IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

IN RE AFLIBERCEPT PATENT LITIGATION **THIS DOCUMENT RELATES TO:** *Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*, Case No. 1:25-cv-74-TSK	MDL No. 1-24-md-3103-TSK

AMGEN INC.'S ANSWER TO COMPLAINT AND COUNTERCLAIMS

September 12, 2025

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ANSWER AND ADDITIONAL DEFENSES OF AMGEN

Amgen Inc. ("Amgen"), Defendant in the above-captioned action, hereby answers the Complaint (the "Complaint") of Plaintiff, Regeneron Pharmaceuticals, Inc. ("Regeneron"), and counterclaims against Regeneron as follows. Each of the paragraphs below corresponds to the same-numbered paragraphs in the Complaint. Headings are included as a matter of organization/formatting consistent with the Complaint, and do not require admitting or denying.

Amgen denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that may arguably follow from the admitted facts. Amgen denies that Regeneron is entitled to the relief requested or to any other relief.

INTRODUCTION

1. Amgen admits that Regeneron markets EYLEA®, which is FDA-approved to treat patients with certain eye diseases. Amgen admits that it sought and obtained FDA approval under the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. §§ 262(k)-(*l*), to commercialize "ABP 938," Amgen's biosimilar of Regeneron's EYLEA product. Amgen admits that it obtained FDA approval to market ABP 938 under the trademark PAVBLU® and that it offers to sell and sells PAVBLU in vials and pre-filled syringes in the United States. Amgen admits that Regeneron purports to bring its Complaint under 35 U.S.C. §§ 271(a), (b), and (c). Amgen lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 1, and on that basis, Amgen denies them.

2. Amgen admits that Regeneron markets EYLEA, and that FDA first approved EYLEA in 2011. Amgen lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 2, and on that basis, Amgen denies them.

3. Amgen admits that the active ingredient in EYLEA is a genetically engineered fusion protein called aflibercept. Amgen admits that the FDA first approved EYLEA in 2011 to treat neovascular (wet) age-related macular degeneration. Amgen admits that the FDA has also approved EYLEA for the treatment of diabetic macular edema, macular edema following retinal vein occlusion, diabetic retinopathy, and retinopathy of prematurity. Amgen lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 3, and on that basis, Amgen denies them.

PLAINTIFF

4. Amgen lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 4, and on that basis, Amgen denies them.

DEFENDANT

5. Amgen admits that Amgen is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen admits that its business is focused on the development of biologic medicines, which includes development of biosimilar medicines, including ABP 938, a biosimilar version of Regeneron's EYLEA product. Amgen denies the remaining allegations of Paragraph 5.

6. Amgen admits that it, directly or indirectly, manufactures drug products in the United States. Amgen admits that it, directly or indirectly, develops, distributes, and sells within the United States, or imports into the United States, Amgen's drug products. Amgen

admits that it has general direction and control over the development, distribution, and sale of its drug products within the United States or importation of its drug products into the United States. Amgen admits that it, directly or indirectly, distributes and sells ABP 938 in the United States, and imports ABP 938 into the United States. Amgen admits that after it received FDA licensure, and after Regeneron's motion for a preliminary injunction was denied, Amgen began offering to sell and selling ABP 938 in the United States under the trademark PAVBLU. Amgen denies the remaining allegations of Paragraph 6.

7. Amgen admits that it, directly or indirectly, manufactures ABP 938, imports ABP 938 into the United States, and sells or offers for sale ABP 938 in the United States. Amgen admits that after it received FDA licensure, and after Regeneron's motion for a preliminary injunction was denied, Amgen began offering to sell and selling ABP 938 in the United States under the trademark PAVBLU. Amgen admits that it has general direction and control over the manufacture, importation, sale, or offer to sell ABP 938. Amgen denies the remaining allegations of Paragraph 7.

8. Amgen admits that it, directly or indirectly, develops, manufactures, distributes, sells, and imports drug products into the United States. Amgen denies the remaining allegations of Paragraph 8.

JURISDICTION AND VENUE

9. Amgen admits that this action arises under 42 U.S.C. § 262(l) and the patent laws of the United States, Title 35 of the Unites States Code. Amgen admits that the United States District Court for the Central District of California, where the Complaint was initially filed, has subject matter jurisdiction over this action. Amgen denies the remaining allegations of Paragraph 9.

10. Amgen admits the allegations of Paragraph 10.

11. Amgen admits the allegations of Paragraph 11.

12. Amgen admits the allegations of Paragraph 12.

13. Amgen admits that the United States District Court for the Central District of California, where the Complaint was initially filed, has personal jurisdiction over Amgen. Amgen admits that it sought and obtained FDA licensure to commercially market ABP 938 in the United States, including in the State of California, and that it is marketing, distributing, and selling ABP 938 under the trademark PAVBLU in the United States, including in the State of California. Amgen admits that after it received FDA licensure, and after Regeneron's motion for a preliminary injunction was denied, Amgen began offering to sell and selling ABP 938 in the United States under the trademark PAVBLU. Amgen denies the remaining allegations of Paragraph 13.

14. Amgen admits that venue for this action is proper in the United States District Court for the Central District of California, where the Complaint was initially filed. Amgen denies the remaining allegations of Paragraph 14.

FACTUAL ALLEGATIONS

15. Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Amgen admits that the BPCIA provides a pathway for the approval of biologic products that are "biosimilar" to previously licensed biologic products. 42 U.S.C. § 262(k). Amgen admits that under 42 U.S.C. § 262(*l*), the BPCIA provides for a series of information exchanges and negotiations between a biosimilar applicant and a Reference Product Sponsor regarding patents and potential litigation concerning patent infringement. Amgen denies the remaining allegations of Paragraph 15.

16. Amgen admits that on October 31, 2023, Amgen publicly announced that FDA had accepted its BLA for ABP 938, a biosimilar version of EYLEA. Amgen denies the remaining allegations of Paragraph 16.

17. Amgen admits that it timely provided to Regeneron its BLA for ABP 938 under 42 U.S.C. § 262(*l*)(2)(A) along with such other information that describes the process or processes Amgen uses to manufacture ABP 938. Amgen admits that it sent a letter to Regeneron agreeing to "proceed to litigation on all the patents identified" in Regeneron's statement pursuant to 42 U.S.C. § 262(*l*)(3)(C). However, in that letter Amgen also informed Regeneron that Amgen "does not agree that Regeneron has any meritorious claims of patent infringement to assert against Amgen." In fact, prior to sending that letter, Amgen notified Regeneron that Regeneron's purported statement under 42 U.S.C. § 262(*l*)(3)(C) provided cursory infringement allegations and, worse yet, for numerous patents, Regeneron completely failed to provide any infringement contentions, instead declaring that Amgen "failed to exclude the possibility" of infringement, improperly purporting to shift the burden of proving non-infringement to Amgen, rather than undertaking to provide any actual infringement contentions as required under § 271(*l*)(3)(C). To obtain timely resolution, however, Amgen agreed to proceed to litigation on the patents in Regeneron's statement pursuant to § 271(*l*)(3)(C). Amgen admits that on January 10, 2024, Regeneron brought an action against Amgen in the United States District Court for the Central District of California seeking a judgment of infringement under 35 U.S.C. § 271(e) (the "First Amgen Action"). Amgen denies the remaining allegations of Paragraph 17.

18. Amgen admits that on April 11, 2024, the U.S. Judicial Panel on Multidistrict Litigation transferred the First Amgen Action to the United States District Court for the

Northern District of West Virginia for coordinated pretrial proceedings with the cases Regeneron filed against Biocon Biologics Inc. ("Biocon"), Samsung Bioepis Co., Ltd. ("Samsung"), Celltrion, Inc. ("Celltrion"), and Formycon AG ("Formycon") that were already pending in that court. Amgen admits that on June 7, 2024, Regeneron filed a motion for preliminary injunction against Amgen. Amgen denies the remaining allegations of Paragraph 18.

19. Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Amgen admits that EYLEA's regulatory exclusivity expired on May 18, 2024. Amgen admits that on August 23, 2024, FDA approved Amgen's ABP 938 to be marketed under the trademark PAVBLU. Amgen admits that Regeneron's motion for a preliminary injunction was denied on September 23, 2024. Amgen admits that after it received FDA licensure, and after Regeneron's motion for a preliminary injunction was denied, Amgen began offering to sell and selling ABP 938 in the United States under the trademark PAVBLU. Amgen denies the remaining allegations of Paragraph 19.

20. Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Amgen admits that, on its face, Patent No. 12,331,099 (the "'099 Patent") indicates that it issued on or about June 17, 2025, and that it is titled "VEGF Antagonist Formulations Suitable for Intravitreal Administration." Amgen denies the remaining allegations of Paragraph 20.

21. Amgen denies the allegations of Paragraph 21 and avers that Regeneron filed a Notice of Potential Tag-Along Action with the U.S. Judicial Panel on Multidistrict Litigation to transfer this action to the United States District Court for the Northern District of West Virginia and consolidate it with MDL No. 1:24-md-3103-TSK for coordinated and consolidated pretrial

proceedings pursuant to 28 U.S.C. § 1407 on July 2, 2025, over two weeks after Regeneron filed the Complaint. The Action was transferred and consolidated with MDL No. 1:24-md-3103-TSK for pretrial proceedings.

CLAIM FOR RELIEF

COUNT 1: ALLEGED INFRINGEMENT OF U.S. PATENT NO. 12,331,099 UNDER 35 U.S.C. § 271(A), (B), AND (C)

22. Amgen incorporates by reference all of its responses set forth above as if fully set forth below. Amgen denies any "Infringement of U.S. Patent No. 12,331,099", as alleged in the title preceding Paragraph 22.

23. Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer is required, Amgen admits that, on its face, the '099 Patent indicates that it was issued on June 17, 2025, and that Regeneron purports to attach a copy of the '099 Patent as Exhibit 4 to the Complaint. Amgen denies the remaining allegations of Paragraph 23.

24. Amgen lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 24, and on that basis, denies the allegations of Paragraph 24.

25. Amgen lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 25, and on that basis, denies the allegations of Paragraph 25.

26. Amgen admits that after it received FDA licensure, and after Regeneron's motion for a preliminary injunction was denied, Amgen began offering to sell and selling ABP 938 in the United States under the trademark PAVBLU. Amgen admits that it offers for sale and sells ABP 938 in the United States under the trademark PAVBLU. Amgen denies the remaining allegations of Paragraph 26.

27. Amgen denies the allegations of Paragraph 27.

28. Amgen denies the allegations of Paragraph 28.

29. Amgen admits that it is aware of the ’099 Patent, and Amgen denies the remaining allegations of Paragraph 29.

30. Amgen denies the allegations of Paragraph 30.

31. Amgen denies the allegations of Paragraph 31.

32. Amgen denies the allegations of Paragraph 32.

33. Amgen denies the allegations of Paragraph 33.

34. Amgen denies the allegations of Paragraph 34.

PRAYER FOR RELIEF

35. Amgen denies each and every allegation, averment, and request for relief contained in Regeneron’s Prayer For Relief.

GENERAL DENIAL

36. To the extent that any allegations of the Complaint are not specifically admitted, Amgen hereby denies them.

ADDITIONAL DEFENSES

37. Amgen asserts the following additional defenses and other defenses and reserves the right to amend its Answer to assert further additional defenses as more information becomes available. In asserting the defenses below, Amgen does not assume any burden it would otherwise not have.

FIRST ADDITIONAL DEFENSE
(Failure to State a Claim)

38. Regeneron’s Complaint fails to state a claim on which relief can be granted.

SECOND ADDITIONAL DEFENSE
(Non-Infringement)

39. Amgen does not infringe and has not infringed (directly, contributorily, or by inducement), either literally or under the doctrine of equivalents, and is not liable for infringement of any valid and enforceable claim of the '099 Patent.

THIRD ADDITIONAL DEFENSE
(Invalidity)

40. The '099 Patent is invalid for failure to satisfy the conditions of patentability set forth in 35 U.S.C. §§ 1 *et seq*., including sections 101, 102, 103, 112, 115, 116, 119, 132, 251, 256, and/or 282, or under other judicially created bases for invalidation.

FOURTH ADDITIONAL DEFENSE
(Equitable Doctrines)

41. Regeneron's claim of patent infringement is barred in whole or in part by the equitable doctrines of waiver, estoppel, and/or unclean hands.

FIFTH ADDITIONAL DEFENSE
(Prosecution History Estoppel)

42. Regeneron's claims of patent infringement under the doctrine of equivalents, if any, are barred in whole or in part by the doctrine of prosecution history estoppel and/or prosecution disclaimer.

SIXTH ADDITIONAL DEFENSE
(No Injunction)

43. Regeneron is not entitled to an injunction with respect to the '099 Patent under any theory, because the claims of the '099 Patent are invalid, unenforceable and not infringed and Regeneron has not suffered and will not suffer irreparable harm, Regeneron is not without an adequate remedy at law, and public policy concerns weigh against injunctive relief.

SEVENTH ADDITIONAL DEFENSE
(Not an Exceptional Case)

44. Even if Regeneron were entitled to any remedy, it would not be entitled to a finding that this case is exceptional warranting attorney's fees under 35 U.S.C. § 285, or pursuant to the Court's inherent power.

EIGHTH ADDITIONAL DEFENSE
(Limitation on Damages Under 35 U.S.C. § 287)

45. On information and belief, Regeneron has failed to mark articles in accordance with the requirements of 35 U.S.C. § 287. Regeneron's claim is barred or limited under 35 U.S.C. § 287.

NINTH ADDITIONAL DEFENSE
(Costs Barred Under 35 U.S.C. § 288)

46. Regeneron's demand for costs is barred or limited under 35 U.S.C. § 288.

TENTH ADDITIONAL DEFENSE
(Lack of Standing)

47. Regeneron lacks standing to assert the '099 Patent.

ELEVENTH ADDITIONAL DEFENSE
(Prosecution Laches)

48. Amgen incorporates by reference the foregoing paragraphs as if fully set forth herein.

49. The '099 Patent is not enforceable against Amgen based on the doctrine of prosecution laches. Regeneron unreasonably and inexcusably delayed filing and prosecuting the claims of the '099 Patent asserted against Amgen. While the '099 Patent claims priority to U.S. Provisional Application No. 60/814,484 ("the '484 Provisional"), Regeneron delayed

pursuing the claims of the ’099 Patent for over eighteen years after the ’484 Provisional was filed on June 16, 2006. Regeneron and Regeneron’s counsel filed the application for ’099 Patent seeking claims that allegedly encompass buffer-free ophthalmic formulations only after: (i) Amgen invested significant resources into the development of a buffer-free aflibercept formulation; (ii) upon information and belief, Regeneron and its counsel became aware of Amgen’s published patent application describing buffer-free aflibercept formulations, U.S. Application No. 16/764,463 and/or its counterparts such as PCT Publication No. WO2019/099921 (collectively, the “’463 Application”); (iii) Regeneron and its counsel became aware of the components of Amgen’s PAVBLU formulation; (iv) the United States District Court for the Northern District of West Virginia denied Regeneron’s motion for a preliminary injunction based on related U.S. Patent No. 11,084,865 (the “’865 Patent”); and (v) the United States Court of Appeals for the Federal Circuit (“Federal Circuit”) denied Regeneron’s motion for an injunction pending appeal of the United States District Court for the Northern District of West Virginia’s denial of Regeneron’s motion for preliminary injunction.

50. Regeneron’s delay in filing the claims of the ’099 Patent has prejudiced Amgen, which has invested significant resources into the development of a buffer-free aflibercept formulation and obtained FDA approval for the first buffer-free fusion protein formulation. No buffer-free aflibercept formulation was publicly disclosed in the patent application prior to Amgen’s investment of those resources.

TWELFTH ADDITIONAL DEFENSE
(No Willful Infringement)

51. Amgen has not and will not intentionally, willfully or deliberately infringe any claim of the ’099 Patent.

THIRTEENTH ADDITIONAL DEFENSE

(Inequitable Conduct)

52. Amgen incorporates by reference the foregoing paragraphs as if fully set forth herein.

53. The ’099 Patent is unenforceable due to inequitable conduct before the U.S. Patent and Trademark Office (“USPTO”).

54. The following individuals are subject to a duty to disclose information material to the patentability of claims under examination: (1) each inventor named in the application; (2) each attorney or agent who prepares or prosecutes the application; and (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application.

55. At least those persons materially involved in the prosecution of the ’099 Patent, including Regeneron’s counsel, Ms. Nickols, Mr. Lewis, Mr. Marsh, Ms. Ho, and any other counsel for Regeneron who directed prosecution strategy (collectively, “Regeneron’s Counsel”), are subject to a duty to disclose information material to the patentability of the ’099 Patent claims to the USPTO.

Regeneron’s Counsel Misrepresented to the USPTO that the Inventors of the ’865 Patent Also Invented the Subject Matter Claimed in the ’099 Patent

56. Regeneron’s Counsel engaged in inequitable conduct at least by misrepresenting to the USPTO the inventorship of the claimed subject matter of the ’099 Patent and by falsely asserting that the claims of the ’099 Patent did not present new matter beyond the description in the originally filed application.

57. On October 23, 2024, when Regeneron’s Counsel filed the application for the ’099 Patent, Ms. Nickols signed an Application Data Sheet identifying Eric Furfine, Daniel Dix,

Kenneth Graham, and Kelly Frye as the inventors of the subject matter claimed in the application, including claims allegedly encompassing a buffer-free aflibercept formulation.

58. Rather than submitting to the USPTO oaths or declarations from Eric Furfine, Daniel Dix, Kenneth Graham, and Kelly Frye pursuant to 35 U.S.C. § 115 averring that they authorized the application and believed themselves to be original joint inventors of the subject matter claimed in the application, Regeneron's Counsel instead resubmitted declarations that were signed by those individuals in February 2014 and were previously submitted during prosecution of U.S. Application No. 13/914,996 (the "'996 Application"). The '996 Application is related to the '099 Patent but did not contain claims allegedly encompassing a buffer-free aflibercept formulation.

59. The '996 Application claimed only formulations requiring a phosphate buffer, and the '996 Application neither described nor claimed the formulations allegedly claimed in the '099 Patent, which as written do not recite a buffer.

60. On information and belief, Regeneron's Counsel was aware that the inventors listed for the '099 Patent did not invent any buffer-free aflibercept formulations.

61. On information and belief, Regeneron's Counsel was aware that employees of Amgen, not Regeneron, were the true inventors of buffer-free aflibercept formulations.

62. When filing the application for the '099 Patent on October 23, 2024, Ms. Nickols presented a preliminary amendment adding new claims that as written do not recite a buffer. Ms. Nickols represented to the USPTO that "[n]o new matter enters by way of the present amendments." Preliminary Amendment dated October 23, 2024 in '099 Patent File History at 9. On information and belief, Regeneron's Counsel, including Ms. Nickols, knew that the '099 Patent does not disclose any buffer-free formulations and for at least that reason, knew that the

new claims did not present new matter and the statement to the contrary was materially false and misleading.

63. While the ’099 Patent claims priority to the ’484 Provisional, which was filed on June 16, 2006, Regeneron did not file the application for ’099 Patent until October 23, 2024, over eighteen years after the earliest priority application.

64. Prior to the filing of the application for the ’099 Patent, Regeneron brought suit against Amgen alleging infringement of a parent patent to the ’099 Patent, the ’865 Patent, in *Regeneron Pharms., Inc. v. Amgen Inc.*, MDL No. 24-md-03103-TSK-JPM (N.D.W. Va.) (defined above as the “First Amgen Action”). The claims of the ’865 Patent all require a VEGF antagonist (e.g., aflibercept) and a buffer.

65. In the First Amgen Action, Regeneron filed a motion for a preliminary injunction against Amgen based on the ’865 Patent. In support of its preliminary injunction motion, Regeneron argued that there was a reasonable likelihood of success because Amgen’s buffer-free ABP 938 product infringed the claims of the ’865 Patent.

66. “[T]he parties’ central dispute [was] whether the Asserted Claims require that the ‘VEGF antagonist’ and the ‘buffer’ be separate and distinct components of the claimed formulation.” *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343, at 27 (N.D.W. Va. Sept. 23, 2024). “Regeneron argue[d] that the VEGF antagonist [i.e., aflibercept] can also satisfy the limitation of the claimed buffer.” *Id.* In opposing Regeneron’s preliminary injunction motion, “Amgen propose[d] that the Asserted Claims require that the claimed ‘VEGF antagonist’ and the claimed ‘buffer’ be separate components.” *Id.*

67. The United States District Court for the Northern District of West Virginia denied Regeneron’s application for a preliminary injunction, holding that “Regeneron has not shown a

reasonable likelihood of success on the merits because Amgen has raised a substantial question of noninfringement based on the specific formulation of Amgen's proposed biosimilar product." *See id.* at 2. That decision was affirmed on appeal by the United States Court of Appeals for the Federal Circuit in *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372 (Fed. Cir. 2025).

68. The application for the '099 Patent was filed after: (i) Regeneron's motion for a preliminary injunction in the First Amgen Action was denied by the United States District Court for the Northern District of West Virginia on September 23, 2024; and (ii) Regeneron's motion for an injunction pending appeal was denied by the United States Court of Appeals for the Federal Circuit on October 22, 2024.

69. Upon information and belief, Regeneron's Counsel was aware of Amgen's buffer-free ABP 938 formulation before filing the application for the '099 Patent. On August 23, 2024, prior to the filing of the application for the '099 Patent, the FDA published its approval letter for Amgen's ABP 938 product, which was the first ever FDA-approved buffer-free aflibercept product. When Amgen's ABP 938 product was approved, the product label, which identified the components in the formulation, became publicly available. Upon information and belief, Regeneron's Counsel was aware of Amgen's product label and the components of Amgen's ABP 938 product, prior to filing the application for the '099 Patent. Upon information and belief, Regeneron's Counsel used information about Amgen's product label and the components of Amgen's ABP 938 product in drafting the claims of the '099 Patent.

70. On information and belief, before filing the application for the '099 Patent, Regeneron's Counsel was also aware of Amgen's research on buffer-free aflibercept formulations, which were disclosed in public patent filings. Amgen scientists invented a buffer-

free aflibercept formulation as reflected in, for example, Amgen's '463 Application, which published on October 29, 2020—fourteen years after the earliest claimed priority date of the '099 Patent. Amgen's '463 Application later issued as U.S. Patent No. 12,156,900. On information and belief, Regeneron's Counsel was aware of the '463 Application before filing the application for the '099 Patent.

71. The application for the '099 Patent was also filed after Regeneron and Regeneron's Counsel became aware that the United States District Court for the Northern District of West Virginia had denied Regeneron's motion for a preliminary injunction against Amgen involving the parent '865 Patent ("Order Denying PI") (filed under seal on September 23, 2024 and filed publicly with redactions on October 1, 2024). The application was also filed after the United States Court of Appeals for the Federal Circuit denied Regeneron's motion for an injunction pending appeal on October 22, 2024 ("Order Denying PI Pending Appeal"). Upon information and belief, Regeneron's Counsel understood that the Order Denying PI Pending Appeal could potentially lead to Amgen launching its ABP 938 product.

72. On information and belief, Regeneron's Counsel identified Eric Furfine, Daniel Dix, Kenneth Graham and Kelly Frye as the inventors of the '099 Patent despite being aware of the Order Denying PI and Order Denying PI Pending Appeal. Further, Regeneron's Counsel filed the declarations alleging that Eric Furfine, Daniel Dix, Kenneth Graham and Kelly Frye were inventors of the subject matter claimed in the '099 Patent despite being aware of the Order Denying PI and Order Denying PI Pending Appeal.

73. In the Order Denying PI, the Court found that Regeneron failed to show a reasonable likelihood of success in proving that Amgen's ABP 938 formulation infringes the

’865 Patent, because Amgen’s product lacks the claimed buffer. *See In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 (N.D.W. Va. Sept. 23, 2024).

