an aflibercept formulation suitable for intravitreal administration at the claimed “at least 100 mg/ml” (claim 1), “about 114.3 mg/ml” (claim 31), and “about 103–126 mg/ml” (claim 35) concentrations with the claimed 5–15 cP viscosity would begin by looking to prior-art aflibercept formulations that were suitable for intravitreal administration and that would have been understood to be of an appropriate viscosity level for intravitreal injection, such as Eylea[®] and the aflibercept formulations described in Furfine and Vitti. Eylea[®] is an intravitreal formulation containing 40 mg/mL aflibercept, 10 mM sodium phosphate, 40 mM sodium chloride, 0.03% polysorbate 20, and 5% sucrose, pH 6.2. EX1053 (Eylea[®] 2016 Label) at 13. Furfine teaches and claims an intravitreal formulation including 1-100 mg/ml aflibercept, 10 mM sodium phosphate buffer, 40 mM NaCl, 0.03% polysorbate, and 5% sucrose, pH about 6.2-6.3.² EX1005 (Furfine) at claim 3. Vitti expressly refers to Furfine (U.S. Patent No. 7,608,261) for its disclosure of “[e]xemplary formulations comprising a VEGF

² As I explained in my initial Declaration, a POSA would expect from Furfine's teaching that its formulations containing up to 100 mg/mL aflibercept are “suitable for intravitreal administration” would have an appropriately low viscosity. EX1004 (Falconer Decl.) ¶ 195.

antagonist” that can be used in the context of its invention. EX1007 (Vitti) ¶ 107. The skilled formulator could have then increased the concentration of those prior-art suitable intravitreal aflibercept formulations up to 100 mg/mL to 115 mg/mL, as taught by Vitti and Furfine. EX1004 (Falconer Decl.) ¶¶ 114–118, 120–122, 125, 171–178, 184–185, 190–191, 193, 195, 242–253, 259–260.

21. Because, as Dr. Trout notes, “[v]iscosity is an especially important consideration for injectable protein formulations,” especially intravitreal formulations, EX2051 (Trout Decl.) ¶ 93, a skilled formulator would understand that even though the viscosity levels of those formulations would have been expected to be suitable for intravitreal injection, they would nevertheless need to be measured to confirm that the viscosity was acceptable.

22. Measuring viscosity was a routine and conventional aspect of high-concentration protein formulation well before 2018. Dr. Trout testified that, as of 2018, a skilled formulator seeking to develop an intravitreal protein formulation would “think about viscosity ... as a potential concern, whether that might be a concern or not.” EX1081 (Trout Tr.) at 105:5–106:16. Dr. Trout also testified that to determine the viscosity of the formulation, “one has to measure the viscosity,” and that there were “different ways of doing that,” including commercially available devices. EX1081 (Trout Tr.) at 106:18–107:20 (“... there are various microfluidic methods that were available as of 2018, so one has to measure the viscosity. There

are different ways of doing that....”), 107:21–108:3 (“Q. ... so there are commercially available devices for measuring viscosities of these protein formulations we’ve been discussing? A. Yes.”), 109:16-110:18 (“Q. How does the viscometer work that you have in your lab? A. Oh, I was just talking about a standard viscometer. ... That is sort of the traditional one, maybe been around for many many decades....”). I agree with Dr. Trout on both points.

23. After measuring the viscosity of the aflibercept formulation at concentrations ranging from 100 mg/mL to 115 mg/mL (which overlap the claimed concentrations of “at least 100 mg/ml” (claim 1), “about 114.3 mg/ml” (claim 31), and “about 103–126 mg/ml” (claim 35)), a skilled formulator would determine and confirm that at those concentrations and with similar excipients to those in the Eylea[®], Furfine, and/or Vitti aflibercept formulations (including for example, 10 mM sodium phosphate and 5% sucrose), the viscosity levels were appropriately low and, thus, the formulations were suitable for intravitreal administration.

24. Indeed, Examples 3 and 5 of the ’036 patent describe viscosity testing for aflibercept formulations that, like Eylea[®] and those taught by Furfine and Vitti, include 10 mM sodium phosphate and 5% sucrose. Example 3 and Figure 3C describe viscosity of VEGF Trap (aflibercept) “between the concentrations of 10 mg/ml and 160 mg/ml, with 10 mM sodium phosphate, 5% sucrose at a pH of 6.2 in the absence of arginine, and in 50 mM of arginine chloride”:

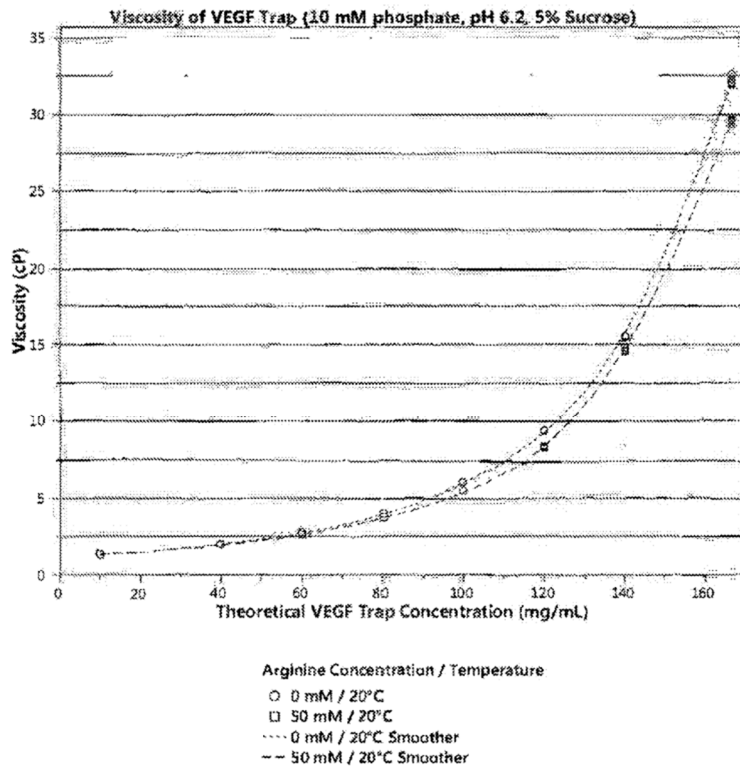


FIG. 3C

EX1001 ('036 patent) at 38:55–67, Fig. 3C. Example 5 and Figure 5 describe viscosity of 10 mg/ml to 170 mg/ml VEGF Trap (afibercept), in 10 mM phosphate buffer and 5% sucrose at a pH of 6.2 and in 10 mM histidine buffer and 5% sucrose at a pH of 6.0:

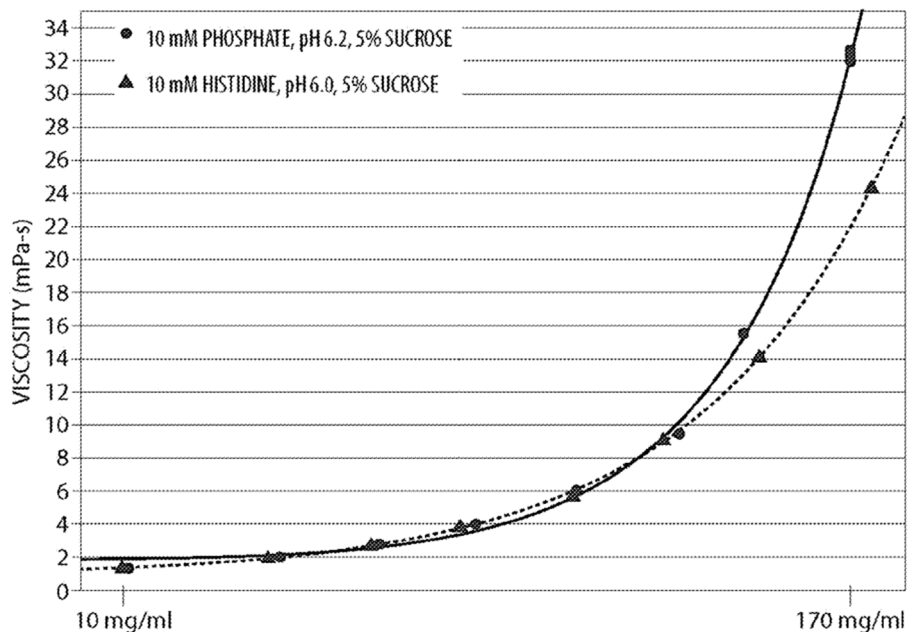


FIG. 5

EX1001 ('036 patent) at 42:14–22, Fig. 5. As the data in Figures 3C and 5 shows, the viscosity levels for each of aflibercept formulations at concentrations ranging from approximately 100 mg/mL to 115 mg/mL and formulated with 10 mM phosphate and 5% sucrose, are well within the claimed viscosity range of 5–15 cP. The same data confirms that at that same concentration range, the similar Eylea[®], Furfine, and Vitti formulations would have a similarly low viscosity when measured.

25. Even if the higher-concentration 100 mg/mL to 115 mg/mL Eylea[®], Furfine, and/or Vitti intravitreal aflibercept formulations did not achieve the desired viscosity, a skilled formulator would have understood how to reduce the viscosity using well-established and conventional formulation techniques, such as “adjusting pH, adding salts or amino acids or optimizing buffer selection,” among others.

EX1081 (Trout Tr.) at 129:19–130:17; *see also* EX1004 (Falconer Decl.) ¶¶ 52–70, 127, 198. Dr. Trout agreed that “[i]f a formulator wanted to reduce the viscosity of an aflibercept formulation, these strategies could be employed, subject to empirical testing.” EX1081 (Trout Tr.) at 129:19–131:20. Such “empirical testing” is merely the standard, routine testing a skilled formulator performs as a matter of course in formulation development to confirm the expectation of success in achieving the claimed viscosity after the formulation is made rather than negating it at the outset. While Dr. Trout noted that such strategies “do not always succeed” and are “protein-specific,” EX1081 (Trout Tr.) at 131:13–132:16, that caveat does not mean that a skilled formulator would not have a reasonable expectation of success because it suggests only that testing may be needed to confirm the viscosity properties of the formulation, not that success was improbable. Measuring the viscosity of the resulting formulation simply verifies what the skilled formulator already reasonably expected. And as Shire 2009 explains, the development of high-concentration formulations for injection via narrow-bore needles, such as subcutaneous formulations, routinely involved designing formulations “to minimize protein aggregation and decrease viscosity,” with viscosity measured and managed as a normal part of that development. EX1083 (Shire 2009) at 708–09 & Fig. 1 (plotting viscosity versus concentration for a monoclonal antibody, with and without added excipients that decrease viscosity).