74. In its Order Denying PI, the Court found that “[t]here is no dispute that, in every example and every embodiment in the ’865 Patent, the formulation is described as containing both a VEGF antagonist and a separate buffer.” *Id*. at 45-46; *see also id*. at 50 (“[T]he ’865 patent does not exemplify or suggest that the aflibercept can satisfy both the ‘VEGF antagonist’ and ‘buffer’ limitations, and every example and embodiment includes a buffer that is separate from, and present in addition to, the aflibercept.”). Regeneron did not cite “any contrary examples or embodiments in the specification indicating that the VEGF antagonist could serve as the buffer.” *Id*. at 46.

75. The Court found that “there appears to be no factual dispute that, as of June 2006, there were no formulations of any fusion protein (or aflibercept specifically) or any intravitreal protein formulation that lacked a separate buffer.” *Id*. at 65.

76. The Order Denying PI also rejected Regeneron’s reliance on extrinsic evidence. *Id.* at 57. Regeneron had argued that using aflibercept as a buffer was so “well known in the art” that no description in the specification was necessary for a person of ordinary skill in the art to understand that the claimed VEGF antagonist can serve as the separately claimed “buffer.” *Id.* The Court rejected this argument and found that “none of the extrinsic evidence discloses that aflibercept can function as a buffer in a pharmaceutical formulation, let alone in a manner that indicates this was so well known such that disclosure in the patent was not needed, as Regeneron argues.” *Id*. at 62-63.

77. The only reference on which Regeneron relied that disclosed buffer-free pharmaceutical compositions was a patent publication, entitled “Self-Buffering Protein

Formulations," which published as WO 2006/138181 (the "Gokarn Application"). The Gokarn Application was and is assigned to Amgen and published on December 28, 2006—more than six months after the claimed priority date of Regeneron's '865 Patent. It therefore did not and could not reflect the knowledge of a person of ordinary skill in the art as of that claimed priority date. *See In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 at 66-69 (N.D.W. Va. Sept. 23, 2024).

78. Indeed, in the context of prior proceedings involving the '865 Patent or during prosecution of other Regeneron patent applications, public statements made by the named inventors confirm that those individuals did not invent a buffer-free aflibercept formulation. For example, Dr. Daniel Dix, an inventor of the '865 Patent, submitted a declaration to the USPTO in June 2009 purporting to describe the importance of the specific buffer system he selected for an aflibercept formulation claimed in a different patent application filed March 22, 2006. Dix Declaration in U.S. App. No. 11/387,256, June 8, 2009. Dr. Dix stated: "In order to formulate the VEGF Trap at about pH 5.9 to about 6.5, a buffer system needed to be chosen that had significant buffering capacity in that range," and that "[i]n order to have a good buffering capacity, . . . a combination of phosphate and citrate (5 mM each) was used." *Id*. ¶ 7. Similarly, during the bench trial in *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 22-cv-61 (N.D.W. Va.), Dr. Eric Furfine, another inventor of the '865 Patent, testified that he "invented the use of a phosphate buffer in this formulation to stabilize aflibercept." Trial Tr. Day 3, June 14, 2023, at 543:6-7. Upon information and belief, Regeneron's Counsel was aware of these statements when prosecuting the application that led to the '099 Patent. The Dix Declaration was not submitted to the USPTO during prosecution of the '099 Patent.

79. By resubmitting the same inventor declarations from the ’996 Application and naming the same inventors on the Application Data Sheet, Regeneron’s Counsel falsely represented to the USPTO that Eric Furfine, Daniel Dix, Kenneth Graham and Kelly Frye invented the subject matter allegedly encompassed by the claims of the ’099 Patent, *i.e.* liquid ophthalmic formulations comprising aflibercept that do not contain a separate buffer. No inventor oath was submitted in which the named inventors averred that they were original and joint inventors of the subject matter newly claimed in the application for the ’099 Patent.

80. Pursuant to 35 U.S.C. § 101, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” Further, pursuant to 35 U.S.C. § 115(a), “[e]ach individual who is the inventor or a joint inventor of a claimed invention in an application for patent shall execute an oath or declaration in connection with the application.” 35 U.S.C. § 116 provides that “[w]hen an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath.”

81. The misrepresentations by Regeneron’s Counsel regarding inventorship and lack of new matter were material to patentability. The USPTO would not have issued the ’099 Patent to Regeneron without the submission of the false inventor declarations, which misrepresented that Eric Furfine, Daniel Dix, Kenneth Graham, and Kelly Frye were inventors of subject matter claimed in the ’099 Patent. The USPTO also would not have issued the ’099 Patent had the Examiner been apprised by Regeneron and its counsel that the claims encompassed new matter not supported by the original specification.

The Prosecution History of the ’099 Patent Reflects that Regeneron’s Counsel Acted with a Specific Intent to Deceive the USPTO

82. The prosecution history of the ’099 Patent evinces that Regeneron’s Counsel misrepresented the true inventors of the ’099 Patent with a specific intent to deceive the USPTO.

83. The timing of the filing of the application for the ’099 Patent reflects that Regeneron’s Counsel acted with a specific intent to deceive the USPTO. Regeneron did not seek to obtain the claims of the ’099 Patent for the first eighteen years after the earliest priority application. Less than one month after the issuance of the Order Denying PI in the First Amgen Action and one day after the issuance of the Order Denying PI Pending Appeal, however, Regeneron’s Counsel filed the application for the ’099 Patent with a request for expedited examination under the Patents for Humanity Program. Upon information and belief, they did so with specific knowledge of Amgen’s invention of a buffer-free aflibercept formulation.

84. In prosecuting the ’099 Patent, Regeneron delayed in disclosing information relating to the First Amgen Action and Amgen’s development of a buffer-free formulation. This delay reflects that Regeneron’s Counsel acted with a specific intent to deceive the USPTO. When Regeneron’s Counsel filed the application for the ’099 Patent, it did not submit an Information Disclosure Statement to the USPTO disclosing any material information. When Regeneron’s Counsel filed the application for the ’099 Patent, however, on information and belief, Regeneron’s Counsel was aware of at least: (i) the ongoing litigation between Regeneron and Amgen; (ii) the Order Denying PI; (iii) the publicly available label for Amgen’s ABP 938 product; (iv) the identity of the components in Amgen’s ABP 938 product; and (v) Amgen’s ’463 Application relating to buffer-free aflibercept formulations. Regeneron’s

Counsel, however, failed to disclose any of items (i)-(v) to the USPTO when they filed the application for the ’099 Patent.

85. On November 29, 2024, the USPTO issued an Office Action in connection with the application for the ’099 Patent. Regeneron’s Counsel submitted a response to that office action on January 30, 2025. When Regeneron’s Counsel submitted its response on January 30, 2025, Regeneron’s Counsel did not submit an Information Disclosure Statement to the USPTO disclosing any material information. For example, Regeneron’s Counsel failed to submit, at least: (i) the ongoing litigation between Regeneron and Amgen; (ii) the September 2024 Order Denying PI; (iii) the publicly available label for Amgen’s ABP 938 product; (iv) the identity of the components in Amgen’s ABP 938 product; and (v) Amgen’s ’463 Application relating to buffer-free aflibercept formulations published in October 2020.

86. The Examiner signed a Notice of Allowance on February 6, 2025. Only after this Notice of Allowance was issued did Regeneron’s Counsel submit an Information Disclosure Statement. On February 17, 2025, Regeneron’s Counsel submitted an Information Disclosure Statement containing over 600 references to the USPTO. The February 17, 2025 Information Disclosure Statement did not include a disclosure of, at least: (i) the ongoing litigation between Regeneron and Amgen; (ii) the September 2024 Order Denying PI; (iii) the publicly available label for Amgen’s ABP 938 product; (iv) the identity of the components in Amgen’s ABP 938 product; and (v) Amgen’s ’463 Application relating to buffer-free aflibercept formulations published in October 2020.

87. On February 18, 2025, Regeneron’s Counsel submitted another Information Disclosure Statement, including, among other things, decisions from other district court proceedings involving the ’865 Patent. The February 18, 2025 Information Disclosure

Statement did not include a disclosure of, at least: (i) the ongoing litigation between Regeneron and Amgen; (ii) the September 2024 Order Denying PI; (iii) the publicly available label for Amgen's ABP 938 product; (iv) the identity of the components in Amgen's ABP 938 product; and (v) Amgen's '463 Application relating to buffer-free aflibercept formulations published in October 2020. Regeneron's Counsel did not disclose the Order Denying PI in an Information Disclosure Statement until April 3, 2025, after receiving another Notice of Allowance.

88. On information and belief, during prosecution of the application for the '099 Patent, Regeneron's Counsel became aware of the Federal Circuit's March 14, 2025 opinion affirming the Court's Order Denying PI ("Federal Circuit Order Affirming Denial of PI"). The Federal Circuit Order Affirming Denial of PI was a unanimous and precedential opinion in which the Federal Circuit "agree[d] with the district court that '[l]ike the claims, the specification of the '865 Patent uniformly describes the 'VEGF antagonist' and the 'buffer' as separate and distinct components of the formulation.'" *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372, 1381 (Fed. Cir. 2025) (quoting *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 (N.D.W. Va. Sept. 23, 2024)). On information and belief, Regeneron's Counsel became aware of these statements from the Federal Circuit Order Affirming Denial of PI around the time that the order was issued.

89. The Federal Circuit determined that the Court correctly recognized that "[t]he specification does not suggest that the VEGF antagonist can be a buffer or vice versa," and "Regeneron has not identified any such disclosure." *Id*. at 1382 (quoting *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 (N.D.W. Va. Sept. 23, 2024)).

90. The Federal Circuit confirmed that "[t]he specification makes clear what 'the inventors actually invented and intended to envelop,' . . . and that is, a formulation containing a

VEGF antagonist *plus* a distinct buffer." *Id*. at 1383 (emphasis in original) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc)).

91. The Federal Circuit emphasized that "the specification describes a formulation containing a VEGF antagonist plus a distinct buffer component" and that "that understanding is reinforced consistently throughout the specification, which 'includes eight example formulations and twenty-two (22) embodiments, each of which describes the VEGF antagonist (aflibercept) plus a buffer.'" *Id*. at 1382 (quoting *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 (N.D.W. Va. Sept. 23, 2024)).

92. The Federal Circuit Court of Appeals concluded that, "[a]dditionally, it was reasonable for the district court to determine that, given the proximity of [the Gokarn Application's] publication date to the '865 [P]atent's filing date, the reference actually supports Amgen's contention that self-buffering proteins were not well known and that '[the Gokarn Application] **advanced the art** over the '865 [P]atent precisely by disclosing certain buffer-free formulations in which the therapeutic protein is itself capable of maintaining pH stability.'" *Id*. at 1384 (emphasis added) (quoting, in part, Amgen's Brief in Opposition to Regeneron's Motion for Preliminary Injunction at 51). Thus, as the Federal Circuit concluded, it was Amgen, not Regeneron, that pioneered the invention of buffer-free therapeutic protein formulations.

93. Upon information and belief, Regeneron's Counsel became aware of the March 14, 2025 Federal Circuit Order Affirming Denial of PI around the time that the order issued, and by no later than April 2, 2025, when Regeneron's Counsel paid the issue fee for the '099 Patent. That order further confirmed for Regeneron's Counsel that the inventors named in the '099 Patent did not invent a buffer-free aflibercept formulation allegedly encompassed by the claims

of that patent. Despite being aware of the Federal Circuit Order Affirming Denial of PI, Regeneron's Counsel proceeded to pay the issue fee without filing an Information Disclosure Statement disclosing the Federal Circuit Order Affirming Denial of PI to the USPTO. Only after paying the issue fee did Regeneron's Counsel submit a Quick Path Information Disclosure Statement on April 3, 2025 to the USPTO with the Federal Circuit Order Affirming Denial of PI. When Regeneron's Counsel did submit the Federal Circuit Court of Appeals Order Affirming Denial of PI, it did so along with other voluminous Court decisions, including decisions favorable to Regeneron that concerned buffer-containing aflibercept formulations (not buffer-free aflibercept formulations) that were previously disclosed to the USPTO in the February 18, 2025 Information Disclosure Statement. Regeneron's Counsel did not specifically draw the Examiner's attention to the Federal Circuit Order Affirming Denial of PI, despite the highly relevant nature of the findings in that order.

94. On information and belief, Regeneron's Counsel was not in possession of any evidence to support that (i) the alleged inventors of the '099 Patent conceived of or reduced to practice a liquid ophthalmic formulation containing a VEGF antagonist without an excipient buffer, (ii) the alleged inventors of the '099 Patent ever invented a liquid ophthalmic formulation containing a VEGF antagonist without an excipient buffer, or (iii) the specification of the '099 Patent in any way described an aflibercept formulation without an excipient buffer. Yet, Regeneron's Counsel proceeded to petition for issuance of the '099 Patent. In summary, the following and foregoing facts support that the '099 Patent is unenforceable due to inequitable conduct.

95. **Individuals with a duty of candor**. Regeneron's Counsel and the named inventors are subject to a duty of candor to the USPTO.

96. **Material Misrepresentation.** Regeneron's Counsel misrepresented that the same inventors of the '865 Patent invented the subject matter claimed in the '099 Patent, which as written recite aflibercept formulations that do not include a buffer. Despite the court findings that the inventors of the '865 Patent did not disclose in the identical specification any buffer-free aflibercept formulation, and that Amgen "advanced the art" by developing such buffer-free formulations, Regeneron's Counsel misrepresented the inventors of the '865 Patent as the inventors of such buffer-free formulations. Regeneron's Counsel submitted an Application Data Sheet and re-submitted inventor declarations falsely identifying Eric Furfine, Daniel Dix, Kenneth Graham, and Kelly Frye as inventors of the subject matter claimed in the '099 Patent. Additionally, Regeneron's Counsel failed to disclose statements from the inventors confirming that they believed an excipient buffer was necessary to an aflibercept formulation. Regeneron's Counsel also falsely stated that the claim amendments presented in the application for the '099 Patent did not add new matter. But for these material misrepresentations, the USPTO would not have issued the '099 Patent.

97. **Specific intent to deceive**. Regeneron's Counsel acted with a specific intent to deceive the USPTO. Regeneron's Counsel filed the application for the '099 Patent under an accelerated examination program despite failing to pursue the claimed subject matter for over eighteen years after the filing of the earliest priority application. Upon information and belief, Regeneron's Counsel filed the application for the '099 Patent only after learning of Amgen's ABP 938 formulation and '463 Application relating to buffer-free aflibercept formulations. Additionally, Regeneron's Counsel filed the application for the '099 Patent only after receiving adverse decisions in the First Amgen Action. Regeneron's Counsel filed the application for the '099 Patent without an Information Disclosure Statement and without informing the USPTO of

at least the adverse decisions from the First Amgen Action. Rather, Regeneron's Counsel waited until after obtaining a Notice of Allowance from the USPTO before disclosing the Order Denying PI, along with numerous other references. Further, Regeneron's Counsel did not disclose the Federal Circuit Order Affirming Denial of PI to the USPTO before paying the issue fee for the '099 Patent. Only after paying the issue fee did Regeneron's Counsel submit the Federal Circuit Order Affirming Denial of PI to the USPTO with a Quick Path Information Disclosure Statement, and even then Regeneron's Counsel buried the Federal Circuit Order Affirming Denial of PI with other more favorable orders that had already been disclosed to the USPTO. Regeneron's Counsel knew that the contents of the Federal Circuit Order Affirming Denial of PI are highly material to the patentability of the then-pending claims of the '099 Patent. These acts of delay and omission were intentional and performed with the specific intent to mislead the USPTO into granting the claims of the '099 Patent, without the benefit of the highly material information within the court orders.

98. Accordingly, the '099 Patent is unenforceable due to inequitable conduct.

FOURTEENTH ADDITIONAL DEFENSE
(Patent Misuse)

99. Amgen incorporates by reference the preceding paragraphs in Amgen's Counterclaims as if fully set forth herein.

100. Regeneron's claims of patent infringement are barred, in whole or in part, by the doctrine of patent misuse.

101. As reflected in paragraphs 53-97 above, which are incorporated herein by reference, Regeneron engaged in inequitable conduct to procure the '099 Patent. For at least the reasons relating to Regeneron's egregious misconduct and abuse of the patent system by filing and prosecuting the '099 Patent and the reasons relating to Regeneron's inequitable conduct,

Regeneron's claims of patent infringement are barred in whole or in part by the doctrine of patent misuse.

102. Regeneron's claims of infringement of the '099 Patent are barred in whole or in part under the doctrine of patent misuse because Regeneron impermissibly broadened the scope of the '099 Patent to include claims that Regeneron knew to be invalid. Regeneron impermissibly broadened the scope of the application for the '099 Patent by filing a preliminary amendment on October 23, 2024 that presented claims allegedly encompassing Amgen's novel buffer-free formulation, which is not described in the patent specification and was not invented by the individuals named as inventors. Regeneron prosecuted those claims to issuance despite knowing they are invalid. Regeneron filed the Complaint in this matter in bad faith to harass and further attempt to deter Amgen, and other potential competitors, as part of an egregious misuse of the patent system. Regeneron is seeking to enforce the '099 Patent—a patent Regeneron knows is not valid—for the improper purpose of attempting to remove Amgen's competitive product from the market and forcing Amgen to commit time and resources to defending a baseless allegation of patent infringement.

103. Regeneron unreasonably and inexcusably delayed pursuing the claims of the '099 Patent for over eighteen years after filing the earliest claimed priority application, the '484 Provisional filed June 16, 2006. Regeneron and Regeneron's Counsel filed the application for the '099 Patent seeking claims allegedly encompassing buffer-free ophthalmic formulations only after: (i) Amgen invested significant resources into the development of a buffer-free aflibercept formulation; (ii) upon information and belief, Regeneron's counsel became aware of the components of Amgen's PAVBLU formulation and Amgen's '463 Application disclosing buffer-free aflibercept formulations; (iii) the United States District Court for the Northern

District of West Virginia issued the Order Denying PI involving the related ’865 Patent; and (iv) the Federal Circuit issued the Order Denying PI Pending Appeal.

104. Upon information and belief, Regeneron’s Counsel pursued claims allegedly encompassing a buffer-free aflibercept formulation despite knowing that (i) the listed inventors on the ’099 Patent did not invent buffer-free ophthalmic formulations comprising a VEGF antagonist; and (ii) the specification contains no disclosures supporting such an invention.

105. Upon information and belief, Regeneron and Regeneron’s Counsel were aware that the claims of the ’099 Patent are invalid and never should have been issued by the USPTO because the claims fail to meet the requirements of at least 35 U.S.C. § 112 for lack of written description support and lack of enablement.

106. As set forth in paragraphs 49-50, Regeneron’s and Regeneron’s Counsel’s delay in filing the application for ’099 Patent and Regeneron’s Counsel’s deceptive conduct during prosecution constitute an egregious misuse of the statutory patent system. As courts have recognized, facts giving rise to prosecution laches “constitutes an egregious misuse of the statutory patent system.” *Personalized Media Comm’ns, LLC v. Apple Inc.*, 57 F.4th 1346, 1354 (Fed. Cir. 2023); *see also Miracor Medical SA v. Abbott Labs.*, No. 23-cv-16257, 2024 WL 4487294, at *2 (N.D. Ill. Oct. 7, 2024) (“[T]he patents are barred by prosecution laches based on an unreasonable and unexplained delay of over ten years in the prosecution process with the United States Patent and Trademark Office (USPTO) constituting an egregious misuse of the statutory patent system.”).

107. As of June 16, 2006, when the ’484 Provisional was filed at the USPTO, the listed inventors of the ’099 Patent had neither invented nor possessed any buffer-free ophthalmic formulations comprising a VEGF antagonist. The specification of the ’099 Patent includes no

disclosure that would inform the person of ordinary skill in the art that the inventors possessed the claimed buffer-free aflibercept formulations. Likewise, without any guidance in the specification or in the art about how to make buffer-free protein formulations, the person of ordinary skill in the art would have had to engage in undue experimentation to make a buffer-free liquid ophthalmic formulation of a VEGF antagonist that is able to maintain the claimed pH range and stability.

108. As such, by prosecuting the claims of the '099 Patent, Regeneron and Regeneron's Counsel impermissibly broadened the scope of the '099 Patent to include claims that they knew to be invalid and unenforceable. *See Bayer CropSci. AG v. Dow AgroSci. LLC*, No. 10-cv-1045, 2011 WL 6934557, at *4 (D. Del. Dec. 30, 2011) ("all Defendant [is] required to allege" to maintain a patent misuse claim at the pleading stage is that plaintiff "was enforcing a patent it knew was invalid, unenforceable, and/or not infringed"); *CMC Materials, LLC v. DuPont de Nemours, Inc.*, No. 20-738-GBW, Dkt. 218 at 19 (D. Del. Nov. 13, 2023) (denying motion to dismiss patent misuse because defendant adequately alleged "that the [asserted] Patent was fraudulently procured and invalid, and that CMC knew of the fraud").

109. Regeneron's infringement claims are also "objectively baseless" because "no reasonable litigant could realistically expect success on the merits." *See Nalco Co. v. Turner Designs, Inc.*, No. 13-cv-02727, 2014 WL 645365, at *10 (N.D. Cal. Feb. 19, 2024) (quoting *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993)).

110. No reasonable litigant could conclude that Regeneron's infringement claim is reasonably likely to succeed, at least because the claims of the '099 Patent lack written description support and are not enabled, which is confirmed by the Order Denying PI and the Federal Circuit Order Affirming Denial of PI. *See Miracor Med. SA v. Abbott Labs.*, No. 23-cv-

16257, 2024 WL 4487294, at *3 (N.D. Ill. Oct. 7, 2024) (denying motion to strike patent misuse defense where "Defendants assert that Plaintiff improperly drafted the six Asserted Patents to cover Defendants' [] device" and "Defendants contend that Plaintiff knew the Asserted Patents were invalid and pursued them anyway in bad faith"). Further, no reasonable litigant could conclude that Regeneron's infringement claim is reasonably likely to succeed, because the claims are unenforceable against Amgen under the doctrine of prosecution laches.

111. On information and belief, Regeneron brought its infringement claim to harass Amgen, and obtain another opportunity to remove Amgen's PAVBLU product from the market. Regeneron knows, knew, or should have known that the claims of the '099 Patent are invalid and/or unenforceable, and nevertheless brought this action against Amgen in bad faith for the improper purpose of obtaining another opportunity to exclude Amgen from the market and restrict rightful competition. Regeneron's enforcement of the '099 Patent against Amgen is an egregious misuse of the statutory patent system.

COUNTERCLAIMS OF AMGEN

Pursuant to Federal Rule of Civil Procedure 13, Amgen counterclaims against Regeneron and, in support thereof, alleges the following:

I. INTRODUCTION

1. These counterclaims concern an illegal scheme by Regeneron to foreclose biosimilar competition for 2 milligram ("mg") versions of EYLEA® (aflibercept), an anti-vascular endothelial growth factor ("VEGF") agent, administered by intravitreal injection, which is manufactured and sold in the United States by Regeneron. EYLEA has been approved by the FDA for sale in the United States since 2011, and is indicated for the treatment of a range of serious angiogenic eye diseases, including neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy.

2. Regeneron has a long-standing, highly profitable monopoly over 2 mg aflibercept-based anti-VEGF treatments. Regeneron may have initially obtained its monopoly lawfully, but as described herein, it is attempting to maintain or reclaim its monopoly through anticompetitive, unlawful means directed at Amgen.

3. As the first company to market aflibercept in the United States, Regeneron was afforded a period of statutory exclusivity of twelve-and-a-half years, from November 18, 2011 to May 17, 2024, during which no other company could market an aflibercept biosimilar in the United States, pursuant to the framework established by the Biologics Price Competition and Innovation Act ("BPCIA"). At the time of its launch, and for many years following, the primary anti-VEGF treatments available in the United States to treat angiogenic eye diseases, besides EYLEA, were bevacizumab (sold under the brand name AVASTIN®), an off-label treatment, and ranibizumab (sold under the brand name LUCENTIS®). In part due to the superior efficacy

and safety profile of aflibercept as compared to AVASTIN and LUCENTIS, EYLEA, as the only aflibercept-based anti-VEGF treatment on the market, rapidly became the dominant treatment, while commanding a significant price premium over other available treatments.

4. That dominant position has been and remains highly profitable for Regeneron. Since its launch, EYLEA has consistently been Regeneron's most successful and valuable product, generating enormous and supracompetitive revenues and profits for the company. Since 2013, EYLEA's annual sales in the United States have consistently been above $1 billion, and above $3 billion since 2016. EYLEA's sales have also consistently represented a substantial percentage of Regeneron's total sales in every year since it launched. In 2012, the year after its launch, EYLEA's U. S. sales represented over 50% of Regeneron's total revenues. In 2023 and 2024, Regeneron earned over $5.8 billion and $5.9 billion, respectively, from EYLEA sales in the United States, representing over 40% of Regeneron's total sales in each of those years. Moreover, more recently, Regeneron has been using its 2 mg EYLEA as a pathway, or launch pad, to convert patients to its 8 mg EYLEA HD product.

5. Pursuant to the framework of the BPCIA, EYLEA's market dominance in the market for 2 mg versions of aflibercept would eventually be put at risk by the potential emergence of aflibercept biosimilars, following the expiration of EYLEA's statutory exclusivity. Generally, a biosimilar is a pharmaceutical product approved by the FDA that (a) is made from the same types of sources (here, living cells or microorganisms) as the reference product (here, EYLEA); (b) has been determined by the FDA to have the same treatment risks and benefits as the reference product; and (c) is administered in the same strength and dosage as the reference

product (here, 2 mg).[1] Studies have shown that competition from biosimilar products can benefit patients and providers by having an impact on their acquisition costs. This is by statutory design—the BPCIA, enacted approximately 1.5 years before EYLEA's commercial launch, was intended to provide a pathway for biosimilar entry in order to "promote competition, reduce healthcare costs, and increase access to biologic therapies by introducing biosimilar treatment options for already FDA-approved reference products."[2]

6. Pursuant to and in accordance with the BPCIA, Amgen launched its 2 mg aflibercept biosimilar product, PAVBLU, in October 2024, after Regeneron's motion to preliminarily enjoin PAVBLU's launch was denied by this Court (the Order Denying PI, referenced earlier) and Regeneron failed to convince the Federal Circuit to impose a further stay on PAVBLU's launch pending appeal of that denial (the Order Denying PI Pending Appeal, also referenced earlier). Amgen prevailed in those proceedings—including, ultimately before the Federal Circuit Court of Appeals (via the aforementioned Federal Circuit Order Affirming Denial of PI), due to the unique buffer-free formulation that Amgen discovered and invented while developing its aflibercept biosimilar, thereby eliminating the need for an excipient buffer (*i.e.*, a buffer comprised of an inactive ingredient), like the kind present in Regeneron's EYLEA formulation and required by the patent upon which Regeneron sought a preliminary injunction.

7. As the first and only aflibercept biosimilar competitor to EYLEA in the United States—and one with unique benefits such as a silicone oil-free pre-filled syringe and a vial version with a longer shelf life—PAVBLU presents an acute and growing threat to EYLEA's

[1] *See* U.S. Food & Drug Admin., Biosimilars Basics for Patients, *available at* https://www.fda.gov/drugs/biosimilars/biosimilars-basics-patients (last accessed on Sept. 12, 2025).

[2] *See* U.S. Food & Drug Admin., Commemorating the 15th Anniversary of the Biologics Price Competition and Innovation Act, *available at* https://www.fda.gov/drugs/cder-conversations/commemorating-15th-anniversary-biologics-price-competition-and-innovation-act (last accessed on Sept. 12, 2025).

dominance in the 2 mg aflibercept market. Since entering that market, PAVBLU, over time and through great effort and expense, has been able to establish key relationships with retinal specialists, and educate patients and retinal specialists about PAVBLU and its safety and efficacy. PAVBLU continues to make inroads with practice groups, providers, and patients. As a result, PAVBLU has been growing its share of the relevant market, finally creating competitive pressure on EYLEA in the relevant market, to the benefit of patients and providers.

8. Regeneron has responded to the threat of aflibercept biosimilar competition, and specifically competition from PAVBLU, through anticompetitive means. In particular, Regeneron has sought to maintain or re-acquire its highly profitable monopoly in the 2 mg aflibercept market through the enforcement of fraudulently-procured patents.

9. First, starting no later than 2012, Regeneron set out to broaden its set of aflibercept-related patents by defrauding the USPTO into issuing at least twelve aflibercept-related patents that the USPTO would not have issued but for Regeneron's fraudulent conduct. Then, in early 2024, as EYLEA's statutory exclusivity neared expiration, Regeneron asserted its twelve fraudulently-obtained patents against Amgen (the "2024 Litigation"), as well as other aflibercept biosimilar manufacturers. To this day, Regeneron continues to assert those twelve fraudulently-procured patents against Amgen, seeking a permanent injunction that would exclude PAVBLU from the market altogether.

10. Second, immediately after the Federal Circuit's administrative stay against the launch of PAVBLU was lifted, Regeneron once again set out to defraud the USPTO into issuing an aflibercept formulation patent, but this time one—the '099 Patent—that was specifically tailored as an attempt to remove PAVBLU from the market.. As described more above and below, Regeneron did so by, among other things, falsely representing—upon information and

belief, knowingly and willfully—to the USPTO that Regeneron invented the novel buffer-free formulation used by PAVBLU and purportedly claimed in the '099 Patent, and engaging in tactics that, upon information and belief, were intended to, and in fact did, make it substantially likely the Patent Examiner would not review and consider the decisions from this Court and the Federal Circuit making clear that Regeneron was not in fact the inventor of Amgen's buffer-free innovation. The '099 Patent would not have issued but for Regeneron's fraud. Then, on the day that the '099 Patent issued, Regeneron filed the instant lawsuit—upon information and belief, with knowledge of the '099 Patent's fraudulent procurement—seeking to enforce the fraudulently-procured '099 Patent against Amgen. The assertion of the fraudulently-procured '099 Patent constitutes an independent anticompetitive act by Regeneron, targeted at excluding PAVBLU, Regeneron's only 2 mg aflibercept rival, and thus protecting or reclaiming its monopoly in the 2 mg aflibercept market..

11. Regeneron's purpose and intent in asserting these fraudulently-procured patents has been to try to stop PAVBLU from competing in the relevant market against EYLEA, thereby removing the only real threat to EYLEA's market dominance. Specifically, Regeneron's anticompetitive conduct is designed to maintain EYLEA's monopolistic position in the market for 2 mg aflibercept-based anti-VEGF treatments or to recreate that monopoly position, which PAVBLU is increasingly challenging. Before PAVBLU's entry, EYLEA maintained 100% of the market for 2 mg aflibercept-based anti-VEGF treatments. PAVBLU's launch brought competition to this market for the very first time, expanding patient choice and lowering prices. Notwithstanding that, Regeneron has consistently maintained a share of at least 70% of that market and is actively engaged in anticompetitive tactics to thwart the burgeoning competition from PAVBLU, as described herein. If Regeneron were successful in marginalizing or

eliminating PAVBLU through the anticompetitive conduct described herein, Regeneron would fortify and expand its monopolist position in the relevant market, for 2 mg aflibercept treatments, to the detriment of patients, providers, and competition, as well as Amgen.

12. For the reasons set forth herein, Regeneron's assertion of the twelve fraudulently-procured patents, described below, in the 2024 Litigation, as well as, Regeneron's assertion of the fraudulently-procured '099 Patent in the instant lawsuit, each constitutes independent violations of Section 2 of the Sherman Act and of California's Unfair Competition Law.

II. PARTIES

13. Amgen is an American multinational biopharmaceutical corporation existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

14. Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry to fight some of the world's most debilitating diseases.

15. Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that dramatically improve people's lives, while also reducing the social and economic burden of disease. Amgen helped launch the biotechnology industry more than 40 years ago and has grown to be one of the world's leading independent biotechnology companies.

16. Amgen's biosimilars business is committed to building on Amgen's experience in the development, manufacture, and distribution of biological medicines.

17. Regeneron is an American biotechnology corporation organized and existing under the laws of the State of New York with its principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

III. JURISDICTION AND VENUE

18. Amgen's Counterclaims arise under the patent laws of the United States, 35 U.S.C. § 101 *et seq*., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, Federal Antitrust Laws, 15 U.S.C. §§ 1, 2, and 1125, and California state law.

19. The United States District Court for the Central District of California (the "C.D. Cal. Court"), where Regeneron filed the Complaint in this Action, has subject matter jurisdiction under 28 U.S.C. §§ 1331 (federal question), 1337 (commerce and antitrust regulations), 2201(a), and 2202. The United States District Court for the Northern District of West Virginia (the "N.D.W. Va. Court"), where this Action was transferred, by order dated July 17, 2025, to be consolidated with MDL No. 3103, also has subject matter jurisdiction pursuant to the same foregoing provisions. The C.D. Cal. Court and the N.D.W. Va. Court have supplemental jurisdiction over Amgen's state law claims pursuant to 28 U.S.C. § 1367.

20. In the alternative, the C.D. Cal. Court and N.D.W. Va. Court have subject matter jurisdiction over the case under 28 U.S.C. § 1332 because there is complete diversity of citizenship among the parties and the amount in controversy, without interest and costs, exceeds $75,000.

21. The C.D. Cal. Court has personal jurisdiction over Regeneron because Regeneron has submitted to its personal jurisdiction by filing the Complaint in that Court, in response to which Amgen has filed these Counterclaims. The N.D.W. Va. Court has personal jurisdiction over Regeneron because Regeneron has submitted to the personal jurisdiction of the N.D.W. Va. Court by petitioning the Judicial Panel on Multidistrict Litigation ("JPML") to consolidate the instant Action with the pending MDL in the N.D.W. Va, which was granted by order dated July 17, 2025.

22. The C.D. Cal. Court and N.D.W. Va. Court also have personal jurisdiction over Regeneron because Regeneron regularly transacts and solicits business in both the State of California and the State of West Virginia.

23. Venue is proper in the Central District of California under 28 U.S.C. § 1391 because Regeneron submitted to venue in that district by filing the Complaint in the C.D. Cal. Court. Venue is also proper in the Northern District of West Virginia under 28 U.S.C. §§ 1391 and 1407 because Regeneron submitted to the venue of the N.D.W. Va. Court by petitioning the JPML to consolidate the instant action, which gave rise to these Counterclaims, with the pending MDL in N.D.W. Va. Such petition was granted by order dated July 17, 2025.

IV. FACTUAL ALLEGATIONS

A. Statutory Background

24. Biologics, which are manufactured using living organisms, are groundbreaking medicines used to treat a range of complex and debilitating illnesses. The Biologics Price Competition and Innovation Act ("BPCIA") provides a regulatory path for FDA approval of "biosimilar" versions of biologic drugs.

25. Under 42 U.S.C. § 262(a), a biologic manufacturer must submit a Biologic License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") before it can market its drug. 42 U.S.C. § 262(a). The FDA may grant the BLA if, among other things, the manufacturer has demonstrated that the biologic is "safe, pure, and potent." *Id.* § 262(a)(2)(C)(i)(I).

26. To balance innovation and price competition, the BPCIA established a streamlined development and application pathway for biosimilars to gain FDA approval and enter the market after the original manufacturer enjoys a period of statutory exclusivity. *Id.* § 262(k).

27. Under the BPCIA's streamlined pathway, an applicant can submit a BLA, also known as a subsection (k) application, that "reference[s]" another company's (the "sponsor's") previously approved biologic (the "reference product"). *Id.* § 262(i)(4). The FDA evaluates the abbreviated application ("aBLA") against the reference product and approves it if the applicant's product is "biosimilar to [the] reference product," meaning that it is "highly similar to the reference product" and there are "no clinically meaningful differences" between the two products with respect to "safety, purity, and potency." *Id.* §§ 262(i)(2)(A), (B), (k)(2)(A)(i)(I).

28. To help ensure that companies will continue investing in the development and approval of new biologics, a biosimilar manufacturer may not submit an aBLA until four years after the reference product is first licensed, and an aBLA may not be approved until twelve years after the reference product is first licensed. *Id.* § 262(k)(7). Thus, a sponsor of an approved reference product (the "reference product sponsor" or "RPS") enjoys a statutory period of at least twelve-years without biosimilar competition. Certain products are granted an additional six months' exclusivity (twelve-and-a-half years total) if the manufacturer conducts studies into the drug's pediatric uses. 21 U.S.C. § 355a(b)(1).

29. Moreover, the BPCIA established a patent-dispute-resolution regime by amending the Patent Act to create an artificial "act of infringement" and to allow infringement suits based on the submission of an application for a biosimilar license prior to FDA approval and prior to marketing of the biological product. *See* 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6).

30. The BPCIA also established a multi-step process for information exchanges between the biosimilar applicant and the RPS and a process to facilitate resolution of patent disputes (the "BPCIA information exchange process"). *See* 42 U.S.C. § 262(*l*). Under that process, the biosimilar applicant may grant the RPS confidential access to a copy of its aBLA

and "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application" no later than 20 days after the FDA notifies the applicant that its accepted the application for review. *Id.* § 262(*l*)(1)-(2). The parties then exchange lists of patents for which they contend a claim of patent infringement could reasonably be asserted by the RPS, if any, as well as their respective positions on infringement, validity, and enforceability of those patents. *Id.* § 262(*l*)(3). Following that exchange, the parties are required to negotiate a list of patents that would be the subject of an immediate infringement action, *id.* § 262(*l*)(4)-(5), solely for the purpose of immediately addressing material patent disputes, after which the RPS may sue the biosimilar applicant within 30 days, *id.* § 262(*l*)(6). This early litigation process is designed to enable a biosimilar applicant to address material patent disputes immediately, so as to avoid unnecessary delay in entering the market. *See id.* § 262(*l*)(7)-(8). Importantly, while the biosimilar applicant has the opportunity under the BPCIA to identify enforceability issues, the applicant cannot avoid the negotiation and agreement process prescribed by the BPCIA, even if the applicant believes the patents to have been procured inequitably and/or by fraud.

B. Regeneron Launches 2 mg EYLEA, the First Aflibercept-Based Treatment for Angiogenic Eye Diseases.

31. Regeneron is the holder of BLA No. 125387 for EYLEA, which the FDA first approved on November 18, 2011. EYLEA is an ophthalmic drug product that has been used to treat patients suffering from angiogenic diseases (*i.e.*, related to forming new blood vessels in the eye) that can cause vision loss or blindness. Regeneron initially developed EYLEA for treating wet Age-Related Macular Degeneration ("wAMD"). The active ingredient in EYLEA is the fusion protein aflibercept, a vascular endothelial growth factor ("VEGF") inhibitor. The EYLEA formulation contains 40 mg/mL aflibercept, 10 mM sodium phosphate, 40 mM sodium chloride,

0.03% polysorbate 20, and 5% sucrose, pH at 6.2. After the November 2011 FDA approval of EYLEA, the product was launched into the U.S. marketplace. Following its initial FDA approval, Regeneron tested EYLEA on patients with other angiogenic eye disorders, ultimately obtaining approval for EYLEA's use to treat those conditions as well.

32. As the first company to market aflibercept in the United States, Regeneron was afforded a period of statutory exclusivity of twelve-and-a-half years, from November 18, 2011 to May 17, 2024, during which no manufacturer could get the requisite FDA approval to market an aflibercept biosimilar in the United States, pursuant to the framework established by the BPCIA. At the time of its launch and in the years immediately following, the primary anti-VEGF treatments available in the United States to treat angiogenic eye diseases, besides EYLEA, were bevacizumab (sold under the brand name AVASTIN), an off-label treatment, and ranibizumab (sold under the brand name LUCENTIS). In part due to the superior efficacy and safety profile of aflibercept as compared to AVASTIN and LUCENTIS, EYLEA, as the only aflibercept-based anti-VEGF treatment, rapidly became the dominant treatment in the space, while commanding a significant price premium over other available treatments.

33. Since its launch, EYLEA has been Regeneron's most successful product, generating enormous revenues and profits for the company year over year. Since 2013, EYLEA's sales in the United States have consistently been above $1 billion annually, and above $3 billion annually since 2016. EYLEA's sales have also consistently represented a substantial percentage of Regeneron's total sales in every year since it launched. In 2012, the year after its launch, EYLEA's U.S. sales represented over 50% of Regeneron's total revenues. In 2023 and 2024, Regeneron earned over $5.8 billion and $5.9 billion, respectively, from EYLEA sales in the United States, representing over 40% of Regeneron's total revenue in each of those years.

34. In more recent years, Regeneron has focused on developing and promoting a 8 mg version aflibercept-based product, which it launched in August 2023 under the brand name EYLEA HD. Regeneron has described EYLEA HD as a strategic imperative for the company—as Regeneron's leadership put it, the company's strategy is to "move this market to" EYLEA HD as "the new standard of care" in anti-VEGF treatment.[3] Regeneron's stated strategy is to use 2 mg EYLEA as a pathway, or launch pad, to convert patients to EYLEA HD,[4] for which there are currently no biosimilars with FDA approval on the market or ready to launch.

35. Reflecting the reality that EYLEA HD sales are more valuable to Regeneron than 2 mg EYLEA sales, on information and belief, Regeneron surreptitiously pulled its application for a 16-week (longer duration) dosing label for 2 mg EYLEA for the treatment of diabetic retinopathy when it learned that EYLEA HD would be approved by the FDA, ensuring that EYLEA HD would be the only aflibercept option on the market with 16-week dosing in its label.[5] Meanwhile, Regeneron's leadership has touted the benefits of EYLEA HD. For example, at Regeneron's Q1 2025 earnings call, Marion McCourt stated, "[i]f approved, in RVO EYLEA HD would be the first and only treatment that can be dosed up to every eight weeks, which is

[3] *Regeneron Pharmaceuticals, Inc. (REGN) Management Presents at 2023 Wells Fargo Healthcare Conference (Transcript)*, Seeking Alpha (Sep. 6, 2023 at 13:46 ET), https://seekingalpha.com/article/4633426-regeneron-pharmaceuticals-inc-regn-management-presents-at-2023-wells-fargo-healthcare.

[4] *Id.*

[5] *EYLEA (aflibercept) Injection sBLA for Every 16-week Dosing Regimen in Patients with Diabetic Retinopathy Accepted for FDA Review*, PR Newswire (Jun. 29, 2022 at 7:30 ET), https://www.prnewswire.com/news-releases/eylea-aflibercept-injection-sbla-for-every-16-week-dosing-regimen-in-patients-with-diabetic-retinopathy-accepted-for-fda-review-301577424.html?utm_source=chatgpt.com.

twice as long as any other product in the category."[6] Regeneron has thus been "laser-focused on growing EYLEA HD adoption."[7]

C. Regeneron Recognizes the Threat to EYLEA Posed by 2 mg Aflibercept Biosimilar Competition.

36. Pursuant to the framework of the BPCIA, EYLEA's market dominance in the market for 2 mg versions of aflibercept would eventually be put at risk by the potential emergence of aflibercept biosimilars, following the expiration of EYLEA's statutory exclusivity. Generally, a biosimilar is a pharmaceutical product approved by the FDA that (a) is made from the same source (here, aflibercept) as the reference product (here, living cells or microorganisms); (b) has been determined by the FDA to have the same treatment risks and benefits as the reference product; and (c) is administered in the same strength and dosage as the reference product (here, 2 mg).[8] Studies have shown that competition from biosimilar products can benefit patients and providers by having an impact on their acquisition costs. .

37. This is by statutory design—indeed, the BPCIA, enacted approximately 1.5 years before EYLEA's commercial launch, was intended to provide a pathway for biosimilar entry in order to "promote competition, reduce healthcare costs, and increase access to biologic therapies by introducing biosimilar treatment options for already FDA-approved reference products."[9]

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[6] Statement by Marion McCourt, Regeneron Pharmaceuticals Inc. Executive Vice President – Commercial, during Q1 2025 Earnings Call (Apr. 29, 2025).

[7] Statement by Marion McCourt, Regeneron Pharmaceuticals Inc. Executive Vice President – Commercial, during Q4 2024 Earnings Call (Feb. 4, 2025).

[8] *See Biosimilars Basics for Patients*, U.S. Food & Drug Admin. (last updated Aug. 1, 2024), https://www.fda.gov/drugs/biosimilars/biosimilars-basics-patients.

[9] *See Commemorating the 15th Anniversary of the Biologics Price Competition and Innovation Act*, U.S. Food & Drug Admin. (last updated Mar. 26, 2025), https://www.fda.gov/drugs/cder-conversations/commemorating-15th-anniversary-biologics-price-competition-and-innovation-act.

38. While beneficial to patients and providers, aflibercept biosimilar competition posed, and poses, a particularly significant threat to Regeneron in that it puts at risk the massive revenues and supracompetitive profits that Regeneron has long enjoyed from sales of 2 mg EYLEA, as described above. In addition, Regeneron has indicated that it perceives 2 mg aflibercept biosimilar competition as making it more difficult for Regeneron to use its 2 mg product as a springboard to grow patient adoption and use of EYLEA HD. Reflecting this view, Regeneron's leadership has explained that, "the longer you have without [2 mg aflibercept] biosimilars . . . the longer the runway to convert patients" to EYLEA HD,[10] for which there are no FDA approved biosimilars. Regeneron's statements reflect the fact that patients who have already made the switch to EYLEA HD are unlikely to switch back to the 2 mg formulation, whereas patients who have not yet converted from EYLEA to EYLEA HD are more at risk of being lost to biosimilar competition.

D. Regeneron Fraudulently Secures Numerous Patents Prior to the End of Statutory Exclusivity, and Eventually Asserts Them Against Amgen.

39. Regeneron's anticompetitive scheme to prolong the dominance of its EYLEA franchise started around when Regeneron launched EYLEA in 2011. Specifically, as early as 2012, Regeneron set out to broaden its set of aflibercept-related patents by defrauding the USPTO into issuing a dozen aflibercept-related patents that the USPTO would not have issued but for Regeneron's fraudulent conduct. As detailed below, Regeneron procured these patents by making false and misleading statements and omissions of material fact to the USPTO—on information and belief, knowingly and willfully—on which the USPTO Examiners assigned to

[10] *Regeneron Pharmaceuticals, Inc. (REGN) Management Presents at 2023 Wells Fargo Healthcare Conference (Transcript)*, Seeking Alpha (Sep. 6, 2023 at 13:46 ET), https://seekingalpha.com/article/4633426-regeneron-pharmaceuticals-inc-regn-management-presents-at-2023-wells-fargo-healthcare.

those patent applications justifiably relied in incorrectly issuing those patents. These patents would not have issued but for Regeneron's misrepresentations and omissions. Subsequently, as described below, Regeneron asserted these fraudulently-procured patents against Amgen in the 2024 Litigation.

40. Regeneron's first patent relating to aflibercept was issued on July 4, 2006. That patent, a composition of matter patent for the molecule later named aflibercept (issued as U.S. Patent No. 7,070,959 ("the '959 Patent"), provided Regeneron patent protection through June 16, 2023—*i.e.*, the '959 Patent was set to expire before the end of Regeneron's statutory exclusivity for EYLEA. Because it expired before the end of statutory exclusivity, the '959 Patent did not give Regeneron what it ultimately wanted—protection for EYLEA from the aflibercept biosimilar competition that, upon information and belief, Regeneron anticipated would start entering the market following the end of EYLEA's statutory exclusivity period. In an attempt to obtain that protection, Regeneron resorted instead to obtaining a number of additional patents by fraud, which it could then use to block entry into the market by aflibercept biosimilar competitors.

41. Regeneron's procurement of fraudulent patents before the expiration of statutory exclusivity gave Regeneron more opportunities to assert claims in an attempt to stymie, deter, delay, and increase the costs incurred by aflibercept biosimilar competitors, such as Amgen in advance of their entry into the market upon the expiration of EYLEA's statutory exclusivity.

42. Regeneron would go on to assert these fraudulently-procured patents against Amgen in the 2024 Lawsuit. But that was not the end of it— as described further below, when Regeneron failed to prevent the entry into the market of Amgen's product PAVBLU, Regeneron

returned to its earlier strategy and obtained another patent—the '099 Patent—by fraud on the USPTO, which it then sought to assert against Amgen in this Action.