26. In sum, a skilled formulator would have had a reasonable expectation of success in achieving high-concentration, low-viscosity aflibercept formulations as claimed, including the means to confirm that expectation via routine viscosity measurements and testing. The prior art, such as Furfine and Vitti, teaches high-concentration aflibercept formulations suitable for intravitreal administration that a skilled formulator would have understood to have appropriate viscosity levels for intravitreal injection. EX1004 (Falconer Decl.) ¶¶ 115–117, 121–122, 191, 195. Even in the absence of aflibercept-specific concentration-viscosity data in the prior art, a skilled formulator would have reasonably expected that the claimed viscosity levels could be achieved using routine formulation strategies, and would have confirmed the result by conventional measurement techniques that Dr. Trout agreed a formulator would understand how to perform.

D. Vitti Teaches an Intravitreal Formulation Containing Up to 100±15 mg/mL of Aflibercept

27. Dr. Trout opines that Vitti does not teach an intravitreal formulation with at least 100 mg/mL aflibercept because it (a) discloses a “broad range that encompasses many discrete VEGF antagonist concentrations,” and (b) it “fails to specify both which VEGF antagonist is being used in the liquid pharmaceutical formulation and the method of administration of the pharmaceutical formulation.” EX2051 (Trout Decl.) ¶¶ 115–125. I disagree with Dr. Trout.

28. Paragraph 94 of Vitti, reproduced in full below, states:

In certain embodiments, the pharmaceutical formulations are liquid formulations that may contain 5 ± 0.75 mg/mL to ***100±15 mg/mL of a VEGF antagonist. For example***, the formulations of the present invention may comprise about 5 mg/mL; about 10 mg/mL; about 15 mg/mL; about 20 mg/mL; about 25 mg/mL; about 30 mg/mL; about 35 mg/mL; about 40 mg/mL; about 50 mg/mL; about 60 mg/mL; about 70 mg/mL; about 80 mg/mL; about 90 mg/mL; or ***about 100 mg/mL of a VEGF antagonist such as aflibercept.***

EX1007 (Vitti) ¶ 94 (emphasis added).

29. A skilled formulator reading Vitti as a whole would have understood that it taught formulations of ***aflibercept***, specifically, rather than just VEGF antagonists generally. Vitti's definition of "VEGF antagonist" is broad enough to encompass a family of molecules that, like aflibercept, binds to or interacts with VEGF. EX2046 (Falconer Tr.) at 40:6–10, 46:16–47:1; EX1007 (Vitti) ¶ 85. However, as explained above, Paragraph 94 of Vitti specifically teaches liquid pharmaceutical formulations containing " 5 ± 0.75 mg/mL to 100 ± 15 mg/mL of a VEGF antagonist," and expressly identifies as an "example" a "formulation[] of the present invention" comprising "about 100 mg/mL of a VEGF antagonist ***such as aflibercept.***" EX1007 (Vitti) ¶ 94 (emphasis added). Additionally, Paragraph 127 of Vitti expressly discloses a "liquid formulation" comprising anti-Ang-2 antibody and "from 10 mg/mL to ***100 mg/mL aflibercept*** is comprised in a prefilled syringe

and is *administered intravitreally* in a volume of approximately upto [*sic*] 100 μ L.” EX1007 (Vitti) ¶ 127 (emphasis added). Moreover, as I explained during my deposition, the only VEGF antagonist described and tested in Vitti’s Examples is aflibercept. EX2046 (Falconer Tr.) at 46:15–47:1 (“And then in the examples in the patent self, they all focus in on aflibercept . . .”); EX1007 (Vitti) ¶¶ 141–309.

30. I also disagree with Dr. Trout’s opinion that a POSA reading Vitti would not understand formulations containing a VEGF antagonist at the top end of the “ 5 ± 0.75 mg/mL to 100 ± 15 mg/mL” concentration range (115 mg/mL) or aflibercept at the top end of the 10 mg/mL to 100 mg/mL concentration range (100 mg/mL) to be stable. EX2051 (Trout Decl.) ¶ 121. As explained above, Dr. Trout admitted during his deposition that the claims do not contain a “stability” limitation. Rather, all the claims require is that the formulation must be suitable for intravitreal injection at the time of administration. EX1081 (Trout Tr.) at 153:10–154:20, 162:5–163:6, 164:8–165:10. Additionally, Vitti expressly refers to Furfine for its disclosure of “[e]xemplary formulations comprising a VEGF antagonist that can be used in the context of the present invention.” EX1007 (Vitti) ¶ 107. And Dr. Trout confirmed that Furfine teaches ophthalmic formulations of up to 100 mg/mL of aflibercept that are suitable for intravitreal injection. EX1081 (Trout Tr.) at 199:7–21, 202:1–16.