43. Prior to the expiration of statutory exclusivity for EYLEA, Regeneron fraudulently obtained, and subsequently asserted against Amgen, the following patents:

	Patent No.	App Filed	Patent Issued	Title	Inventors
1	9,254,338	07/12/13	02/09/16	Use of a VEGF antagonist to treat angiogenic eye disorders	Yancopoulos
2	10,130,681	03/28/17	11/20/18	Use of a VEGF antagonist to treat angiogenic eye disorders	Yancopoulos
3	10,828,345	10/12/18	11/10/20	Use of a VEGF antagonist to treat angiogenic eye disorders	Yancopoulos
4	10,888,601	04/29/19	01/12/21	Use of a VEGF antagonist to treat angiogenic eye disorders	Yancopoulos
5	11,707,506	06/17/21	07/25/23	Use of a VEGF antagonist to treat angiogenic eye disorders	Yancopoulos
6	11,253,572	06/21/21	02/22/22	Use of a VEGF antagonist to treat angiogenic eye disorders	Yancopoulos
7	11,306,135	08/30/21	04/10/22	Anti-VEGF protein compositions and methods for producing the same	Wang, Li, Chen, Bhalla
8	11,459,374	02/08/22	10/04/22	Anti-VEGF protein compositions and methods for producing the same	Tustian, Vartak, Daly, Pyles, Palackal, Wang, Li
9	11,505,593	02/08/22	11/22/22	Anti-VEGF protein compositions and methods for producing the same	Wang, Li, Chen, Bhalla
10	11,559,564	05/10/22	01/24/23	Use of a VEGF antagonist to treat angiogenic eye disorders	Yancopoulos
11	11,542,317	06/16/22	01/03/23	Anti-VEGF protein compositions and methods for producing the same	Wang, Li, Chen, Bhalla
12	11,753,459	07/06/22	09/12/23	Anti-VEGF protein compositions and methods for producing the same	Wang, Li, Chen, Bhalla, Lawrence, Johnson, Casey, Grapel

44. As detailed below, Regeneron obtained these patents by making false and misleading statements and omissions of material fact—upon information and belief, knowingly and willfully, with the intent to mislead and deceive—to the USPTO. The USPTO Examiners

justifiably relied on the representations and information provided (or not provided) by Regeneron, and but for Regeneron's fraudulent conduct, the patents would not have issued. Regeneron perpetrated this fraud through patent prosecution counsel, who, upon information and belief, was being instructed by Regeneron's in-house counsel and/or senior executives including, at a minimum, board co-chair, President, and Chief Scientific Officer George D. Yancopoulos.

45. In this way, Regeneron sought and obtained by fraud patents on methods of treatment for using aflibercept, various processes purportedly relating to the manufacture of aflibercept, and formulations relating to aflibercept.

46. Each of the patents discussed below was secured by fraud, for at least the reasons discussed below. Regeneron's efforts were extensive and pervasive, and evidence a wider underlying scheme to mislead, manipulate, and commit fraud on the USPTO. As presented in the order listed in the table above, Regeneron subsequently asserted—and continues to assert—all of these fraudulently-obtained patents against Amgen.

1. Regeneron Fraudulently Obtained the '338 and '681 Patents

47. The '338 and '681 Patents concern the "Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders."

48. Regeneron fraudulently obtained these patents by failing to disclose prior art, upon information and belief, of which it was aware, during the prosecution of the patents—upon information and belief, knowingly and willfully—with the intent to mislead and deceive the USPTO. The prior art contained the same dosing regimen set forth in the claims of the '338 and '681 Patents and their respective applications, disclosure of which would have prevented the issuance of the '338 and '681 Patents. As such, to ensure issuance of the patents, Regeneron intentionally omitted material information in its submissions to the USPTO.

49. The following individuals representing Regeneron are subject to a duty to disclose information material to the patentability of claims under examination: (1) each inventor named in the application; (2) each attorney or agent who prepares or prosecutes the application; and (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application.

50. Dr. George Yancopoulos, Chief Scientific Officer and President of Regeneron, is listed as the sole named inventor of the '338 and '681 Patents, and all other patents in the same patent family. In representing Regeneron before the USPTO, Dr. Yancopoulos failed to disclose at least the following Regeneron documents (collectively, the "Withheld References") with the intent to mislead and deceive the USPTO:

- U.S. Securities and Exchange Commission, Form 10-K, Regeneron Pharmaceuticals, Inc. (February 27, 2008) ("Regeneron 10-K 27-Feb-2008");
- Press Release, Regeneron, Regeneron and Bayer Healthcare Announce Encouraging 32-Week Follow-Up Results From a Phase 2 Study of VEGF Trap-EYE in Age-Related Macular Degeneration (Apr. 28, 2008) ("Regeneron 28-Apr-2008");
- U.S. Securities and Exchange Commission, Form 10-Q, Regeneron Pharmaceuticals, Inc. (May 2, 2008) ("Regeneron 10-Q 2-May-2008");
- U.S. Securities and Exchange Commission, Form 10-Q, Regeneron Pharmaceuticals, Inc. (August 1, 2008) ("Regeneron 10-Q 1-Aug-2008");
- Press Release, Regeneron, Regeneron and Bayer Healthcare Announce VEGF Trap-Eye Achieved Durable Improvement in Vision Over 52 Weeks in a Phase 2 Study in Patients with Age Related Macular Degeneration (Aug. 19, 2008) ("Regeneron 19-Aug-2008");
- U.S. Securities and Exchange Commission, Form 10-Q, Regeneron Pharmaceuticals, Inc. (November 5, 2008) ("Regeneron 10-Q 5-Nov-2008");

- U.S. Securities and Exchange Commission, Form 10-K, Regeneron Pharmaceuticals, Inc. (February 26, 2009) ("Regeneron 10-K 26-Feb-2009");

- Press Release, Regeneron Pharmaceuticals, Inc., Bayer and Regeneron Extend Development Program for VEGF Trap-Eye to Include Central Retinal Vein Occlusion (Apr. 30, 2009) ("Regeneron 30-Apr-2009");

- U.S. Securities and Exchange Commission, Form 10-Q, Regeneron Pharmaceuticals, Inc. (August 4, 2009) ("Regeneron 10-Q 4-Aug-2009");

- Press Release, Regeneron, Enrollment Completed in Regeneron and Bayer HealthCare Phase 3 Studies of VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration (Wet AMD) (Sept. 14, 2009) ("Regeneron 14-Sept-2009");

- U.S. Securities and Exchange Commission, Form 10-Q, Regeneron Pharmaceuticals, Inc. (Nov. 3, 2009) ("Regeneron 10-Q 3-Nov-2009");

- Press Release, Regeneron Pharmaceuticals, Inc., VEGF Trap-Eye Shows Positive Results in a Phase 2 Study in Patients With Diabetic Macular Edema, (Feb. 18, 2010) ("Regeneron 18-Feb-2010"); and

- U.S. Securities and Exchange Commission, Form 10-Q, Regeneron Pharmaceuticals, Inc. (April 29, 2010) ("Regeneron 10-Q 29-Apr-2010").

51. During the prosecution of the '338 Patent, Dr. Yancopoulos also failed to disclose the following:

- Press Release, Regeneron, VEGF Trap-Eye Final Phase 2 Results in Age-related Macular Degeneration Presented at 2008 Retina Society Meeting (Sept. 28, 2008) ("Regeneron 28-Sept-2008").

52. Each of the aforementioned documents was published prior to the earliest claimed priority dates of the patent applications and is evidence of prior art that would have been relevant to the '338 and '681 Applications pursuant to 35 U.S.C. § 102.

53. Given that the aforementioned references are Regeneron's own publications and disclosures, Dr. Yancopoulos, as Chief Scientific Officer and President of Regeneron, knew about them and knew of their materiality to the claims Regeneron was pursuing, but Regeneron

failed to disclose them to the USPTO. Further, Dr. Yancopoulos knew about these references because many of them contain quotations directly from him regarding the prior art.

54. For example, Regeneron 28-Sept-2008 reads: "'These study results confirm the rationale for our Phase 3 clinical program for VEGF Trap-Eye in wet AMD,' said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. 'These trials are designed to optimize improvement in visual acuity with fixed-dosing regimens of either every 4 weeks or every 8 weeks for one year and then study how these vision improvements can be maintained with as-needed dosing in the second year.'" Regeneron Press Release, "VEGF Trap-Eye Final Phase 2 Results in Age-related Macular Degeneration Presented at 2008 Retina Society Meeting", Sept. 28, 2008, at 1.

55. Similarly, Regeneron 28-Apr-2008 reads: "'These study results further increase our confidence in the design of our Phase 3 clinical program for VEGF Trap-Eye in wet AMD,' said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. 'These studies are evaluating the clinical efficacy and safety of VEGF Trap-Eye, using a monthly loading dose of 0.5 mg or 2.0 mg for 12 weeks, followed by a nine-month fixed-dosing regimen of 0.5 mg monthly, 2.0 mg monthly, or 2.0 mg every eight weeks. In the second year of the studies, all patients will be dosed on a PRN basis.'" Regeneron Press Release, "Regeneron and Bayer Healthcare Announce Encouraging 32-Week Follow-Up Results From a Phase 2 Study of VEGF Trap-EYE in Age-Related Macular Degeneration", Apr. 28, 2008, at 1.

56. The Withheld References and Regeneron 28-Sept-2008 were material to the patentability of the claims of the '338 and '681 Patents because the references disclose the same dosing regimen set forth in the claims of those patents and their respective applications filed with the USPTO.

57. On June 15, 2015 and April 3, 2017, the Patent Examiner rejected Regeneron's applications for the '338 and '681 Patents, respectively, in Non-Final Office Actions. In response to the rejections, Regeneron relied on the dosing regimen described in Heier et al., "Intravitreal Aflibercept (VEGF Trap-Eye) in Wet Age-Related Macular Degeneration, Ophthalmology," 119(12), pg. 2537-2548 (2012) ("Heier 2012") and the results of human clinical trials reported in Heier 2012, stating that "[t]he studies summarized in the Heier et al. paper correspond to the clinical trials disclosed in Example 4 of the present application" and that "[t]he results clearly show that by administering the VEGF antagonist in accordance with a dosage regimen as claimed in independent claims 1 and 21, it is possible to treat angiogenic eye disorders such as AMD." '338 Patent Prosecution History, Office Action Response, Sept. 11, 2015, at 7); '681 Patent Prosecution History, Office Action Response, June 25, 2018, at 9.

58. Heier-2012 discloses the results from Regeneron's two phase-3 studies (VEGF Trap: Investigation of Efficacy and Safety in Wet AMD) (VIEW1 and VIEW2). By connecting Heier-2012 with the applications for the '338 and '681 Patents, Regeneron created the perception that those patents were based on novel dosing regimens for intravitreal aflibercept treatments. But the aforementioned Withheld References and Regeneron 28-Sept-2008—most of which pre-dated Heier-2012 by at least two years—disclose the same dosing regimen as the one disclosed in Heier 2012. For example, Regeneron 19-Aug-2008 discloses that in "VIEW 1 and VIEW 2" Regeneron evaluated VEGF Trap-Eye dosed at "2 mg every 8 weeks (following three monthly doses)." Regeneron Press Release, "Regeneron and Bayer HealthCare Announce VEGF Trap-Eye Achieved Durable Improvement in Vision over 52 Weeks in a Phase 2 Study in Patients with Age-related Macular Degeneration", Aug. 19, 2008, at 1.)

59. These Withheld References and Regeneron 28-Sept-2008 are not cumulative or duplicative of the prior art of record that was considered by the Examiner during prosecution, and they objectively show that the dosing regimen disclosed in Heier-2012 was not novel, and therefore not patentable. Thus, but for the omission of these material references, the USPTO would not have issued the claims of the ’338 and ’681 Patents.

60. Given that many of the Withheld References and Regeneron 28-Sept-2008 were Regeneron’s own publications and even included Dr. Yancopoulos’s own statements, Regeneron’s actions evidence a specific intent to deceive the USPTO into issuing the ’338 and ’681 Patents.

61. That Regeneron’s motivation in securing these patents was to create anticompetitive roadblocks to competition, rather than protect patentable inventions, can also be seen in Regeneron’s pattern and practice of abandoning, disclaiming, and withdrawing patents or patent claims, yet continuing to assert patents from this family against Amgen, the only competitor to date to introduce an aflibercept biosimilar into the market.

62. For example, as detailed below, Regeneron has previously abandoned appeals involving patents from its family of patents directed to dosing regimens using aflibercept for the treatment of angiogenic eye disorders, including the ’338 Patent, the ’681 Patent, and U.S. Patent No. 10,888,601 (the “’601 Patent”). Regeneron has also disclaimed several patents, including the ’601 Patent and U.S. Patent No. 11,253,572 (the “’572 Patent”). In other words, Regeneron has shown a pattern of requiring rivals to spend time and money litigating invalid claims, and then upon losing, filing disclaimers or abandoned appeals so as to avoid adverse precedential decisions and preserve Regeneron’s ability to assert these patents against Amgen. The following timeline sets forth the pertinent events for each of these patents.

63. On May 5, 2021, Mylan filed an IPR petition challenging claims 1, 3-11, 13, 14, 16-24, and 26 of the ’338 Patent. *See* IPR2021-00881. On November 9, 2022, the PTAB issued a final written decision finding all challenged claims of the ’338 Patent unpatentable. On January 10, 2023, Regeneron appealed the final written decision to the Federal Circuit. *See Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 23-1396 (Fed. Cir. Mar. 13, 2024). However, on July 8, 2024, Regeneron and Mylan filed a joint stipulation to voluntarily dismiss the appeal.

64. Despite the foregoing, Regeneron continues to assert the ’338 Patent, obtained by fraud as described above, against Amgen.

65. On July 1, 2022, Mylan filed an IPR petition challenging claims 1, 3-11, 13, 14, 16-24, and 26 of the ’681 Patent. *See* IPR2022-01225. On January 6, 2023, Samsung filed a separate IPR petition challenging claims 1, 3-11, 13-14, 16-24, and 26 of the ’681 Patent. *See* IPR2023-00442. On January 9, 2024, the PTAB issued a final written decision in the Mylan IPR finding all challenged claims of the ’681 Patent unpatentable. On March 12, 2024, Regeneron appealed the final written decision in the Mylan IPR to the Federal Circuit. *See Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 24-1564 (Fed. Cir. Mar. 12, 2024).

66. On June 14, 2024, the PTAB issued a final written decision in the Samsung IPR finding all challenged claims of the ’681 Patent unpatentable. On August 5, 2024, upon information and belief, to avoid an appeal decision on the merits, Regeneron filed a motion to voluntarily dismiss the Mylan IPR appeal. Regeneron likewise did not appeal the Samsung IPR decision.

67. Despite the foregoing, Regeneron continues to assert the ’681 Patent, obtained by fraud as described above, against Amgen.

68. On July 1, 2022, Mylan filed an IPR petition challenging claims 1-9, 34-39, 41-43, and 45 of the '601 Patent. *See* IPR2022-01226. On January 11, 2023, the PTAB granted institution of Mylan's IPR petition. On March 26, 2023, Samsung filed a separate IPR petition challenging claims 10-33 and 46-47 of the '601 Patent. *See* IPR2023-00739. On July 25, 2023, Regeneron filed a statutory disclaimer at the USPTO, disclaiming claims 15-16, 20, 23-24, 31-32, and 46-47 of the '601 Patent. On October 20, 2023, the PTAB granted institution of Samsung's IPR petition. On December 27, 2023, the United States District Court for the Northern District of West Virginia issued an opinion finding claims 11 and 19 of the '601 Patent invalid for obviousness. *See Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 714 F. Supp. 3d 652 (N.D.W. Va. 2024). On January 9, 2024, the PTAB issued a final written decision in the Mylan IPR finding claims 1-9, 34-39, 41-43, and 45 of the '601 Patent unpatentable. On March 12, 2024, Regeneron appealed the final written decision in the Mylan IPR to the Federal Circuit. *See Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 24-1567 (Fed. Cir. Mar. 13, 2024). On July 10, 2024, Regeneron filed a statutory disclaimer at the USPTO, disclaiming claims 10-12, 17-19, 21, 25-28, and 33 of the '601 Patent and requested an adverse judgment and termination of Samsung's IPR prior to the issuance of a final written decision. On July 30, 2024, the PTAB entered an adverse judgment against Regeneron in the Samsung IPR. On August 5, 2024, Regeneron filed a motion to voluntarily dismiss the Mylan IPR appeal. On August 20, 2024, the Federal Circuit dismissed the Mylan IPR appeal.

69. Despite the foregoing, Regeneron continues to assert the '601 Patent, obtained by fraud as described below, against Amgen.

70. On April 27, 2023, Samsung filed an IPR petition seeking review of claims 1-30 of the '572 Patent. *See* IPR2023-00884. On November 17, 2023, the PTAB granted institution

of Samsung's IPR petition. On December 27, 2023, the Northern District of West Virginia issued an opinion finding claims 6 and 25 of the '572 Patent invalid for obviousness. *See Mylan*, 714 F. Supp. 3d at 652. On July 10, 2024, Regeneron filed a statutory disclaimer at the USPTO, disclaiming claims 1-30 of the '572 Patent. On July 10, 2024, Regeneron requested termination of Samsung's IPR petition. On July 23, 2024, the PTAB entered an adverse judgment against Regeneron in the IPR.

71. Despite the foregoing, Regeneron continues to assert the '572 Patent, obtained by fraud as described below, against Amgen.

72. Despite the foregoing, Regeneron continues to prosecute and obtain patents from this patent family from the USPTO.

2. Regeneron Fraudulently Obtained the '345 Patent

73. The '345 Patent concerns the "Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders."

74. Regeneron fraudulently obtained this patent by making materially false and misleading statements about prior art—upon information and belief, knowingly and willfully, with the intent to mislead and deceive the USPTO. To overcome the USPTO Examiner's anticipated rejection, Regeneron's counsel, including Mr. Karl Bozicevic, made a material misrepresentation, explicitly denying that a study described in one source of prior art was directed towards patients with wAMD. Regeneron also falsely denied, without any basis, that a previous Regeneron press release was prior art that would have precluded the '345 Patent from patentability. But for Regeneron's materially false and misleading statements, the '345 Patent would not have issued.

75. On October 1, 2019, the Examiner issued a Non-Final Office Action rejecting certain claims as anticipated by James A. Dixon et al., "VEGF Trap-Eye for the treatment of

neovascular age-related macular degeneration, Expert Opin. Investig. Drugs" 18(10): 15730-1580 (2009) ("Dixon 2009"), relying on the CLEAR-IT2 study discussed in Section 2.6.2 of the reference. The Examiner also rejected certain claims as anticipated by Regeneron 14-Sept-2009.

76. To overcome the Examiner's anticipation rejection based on Dixon 2009, Mr. Bozicevic falsely represented that "Section 2.6.2 did not disclose treatment of age-related macular degeneration" or other angiogenic eye disorders listed in the specification. '345 Patent Prosecution History, Office Action Response, Jan. 23, 2020 at 6. Mr. Bozicevic made these statements knowing that they were false because the CLEAR-IT2 study was Regeneron's own clinical trial and numerous prior art documents, including Dixon 2009, confirmed that the CLEAR-IT2 study assessed the efficacy of VEGF Trap-Eye in the treatment of patients with age-related wet macular degeneration.

77. For example, Dixon 2009 Section 2.6.2 cites a presentation whose title clearly states that the CLEAR-IT2 study was directed at patients with wet age-related macular degeneration: "VEGF Trap-Eye in Wet AMD CLEAR-IT-2: Summary of One Year Key Results." James A. Dixon et al., "VEGF Trap-Eye for the treatment of neovascular age-related macular degeneration, Expert Opin. Investig. Drugs" 18(10): 15730-1580 (2009), ref. 45. Indeed, "AMD" stands for Age-Related Macular Degeneration. Likewise, Regeneron 28-Sept-2008 discloses that "VEGF Trap-Eye achieved durable improvements in visual acuity and in biologic measures of neovascular disease, including retinal thickness and active choroidal neovascularization lesion size, for up to one year in a Phase 2 study in the neovascular form of Age-related Macular Degeneration (wet AMD)." Regeneron Press Release, "VEGF Trap-Eye Final Phase 2 Results in Age-related Macular Degeneration Presented at 2008 Retina Society Meeting", Sept. 28, 2008, at 1. And in a Regeneron-authored Retina Society Meeting

Presentation entitled "Retina Society, VEGF Trap-Eye in Wet AMD CLEAR-IT 2," the "CLEAR-IT2" study is described as a "Phase 2, Randomized, Controlled Dose-and Interval-Ranging Study of Intravitreal VEGF Trap-Eye in Patients With Neovascular, Age-Related Macular Degeneration." Regeneron Presentation, "VEGF Trap-Eye in Wet AMD CLEAR-IT 2: Summary of One-Year Key Results", Sept. 28, 2008, at 1.

78. Mr. Bozicevic likewise made a material misstatement about Regeneron 14-Sept-2009 by denying the prior art status of Regeneron 14-Sept-2009 in order to overcome the Examiner's anticipated rejection. Specifically, the Examiner observed that "Applicant points out that the 'Press Release' which, on its face, displays a date of September 14, 2009, has not been shown to be prior art and the Applicant does not concede to such." '345 Patent Prosecution History, Supplemental Response, Mar. 16, 2020, at 4. In other words, Regeneron refused to acknowledge that its own press release was issued on the date that was on the face of the document, which was prior to the date of the patent application for the '345 Patent.

79. Given that the press release was Regeneron's own document, was a public press release, and bore a September 14, 2009 date, Mr. Bozicevic knowingly and falsely denied the prior art status of the press release.

80. Regeneron also knew of the materiality to patentability of Dixon 2009 and Regeneron 14-Sept-2009, and the pertinent disclosures therein, because the Examiner relied on these references as the bases for its anticipation rejections.

81. Moreover, upon information and belief, Dixon 2009 is material to patentability as the PTAB and a district court later found similar claims of related patents anticipated by and/or obvious based on Dixon 2009. *See Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-

00881, Paper 94 at 61-62 (PTAB Nov. 9, 2022); *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-00880, Paper 89 at 75 (PTAB Nov. 9, 2022); *Mylan*, 714 F. Supp. 3d 652.

82. Because Mr. Bozicevic knew that Regeneron's CLEAR-IT2 study was directed towards patients with wAMD, and that Regeneron published Regeneron 14-Sept-2009 in the prior art, his statements are deliberate misrepresentations of fact with an intent to deceive the USPTO.

83. Had Mr. Bozicevic not made these false and misleading statements about Dixon 2009 and Regeneron 14-Sept-2009, the Examiner would have maintained the anticipation rejections and would not have granted Regeneron the '345 Patent.

3. Regeneron Fraudulently Obtained the '601, '572, '564, and '506 Patents

84. The '601, '572, '564, and '506, Patents (the "Continuation Patents") concern the "Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders" and are part of the same patent family as the earlier '338, '681, and '345 Patents. These patents claim minor and incremental variations on the earlier patents, and in some instances simply identify new results or exclusion criteria for the previously claimed dosing regimen.

85. Regeneron obtained the "Continuation Patents" by committing fraud during the prosecution of the above related parent applications—for the '338, '681, and '345 Patents—that led to the Continuation Patents' issuance. As described above, Regeneron committed fraud during prosecution of the '338, '681, and '345 Patents by failing to disclose material prior art and/or making materially false and misleading statements about prior art—upon information and belief, knowingly and willfully, with the intent to mislead or deceive the USPTO.

86. Further, on information and belief, Regeneron did not cure that fraud during the process of obtaining the Continuation Patents and instead relied upon and reinforced the prior

fraudulent conduct. Even when Regeneron disclosed certain of the aforementioned Withheld References and Regeneron 28-Sept-2008 during prosecution of the Continuation Patents, it intentionally buried those references among numerous other references to prevent the USPTO from realizing the parent patents were illegitimately obtained. Regeneron also failed to correct the aforementioned material misstatements, while prosecuting the Continuation Patents.

87. The fraud Regeneron committed, as a result of Dr. Yancopoulos's and Mr. Bozicevic's actions, in obtaining the '338, '681, and '345 Patents bears an immediate and necessary relation to Regeneron's acquisition of the Continuation Patents. The Continuation Patents are part of a chain of continuation applications that share the same specification and named inventor, Dr. Yancopoulos, and claim priority back to the application that issued as the '338 Patent. But for the '338, '681, and '345 Patents, the Continuation Patents could not claim priority back to the application underlying the '338 Patent or any of the relevant provisional applications. The claims of the Continuation Patents are also related to the claims of the earlier patents as they are likewise directed toward methods for treating angiogenic eye disorders.

88. Because the claims at issue in the Continuation Patents are closely related to—and, indeed, are based on—the prior patents Regeneron obtained by knowingly withholding material references from, and making misleading statements to, the USPTO, the Continuation Patents were likewise obtained through fraud on the USPTO.

4. Regeneron Fraudulently Obtained the '135, '593, '317, '459, '374, and '533 Patents

89. The '135, '593, '317, '459, '374, and '533 Patents concern "Anti-VEGF protein compositions and methods for producing the same." Like the patents above, prior art had definitively foreclosed the validity of these six patents. Also like the patents above, the qualifying prior art was of Regeneron's own making: commercially available EYLEA, which

had been sold since 2011, *always* had the characteristics (oxidized tryptophan and histidine residues) that Regeneron purported to be novel in these six new patents, which were filed years after 2011. When the Examiner confronted Regeneron regarding this fatal flaw of its new patent applications, instead of withdrawing its invalid claims, Regeneron committed fraud on the USPTO by misrepresenting that these characteristics were not known in the prior art.

90. More specifically, Regeneron fraudulently obtained these six patents by withholding or failing to disclose material information and making materially false and misleading statements about the oxidation of tryptophan or histidine in EYLEA—upon information and belief, knowingly and willfully, with the intent to mislead and deceive the USPTO. But for the withholding of information from, and the material misrepresentations made to, the Examiner that commercially available EYLEA on sale before December 6, 2018 (*i.e.*, one year before the filing of the provisional application described in Paragraph 91), contained oxidized histidine and tryptophan, the Examiner would not have allowed the claims of the '135, '593, '317, '459, or '374 Patents to issue.

91. Regeneron filed U.S. Provisional Patent Application No. 62/944,635 on December 6, 2019, entitled "VEGF Mini-Traps and Methods of Use Thereof" ("the '635 Provisional Application").

92. On November 13, 2020, and November 23, 2020, Regeneron filed Application Data Sheets and Petitions to Correct Inventorship for the '635 Provisional Application listing the following inventors: Joel Martin, Samuel Davis, Shawn Lawrence, Amy Johnson, Meghan Casey, Jaimie Mastrogiacomo, Shunhai Wang, Ning Li, Andrew Tustian, Ankit Vartak, and Matthew Franklin.

93. The ’135, ’593, and ’317 Patents name the following inventors: Shunhai Wang, Ning Li, Hunter Chen, and Amardeep Singh Bhupender Bhalla. The ’459 Patent additionally names Shawn Lawrence, Amy Johnson, Meghan Casey, and Jaime Grapel. The ’374 and ’533 Patents name Andrew Tustian, Ankit Vartak, Thomas Daly, Erica Pyles, Nisha Palackal, Shunhai Wang, and Ning Li.

94. These six patents (’135, ’593, ’317, ’459, ’374, and ’533), filed between August 2021 and July 2022, claim priority to the ’635 Provisional Application filed in December 2019. In the ’635 Provisional Application, Regeneron stated that “commercially available” EYLEA contained oxidized histidine and tryptophan residues. Specifically, Regeneron stated in the ’635 Provisional Application: “Only very minimal 2-oxo-histidine has been observed in commercially available VEGF Trap molecules (e.g., [EYLEA]) . . . .”[11] In the ’635 Provisional Application, Regeneron further stated: “A set of experiments were performed to evaluate the percentage of 2-oxo-histidines (and tryptophan dioxidation) in aflibercept . . . .”[12] The experiments in the ’635 Provisional Application likewise show the presence of 2-oxo-histidines (oxidized histidine) and dioxidated tryptophan (oxidized tryptophan) in commercially available EYLEA.[13]

95. Jonathan S. Caplan, attorney of record for Regeneron during prosecution of the six patents, filed the Application Data Sheet and specification for the applications of the six patents.

[11] ’635 Provisional Application, Dec. 6, 2020, at 51 ¶ 165, *see also id.* at 50-51 ¶¶ 164, 167.

[12] *Id.* at 135 ¶ 369.

[13] *Id.* at 135 ¶ 369 & Table 9-5.

96. The specifications of the six patents do not disclose any information about the oxidation of tryptophan or histidine in EYLEA. Rather, the specifications that Regeneron, through Mr. Caplan, submitted to the USPTO for examination on behalf of Regeneron omit the discussion and results of the experiments in the '635 Provisional Application showing that commercially available EYLEA contained oxidized histidine and tryptophan.

97. On information and belief, Regeneron has been offering for sale and selling its EYLEA product to the public since at least 2011.

98. On information and belief, EYLEA was on sale before December 6, 2018 (*i.e.*, one year before the filing date of the '635 Provisional Application), and at all applicable times contained oxidized histidine and tryptophan.

99. On information and belief, based at least on the above disclosures of the '635 Provisional Application, Regeneron, through Mr. Caplan and the inventors on the above listed patents, knew that commercially available EYLEA contained oxidized histidine and tryptophan.

100. Furthermore, during prosecution of U.S. Patent No. 11,186,625 ("the '625 Patent"), from which the '135, '593, '317, '459, and '533 Patents descend, the Examiner initially rejected the claims that eventually issued in the '625 Patent as obvious under 35 U.S.C. § 103. In response to the Examiner's rejection, Mr. Caplan stated to the Examiner: "As discussed during the Interview on June 14, and further explained below, the art of record does not teach or describe a composition of oxo-aflibercept with oxo-Trp and/or oxo-His. . . . Unlike the Danos '025 application which discusses theoretical possibilities, all of the references that actually tested aflibercept found no evidence of oxo-Trp or oxo-His." Regeneron Response to Final Office Action, July 26, 2021 in '625 Patent File History at 2-3. In this Response, Regeneron, through Mr. Caplan, cited the European Medicines Agency ("EMA") report, which discusses

commercially available EYLEA as approved by the EMA. Pointing to the EMA report as evidence, Regeneron stated to the Examiner: "EMA Report makes no mention of oxidized residues of aflibercept, other than methionine, that are oxidized or prone to oxidation. Notably, the EMA Report explains that '[e]xtensive bioanalytical testing studies' were performed." *Id*. at 4.

101. In making this statement, Mr. Caplan withheld the material information that the "commercially available" EYLEA on sale before December 6, 2018, contained oxidized histidine and tryptophan. On information and belief, Mr. Caplan's failure to inform the Examiner that EYLEA on sale before December 6, 2018, contained oxidized histidine and tryptophan, either in the July 26, 2021 Response or at any other time during prosecution, was an intentional omission. The same failure extends to those listed as inventors, who also had a duty to disclose material information to the USPTO during prosecution of the '625 Patent. The most reasonable inference to be drawn from these facts is that at least Mr. Caplan and the inventors on the above listed patents knowingly and intentionally withheld material information about the oxidation profile of EYLEA that was on sale before December 6, 2018, upon information and belief, with the intent to mislead and deceive the USPTO.

102. Regeneron also made affirmative misrepresentations of material fact to the Examiner in seeking to overcome a rejection based on whether it was known that prior-art EYLEA contained oxidized histidine and tryptophan. This includes directing the Examiner to the EMA report but not informing the Examiner that commercially available EYLEA that was on sale before December 6, 2018, contained oxidized histidine and tryptophan. Because Mr. Caplan made these statements seeking to distinguish the pending claims over the prior art in a manner focused on whether the prior art disclosed that aflibercept contained oxidized histidine and

tryptophan, on information and belief, at least Mr. Caplan made these material misrepresentations with intent to deceive the Examiner.

103. After considering the July 26, 2021 Response, the Examiner issued a Notice of Allowance for the '625 Patent. '625 Notice of Allowance, Aug. 11, 2021. In the Notice of Allowance, the Examiner stated in the "Reasons for Allowance":

> [T]he closest prior art (US 2021/0010025 A1 as cited previously) teaches that aflibercept is oxidized at two methionines. The '025 art is silent as to tryptophan or histidine oxidation events. As discussed by the Applicants and agreed to by the Examiner, other prior art (see e.g. US2018/0326126 or WO 2020/229584) indicates that attempts to uncover other oxidation events in aflibercept are not detected via LC-MS analysis, even after storage (i.e. potential for air exposure and oxidation and Met, His and Trp residues). The '584 art further supports that oxo-Trp and oxo-His do not occur even without specific culture conditions, as control experiments without antioxidants still do not demonstrate production of oxo-Trp or oxo-His (See e.g. p. 81). Accordingly, the examiner agrees that there would be no reasonable expectation that any combination of Sivertsen with '025 alone or in combination with '685 would produce oxo-His or oxo-Trp forms of aflibercept. The claimed composition is novel and unobvious.

Id. at 3-4.

104. In the Notice of Allowance, the Examiner explained that allowance was being granted on the sole basis that the prior art before the Examiner did not contain evidence that prior-art aflibercept contained oxidized tryptophan or histidine. But for the withholding of information from the Examiner that commercially available EYLEA on sale before December 6, 2018, contained oxidized histidine and tryptophan, the Examiner would not have allowed the claims of the '625 Patent.

105. The misrepresentations and omissions made by Mr. Caplan and those named as inventors on the '625 Patent during the prosecution of the '625 Patent permeated the prosecution of the relevant patents and relate to the claims of those patents. Following the allowance of the '625 Patent, Mr. Caplan and those named as inventors on the '625 Patent, as well as the inventors listed on '135, '593, '317, and '459 Patents, continued to withhold or otherwise failed

to disclose during prosecution of the relevant patents that commercially available EYLEA on sale before December 6, 2018, contained oxidized histidine and tryptophan. The most reasonable inference to be drawn from these facts is that Mr. Caplan and the inventors listed on the ’625 Patent and the other relevant patents knowingly and intentionally withheld this material information with the intent to deceive the Examiner to secure allowance of the claims of the patents.

106. As during prosecution of the ’625 Patent, the Examiner issued Notices of Allowance for the ’135, ’593, ’317, and ’459 Patents. In them, the Examiner stated in the “Reasons for Allowance” that the claims were novel and nonobvious. *See* ’135 Patent Notice of Allowance, Jan. 20, 2022; ’593 Patent Notice of Allowance, Jun. 13, 2022; ’317 Patent. Notice of Allowance, Oct. 13, 2022; ’459 Patent Notice of Allowance, Mar. 15, 2023.

107. The Examiner likewise explained that the ’135, ’593, ’317, and ’459 Patents were being allowed on the sole basis that the prior art before the Examiner did not contain evidence that prior-art aflibercept contained oxidized tryptophan or histidine. But for the withholding of information from the Examiner that commercially available EYLEA on sale before December 6, 2018, contained oxidized histidine and tryptophan, the Examiner would not have allowed the claims of the ’135, ’593, ’317, or ’459 Patents to issue.

108. Regeneron committed additional fraud during the prosecution of the ’374 and ’533 Patents. The claim which, following amendment, eventually issued as Claim 20 in the ’374 Patent (as-filed Claim 22), and claims depending therefrom, were rejected as obvious in a non-final rejection in the April 15, 2022 Office Action (sections 22 and 23 at 16-20). In response, Regeneron, through Mr. Caplan, amended Claim 22 (later issued as Claim 20) as follows:

> 22. (Currently Amended) A method of preparing a prefilled syringe comprising aflibercept,

(a) producing ~~wherein~~ said aflibercept ~~is produced~~ in a chemically defined media (CDM), wherein ~~and~~ said aflibercept has ~~an~~ a BY value of less than 5, when the concentration of aflibercept is normalized to 5 g/L protein concentration[,];

(b) purifying said aflibercept ~~before purification and is then purified~~ by a process that includes the following chromatography steps to obtain aflibercept having a BY value of at least 5:

(c) affinity chromatography; and

(d) ion exchange chromatography[.], wherein the purified aflibercept has a BY value of at least 5 and wherein said aflibercept includes one of an oxidized histidine selected from the group consisting of His86, His110, His145, His209, His95, His19, His203, and a combination thereof, and an oxidized tryptophan selected from the group consisting of Trp58, Trp138, and combinations thereof.

Regeneron's Response to Non-Final Office Action, Apr. 22, 2022, at 5-6. When amending the claim to add the limitation requiring that the aflibercept contain oxidized histidine and oxidized tryptophan, Mr. Caplan intentionally withheld from the Examiner that "commercially available" EYLEA, *i.e.*, EYLEA on sale before December 6, 2018, contained oxidized histidine and tryptophan.

109. Mr. Caplan and those named as inventors on the '374 Patent—including Shunhai Wang and Ning Li (who were also named as inventors on the '625 Patent)—knowingly withheld or otherwise failed to disclose material information about the oxidation profile of EYLEA that was on sale before December 6, 2018, with the intent to deceive the Examiner.

110. Later in the prosecution of the '374 Patent, in the May 6, 2022 Office Action, on page 4, the Examiner stated that "the obviousness rejections set forth in sections 22 and 23 of the Office Action mailed April 15, 2022 are overcome by the amendment to the claims." '374 Office Action, at 4. The Examiner allowed amended Claim 22 (issued as Claim 20 of the '374 Patent), among other claims.

111. The Examiner allowed amended Claim 22 (issued as Claim 20) of the ’374 Patent only after Mr. Caplan amended the claim to add the limitation requiring that the aflibercept contain oxidized histidine and oxidized tryptophan. Mr. Caplan’s failure to disclose material information, *i.e.*, that the “commercially available” EYLEA that was on sale to the public before December 6, 2018, contained oxidized histidine and oxidized tryptophan, was but-for material to the allowance of the claims of the ’374 Patent. Thus, the ’374 Patent was also obtained through fraudulent conduct.

112. Later, in the prosecution of the ’533 Patent, on July 6, 2022, with the knowledge that the Examiner had allowed the related ’374 Patent based on the claim elements requiring that the purified aflibercept contain oxidized histidine and tryptophan, Mr. Caplan filed U.S. Application No. 17/858,629 (the “’629 Application”). Claim 1 of the ’629 Application, which is identical to claim 1 of the later issued ’533 Patent, is the sole independent claim in the patent, and includes the following limitation:

> [c]ollecting said aflibercept following purification wherein said aflibercept includes between 1% and 0.03% aflibercept with at least one oxidized amino acid residue selected from the group consisting of tryptophan, histidine and a combination thereof.

113. When filing the ’629 Application and prosecuting the ’533 Patent, Regeneron failed to disclose that EYLEA on sale before December 6, 2018, contained oxidized histidine and tryptophan, such that between 1% and 0.03% of that aflibercept contained at least one oxidized amino acid residue selected from the group consisting of tryptophan, histidine, and a combination thereof.

114. Thus, Mr. Caplan and the individuals identified as inventors in the ’533 Patent intentionally withheld or otherwise failed to disclose the material information that the aflibercept in EYLEA sold prior to December 6, 2018, as well as the other aflibercept-based products

Regeneron offered for sale and sold prior to December 6, 2018, contained oxidized histidine and tryptophan, with the intent to deceive the Examiner. Thus, the '533 Patent was obtained through fraud on the USPTO.

* * *

115. In sum, for at least twelve of the aflibercept-based patents that Regeneron procured prior to the expiration of EYLEA's statutory exclusivity, Regeneron, through its patent prosecution counsel and the inventors of its relevant patents, made false representations regarding, and omitted facts material to, patentability. Upon information and belief, Regeneron did so knowingly and intentionally with the intent to deceive the Patent Examiners who justifiably relied on the information before them in granting the applications. But for these misrepresentations and omissions, the aforementioned twelve patents would not have issued.

116. Regeneron has since asserted each of these fraudulently-procured patents against Amgen, with, upon information and belief, knowledge of their fraudulent procurement—and, to this day, continues to seek a permanent injunction against Amgen, based at least in part, on these fraudulently obtained patents.

E. Amgen Invents a Novel Formulation for its Aflibercept Biosimilar and Commences the BPCIA Information Exchange Process

117. While developing its aflibercept biosimilar, Amgen discovered that, if the aflibercept is prepared and formulated using a specific process, the aflibercept protein itself will have a sufficient buffering capacity to maintain pH stability over long periods of time, eliminating the need for an excipient buffer (*i.e.*, a buffer comprised of an inactive ingredient), like the kind present in Regeneron's EYLEA formulation and required by Regeneron's patents. In addition to dispensing with the need for an excipient buffer or any other salt, Amgen's formulation also improves overall stability, providing a 50% longer shelf life than EYLEA.

Amgen's innovative formulation and the process to make it are the subject of multiple of Amgen's own patents and patent applications.

118. Amgen filed BLA No. 761298 ("Amgen's BLA") with the FDA on August 23, 2023, seeking to market a biosimilar formulation of aflibercept called ABP 938 (now branded as "PAVBLU"). Specifically, Amgen's BLA sought approval to market ABP 938 for the treatment of wAMD, macular edema following retinal vein occlusion ("RVO"), Diabetic Macular Edema ("DME"), and Diabetic Retinopathy ("DR").[14] Amgen initiated the BPCIA information exchange process with Regeneron in September 2023. Pursuant to 42 U.S.C. § 262(*l*)(2), Amgen produced to Regeneron both a copy of the Amgen BLA and "such other information that describes the process or processes used to manufacture the biological product that is the subject of" the Amgen BLA, totaling over 145,000 pages.

119. After reviewing the Amgen BLA and other manufacturing information for 60 days (the full amount of time permitted under the statute), Regeneron provided to Amgen a list of thirty-four patents under 42 U.S.C. § 262(*l*)(3)(A) ("Regeneron's (3)(A) List"), for which Regeneron purportedly "believe[d] a claim of patent infringement could reasonably be asserted" against Amgen, including the twelve patents procured by fraud described above.

120. Thereafter, Amgen gave Regeneron a detailed statement under 42 U.S.C. § 262(*l*)(3)(B)(ii) ("Amgen's (3)(B) Statement"), providing Amgen's opinion that each of the thirty-four patents on Regeneron's list was "invalid, unenforceable, or will not be infringed by Amgen's commercial marketing of [ABP 938]." Amgen specifically pointed out that twelve of the patents were procured by fraud. .

[14] Amgen's BLA sought approval for two presentations of ABP 938: (1) a single-dose vial containing 2 mg aflibercept, sucrose, α,α-trehalose dihydrate, polysorbate 80, and water for injection; and (2) a single-dose pre-filled syringe ("PFS") containing the same formulation as in the single-dose vial.

121. In response to Amgen's (3)(B) Statement, Regeneron sent Amgen a statement under 42 U.S.C. § 262(*l*)(3)(C) purporting to provide infringement, validity, and enforceability contentions for each of the thirty-four patents on Regeneron's (3)(A) List, including the twelve patents procured by fraud. However, Regeneron's § 262(*l*)(3)(C) statement did not comply with the statutory requirement that Regeneron provide "a detailed statement that describes, with respect to each patent [in Amgen's (3)(B) Statement], on a claim by claim basis, the factual and legal basis of the opinion of [Regeneron] that such patent will be infringed by the commercial marketing of the biological product that is the subject of [the Amgen BLA]." Rather, in numerous instances, Regeneron merely provided conclusory infringement allegations or failed entirely to provide any infringement contentions at all, instead declaring that the documents cited in Amgen's (3)(B) Statement "failed to exclude the possibility" of infringement. In so doing, Regeneron improperly purported to shift the burden of proving non-infringement to Amgen rather than undertaking to provide any actual infringement contentions, as required under § 271(*l*)(3)(C).

122. Regeneron then took its obstruction tactics to the next level by proposing that the parties "proceed to litigation on all the patents identified in [Regeneron's] (*l*)(3)(C) contentions," pursuant to the process set forth under 42 U.S.C. § 262(*l*)(3)(C), including the twelve patents procured by fraud (as referenced above). Knowing that it would face a lawsuit with respect to those twelve fraudulently-obtained patents at some point, subject to those processes, Amgen, solely for the purpose of concluding the statutorily required "negotiations" under the BPCIA, agreed that the thirty-four patents identified in Regeneron's § 262(*l*)(3)(C) statement "shall be the subject of an action for patent infringement under [42 U.S.C. § 262(*l*)(6)]," while making clear that "Amgen does not agree that Regeneron has any meritorious claims of patent

infringement to assert against Amgen, and Regeneron must have a good faith basis under Federal Rule of Civil Procedure 11 to assert any of its patents against Amgen." Letter from John Labbe Re: Amgen Inc.'s Biologic License Application for ABP 938, Jan. 5, 2024, at 1-2.

F. Following the BPCIA Information Exchange Process, Regeneron Files an Infringement Suit.

123. Following the BPCIA information exchange process, in January 2024, Regeneron filed a lawsuit against Amgen (defined above as the "First Amgen Action") asserting 34 patents, including all of the aforementioned twelve patents that Regeneron secured by fraud, with, upon information and belief, knowledge of their fraudulent procurement. *Regeneron Pharm., Inc. v. Amgen, Inc.*, No. 2:24-cv-264 (C.D. Cal.), Dkt. 1. That lawsuit, which remains pending as of the time of this filing, seeks a permanent injunction against Amgen—seeking to permanently enjoin PAVBLU from participating in the market—in part on the basis of those twelve fraudulently-obtained patents.

124. Shortly after filing that lawsuit, as part of those same proceedings, Regeneron sought in June 2024 a preliminary injunction to prevent Amgen from launching PAVBLU. *Id.*, Dkt. 157. The previous month, Amgen had obtained FDA approval to launch PAVBLU in August 2024. Regeneron's preliminary injunction motion relied on Regeneron's '865 Patent, which describes the EYLEA formulation.

125. As this Court noted in its decision denying Regeneron's motion for a preliminary injunction (the above-referenced Order Denying PI), in its proceeding against Amgen, Regeneron took the exact opposite position as to the scope of the '865 Patent than it did in an earlier litigation asserting the same patent against Mylan/Biocon. Specifically, during the Mylan/Biocon litigation, in response to arguments by Mylan/Biocon that the claims of the '865 patent were invalid under 35 U.S.C. § 112 for lack of written description and lack of

enablement,[15] Regeneron repeatedly asserted that the claims of the '865 patent were valid, among other things, *because* they required the use of a separate, excipient buffer. For example, during opening arguments in the Mylan/Biocon trial, Regeneron's counsel proclaimed, "If you don't have an organic cosolvent **or a buffer, you're out of our claim**." Transcript of Trial at 33:1-8*, Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 714 F. Supp. 3d 652 (N.D.W. Va. 2024) (emphasis added) (emphasis added). Likewise, Regeneron asserted that the claims were limited to a "'very specific' VEGF antagonist ***and*** the categories of organic co-solvent, buffer, and stabilizing agent." *Mylan*, 714 F. Supp. 3d at 751 (emphasis added). As another example, Regeneron's expert, Dr. Trout, testified that the claims of the '865 patent "claim 'one specific biologic molecule . . . with a specific sequence ID' at just one concentration (40 mg/m[l]), in a vial for intravitreal administration, and **further claim** specific structural components, **including a buffer**. . . ." *Id.* at 754 (emphasis added).

[15] Specifically, Mylan/Biocon "criticize[d] the claims for reciting the structural categories of 'buffer' and 'stabilizing agent' instead of specific chemical structures." *Mylan*, 714 F. Supp. 3d at 752.