31. Dr. Trout and Regeneron cite certain portions of my deposition testimony out of context to suggest that I “agreed” that Vitti does not teach that

aqueous formulations of aflibercept at greater than 100 mg/mL are stable and “admit” that a skilled formulator would not have a reasonable expectation of success achieving aflibercept formulations that are suitable for intravitreal administration. Paper 28 (Patent Owner’s Response) at 38, 43, 45 (citing EX2046 (Falconer Tr.) at 73:10–21, 74:17–24); EX2051 (Trout Decl.) ¶¶ 121, 133, 174 (citing 73:14–17, 75:5–7). This testimony is not inconsistent with my opinions regarding the skilled formulator’s expectation of success in achieving the claimed intravitreal aflibercept formulations, and I disagree with any suggestion that it is.

32. The full context of the first portion of the cited testimony is as follows:

Q. So you can’t predict the aggregation of a protein without experimental data, is that right?

...

A. Correct.

Q. Okay. But it’s critical to know that a protein is stable at a given concentration in order to be able to formulate it for intravitreal administration, right?

A. Correct.

Q. Okay. Does Vitti teach that aqueous formulations of aflibercept at greater than 100 mgs per ml are stable?

...

A. ... Yes. I was looking at *Vitti in 108 where it does discuss stability*, but *looking at that particular paragraph it’s talking about antibody stability*.

Q. Right. And so Vitti doesn't teach that aqueous formulations of aflibercept at greater than 100 mgs per ml are stable, right?

A. No. I don't believe it does.

Q. And Vitti doesn't teach that aqueous formulations of aflibercept at 114.3 mgs per ml are stable, correct?

A. Correct.

Q. And Vitti doesn't teach that aqueous pharmaceutical formulations of about 103 to 126 mgs per ml of aflibercept would be stable, correct?

A. Correct.

...

Q. Because the POSA doesn't have an understanding from Vitti that aflibercept would be stable, the POSA wouldn't have a reasonable expectation of success in achieving formulations of aflibercept that would be suitable for intravitreal administration, correct?

...

A. Correct.

EX2046 (Falconer Tr.) at 72:16–74:24 (emphasis added).

33. My testimony reflects the observation that I had made regarding Paragraph 108 of Vitti, which contains a discussion regarding the stability of its disclosed pharmaceutical formulations and expressly addresses the stability of antibodies. EX1007 (Vitti) ¶ 108 (“The pharmaceutical formulations of the present

invention typically exhibit high levels of stability. The term ‘stable’, as used herein in reference to the pharmaceutical formulations, means that the antibodies within the pharmaceutical formulations retain an acceptable degree of chemical structure or biological function after storage under defined conditions.”). I therefore agreed only that Vitti does not, through an express teaching, state that aflibercept is stable at the specified concentrations of 100 mg/mL, 114.3 mg/mL, and 103 to 126 mg/mL. As for reasonable expectation of success, I merely confirmed that there would be no reasonable expectation of success in broadly achieving aflibercept formulations of unspecified concentration or character in general. I did not state that a skilled formulator would not have a reasonable expectation of success in view of Vitti and the knowledge in the art in achieving suitable intravitreal formulations of aflibercept at the claimed concentrations of 100 mg/mL, 114.3 mg/mL and 103 to 126 mg/mL, and I disagree with Dr. Trout and Regeneron’s assertions to the contrary.

34. Indeed, to the extent stability data regarding aggregation is required (it is not), Vitti itself plainly includes data showing that formulations containing aflibercept were stable. EX1007 (Vitti) ¶¶ 205–209 (describing results of stability studies of co-formulations comprising anti-Ang-2 antibody and 40 mg/mL aflibercept). So does Furfine, which Vitti states and Dr. Trout agrees discloses exemplary formulations comprising a VEGF antagonist. EX1007 (Vitti) ¶ 107; EX1005 (Furfine) at 7:60–12:23 (describing results of stability studies on

formulations comprising 40 mg/mL and 50 mg/mL aflibercept); EX1081 (Trout Tr.) at 260:11–261:9. And Furfine confirms its ophthalmic formulations containing up to 100 mg/mL of aflibercept are stable and suitable for intravitreal administration. EX1005 (Furfine) at 1:17–24 (“The present invention is directed to pharmaceutical formulations suitable for intravitreal administration comprising agents capable of inhibiting vascular endothelial growth factor (VEGF)”), 2:4–9 (“In one aspect, a stable liquid ophthalmic formulation is provided that comprises 1–100 mg/ml VEGF-specific fusion protein antagonist”), claim 1 (“An ophthalmic formulation of a vascular endothelial growth factor (VEGF) antagonist, comprising a) 1-100 mg/ml of a VEGF antagonist comprising the amino acid sequence of SEQ ID NO:4”); EX1081 (Trout Tr.) at 199:7–21, 202:1–16.

35. The second portion of the cited testimony is to the same effect: “Q. Vitti contains no stability data for aflibercept at 100 mgs per ml or above, correct? A. Correct.” EX2046 (Falconer Tr.) at 75:5–7. I agreed only that Vitti does not report stability *data* for the specified concentration range of 100 mg/mL or above.