126. As this Court found in its decision denying Regeneron's motion for a preliminary injunction against Amgen, "[d]uring the Mylan trial Regeneron and its expert referred to the 'buffer' of the '865 patent claims as an 'excipient,' which also supports that it is a separate and distinct component from the claimed 'VEGF antagonist' active ingredient." *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 at 76 (N.D.W. Va. Sept. 23, 2024) (citing Regeneron's Proposed Findings and Facts and Conclusions of Law from the Mylan/Biocon litigation). Further, "Dr. Trout repeatedly used the term 'excipient' to refer to the 'buffer' recited in the claims of the '865 patent." *Id.* (citing the Mylan Trial Transcript and Dr. Trout's expert report). Regeneron's arguments had their intended effect—in the Mylan/Biocon action, this Court "credited Dr. Trout's trial testimony and found that the claims required 'a specific protein molecule at a specific concentration **along with other** known structures (a buffer, stabilizing agent, and polysorbate 20).'" *Mylan*, 714 F. Supp. 3d at 753; *see also id.* at 751. (emphasis added). This Court adopted Regeneron's finding that "[t]he claimed composition" was "40 mg/ml of aflibercept, **with** polysorbate 20, a buffer, and a stabilizing agent. . . ."). *Id.* at 747 (emphasis added). The district court also noted that "the claimed structure" required "40 mg/ml of glycosylated aflibercept and polysorbate 20 within the specified concentration range, **plus a buffer** and a stabilizing agent." *Id.* at 758-59 (emphasis added).Yet, in its first set of proceedings against Amgen (the First Amgen Action), Regeneron flipped its position entirely, asserting that the '865 Patent did *not* require a separate, excipient buffer, in an attempt to fit the claims of the '865 Patent to Amgen's novel buffer-free formulation. As described further below, that attempt ultimately failed, and Regeneron's motion for a preliminary injunction was denied, which enabled Amgen subsequently to launch PAVBLU. But Regeneron was not finished—in response, Regeneron launched a second phase of its anticompetitive scheme to attempt to

prevent PAVBLU and Amgen from competing against EYLEA, including in particular by procuring by fraud another patent (the ’099 Patent) and asserting it against Amgen in this lawsuit.

127. Another illustration of the lengths Regeneron was willing to go in trying to stop Amgen from launching PAVBLU can be found in Regeneron’s arguments to this Court in its litigation against Formycon, another pharmaceutical company that has an aflibercept biosimilar candidate, which, like EYLEA, uses a separate, excipient buffer.

128. As noted above, in the litigation against Mylan/Biocon, Regeneron repeatedly argued that EYLEA contained an excipient buffer. Those contentions were all asserted *before* the BPCIA information exchange process pursuant to which Amgen disclosed its unique buffer-free formulation to Regeneron. That disclosure occurred on September 18, 2023, when Amgen produced its BLA to Regeneron, which was also provided to Dr. Bernhardt Trout, Regeneron’s expert in its lawsuits against aflibercept biosimilar manufacturers, and who Regeneron would later proffer to offer opinions that Amgen’s PAVBLU product infringes the claims of the ’865 Patent.

129. Regeneron's preliminary injunction proceedings against Formycon, in February 2024, provided Regeneron its first opportunity to argue the scope of the '865 Patent *after* Amgen's disclosure of its buffer-free formulation. In those proceedings, Regeneron asserted, for the first time ever, that "buffer" should be construed to mean, among other things, "proteins like aflibercept," meaning, according to Regeneron, a "buffer-free" formulation. *Regeneron Pharms., Inc. v. Formycon AG*, 1:23-cv-97, Dkt. No. 252 at 47. The argument was, notably, pointless in the *Formycon* case because the question of whether aflibercept could itself serve as the buffer in the claimed formulation was not at issue in that case. Upon information and belief, Regeneron slipped the argument into its briefing in the *Formycon* case, after having learned of Amgen's buffer-free formulation via the BPCIA disclosure process, in order to set up, and create a record in support of, the argument it anticipated it would need to make against Amgen in an attempt to enjoin PAVBLU's launch.

130. Indeed, Regeneron no doubt knew that Formycon would have no reason to address that particular aspect of Regeneron's proffered construction, since, as this Court has noted, the dispute in the *Formycon* litigation was whether the "buffer term" should be limited to a "phosphate buffer", not whether aflibercept itself could comprise the buffer. *See In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 at 26 (N.D.W. Va. Sept. 23, 2024). This Court then "adopted Regeneron's construction for the purpose of resolving the disputes at issue" in *Formycon*. *Id.*

131. Regeneron then attempted to use that construction against Amgen in its attempt to enjoin PAVBLU's launch, pointing to the *Formycon* decision as support for its baseless (and ultimately unsuccessful position.

132. Moreover, upon information and belief, Regeneron misused Amgen confidential information that Regeneron received during the BPCIA process to effectuate this strategy. Pursuant to 42 U.S.C. § 262(l)(1), confidential information that Regeneron received from Amgen during the BPCIA information exchange process may be "used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted." However, the events and timing relating to the Formycon litigation indicate that Regeneron used the confidential information it learned about Amgen's formulation during the BPCIA information exchange process in an attempt to improperly bolster its baseless claim against Amgen in subsequent litigation in an effort to keep PAVBLU off the market. Such misuse again illustrates the lengths to which Regeneron has been willing to go, to keep PAVBLU off the market.

G. Regeneron's Litigation Against Amgen Fails to Prevent PAVBLU's Launch.

133. On September 23, 2024, the Court denied Regeneron's motion for a preliminary injunction against Amgen (previously defined as "Order Denying PI"). The Court found that Regeneron failed to show a reasonable likelihood of success in proving that Amgen's formulation infringes the '865 Patent because Amgen's product lacks the claimed buffer component. *See In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 (N.D.W. Va. Sept. 23, 2024). That decision was based on the careful review of a well-developed evidentiary record, including the '865 Patent and its intrinsic record (*i.e.*, prosecution history), multiple expert declarations that totaled hundreds of pages, deposition testimony of Amgen's technical expert, dozens of extrinsic technical references, and the public trial record from Regeneron's prior litigation against Mylan/Biocon on the '865 Patent.

134. In its Order Denying PI, the Court construed the claims of the '865 Patent to require that the claimed "VEGF antagonist" be a separate component from the claimed "buffer." The Court determined that the specification "uniformly describes the 'VEGF antagonist' and the 'buffer' as separate and distinct components of the formulation." *Id*. at 44-45. The Court concluded that "[t]he specification does not suggest that the VEGF antagonist can be a buffer or vice versa" and that "Regeneron has not identified any such disclosure in the specification of the '865 [P]atent." *Id*. at 45. The Court found that "neither the claims nor the specification of the '865 [P]atent explain or suggest that the VEGF antagonist can serve as the buffer, or vice versa, or that these components can overlap in function. Rather, the claims and the specification further support and confirm that they cannot be one and the same." *Id*. at 55.

135. The Court also pointed out that "[t]here is no dispute that, in every example and every embodiment in the '865 [P]atent, the formulation is described as containing both a VEGF antagonist and separate buffer." *Id*. at 45-46; *see also id*. at 50 ("[T]he '865 [P]atent does not exemplify or suggest that the aflibercept can satisfy both the 'VEGF antagonist' and 'buffer' limitations, and every example and embodiment includes a buffer that is separate from, and present in addition to, the aflibercept."). Regeneron had not cited "any contrary examples or embodiments in the specification indicating that the VEGF antagonist could serve as the buffer." *Id*. at 46. Importantly, the Court found that "there appears to be no factual dispute that, as of June 2006, there were no formulations of any fusion protein (or aflibercept specifically) or any intravitreal protein formulation that lacked a separate buffer." *Id*. at 65.

136. The Court further rejected Regeneron's argument, based on extrinsic evidence, that using aflibercept as a buffer was so "well known in the art" that no description in the specification was necessary for a person of ordinary skill in the art to understand that the claimed

VEGF antagonist can serve as the separately claimed "buffer." In fact, it found that "*none* of the extrinsic evidence discloses that aflibercept can function as a buffer in a pharmaceutical formulation, let alone in a manner that indicates this was so well known such that disclosure in the patent was not needed, as Regeneron argues." *Id*. at 62-63 (emphasis added).

137. Notably, the only reference on which Regeneron relied that did disclose buffer-free pharmaceutical compositions was an Amgen patent publication, entitled "Self-Buffering Protein Formulations," which published as WO 2006/138181 ("Gokarn") on December 28, 2006. Moreover, as Amgen noted in its opposition to Regeneron's preliminary injunction motion, Gokarn provides no examples of a buffer-free aflibercept formulation, no data on the buffering capacity of aflibercept, and no teachings on how to formulate aflibercept in a stable ophthalmic formulation for intravitreal injection without the use of a buffer. Amgen's scientists devised a buffer-free aflibercept formulation years later as reflected in Amgen's U.S. Application No. 16/764,463, filed on May 15, 2020, which later issued as U.S. Patent No. 12,156,900. The Court agreed that this extrinsic evidence supports Amgen's contention that a person of ordinary skill in the art "at the relevant time (*i.e.*, June 2006) would not consider a therapeutic fusion protein like aflibercept to be a 'buffer' in the context of the '865 Patent." *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 at 65 (N.D.W. Va. Sept. 23, 2024).

138. The same day of the Order Denying PI, Regeneron filed a notice of appeal, a motion to expedite the appeal, and an emergency motion for an injunction pending resolution of the appeal and for an administrative stay with the U.S. Court of Appeals for the Federal Circuit. On September 25, 2024, the Federal Circuit issued an order temporarily enjoining the launch of PAVBLU on an administrative basis while it considered Regeneron's motion for an injunction pending appeal. On October 22, 2024, the Federal Circuit denied Regeneron's motion for an

injunction pending appeal and lifted the temporary injunction that was entered on September 25, 2024 (the previously-referenced Order Denying PI Pending Appeal). Immediately following the lifting of the administrative stay, on October 30, 2024, Amgen launched PAVBLU and entered the market as the only aflibercept biosimilar to EYLEA, resulting in EYLEA facing biosimilar competition for the first time ever.

H. Unable to Prevent PAVBLU's Launch, Regeneron Committed Further Fraud on the USPTO in Procuring the '099 Patent and Asserting it Against Amgen in the Instant Action.

139. On October 24, 2024, the *day after* the Federal Circuit denied its motion for an injunction pending appeal, and more than eighteen years after the filing of the purported provisional application in June 2006, Regeneron filed Application No. 18/924,707 ("the '707 Application"), which issued as the '099 Patent. The '099 Patent purports to claim certain formulations of aflibercept and, unlike the '865 Patent, does not explicitly recite a separate buffer or a salt in the claims.

140. In obtaining the '099 Patent, Regeneron failed to disclose the fact that Amgen, not Regeneron, pioneered the buffer-free formulation technology that Regeneron now attempts to claim as its own. Specifically, Regeneron falsely represented that the inventors listed on the '707 Application invented the subject matter sought to be claimed in the '707 Application—liquid ophthalmic formulations comprising a VEGF antagonist without an excipient buffer—and also withheld references and court findings demonstrating that they did not. Furthermore, Regeneron engaged in a pattern of egregious conduct by repeatedly burying or delaying disclosure of relevant information to the Examiner until at or around the time that the Examiner allowed the claims, a tactic repeatedly employed by Regeneron and one designed to discourage the Examiner from re-opening the prosecution and carefully considering the belatedly submitted

information. Upon information and belief, Regeneron did all this knowingly and willfully with the intent to deceive the USPTO.

141. Like the '865 Patent, the '707 Application claims priority through continuation and divisional applications to the '484 Provisional, which was filed on June 16, 2006.

142. The listed inventors on the '707 Application and '865 Patent are also identical (Eric Furfine, Daniel Dix, Kenneth Graham, and Kelly Frye). The '707 Application contains the same specification as the '865 Patent, which the Federal Circuit confirmed "makes clear what 'the inventors actually invented and intended to envelop,'… and that is, a formulation containing a VEGF antagonist *plus* a distinct buffer." *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372, 1383 (Fed. Cir. 2025) (emphasis in original) (quoting *Phillips*, 415 F.3d at 1316).

143. Over the first fifteen-plus years following Regeneron's filing of the '484 Provisional on June 16, 2006, Regeneron pursued and obtained twelve patents in the so-called Furfine Patent Family, all of which exclusively contain claims directed to ophthalmic formulations comprising a VEGF antagonist and an excipient buffer. Not a single patent claim in this long history of patent applications even attempted to encompass a buffer-free formulation of aflibercept (or any VEGF antagonist). Regeneron's fifteen-plus year-long pursuit of issued patent claims directed to formulations comprising a buffer evince that the inventors named on the Furfine Patent Family did not in fact invent or describe a buffer-free aflibercept formulation and the inventions of that patent family are ophthalmic formulations comprising a VEGF antagonist *and* an excipient buffer.[16]

[16] Although Regeneron did later pursue patent claims that do not *expressly* require a buffer—U.S. Patent No. 11,732,024 requires a salt and recites a buffer (sodium phosphate) as one of the permissible salts—Regeneron has not asserted that patent against Amgen.

144. In other words, for the first time after eighteen years of filing and prosecuting numerous applications claiming priority to the '484 Provisional, and only after obtaining an unfavorable preliminary injunction decision in the First Amgen Action, Regeneron submitted claims in the '707 Application that are directed to liquid ophthalmic formulations comprising a VEGF antagonist that do not expressly recite a buffer or a salt.

145. However, Amgen's development of a buffer-free protein formulation was first published in December 2006 in Gokarn. And Amgen's scientists discussed buffer-free protein formulations again in a 2008 publication, Yatin R. Gokarn et al., "Self-Buffering Antibody Formulations," Journal of Pharmaceutical Sciences, Vol. 97, 3051-3066 (2008) (the "Gokarn Publication-2008"). Gokarn Publication-2008 discusses buffer-free formulations and describes Amgen's experimental and theoretical work to prepare high-concentration monoclonal antibodies in buffer-free formulations. Gokarn Publication-2008 also explains that, "[i]nstead of employing a conventional buffer, a novel and alternative approach for controlling the pH of a high-concentration protein drug product is to use the protein to buffer the solution."[17] Amgen built upon that research to make further advancements in the area of buffer-free formulations and eventually developed a buffer-free aflibercept formulation.

146. Amgen filed a patent application, U.S. Application No. 16/764,463 ("Amgen's '463 Application"), for its buffer-free aflibercept formulation on May 15, 2020, which claims priority to PCT Pat. App. No. US2018/061644, first filed on November 16, 2018, as well as to U.S. Prov. Pat. App. Nos. 62/587,733 and 62/618,904, filed on November 17, 2017, and January 18, 2018, respectively. Amgen's '463 Application was published on October 29, 2020 and later issued as U.S. Patent No. 12,156,900 on December 3, 2024. Amgen's patent application

[17] At 3052.

includes numerous examples of buffer-free aflibercept formulations and data showing the stability of such buffer-free formulations, unlike Regeneron's '099 Patent.

147. By filing and prosecuting the '707 Application with claims to aflibercept formulations that do not recite a buffer, Regeneron wrongly claimed Amgen's invention as its own and asserted that the inventors of the '707 Application had invented buffer-free aflibercept formulations as of June 16, 2006—which they had not. Indeed, on information and belief, Regeneron first learned of a buffer-free aflibercept formulation when it learned of the Amgen BLA and/or Amgen's published patent application. Regeneron was spurred into filing the claims of the '099 Patent by this Court's decision denying the preliminary injunction motion that Regeneron filed against Amgen and the Federal Circuit's denial of Regeneron's motion for an injunction pending appeal.

148. During prosecution of the '099 Patent, Regeneron's counsel, including Ms. Alyson Nickols, Mr. Michael Lewis, Mr. David Marsh, and Ms. Alice Ho, engaged in a pattern of conduct before the USPTO constituting fraud. Specifically, on October 23, 2024, when Ms. Nickols, Mr. Lewis, Mr. Marsh, and Ms. Ho filed the application for the '099 Patent, they resubmitted declarations of the inventors of the '099 Patent to the USPTO that were signed in February 2014 and were previously submitted during prosecution of U.S. Application No. 13/914,996, which is a parent application of the '099 Patent.

149. U.S. Application No. 13/914,996 exclusively claimed formulations containing a separate phosphate buffer. It neither described nor claimed the buffer-free formulations claimed in the '099 Patent. By resubmitting the same inventor declarations, Regeneron's counsel created the false and misleading impression that the listed inventors (Eric Furfine, Daniel Dix, Kenneth Graham, and Kelly Frye) invented the full scope of the subject matter claimed in the '099 Patent,

including liquid ophthalmic formulations comprising a VEGF antagonist that do not recite an excipient buffer. Those purported inventors have not averred that they are original and joint inventors of the buffer-free formulations encompassed by the claims of the '099 Patent. In fact, Dr. Furfine testified during the bench trial in *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 22-cv-61 (N.D.W. Va.), nearly a year prior to the submission of the application for the '099 Patent, that he "invented the use of a phosphate buffer in this formulation to stabilize aflibercept[.]"[18]

150. Thus, on October 23, 2024, when Ms. Nickols, Mr. Lewis, Mr. Marsh, and Ms. Ho filed the '707 Application, they and the inventors knew that the specification does not describe or enable claims reciting a buffer-free liquid ophthalmic aflibercept formulation.

151. As of June 16, 2006, when the first priority application (*i.e.*, the '484 Provisional) was filed at the USPTO, "there were no formulations of any fusion protein (or aflibercept specifically) or any intravitreal protein formulation that lacked a separate buffer." *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 at 65 (N.D.W. Va. Sept. 23, 2024). In fact, when the '484 Provisional was filed on June 16, 2006, the inventors of the '099 Patent considered a buffer excipient to be required in an aflibercept formulation, and they did not contemplate any formulation in which an excipient buffer was omitted. The Federal Circuit has unequivocally confirmed this fact, finding that "[t]he specification makes clear what 'the [purported] inventors actually invented and intended to envelop'… and that is, a formulation containing a VEGF antagonist *plus* a distinct buffer." *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372, 1383 (Fed. Cir. 2025) (quoting *Phillips*, 415 F.3d at 1316).

[18] *See* Trial Tr. Day 3, June 14, 2023 at 543:6-7.

152. The purported inventors' own admissions further reinforce the Federal Circuit's findings. In June 2009, three years after the '484 Provisional was filed, Dr. Dix admitted in a declaration submitted to the USPTO in a different patent family that:

> In order to formulate the VEGF Trap at about pH 5.9 to about 6.5, a buffer system needed to be chosen that had significant buffering capacity in that range.[19]

153. Likewise, during the bench trial in *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 22-cv-61 (N.D.W. Va.), Dr. Furfine testified that he "invented the use of a phosphate buffer in this formulation to stabilize aflibercept."[20]

154. Importantly, while the '707 Application was pending, on March 14, 2025, the Federal Circuit affirmed the MDL Court's Order Denying PI in a unanimous and precedential opinion (the above-referenced Federal Circuit Order Affirming Denial of PI). As the Federal Circuit confirmed, "the specification describes a formulation containing a VEGF antagonist plus a distinct buffer component" and "that understanding is reinforced consistently throughout the specification, which 'includes eight example formulations and twenty-two (22) embodiments, each of which describes the VEGF antagonist (aflibercept) plus a buffer.'" *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372, 1382 (Fed. Cir. 2025); *see also In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 at 50 (N.D.W. Va. Sept. 23, 2024) ("[E]very example and embodiment [in the '865 Patent specification] includes a buffer that is separate from, and present in addition to, the aflibercept"). In fact, "'[n]othing in the specification indicates' that the VEGF antagonist 'might' also satisfy the distinct 'buffer' component." *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372, 1382 (Fed. Cir. 2025).

[19] Dix Declaration in Support of June 25, 2009 Response to Office Action in File History of U.S. Patent Application No. 11/387,256 at ¶ 7.

[20] *See* Trial Tr. Day 3, June 14, 2023 at 543:6-7.

155. Likewise, the specification of the '099 Patent contains no disclosure to a person of ordinary skill in the art as of June 16, 2006 of a liquid ophthalmic formulation of a VEGF antagonist that does not comprise an excipient buffer and is able to maintain the claimed pH range. Regeneron conceded as much during its appeal of the MDL Court's Order Denying PI. *Regeneron Pharms., Inc. v. Mylan Pharms., Inc.*, 130 F.4th 1372, 1382 (Fed. Cir. 2025).

156. As the MDL Court determined, there is "no factual dispute that, as of June 2006, there were no formulations of any fusion protein (or aflibercept specifically) or any intravitreal protein formulation that lacked a separate buffer." *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 at 45, 70 (N.D.W. Va. Sept. 23, 2024). In fact, Regeneron did not dispute that, once approved, Amgen's PAVBLU would be the first FDA-approved buffer-free fusion protein formulation.

157. Nor would a person of ordinary skill have known that aflibercept could serve as a buffer or be formulated in a stable pharmaceutical formulation without a buffer. As the Federal Circuit confirmed, "none of the extrinsic evidence discloses that aflibercept can function as a buffer in a pharmaceutical formulation as of the effective filing date of the ['707 Application]." *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372, 1383 (Fed. Cir. 2025) (internal quotations omitted); *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 at 65 (N.D.W. Va. Sept. 23, 2024) ("[T]he evidence does not show that aflibercept was known as (or understood to be) a buffer in a pharmaceutical composition during the relevant timeframe[.]"). Given the lack of guidance in both the art and the specification as to how to make a buffer-free aflibercept formulation, a person of ordinary skill in the art would have needed to engage in undue experimentation to arrive at a buffer-free formulation.

158. Furthermore, the Federal Circuit, in its unanimous affirmance of the MDL Court's decision denying Regeneron's motion for a preliminary injunction, confirmed that Gokarn demonstrates that "self-buffering proteins were not well known" and that "Gokarn advanced the art over the '865 [P]atent precisely by disclosing certain buffer-free formulations in which the therapeutic protein is itself capable of maintaining pH stability." *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372, 1384 (Fed. Cir. 2025) (quoting in part Amgen's Brief in Opposition to Regeneron's Motion for Preliminary Injunction).

159. As the MDL Court noted, "Gokarn provides no example of a buffer-free aflibercept formulation, no data for a buffer-free aflibercept formulation, no data on the buffering capacity of aflibercept, no pH range within which aflibercept could provide buffering capacity, and no teaching about how to formulate aflibercept in a stable ophthalmic formulation suitable for intravitreal injection without a separate buffer." *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 at 64-65 (N.D.W. Va. Sept. 23, 2024).

160. It was not until Amgen scientists developed the formulation taught in its '463 Application, after spending years building upon the prior research discussed in Gokarn, that any further advancements in the area of buffer-free aflibercept formulations were made.

161. For these reasons, the specification of the '099 Patent provides no teaching of a formulation containing only aflibercept, water, polysorbate, and a stabilizer with the claimed stability. Nor could it, as Amgen only disclosed this for the first time in its own '463 Application claiming priority to 2017.

162. Moreover, as detailed above, Regeneron only filed the application for the '099 Patent after Amgen's formulation, which did not require an excipient buffer, became publicly available. Regeneron's failure to act with any urgency to obtain the claims of the '099 Patent for

the first eighteen years after the earliest priority application followed by the submission of a request for expedited examination is consistent with the fact that the named inventors did not conceive of the inventions claimed in the ’099 Patent, upon information and belief, as Regeneron well knows.

163. On information and belief, Regeneron’s counsel knew, when the claims that omit the requirement for an excipient buffer were filed, that it was Amgen, not the ’099 Patent’s inventors, who invented a buffer-free aflibercept formulation, and failed to disclose that fact, upon information and belief, knowingly and willfully to deceive the USPTO.

164. In furtherance of its effort to secure the ’099 Patent by fraud, Regeneron buried or delayed disclosure of relevant information to the Examiner until at or around the time that the Examiner allowed the claims. When the ’707 Application was filed on October 23, 2024, Regeneron’s counsel and the inventors knew of hundreds of references, documents and court orders that are material to the patentability of the ’707 Application claims. However, they failed to submit *any* references in an Information Disclosure Statement with the originally filed application, including material references such as the MDL Court’s Order Denying PI, dated September 23, 2024, *In re Aflibercept Pat. Litig.*, No. 24-md-03103 (N.D.W. Va.), establishing that Regeneron did not invent a buffer-free ophthalmic formulation of aflibercept. On information and belief, motivated by anticompetitive intent, Regeneron, through at least Ms. Nickols, Mr. Lewis, Mr. Marsh, Ms. Ho, and the inventors of the ’707 Application, withheld these documents in an effort to speed up prosecution so that Regeneron could obtain a patent that it could assert against Amgen in this litigation.

165. On November 29, 2024, the Examiner issued a non-final Office Action (1) objecting to the format of the sequence listing and (2) rejecting the claims for non-statutory double patenting over other issued patents in the same family.

166. Regeneron's counsel filed a Response to the Office Action on January 30, 2025, correcting the sequence listing and filing a terminal disclaimer to address the double patenting rejections. When filing the Response, again, Regeneron's counsel and the inventors of the '707 Application failed to disclose *any* references, documents or court orders to the USPTO.

167. Regeneron's counsel disclosed critical references and documents to the USPTO for the first time after the '707 Application was already in condition for allowance such that the Examiner had reviewed the claims and signed the Notice of Allowance but had not yet mailed it. The Examiner signed the first Notice of Allowance for the '707 Application on February 7, 2025, without considering any of the additional documents or materials from Regeneron's counsel or anyone else associated with the prosecution of the '707 Application. On February 17, 2025, Regeneron's counsel filed an Information Disclosure Statement of 4,914 pages, listing over 600 references. Regeneron's counsel filed a second Information Disclosure Statement on February 18, 2025, which was 1,317 pages. Notably, neither of these Information Disclosure Statements disclosed the MDL Court's Order Denying PI in which the Court made factual findings about the lack of disclosure in the specification of '865 Patent—the same specification as the '099 Patent—of buffer-free formulations.

168. Only after the Examiner issued the first Notice of Allowance on February 20, 2025, did Regeneron disclose the MDL Court's Order Denying PI along with other orders in an Information Disclosure Statement filed on March 3, 2025—*i.e.*, more than five months after that

order was issued and more than four months after the ’707 Application was originally filed—with a Request for Continued Examination.

169. On information and belief, Regeneron’s late disclosure of the MDL Court’s orders was motivated by an anticompetitive intent to get the Examiner to rubber stamp the Notice of Allowance and issue a patent so that Regeneron could use that patent to remove Amgen’s competitive product from the market. The Examiner issued a second Notice of Allowance on March 7, 2025, as Regeneron had planned. Regeneron withheld the MDL Court’s order until after the Notice of Allowance to prevent the Examiner from rereviewing the specification to assess whether the claims met the statutory requirements for adequate written description and enablement.

170. On information and belief, Regeneron’s counsel knew that the MDL Court’s Order Denying PI was material to the patentability of the ’707 Application but chose to delay its disclosure to impede careful review. And even when it ultimately disclosed the MDL Court’s Order, Regeneron’s counsel did not direct the Examiner to the findings that confirm the lack of written description and enablement in the specification for buffer-free formulations.

171. Regeneron engaged in similarly deceptive behavior regarding the Federal Circuit opinion affirming the MDL Court’s Order Denying PI. Despite the fact that the Federal Circuit issued its opinion on March 14, 2025, in *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372 (Fed. Cir. 2025), and prosecution counsel knew about the opinion, Regeneron’s counsel chose to pay the issue fee for the ’707 Application on April 2, 2025, without disclosing the opinion to the Examiner. Only after paying the issue fee did Mr. Lewis file a Quick Path Information Disclosure Statement (“QPIDS”) on April 3, 2025, listing the Federal Circuit’s

opinion. Regeneron proceeded in this manner in order to process the ’707 Application as quickly as possible and obtain a patent that Regeneron could assert against Amgen in this litigation.

172. Furthermore, in an effort to downplay the key findings of the Federal Circuit Order Affirming Denial of PI for the Examiner, Regeneron disclosed the adverse Amgen opinion along with what Regeneron viewed as the favorable Federal Circuit opinions in the Mylan, Samsung, Formycon, and Celltrion cases, none of which concerned any buffer-free formulations. At least two of these were previously disclosed in the Information Disclosure Statement submitted to the USPTO on February 18, 2025, and so did not need to be disclosed again. Regeneron disclosed the Federal Circuit’s Order Affirming Denial of PI together with the other opinions specifically to mislead the Examiner into believing that all four decisions reached the same results on the same facts—which they did not. The Samsung, Formycon, and Celltrion decisions addressed different issues and reached a different conclusion than the Amgen decision..

173. After receiving these disqualifying disclosures, the Examiner issued another Notice of Allowance on April 16, 2025, and the ’099 Patent issued on June 17, 2025.

174. Regeneron’s prosecution strategy for the ’707 Application is consistent with its repeated pattern of pursuing patents that it knows to be invalid after obtaining unfavorable court decisions, as described in detail above.

175. Regeneron impermissibly broadened the scope of the ’099 Patent to present claims that it knew to be invalid and unenforceable. Regeneron made false representations and/or deliberate omissions of material facts to patentability with the intent of, and with the effect of, deceiving the USPTO. Regeneron acted for the purpose of, and with the effect of, obtaining the ’099 Patent that would not have otherwise issued.

176. On the same date the ’099 Patent was issued (June 17, 2025), Regeneron filed the present Complaint in the C.D. Cal. Court. *See Regeneron Pharm., Inc. v. Amgen, Inc.*, No. 2:25-cv-5499 (C.D. Cal.), Dkt. 1. Regeneron alleges that Amgen infringed on the ’099 Patent through the “manufacture, use, offer for sale, and/or sale in the United States, or import into the United States, of ABP 938 under the market name Pavblu®”. *Id*. The Complaint seeks damages and injunctive relief for this purported infringement. *See id*. Upon information and belief, Regeneron is asserting the ’099 Patent in the instant action with knowledge of its fraudulent procurement. Upon information and belief, Regeneron knows full well that Amgen, not Regeneron, invented a buffer-free formulation and that there is therefore no basis for this lawsuit.

177. Regeneron’s attempt to obtain an injunction on the basis of the fraudulently-procured ’099 Patent is an improper attempt to exclude competition from PAVBLU entirely in order to protect or reclaim EYLEA’s monopoly position in the market.

V. MARKET POWER AND MARKET DEFINITION

178. For purposes of this case, the relevant product market or submarket is comprised of sales of anti-VEGF treatments containing 2 milligrams of aflibercept administered via intravitreal injections, in a relevant geographic market of the United States. Today the relevant market is limited to EYLEA and PAVBLU. At all relevant times to this action, Regeneron has maintained monopoly power and/or a dangerous probability of success in achieving monopoly power within this relevant market or submarket. Regeneron’s monopoly power is demonstrated by both direct and indirect evidence.

A. Direct Evidence of Monopoly Power

179. At all relevant times to this action, Regeneron has maintained supracompetitive prices and profits for 2 mg EYLEA.

180. Regeneron has acknowledged that the prices it charges for 2 mg EYLEA are significantly higher than Regeneron could have charged if there were aflibercept biosimilar competition sooner, or more aflibercept biosimilar competition today. For example, on a recent earnings call, Regeneron's leadership indicated that having only one aflibercept biosimilar competitor—*i.e.*, PAVBLU—enabled Regeneron to maintain the current level of pricing for EYLEA, explaining that if the market dynamic of having only one competitor "holds, that really changes the dynamic quite a bit in terms of pricing and things like that."

181. Regeneron has also underscored the well-documented dynamic of substantial price erosion that a reference product like 2 mg EYLEA commonly experiences when biosimilars to that reference product enter the market. For example, in support of its preliminary injunction applications, Regeneron observed that "[o]pthalmic drugs are not immune from this trend" of "declining ASP following the launch of biosimilars"; Regeneron further projected that such price erosion would likely occur for 2 mg EYLEA if multiple aflibercept biosimilars were allowed to enter and compete with EYLEA, causing Regeneron irreparable harm. Thus, Regeneron, by its own admission, does not need to control anything other than 2 mg aflibercept-based treatments to maintain supracompetitive pricing.

182. Stated differently, while at some level there may be substitution between 2 mg EYLEA and other anti-VEGF treatments such as LUCENTIS and VABYSMO (both marketed by Genentech)—just as products in a relevant market or submarket may be interchangeable to some extent with products outside of it[21]—Regeneron has nonetheless been able to maintain prices for 2 mg EYLEA that, as Regeneron itself has recognized and stated, are substantially

[21] *See, e.g.*, *In re Zetia (Ezetimibe) Antitrust Litig.*, 587 F. Supp. 3d 356, 361 (2022) ("[P]roducts which are interchangeable to some degree, but do not share significant cross-elasticity of demand, are not in the same relevant antitrust product market.")

higher than it would have been able to maintain if there were 2 mg aflibercept biosimilar competitors in the market.

183. Similarly, Regeneron has recognized that the presence of 2 mg aflibercept competition will hamper its plans to convert patients from EYLEA to EYLEA HD (with Regeneron's leadership acknowledging that "the longer you have without [2 mg aflibercept] biosimilars . . . the longer the runway to convert patients" to EYLEA HD), indicating that the current set of treatments in the market do not supply the same competitive constraint as aflibercept biosimilar competition.

184. That reality facing 2 mg EYLEA is consistent with market reports that Regeneron, district and appellate courts, and many others have relied upon to assess the likely impact of biosimilar competition to a reference product's pricing. For example, as this Court noted in its order granting a permanent injunction against Mylan/Biocon's launch of its aflibercept biosimilar, there is a well documented "trend in reference products' declining ASP following the launch of biosimilars", and "[o]phthalmic drugs are not immune from this trend, as the launch of ranibizumab biosimilars has shown." *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 188 at 31 (N.D.W. Va. June 21, 2024) (Order Granting a Permanent Injunction Against Biocon and Mylan).. As one frequently cited industry report has found, "[b]iosimilar launches have led to significant price decreases over time. On average, ASP decreased by 53% within five years of the first biosimilar launch."[22]

185. In conjunction with its supracompetitive pricing, Regeneron has consistently earned supracompetitive profit margins on its sales of 2 mg EYLEA. As detailed above,

[22] *See* Samsung Bioepis Biosimilar Market Report, 9th Ed., Q2 2025, *available at* https://m.samsungbioepis.com/upload/attach/SB+Biosimilar+Market+Report+Q2+2025.pdf (last accessed on Sept. 12, 2025).

Regeneron has earned large profits from 2 mg EYLEA that have alone buoyed Regeneron's earnings and stock prices. .

186. Furthermore, this Court has previously found, at Regeneron's urging, that the market for 2 mg aflibercept PFS represents a distinct product market for purposes of assessing irreparable harm, including the anticipated price effect of 2 mg aflibercept biosimilar entry. *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 188 at 24 (N.D.W. Va. June 21, 2024).

B. Indirect Evidence of Monopoly Power

187. Indirect evidence—to the extent required—also demonstrates that Regeneron has monopoly power in the market or submarket for the sale of 2 mg aflibercept-based anti-VEGF treatments in the United States.

188. There is a relevant product market comprised of 2 mg aflibercept-based anti-VEGF treatments for sale in the United States.

189. The United States is the relevant geographic market, including because of the national FDA regulatory standards and approvals that pharmaceutical products must obtain in order to be purchased by physicians and patients in the United States. Patients and physicians in the United States would not be able to substitute for a non-FDA-approved 2 mg aflibercept-based anti-VEGF treatment in response to a small but significant nontransitory price increase on 2 mg aflibercept-based anti-VEGF treatments in the United States.

190. As described above, the existence of other anti-VEGF treatments has not sufficiently constrained 2 mg EYLEA's pricing to bring it down to competitive levels, whereas 2 mg aflibercept biosimilar entry would cause substantial price erosion for 2 mg EYLEA or, in the alternative, Regeneron would lose substantial sales, indicating a degree of positive cross-elasticity of demand between 2 mg EYLEA and its biosimilars that Regeneron does not experience between EYLEA and other anti-VEGF treatments on the market. Regeneron has not

experienced that same price impact with the products that have been in the market for the last several years, including AVASTIN, LUCENTIS and its biosimilars, and VABYSMO. Indeed, when biosimilars to LUCENTIS entered the market, LUCENTIS was forced to substantially reduce its ASP to or below the ASPs of the competing biosimilars, but their entry did not have a comparable price impact on 2 mg EYLEA.[23]

191. Regeneron has acknowledged this commercial reality. For example, at the J.P. Morgan Spring Biotech Conference on March 15, 2019, Regeneron Executive Vice President – Commercial Marion McCourt said that "unapproved low-cost alternative exists today and EYLEA performs very well." And at the Oppenheimer Healthcare Conference on March 16, 2021, Regeneron Vice President-Investor Relations Justin Holko said: "We know investors are thinking about biosimilar competition and the like. When it comes to biosimilar, just remember, there's already a very low-priced biosimilar in the market today. And despite that, EYLEA continues to grow. We're actually taking share from that low-price biosimilar, Avastin."

192. Patient and prescriber behavior likewise demonstrates that 2 mg aflibercept-based anti-VEGF treatments occupy their own relevant market or submarket. Due to insurance requirements, most patients being treated for angiogenic eye diseases typically start out on AVASTIN (bevacizumab), which is used off-label as a first line treatment due to its substantially lower cost than branded, on-label treatments.[24] AVASTIN is not reasonably interchangeable

[23] *Id.*

[24] *See, e.g.*, Aetna Formulary Coverage Tiers, available at https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/health-care-professionals/aetna-medicare-advantage-with-prescription-drug-coverage-(mapd)-2025-part-B-preferred-drug-list.pdf (last accessed on Sept. 12, 2025). Blue Cross Formulary Coverage Tiers, available at https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/092%20Vascular%20Endothelial%20Growth%20Factor%20%28VEGF%29%20Inhibitors%20Step%20Therapy.pdf (last accessed on Sept. 12, 2025).

with 2 mg aflibercept-based treatments because it is primarily targeted at a different patient population (first-line treatment as required by most insurers), is less effective and has a different safety profile than 2 mg aflibercept-based products. 2 mg aflibercept-based anti-VEGF treatments are seen and used not as a reasonably close substitute to AVASTIN but rather as a second-line treatment that insurers may cover, and providers and patients will utilize, if AVASTIN is not working for the patient.

193. LUCENTIS (ranibizumab) and its biosimilars are also not reasonably interchangeable with 2 mg aflibercept-based anti-VEGF treatments, including because of the superior clinical and safety profile of aflibercept. 2 mg aflibercept-based anti-VEGF treatments also can require less frequent injections than LUCENTIS. For example, 2 mg aflibercept-based anti-VEGF treatments are recommended for intravitreal injection to treat wAMD once a month for the first three months, but then—unlike LUCENTIS—can be injected once every two months. Clinical studies show that EYLEA administered every two months was clinically equivalent to LUCENTIS (the previous standard of care) dosed every month. 2 mg aflibercept-based anti-VEGF treatments also have been proven to provide superior vision gains when compared to treatment with LUCENTIS in certain patients with DME.

194. Because of its unique design (wherein two VEGF-binding domains from two VEGF receptors are grafted onto an antibody "Fc" domain), aflibercept is likely to bind the VEGF target more tightly than LUCENTIS (which has only one VEGF binding domain), resulting in a stronger inhibition of VEGF in the patients' eyes. Furthermore, unlike LUCENTIS, which binds only to VEGF-A, aflibercept has the ability to bind to multiple VEGF family members, including VEGF-A, VEGF-B, and PIGF (placental growth factor). The three-

dimensional configuration of aflibercept enables it to simultaneously bind both sides of the VEGF molecule in a "two-fisted grasp."

195. Aflibercept-based products also have avoided some of the severe safety issues that come with other anti-VEGF medications and, as a result, those medications are also not reasonably interchangeable. For example, immediately after the launch of another anti-VEGF medication in the United States, BEOVU® (brolucizumab-dbll)—which was approved by the FDA for vial presentation in 2019 and PFS in 2022—physicians immediately began reporting that BEOVU patients were suffering from serious adverse reactions, including higher rates of intraocular inflammation (IOI), incidences of retinal artery occlusion (RAO), and occlusive retinal vasculitis (ORV).

196. Moreover, 2 mg aflibercept-based anti-VEGF treatments occupy a separate relevant market or submarket from VABYSMO. VABYSMO uses a different mechanism of action and has different dosing than 2 mg aflibercept-based anti-VEGF treatments. VABYSMO is a bispecific antibody that targets both VEGF and angipoietin-2, whereas aflibercept is a recombinant fusion protein that targets VEGF and placental growth factor. At present, EYLEA is indicated to treat more eye disorders than VABYSMO (*e.g.*, diabetic retinopathy and retinopathy of prematurity).

197. Moreover, at least some formularies classify VABYSMO (along with LUCENTIS and other non-aflibercept-based treatments) as "non-preferred drugs", while classifying aflibercept (EYLEA and PAVBLU) as "second tier preferred drugs after trial/failure of bevacizumab (AVASTIN)", indicating a reasonable interchangeability between EYLEA and

PAVBLU that is not shared as between those treatments on the one hand and the other anti-VEGF treatments on the other.[25]

198. Further, 2 mg aflibercept-based anti-VEGF treatments are not reasonably interchangeable with other anti-VEGF treatments for a meaningful number of patients for whom aflibercept is working well with no side effects. For those patients, the patient and physician would be highly unlikely to switch to a non-aflibercept-based treatment based on a 5% or 10% price increase in price on the aflibercept-based treatment, even relative to Regeneron's existing supracompetitive pricing.

199. Finally, 2 mg aflibercept-based anti-VEGF treatments occupy a separate relevant market or submarket from 8 mg aflibercept-based anti-VEGF treatments. For a meaningful number of patients coming off AVASTIN, EYLEA HD (the only 8 mg aflibercept-based product on the market) is not a reasonably interchangeable alternative to EYLEA or PAVBLU (the only 2 mg aflibercept anti-VEGF treatments on the market), including because physicians and patients typically will want to be sure that the lower-dose treatment works well before progressing to a higher-dose treatment.

200. Regeneron's EYLEA HD conversion strategy, described above, reflects the recognition and reality that patients who switch to EYLEA HD are far less likely to switch back to a 2 mg aflibercept based product (whether EYLEA or a biosimilar), even where the biosimilar comes in at a lower price point. Consistent with that reality, this Court held that "8 mg Eylea HD products . . . represent distinct products and markets for the purposes of assessing irreparable harm." *See, e.g.*, *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 188 at 24 (N.D.W. Va. June

[25] *See, e.g.*, Medicare Part B preferred drug list, Aetna Medicare Advantage plans, *available at* https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/health-care-professionals/aetna-medicare-advantage-with-prescription-drug-coverage-(mapd)-2025-part-B-preferred-drug-list.pdf (last accessed on Sept. 12, 2025).

21, 2024) (Order Granting a Permanent Injunction Against Biocon and Mylan); *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 252 at 147 (N.D.W. Va. July 09, 2024) (Order Granting a Preliminary Injunction Against Formycon); *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 194 at 125 (N.D.W. Va. June 24, 2024) (Order Granting a Preliminary Injunction Against Samsung).

201. Within the relevant market or submarket for 2 mg aflibercept-based anti-VEGF treatments, Regeneron has held and maintains monopoly power, *i.e.*, substantial market power protected by entry barriers. Until PAVBLU's entry in late 2024, Regeneron held 100% of the market since EYLEA's launch in 2011. Even today, with PAVBLU on the market for nearly a year, Regeneron continues to enjoy an approximately 70% share of the market.

202. Further, even if it could be said that Regeneron did not have monopoly power in the market for 2 mg aflibercept-based products, Regeneron's anticompetitive actions create a dangerous probability of Regeneron achieving monopoly power.

203. Moreover, there are significant entry barriers to the market for 2 mg aflibercept-based anti-VEGF treatments, including Regeneron's patents, complex regulatory requirements, the substantial expense of developing and launching an aflibercept-based anti-VEGF treatment, as well as the fact that 2 mg aflibercept-based anti-VEGF treatments are "buy-and-bill" products that are stocked in doctor's offices, resulting in a meaningful supply constraint.

C. Market Effect and Antitrust Injury

204. As the first and only aflibercept biosimilar competitor to EYLEA in the United States—and one with unique benefits such as a silicone oil-free pre-filled syringe and a vial version with a longer shelf life—PAVBLU presents an acute and growing threat to EYLEA's dominance in the relevant market. Since entering the market, PAVBLU, over time and through great effort and expense, has been able to establish key relationships with retinal specialists, and

educate patients and retinal specialists about PAVBLU and its safety and efficacy. PAVBLU continues to make inroads with practice groups, providers, and patients. As a result, PAVBLU has been growing its share of the relevant market, finally creating competitive pressure on EYLEA in the relevant market, to the benefit of patients and providers. As such, Regeneron's anticompetitive attempt to exclude PAVBLU from the market, if successful, would simultaneously harm competition in the market and harm Amgen.

205. Regeneron's assertion of fraudulently-procured patents in the 2024 Litigation and its assertion of the fraudulently procured '099 Patent in the instant Action, if successful, would take PAVBLU off the market, eliminating the only biosimilar competitor in the market today, to the detriment of patients and providers. Regeneron's anticompetitive attempt to remove PAVBLU from the market on the basis of fraudulent patents would, if successful, eliminate that beneficial competition. Further, upon information and belief, additional biosimilar entry is not expected to enter the market, at the soonest, before around the second half of 2026. It is highly unlikely such late entry can replicate the competitive constraint PAVBLU presently exerts and will, absent anticompetitive exclusion, increasingly exert on EYLEA, given the advantages and inroads PAVBLU has made over time, having been first to the market and on the market for nearly a year with a differentiated product that offers unique benefits to patients and providers.

206. As a result of Regeneron's anticompetitive conduct, Amgen has suffered and will continue to suffer injuries that the antitrust laws were designed to prevent and that flow directly from Regeneron's anticompetitive conduct, including incurring substantial costs defending against Regeneron's assertions of fraudulently-procured patents in the 2024 Action and Regeneron's assertion of the fraudulently procured '099 Patent in the instant Action. Additionally, as and to the extent litigation continues on the basis of fraudulently-procured

patent(s), Amgen may suffer a loss of PAVBLU sales due to any uncertainty that providers and physicians may have about the continued future availability of PAVBLU. Upon information and belief, Regeneron is well aware of the prospect for such adverse competitive effects arising from the assertion of fraudulently-procured patents, as Regeneron itself alleged such potential impacts in an unrelated lawsuit.[26]

VI. COUNTS

FIRST COUNTERCLAIM: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NO. 12,331,099

207. Amgen incorporates by reference the foregoing paragraphs as if fully set forth herein.

208. Amgen has not infringed, and will not infringe, any valid and enforceable claim of the ’099 Patent at least because Amgen will not directly or indirectly infringe one or more claims of the ’099 Patent for at least the reasons set forth in Amgen’s (3)(B) Statement for the ’099 Patent.

209. An actual, substantial, and justiciable controversy exists between Amgen and Regeneron about whether Amgen has infringed, and whether Amgen will infringe by its commercial marketing of PAVBLU, any valid and enforceable claim of the ’099 Patent.

210. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

211. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, one or more of the claims of the ’099 Patent.

SECOND COUNTERCLAIM: DECLARATORY JUDGMENT OF INVALIDITY OF U.S. PATENT NO. 12,331,099

[26] *See* First Amended Complaint, *Regeneron v. Novartis Pharma AG, et al.*, No. 1:21-cv-01066-DNH-CFH, Dkt. No. 87 (S.D.N.Y. Jan. 15, 2021).

212. Amgen incorporates by reference the foregoing paragraphs as if fully set forth herein.

213. One or more of the claims of the ’099 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, 112, 115, 116, 119, 132, 251, 256, 282, and/or other judicially created bases for invalidation for at least the reasons set forth in Amgen’s (3)(B) Statement for the ’099 Patent.

214. An actual, substantial, and justiciable controversy exists between Amgen and Regeneron about whether one or more of the claims of the ’099 Patent are invalid.

215. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

216. Amgen is entitled to a judicial declaration that one or more of the claims of the ’099 Patent are invalid under 35 U.S.C. § 101, 102, 103, 112, 115, 116, 119, 132, 251, 256, 282, and/or other judicially created bases for invalidation.