36. None of the cited testimony is inconsistent with my opinions regarding Vitti’s teachings regarding formulations containing 100±15 mg/mL of aflibercept suitable for intravitreal administration and the skilled formulator’s expectation of success of making such formulations, EX1004, ¶¶113-128, 169-178, 182-185, because it answers a different question than my opinions address. My agreement that

Vitti does not expressly teach, and does not report experimental data explicitly demonstrating “stability” under the specified concentrations (which is not required by the claims) does not say anything about what a skilled formulator would understand and reasonably expect from reading Vitti as a whole, in light of the knowledge in the art. I understand from counsel that obviousness requires only a reasonable expectation of success, not absolute predictability, conclusive proof, data, or a guarantee of success.

37. Dr. Trout and Regeneron also incorrectly cite certain portions of my deposition testimony to suggest that I “walked back” my opinion that the disclosure in Paragraph 94 of Vitti of “ 5 ± 0.75 mg/mL to 100 ± 15 mg/mL” is a disclosure related to an intravitreal aflibercept formulation. EX2051 (Trout Decl.) ¶ 167 (citing EX2046 (Falconer Tr.) at 39:10–14); Paper 28 (Patent Owner’s Response) at 35 (citing EX2046 (Falconer Tr.) at 39:10–14).

38. The cited testimony, shown below, merely reflects my confirmation that the specific phrase, “115 mgs per ml of aflibercept,” is not included in Paragraph 94 of Vitti:

Q. You agree that Vitti does not specifically disclose 115 mgs per ml of aflibercept, correct?

A. Yes. It doesn’t specifically disclose it. Correct.

EX2046 (Falconer Tr.) at 39:10–14. It does not, as Dr. Trout and Regeneron assert, suggest that I disclaimed my opinions in my initial Declaration, EX1004 (Falconer Decl.) ¶¶ 114–118, 172, 184, that Vitti teaches intravitreal formulations containing up to 115 mg/mL of aflibercept. Again, Dr. Trout and Regeneron ignore the full context of my testimony, which confirms those opinions.

39. As shown below, I not only expressly reaffirmed my opinion as set forth in my initial Declaration, but I also repeatedly confirmed, immediately before the portion of my testimony that Dr. Trout and Regeneron selectively cited, my understanding as a skilled formulator reading Paragraph 94 of Vitti in full was that its disclosure of “ 5 ± 0.75 mg/mL to 100 ± 15 mg/mL” teaches up to 100 ± 15 mg/mL of aflibercept:

Q. Well, for example, paragraph 94 doesn’t say 100 plus or minus 15 mgs per ml of aflibercept, right?

A. Yes. It talks about the VEGF antagonist.

Q. But your opinion assumes that VEGF antagonist is synonymous with aflibercept here?

A. Yes. *If you look later on in the same paragraph it does talk about a VEGF antagonist such as aflibercept.*

Q. But that’s not a disclosure of plus or minus 100 mgs per ml, right?

A. Certainly my reading of this is *it links the VEGF antagonist to being at least the possibility of being aflibercept.*

Q. You read VEGF antagonist as synonymous with aflibercept, right?

A. My reading of this is that *it certainly can include aflibercept*, yes.

...

Q. ... When you say I don't recall it mentioning another [VEGF] antagonist, is it Vitti there?

A. Yes. It is Vitti. . . . Obviously VEGF antagonist . . . potentially is a broader family than just the one specific molecule which in this case is aflibercept, but *my reading of this is that it is talking about aflibercept*.

Q. So when Vitti uses the term VEGF antagonist it's using it to refer to aflibercept, correct?

A. So it would be *my reading of it is that it could definitely include aflibercept*, yes.

Q. Does VEGF antagonist mean aflibercept or does it mean something else?

A. *My reading of this is it is alluding to aflibercept* but by using the wording VEGF antagonist it could include variants on the theme, you know, other therapeutic proteins that are VEGF antagonists. It's as less precise use of the English language.

Q. So when you say Vitti teaches 115 mgs per ml of aflibercept, you're actually referring to 115 mgs per ml of a group of protein called VEGF antagonists?

A. *And one of those is definitely aflibercept*, yes.

Q. But Vitti doesn't include 115 mgs per ml of aflibercept specifically, right?

A. Vitti doesn't say aflibercept, but as I pointed out, ***there is a very strong link in the same paragraph that points out that that VEGF antagonist can be aflibercept.***

...

Q. So is that the meaning you understand Vitti to be referring to when it refers to VEGF antagonist?

A. ***My reading is when it talks about VEGF antagonist it is alluding to aflibercept*** or a similarly related protein, yes. It's just less precise English.

...

Q. ... can you please tell me . . . what meaning of VEGF antagonist Vitti is using?

A. Yes. ***I think the opinion in paragraph 115 on page 51 of the declaration.***

Q. What about that paragraph?

A. ***I think it spells out my opinion quite nicely.***

Q. The meaning of VEGF antagonist in Vitti is not specific to aflibercept, correct?

A. Yes. A VEGF antagonist is not as well defined a title as being precise in saying aflibercept. ***The exemplary, you know, example here is aflibercept.***

Q. You agree that Vitti does not specifically disclose 115 mgs per ml of aflibercept, correct?

A. Yeah. My reading of this is that *Vitti was alluding to aflibercept* and was using less precise English, so it could include some – the related proteins to aflibercept.

EX2046 (Falconer Tr.) at 34:20–39:6 (emphasis added).

40. Despite explaining my understanding multiple times that Paragraph 94 of Vitti teaches up to 100±15 mg/mL of aflibercept, counsel for Regeneron suggested to me that my testimony did not answer his question and stated he would ask it again:

Q. I don't know if that answers my question. I'll ask it again.

A. Okay.

Q. You agree that Vitti does not specifically disclose 115 mgs per ml of aflibercept, correct?

A. Yes. It doesn't specifically disclose it. Correct.

EX2046 (Falconer Tr.) at 39:7–14. Because I had already explained several times that Paragraph 94 of Vitti discloses up to 100±15 mg/mL of aflibercept, I understood counsel's re-asked question—whether Vitti “does not *specifically disclose* 115 mgs per ml of aflibercept”—to be directed to whether **that specific phrase** appears in Paragraph 94, as my answer reflects. That testimony is fully consistent with my opinion that a skilled formulator would read Paragraph 94 of Vitti's “5±0.75 mg/mL to 100±15 mg/mL” range as disclosing a concentration range for aflibercept.

41. As explained above and in my initial Declaration, Vitti as a whole conveys to a skilled formulator that an aqueous pharmaceutical formulation containing approximately 100±15 mg/mL of aflibercept would be suitable for intravitreal administration. *See, e.g.*, EX1004 (Falconer Decl.) ¶¶ 115, 117, 121, 172, 184 (citing EX1007 (Vitti) ¶¶ 85–86, 94, 107, 127). For example, Vitti specifically discloses liquid pharmaceutical formulations containing “5±0.75 mg/mL to 100±15 mg/mL of a VEGF antagonist,” and expressly identifies as an “example” a “formulation[] of the present invention” comprising “about 100 mg/mL of a VEGF antagonist *such as aflibercept.*” EX1007 (Vitti) ¶ 94 (emphasis added). Vitti also expressly discloses a “liquid formulation” comprising anti-Ang-2 antibody and “from 10 mg/mL to **100 mg/mL of aflibercept** is comprised in a prefilled syringe and is **administered intravitreally** in a volume of approximately upto [*sic*] 100 µL.” EX1007 (Vitti) ¶ 127 (emphasis added). Vitti further expressly refers to Furfine for its “[e]xemplary formulations comprising a VEGF antagonist that can be used in the context of the present invention.” EX1007 (Vitti) ¶ 107; *see, e.g.*, EX1005 (Furfine) at 1:17–24 (“The present invention is directed to pharmaceutical formulations suitable for intravitreal administration comprising agents capable of inhibiting vascular endothelial growth factor (VEGF)”), 2:4–9 (“In one aspect, a stable liquid ophthalmic formulation is provided that comprises 1–100 mg/ml VEGF-specific fusion protein antagonist”), claim 1 (“An ophthalmic formulation of a

vascular endothelial growth factor (VEGF) antagonist, comprising a) 1-100 mg/ml of a VEGF antagonist comprising the amino acid sequence of SEQ ID NO:4 . . .”). The fact that Vitti’s disclosure regarding “stability” and definition of “stable” in Paragraph 108 refers to “antibodies” without expressly referencing aflibercept or VEGF receptor fusion proteins or that Vitti does not contain stability data at the claimed concentrations does not detract from Vitti’s disclosure, which, read as a whole in light of the knowledge in the art, conveys to a skilled formulator a reasonable expectation of success in obtaining an aqueous pharmaceutical formulation at the claimed concentrations that is suitable for intravitreal administration.

42. Dr. Trout also notes that the disclosure of Paragraph 94 of Vitti of “ 5 ± 0.75 mg/mL to 100 ± 15 mg/mL” is “silent as to a particular route of administration” and suggests that a POSA would not have understood that as “specifically applicable to intravitreal formulations” in light of the perceived difficulty in formulating intravitreal formulations. EX2051 (Trout Decl.) ¶¶ 118–119. I disagree with Dr. Trout. A skilled formulator would understand based on Vitti as a whole that Vitti teaches that the concentration range of “ 5 ± 0.75 mg/mL to 100 ± 15 mg/mL” applies to intravitreal formulations. For example, as explained in my initial Declaration, Paragraph 127 of Vitti discloses a liquid formulation comprising “from 10 mg/mL to 100 mg/mL of aflibercept . . . in a prefilled syringe

and is administered intravitreally in a volume of approximately upto [*sic*] 100 µL.”
EX1004 (Falconer Decl.) ¶ 117 (citing EX1007 (Vitti) ¶ 127).

43. Dr. Trout and Regeneron also misread and cite out of context certain other portions of my deposition testimony to support their argument that a POSA would not have been motivated to make or would not have had a reasonable expectation of success in achieving an intravitreal formulation with the claimed concentrations of aflibercept. Paper 28 (Patent Owner’s Response) at 35, 44 (citing EX2046 (Falconer Tr.) at 53:22–54:3, 55:21–56:3); EX2051 ¶¶ 133, 173 (citing EX2046 (Falconer Tr.) at 55:21-56:3).

44. The first two portions of the cited testimony concern the terms “VEGF antagonist” as defined in Paragraph 85 of Vitti and “formulations”:

Q. How many *formulations* suitable for intravitreal administration containing at least 100 mgs per ml of a VEGF-inhibiting fusion protein falling within the scope of Vitti’s VEGF antagonist definition does Vitti disclose to the POSA?

A. None.

EX2046 (Falconer Tr.) at 53:22–54:3 (emphasis added).

Q. The POSA would not have a reasonable expectation of success based upon Vitti in achieving aqueous formulations suitable for intravitreal administration containing at least 100 mgs per ml of a *VEGF-inhibiting fusion protein falling within the scope of Vitti’s VEGF antagonist definition*, correct?

A. That's correct *because the definition is so broad*. Yes.

EX2046 (Falconer Tr.) at 55:21–56:4. I disagree that the cited testimony shows that a skilled formulator would not have been motivated to make or would not have had a reasonable expectation of success in achieving intravitreal formulations with the claimed concentrations of aflibercept.

45. Regarding the first portion of the cited testimony, EX2046 (Falconer Tr.) at 53:22–54:3, I understood the question from Regeneron's counsel as being directed to "formulations" suitable for intravitreal administration containing at least 100 mg/mL of VEGF-inhibiting fusion protein, that is, an express disclosure of the specific types and amounts of excipients included in the composition along with the protein. Although Vitti teaches formulations suitable for intravitreal administration containing at least 100 mg/mL of aflibercept, it does not expressly disclose any compositions containing 100 mg/mL VEGF-inhibiting fusion protein with such specificity other than through its reference to Furfine, EX1007 (Vitti) ¶ 107, which as explained above teaches 100 mg/mL aflibercept formulations suitable for intravitreal administration. Therefore, I confirmed in my testimony that Vitti does not disclose "formulations" suitable for intravitreal administration containing at least 100 mg/mL of VEGF-inhibiting fusion protein that describe in detail the components in the composition.

46. Regarding the second portion of the cited testimony, EX2046 (Falconer Tr.) at 55:21–56:4, I merely explained that because Vitti’s definition of “*VEGF antagonist*” is broad, a skilled formulator would not have a reasonable expectation of success based on Vitti in achieving aqueous formulations suitable for intravitreal administration containing at least 100 mg/mL of *any VEGF-inhibiting antagonist*, including any unspecified VEGF-inhibiting fusion protein, falling within the full scope of that definition. EX2046 (Falconer Tr.) at 55:21–56:4. However, there is a difference between aflibercept, a specific VEGF-inhibiting fusion protein, and “VEGF antagonist” as defined in Vitti, EX1007 (Vitti) ¶¶ 85–86, which I explained in my deposition includes, among other things, a “broad number” of different proteins. EX2046 (Falconer Tr.) at 51:19–52:5 (“... Within the definition of the VEGF antagonists that could be quite a broad number, broad number of different proteins. Yes.”). While a skilled formulator may not have a reasonable expectation of success in achieving an aqueous pharmaceutical formulation suitable for intravitreal administration for *any VEGF antagonist* as defined by Vitti or *any unspecified VEGF-inhibiting fusion protein* at the claimed concentrations, a skilled formulator would have had such an expectation in achieving an aqueous pharmaceutical formulation of *aflibercept* suitable for intravitreal administration at those concentrations. EX1004 (Falconer Decl.) ¶¶ 113–128, 169–178, 182–185.

47. To the extent Regeneron and Dr. Trout imply that this testimony is inconsistent with or contradicts the opinions reflected in my initial Declaration, EX2051 (Trout Decl.) ¶¶ 133, 173; Paper 28 (Patent Owner’s Response) at 8, I disagree. In my initial Declaration, I explained that a skilled formulator would have had a reasonable expectation of success in obtaining an aqueous pharmaceutical *aflibercept* formulation as claimed. EX1004 (Falconer Decl.) ¶¶ 113, 128, 169–178, 182–185, whereas in my deposition, I agreed that because Vitti’s definition of “*VEGF antagonist*” is broad, a skilled formulator would not have a reasonable expectation of success based on Vitti in achieving aqueous formulations suitable for intravitreal administration containing at least 100 mg/mL of *any VEGF-inhibiting fusion protein* falling within the scope of that definition. EX2046 (Falconer Tr.) at 55:21–56:4. Because there is a difference in scope between aflibercept, a specific VEGF antagonist, “VEGF antagonist” as defined in Vitti, and an unspecified VEGF-inhibiting fusion protein, there is no inconsistency or contradiction between my initial Declaration and my deposition testimony. Regardless, I confirmed later in my deposition that based on my analysis of Vitti, it was my opinion that a skilled formulator would have reasonably expected to succeed in obtaining an aflibercept formulation with a concentration of greater than 100 mg/mL, including 114.3 mg/mL. EX2046 (Falconer Tr.) at 226:8–25, 229:15–231:2.

V. RESPONSES TO DR. TROUT AND REGENERON'S COMMENTS REGARDING WRITTEN DESCRIPTION

48. Regeneron asserts incorrectly that I did not understand the written description legal standard that I applied in rendering my written description opinions in this case and that I did not consider information that was well known to the skilled formulator. Paper 28 (Patent Owner's Response) at 66 (citing EX2046 (Falconer Tr.) at 156:9–23, 157:13–19, 160:1–13). I disagree. As I explained in my deposition, I considered and applied what I understand from counsel as factors used to evaluate the sufficiency of disclosure for purposes of satisfying the written description requirement, including (1) the existing knowledge in the particular field, (2) the extent and content of the prior art, (3) the maturity of the science or technology, and (4) the predictability of the claimed method or invention. EX2046 (Falconer Tr.) at 231:18–233:10. I also explained that, in rendering my written description opinions, I considered the full text of the '036 patent from the perspective of and with the background knowledge of a skilled formulator at the time of the alleged invention of the '036 patent. EX2046 (Falconer Tr.) at 233:11–20.

49. Dr. Trout and Regeneron rely on certain portions of my deposition testimony to assert that I agreed the challenged claims are adequately described. EX2051 (Trout Decl.) ¶¶ 238, 261; Paper 28 (Patent Owner's Response) at 67–68. The cited testimony is shown below:

Q. ... There are numerous examples in the patent, both in the figures and in the written description portion describing formulations of aflibercept with at least 100 mgs per ml and viscosities of about 5 to 15 centipoise, correct?

A. Correct.

Q. And the description of those formulations provides adequate written description support for the claims claiming at least 100 mgs per ml of aflibercept with 5 to 15 centipoise viscosity, correct?

A. Correct.

EX2046 (Falconer Tr.) at 179:5–18. That testimony does not reflect the opinion Regeneron and Dr. Trout attribute to me. I only agreed that the examples of the '036 patent specification described *particular* aflibercept formulations with at the identified concentration and viscosity range. Indeed, earlier in the same line of questioning, I agreed that “the '036 patent inventors provided extensive data on viscosities of *particular* high concentration aflibercept formulations in the patent.” EX2046 (Falconer Tr.) at 167:19–23 (emphasis added). But my testimony that the specification describes those *particular* formulations does not mean that the full scope of the claims (which cover a vast number of formulations that achieve the claimed viscosity levels but do not identify specific excipients) was described in the specification (which disclose only a limited subset of specific formulations that achieve the claimed viscosity), EX1004 (Falconer Decl.) ¶¶ 266–276, or that the

specification provides adequate written description for bufferless formulations achieving the claimed viscosity levels and falling within the scope of the claims. EX1004 (Falconer Decl.) ¶¶ 277–286. For example, regarding my opinion that the specification did not provide adequate written description support for bufferless formulations, I testified as follows:

Q. Does the specification of the '036 patent including the examples include any viscosity data for a bufferless, 100 mg per ml aflibercept formulation?

A. No.

Q. Does the specification of the '036 patent including the examples include any viscosity data for a bufferless 114.3 mgs per ml aflibercept formulation?

A. No.

Q. Does the specification of the '036 patent include any examples include any viscosity data for a bufferless 103 to 126 mgs per ml aflibercept formulation?

A. No.

Q. Does the specification of the '036 patent including examples include any viscosity data for any bufferless aflibercept formulation having a concentration of more than 100 mgs per ml of aflibercept?

A. No.

EX2046 (Falconer Tr.) at 234:2–235:9.

50. Dr. Trout and Regeneron also take certain portions of my deposition testimony out of context to assert that I did not have an opinion that claims 31 and 35 lack written description support. EX2051 (Trout Decl.) ¶ 280; Paper 28 (Patent Owner's Response) at 68. The full context of my testimony, including the critical portions that Dr. Trout and Regeneron omitted (emphasized in bold and italics) is shown below:

Q. ... Your written description opinion is directed to claims with no stated upper limit, correct?

A. Correct.

Q. Okay. Claim 31 has a target concentration for aflibercept of 114.3 mgs per ml which inherently contains a stated upper limit for the concentration of aflibercept, correct?

A. Correct.

Q. And you don't have an opinion that claim 31 lacks written description support, correct?

A. Correct.

Q. Claim 35 of the '036 patent recites an aflibercept concentration range of 103 to 126 mgs per ml of aflibercept, correct?

A. Correct.

Q. Claim 35 also has a stated upper limit to aflibercept concentration, correct?

A. Correct.

Q. And you don't have an opinion that claim 35 lacks written description support, correct?

A. Correct.

EX2046 (Falconer Tr.) at 193:6–194:7. However, the cited testimony above concerned only the aspect of my written-description opinions that I was describing related specifically to “claims reciting concentration of at least 100 mgs per ml with no stated upper limit.” EX2046 (Falconer Tr.) at 190:20–25. It has no bearing on my other written-description opinions, such my opinion that specification did not provide adequate written description support for bufferless formulations, as noted above.

VI. ADDITIONAL REMARKS

51. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: September 25, 2026



ROBERT J. FALCONER