THIRD COUNTERCLAIM: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF U.S. PATENT NO. 12,331,099 (PROSECUTION LACHES)

217. Amgen incorporates by reference the foregoing paragraphs as if fully set forth herein.

218. The ’099 Patent is unenforceable based on prosecution laches, because the ’099 Patent issued only after an unreasonable and inexcusable delay in prosecution, and that delay in prosecution has prejudiced Amgen.

219. Regeneron unreasonably and inexcusably waited over eighteen years, from the time it filed the first priority application (i.e., the ’484 Provisional) to the time it filed the application for ’099 Patent, to pursue the claimed formulations requiring neither a buffer nor a salt.

220. Upon information and belief, it was only after Regeneron learned of Amgen's novel buffer-free formulation and was unsuccessful in its efforts to enjoin Amgen from launching its PAVBLU product that Regeneron pursued the claims of the '099 Patent, which Regeneron knows cover subject matter invented by Amgen.

221. Regeneron's dilatory prosecution tactics were designed to overwhelm and deceive the USPTO. Despite failing to act with any urgency for over eighteen years, Regeneron's Counsel filed the application for the '099 Patent with a request for expedited examination under the USPTO's Patents for Humanity Program.

222. Regeneron's Counsel failed to disclose any material information to the USPTO with the initial filing of the application for the '099 Patent, including the Order Denying PI and the fact that Amgen was the first to invent a buffer-free aflibercept formulation. Instead, Regeneron's Counsel waited until the Examiner, without the benefit of the Order Denying PI, determined the claims were in condition for allowance. Only then did Regeneron bury that order among over 600 references. These abusive prosecution tactics constitute an egregious misuse of the patent system.

223. As a result of Regeneron's unreasonable and inexcusable delay, Amgen has been prejudiced. Since at least 2017, Amgen has invested significant time, money and resources in the development of its PAVBLU product. Well before Regeneron submitted claims directed to an ophthalmic aflibercept formulation without a buffer, Amgen worked on developing a buffer-free aflibercept formulation.

224. As the Federal Circuit concluded, Amgen's Gokarn Application "advanced the art over the '865 Patent precisely by disclosing certain buffer-free formulations in which the therapeutic protein is itself capable of maintaining pH stability." *Regeneron Pharms., Inc. v.*

Mylan Pharms. Inc., 130 F.4th 1372, 1384 (Fed. Cir. 2025) (quoting Amgen's Brief in Opposition to Regeneron's Motion for Preliminary Injunction). Following Amgen's work in connection with the Gokarn Application, Amgen developed an innovative and first-in-class buffer-free aflibercept formulation. That formulation was separately patented by Amgen in U.S. Patent No. 12,156,900.

225. Amgen invested significant resources into the launch of its FDA-approved aflibercept biosimilar prior to Regeneron's presentation of the claims of the '099 Patent. Regeneron's years of delay in ultimately pursuing claims that it now contends cover Amgen's aflibercept biosimilar is highly prejudicial to Amgen.

226. As a result of its delay, Regeneron was able to draft claims in view of new information and products that were not available at the time of its initial filing (namely, Amgen's buffer-free aflibercept formulation), rather than the specification which does not support Regeneron's claims.

227. An actual, substantial, and justiciable controversy exists between Amgen and Regeneron about whether one or more claims of the '099 Patent are unenforceable under the doctrine of prosecution laches.

228. Amgen is entitled to a judicial declaration that one or more claims of the '099 Patent are unenforceable under the doctrine of prosecution laches.

FOURTH COUNTERCLAIM: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF U.S. PATENT NO. 12,331,099 (INEQUITABLE CONDUCT)

229. Amgen incorporates by reference the foregoing paragraphs as if fully set forth herein.

230. The '099 Patent is unenforceable due to inequitable conduct before the U.S. Patent and Trademark Office ("USPTO").

231. The following individuals are subject to a duty to disclose information material to the patentability of claims under examination: (1) each inventor named in the application; (2) each attorney or agent who prepares or prosecutes the application; and (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application.

232. At least those persons materially involved in the prosecution of the ’099 Patent, including Regeneron’s counsel, Ms. Nickols, Mr. Lewis, Mr. Marsh, Ms. Ho, and any other counsel for Regeneron who directed prosecution strategy (collectively, “Regeneron’s Counsel”), are subject to a duty to disclose information material to the patentability of the ’099 Patent claims to the USPTO.

Regeneron’s Counsel Misrepresented to the USPTO that the Inventors of the ’865 Patent Also Invented the Subject Matter Claimed in the ’099 Patent

233. Regeneron’s Counsel engaged in inequitable conduct at least by misrepresenting to the USPTO the inventorship of the claimed subject matter of the ’099 Patent and by falsely asserting that the claims of the ’099 Patent did not present new matter beyond the description in the originally filed application.

234. On October 23, 2024, when Regeneron’s Counsel filed the application for the ’099 Patent, Ms. Nickols signed an Application Data Sheet identifying Eric Furfine, Daniel Dix, Kenneth Graham, and Kelly Frye as the inventors of the subject matter claimed in the application, including claims allegedly encompassing a buffer-free aflibercept formulation.

235. Rather than submitting to the USPTO oaths or declarations from Eric Furfine, Daniel Dix, Kenneth Graham, and Kelly Frye pursuant to 35 U.S.C. § 115 averring that they authorized the application and believed themselves to be original joint inventors of the subject

matter claimed in the application, Regeneron's Counsel instead resubmitted declarations that were signed by those individuals in February 2014 and were previously submitted during prosecution of U.S. Application No. 13/914,996 (the "'996 Application"). The '996 Application is related to the '099 Patent but did not contain claims allegedly encompassing a buffer-free aflibercept formulation.

236. The '996 Application claimed only formulations requiring a phosphate buffer, and the '996 Application neither described nor claimed the formulations allegedly claimed in the '099 Patent, which as written do not recite a buffer.

237. On information and belief, Regeneron's Counsel was aware that the inventors listed for the '099 Patent did not invent any buffer-free aflibercept formulations.

238. On information and belief, Regeneron's Counsel was aware that employees of Amgen, not Regeneron, were the true inventors of buffer-free aflibercept formulations.

239. When filing the application for the '099 Patent on October 23, 2024, Ms. Nickols presented a preliminary amendment adding new claims that as written do not recite a buffer. Ms. Nickols represented to the USPTO that "[n]o new matter enters by way of the present amendments." Preliminary Amendment dated October 23, 2024 in '099 Patent File History at 9. On information and belief, Regeneron's Counsel, including Ms. Nickols, knew that the '099 Patent does not disclose any buffer-free formulations and for at least that reason, knew that the new claims did not present new matter and the statement to the contrary was materially false and misleading.

240. While the '099 Patent claims priority to the '484 Provisional, which was filed on June 16, 2006, Regeneron did not file the application for '099 Patent until October 23, 2024 over eighteen years after the earliest priority application.

241. Prior to the filing of the application for the ’099 Patent, Regeneron brought suit against Amgen alleging infringement of a parent patent to the ’099 Patent, the ’865 Patent, in *Regeneron Pharms., Inc. v. Amgen Inc.*, MDL No. 24-md-03103-TSK-JPM (N.D.W. Va.) (defined above as the “First Amgen Action”). The claims of the ’865 Patent all require a VEGF antagonist (e.g., aflibercept) and a buffer.

242. In the First Amgen Action, Regeneron filed a motion for a preliminary injunction against Amgen based on the ’865 Patent. In support of its preliminary injunction motion, Regeneron argued that there was a reasonable likelihood of success because Amgen’s buffer-free ABP 938 product infringed the claims of the ’865 Patent.

243. “[T]he parties’ central dispute [was] whether the Asserted Claims require that the ‘VEGF antagonist’ and the ‘buffer’ be separate and distinct components of the claimed formulation.” *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343, at 27 (N.D.W. Va. Sept. 23, 2024). “Regeneron argue[d] that the VEGF antagonist [i.e., aflibercept] can also satisfy the limitation of the claimed buffer.” *Id.* In opposing Regeneron’s preliminary injunction motion, “Amgen propose[d] that the Asserted Claims require that the claimed ‘VEGF antagonist’ and the claimed ‘buffer’ be separate components.” *Id.*

244. The United States District Court for the Northern District of West Virginia denied Regeneron’s application for a preliminary injunction, holding that “Regeneron has not shown a reasonable likelihood of success on the merits because Amgen has raised a substantial question of noninfringement based on the specific formulation of Amgen’s proposed biosimilar product.” *See id.* at 2. That decision was affirmed on appeal by the United States Court of Appeals for the Federal Circuit in *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372 (Fed. Cir. 2025).

245. The application for the ’099 Patent was filed after: (i) Regeneron’s motion for a preliminary injunction in the First Amgen Action was denied by the United States District Court for the Northern District of West Virginia on September 23, 2024; and (ii) Regeneron’s motion for an injunction pending appeal was denied by the United States Court of Appeals for the Federal Circuit on October 22, 2024.

246. Upon information and belief, Regeneron’s Counsel was aware of Amgen’s buffer-free ABP 938 formulation before filing the application for the ’099 Patent. On August 23, 2024, prior to the filing of the application for the ’099 Patent, the FDA published its approval letter for Amgen’s ABP 938 product, which was the first ever FDA-approved buffer-free aflibercept product. When Amgen’s ABP 938 product was approved, the product label, which identified the components in the formulation, became publicly available. Upon information and belief, Regeneron’s Counsel was aware of Amgen’s product label and the components of Amgen’s ABP 938 product, prior to filing the application for the ’099 Patent. Upon information and belief, Regeneron’s Counsel used information about Amgen’s product label and the components of Amgen’s ABP 938 product in drafting the claims of the ’099 Patent.

247. On information and belief, before filing the application for the ’099 Patent, Regeneron’s Counsel was also aware of Amgen’s research on buffer-free aflibercept formulations, which were disclosed in public patent filings. Amgen scientists invented a buffer-free aflibercept formulation as reflected in, for example, Amgen’s ’463 Application, which published on October 29, 2020—fourteen years after the earliest claimed priority date of the ’099 Patent. Amgen’s ’463 Application later issued as U.S. Patent No. 12,156,900. On information and belief, Regeneron’s Counsel was aware of the ’463 Application before filing the application for the ’099 Patent.

248. The application for the ’099 Patent was also filed after Regeneron and Regeneron’s Counsel became aware that the United States District Court for the Northern District of West Virginia had denied Regeneron’s motion for a preliminary injunction against Amgen involving the parent ’865 Patent (“Order Denying PI”) (filed under seal on September 23, 2024 and filed publicly with redactions on October 1, 2024). The application was also filed after the United States Court of Appeals for the Federal Circuit denied Regeneron’s motion for an injunction pending appeal on October 22, 2024 (“Order Denying PI Pending Appeal”). Upon information and belief, Regeneron’s Counsel understood that the Order Denying PI Pending Appeal could potentially lead to Amgen launching its ABP 938 product.

249. On information and belief, Regeneron’s Counsel identified Eric Furfine, Daniel Dix, Kenneth Graham and Kelly Frye as the inventors of the ’099 Patent despite being aware of the Order Denying PI and Order Denying PI Pending Appeal. Further, Regeneron’s Counsel filed the declarations alleging that Eric Furfine, Daniel Dix, Kenneth Graham and Kelly Frye were inventors of the subject matter claimed in the ’099 Patent despite being aware of the Order Denying PI and Order Denying PI Pending Appeal.

250. In the Order Denying PI, the Court found that Regeneron failed to show a reasonable likelihood of success in proving that Amgen’s ABP 938 formulation infringes the ’865 Patent, because Amgen’s product lacks the claimed buffer. *See In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 (N.D.W. Va. Sept. 23, 2024).

251. In its Order Denying PI, the Court found that “[t]here is no dispute that, in every example and every embodiment in the ’865 Patent, the formulation is described as containing both a VEGF antagonist and a separate buffer.” *Id*. at 45-46; *see also id*. at 50 (“[T]he ’865 patent does not exemplify or suggest that the aflibercept can satisfy both the ‘VEGF antagonist’

and 'buffer' limitations, and every example and embodiment includes a buffer that is separate from, and present in addition to, the aflibercept."). Regeneron did not cite "any contrary examples or embodiments in the specification indicating that the VEGF antagonist could serve as the buffer." *Id*. at 46.

252. The Court found that "there appears to be no factual dispute that, as of June 2006, there were no formulations of any fusion protein (or aflibercept specifically) or any intravitreal protein formulation that lacked a separate buffer." *Id*. at 65.

253. The Order Denying PI also rejected Regeneron's reliance on extrinsic evidence. *Id.* at 57. Regeneron had argued that using aflibercept as a buffer was so "well known in the art" that no description in the specification was necessary for a person of ordinary skill in the art to understand that the claimed VEGF antagonist can serve as the separately claimed "buffer." *Id.* The Court rejected this argument and found that "none of the extrinsic evidence discloses that aflibercept can function as a buffer in a pharmaceutical formulation, let alone in a manner that indicates this was so well known such that disclosure in the patent was not needed, as Regeneron argues." *Id*. at 62-63.

254. The only reference on which Regeneron relied that disclosed buffer-free pharmaceutical compositions was a patent publication, entitled "Self-Buffering Protein Formulations," which published as WO 2006/138181 (the "Gokarn Application"). The Gokarn Application was and is assigned to Amgen and published on December 28, 2006—more than six months after the claimed priority date of Regeneron's '865 Patent. It therefore did not and could not reflect the knowledge of a person of ordinary skill in the art as of that claimed priority date. *See In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 at 66-69 (N.D.W. Va. Sept. 23, 2024).

255. Indeed, in the context of prior proceedings involving the ’865 Patent or during prosecution of other Regeneron patent applications, public statements made by the named inventors confirm that those individuals did not invent a buffer-free aflibercept formulation. For example, Dr. Daniel Dix, an inventor of the ’865 Patent, submitted a declaration to the USPTO in June 2009 purporting to describe the importance of the specific buffer system he selected for an aflibercept formulation claimed in a different patent application filed March 22, 2006. Dix Declaration in U.S. App. No. 11/387,256, June 8, 2009. Dr. Dix stated: “In order to formulate the VEGF Trap at about pH 5.9 to about 6.5, a buffer system needed to be chosen that had significant buffering capacity in that range,” and that “[i]n order to have a good buffering capacity, . . . a combination of phosphate and citrate (5 mM each) was used.” *Id*. ¶ 7. Similarly, during the bench trial in *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 22-cv-61 (N.D.W. Va.), Dr. Eric Furfine, another inventor of the ’865 Patent, testified that he “invented the use of a phosphate buffer in this formulation to stabilize aflibercept.” Trial Tr. Day 3, June 14, 2023, at 543:6-7. Upon information and belief, Regeneron’s Counsel was aware of these statements when prosecuting the application that led to the ’099 Patent. The Dix Declaration was not submitted to the USPTO during prosecution of the ’099 Patent.

256. By resubmitting the same inventor declarations from the ’996 Application and naming the same inventors on the Application Data Sheet, Regeneron’s Counsel falsely represented to the USPTO that Eric Furfine, Daniel Dix, Kenneth Graham and Kelly Frye invented the subject matter allegedly encompassed by the claims of the ’099 Patent, *i.e.* liquid ophthalmic formulations comprising aflibercept that do not contain a separate buffer. No inventor oath was submitted in which the named inventors averred that they were original and joint inventors of the subject matter newly claimed in the application for the ’099 Patent.

257. Pursuant to 35 U.S.C. § 101, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." Further, pursuant to 35 U.S.C. § 115(a), "[e]ach individual who is the inventor or a joint inventor of a claimed invention in an application for patent shall execute an oath or declaration in connection with the application." 35 U.S.C. § 116 provides that "[w]hen an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath."

258. The misrepresentations by Regeneron's Counsel regarding inventorship and lack of new matter were material to patentability. The USPTO would not have issued the '099 Patent to Regeneron without the submission of the false inventor declarations, which misrepresented that Eric Furfine, Daniel Dix, Kenneth Graham, and Kelly Frye were inventors of subject matter claimed in the '099 Patent. The USPTO also would not have issued the '099 Patent had the Examiner been apprised by Regeneron and its counsel that the claims encompassed new matter not supported by the original specification.

The Prosecution History of the '099 Patent Reflects that Regeneron's Counsel Acted with a Specific Intent to Deceive the USPTO

259. The prosecution history of the '099 Patent evinces that Regeneron's Counsel misrepresented the true inventors of the '099 Patent with a specific intent to deceive the USPTO.

260. The timing of the filing of the application for the '099 Patent reflects that Regeneron's Counsel acted with a specific intent to deceive the USPTO. Regeneron did not seek to obtain the claims of the '099 Patent for the first eighteen years after the earliest priority application. Less than one month after the issuance of the Order Denying PI in the First Amgen Action and one day after the issuance of the Order Denying PI Pending Appeal, however, Regeneron's Counsel filed the application for the '099 Patent with a request for expedited

examination under the Patents for Humanity Program. Upon information and belief, they did so with specific knowledge of Amgen's invention of a buffer-free aflibercept formulation.

261. In prosecuting the '099 Patent, Regeneron delayed in disclosing information relating to the First Amgen Action and Amgen's development of a buffer-free formulation. This delay reflects that Regeneron's Counsel acted with a specific intent to deceive the USPTO. When Regeneron's Counsel filed the application for the '099 Patent, it did not submit an Information Disclosure Statement to the USPTO disclosing any material information. When Regeneron's Counsel filed the application for the '099 Patent, however, on information in belief, Regeneron's Counsel was aware of at least: (i) the ongoing litigation between Regeneron and Amgen; (ii) the Order Denying PI; (iii) the publicly available label for Amgen's ABP 938 product; (iv) the identity of the components in Amgen's ABP 938 product; and (v) Amgen's '463 Application relating to buffer-free aflibercept formulations. Regeneron's Counsel, however, failed to disclose any of items (i)-(v) to the USPTO when they filed the application for the '099 Patent.

262. On November 29, 2024, the USPTO issued an Office Action in connection with the application for the '099 Patent. Regeneron's Counsel submitted a response to that office action on January 30, 2025. When Regeneron's Counsel submitted its response on January 30, 2025, Regeneron's Counsel did not submit an Information Disclosure Statement to the USPTO disclosing any material information. For example, Regeneron's Counsel failed to submit, at least: (i) the ongoing litigation between Regeneron and Amgen; (ii) the September 2024 Order Denying PI; (iii) the publicly available label for Amgen's ABP 938 product; (iv) the identity of the components in Amgen's ABP 938 product; and (v) Amgen's '463 Application relating to buffer-free aflibercept formulations published in October 2020.

263. The Examiner signed a Notice of Allowance on February 6, 2025. Only after this Notice of Allowance was issued did Regeneron's Counsel submit an Information Disclosure Statement. On February 17, 2025, Regeneron's Counsel submitted an Information Disclosure Statement containing over 600 references to the USPTO. The February 17, 2025 Information Disclosure Statement did not include a disclosure of, at least: (i) the ongoing litigation between Regeneron and Amgen; (ii) the September 2024 Order Denying PI; (iii) the publicly available label for Amgen's ABP 938 product; (iv) the identity of the components in Amgen's ABP 938 product; and (v) Amgen's '463 Application relating to buffer-free aflibercept formulations published in October 2020.

264. On February 18, 2025, Regeneron's Counsel submitted another Information Disclosure Statement, including, among other things, decisions from other district court proceedings involving the '865 Patent. The February 18, 2025 Information Disclosure Statement did not include a disclosure of, at least: (i) the ongoing litigation between Regeneron and Amgen; (ii) the September 2024 Order Denying PI; (iii) the publicly available label for Amgen's ABP 938 product; (iv) the identity of the components in Amgen's ABP 938 product; and (v) Amgen's '463 Application relating to buffer-free aflibercept formulations published in October 2020. Regeneron's Counsel did not disclose the Order Denying PI in an Information Disclosure Statement until April 3, 2025, after receiving another Notice of Allowance.

265. On information and belief, during prosecution of the application for the '099 Patent, Regeneron's Counsel became aware of the Federal Circuit's March 14, 2025 opinion affirming the Court's Order Denying PI ("Federal Circuit Order Affirming Denial of PI"). The Federal Circuit Order Affirming Denial of PI was a unanimous and precedential opinion in which the Federal Circuit "agree[d] with the district court that '[l]ike the claims, the specification

of the ’865 Patent uniformly describes the ‘VEGF antagonist’ and the ‘buffer’ as separate and distinct components of the formulation.’” *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372, 1381 (Fed. Cir. 2025) (quoting *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 (N.D.W. Va. Sept. 23, 2024)). On information and belief, Regeneron’s Counsel became aware of these statements from the Federal Circuit Order Affirming Denial of PI around the time that the order was issued.

266. The Federal Circuit determined that the Court correctly recognized that “[t]he specification does not suggest that the VEGF antagonist can be a buffer or vice versa,” and “Regeneron has not identified any such disclosure.” *Id*. at 1382 (quoting *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 (N.D.W. Va. Sept. 23, 2024)).

267. The Federal Circuit confirmed that “[t]he specification makes clear what ‘the inventors actually invented and intended to envelop,’ . . . and that is, a formulation containing a VEGF antagonist *plus* a distinct buffer.” *Id*. at 1383 (emphasis in original) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc)).

268. The Federal Circuit emphasized that “the specification describes a formulation containing a VEGF antagonist plus a distinct buffer component” and that “that understanding is reinforced consistently throughout the specification, which ‘includes eight example formulations and twenty-two (22) embodiments, each of which describes the VEGF antagonist (aflibercept) plus a buffer.’” *Id*. at 1382 (quoting *In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 343 (N.D.W. Va. Sept. 23, 2024)).

269. The Federal Circuit Court of Appeals concluded that, “[a]dditionally, it was reasonable for the district court to determine that, given the proximity of [the Gokarn Application’s] publication date to the ’865 [P]atent’s filing date, the reference actually supports

Amgen's contention that self-buffering proteins were not well known and that '[the Gokarn Application] **advanced the art** over the '865 [P]atent precisely by disclosing certain buffer-free formulations in which the therapeutic protein is itself capable of maintaining pH stability.'" *Id*. at 1384 (emphasis added) (quoting, in part, Amgen's Brief in Opposition to Regeneron's Motion for Preliminary Injunction at 51). Thus, as the Federal Circuit concluded, it was Amgen, not Regeneron, that pioneered the invention of buffer-free therapeutic protein formulations.

270. Upon information and belief, Regeneron's Counsel became aware of the March 14, 2025 Federal Circuit Order Affirming Denial of PI around the time that the order issued, and by no later than April 2, 2025, when Regeneron's Counsel paid the issue fee for the '099 Patent. That order further confirmed for Regeneron's Counsel that the inventors named in the '099 Patent did not invent a buffer-free aflibercept formulation allegedly encompassed by the claims of that patent. Despite being aware of the Federal Circuit Order Affirming Denial of PI, Regeneron's Counsel proceeded to pay the issue fee without filing an Information Disclosure Statement disclosing the Federal Circuit Order Affirming Denial of PI to the USPTO. Only after paying the issue fee did Regeneron's Counsel submit a Quick Path Information Disclosure Statement on April 3, 2025 to the USPTO with the Federal Circuit Order Affirming Denial of PI. When Regeneron's Counsel did submit the Federal Circuit Court of Appeals Order Affirming Denial of PI, it did so along with other voluminous Court decisions, including decisions favorable to Regeneron that concerned buffer-containing aflibercept formulations (not buffer-free aflibercept formulations) that were previously disclosed to the USPTO in the February 18, 2025 Information Disclosure Statement. Regeneron's Counsel did not specifically draw the Examiner's attention to the Federal Circuit Order Affirming Denial of PI, despite the highly relevant nature of the findings in that order.

271. On information and belief, Regeneron's Counsel was not in possession of any evidence to support that (i) the alleged inventors of the '099 Patent conceived of or reduced to practice a liquid ophthalmic formulation containing a VEGF antagonist without an excipient buffer, (ii) the alleged inventors of the '099 Patent ever invented a liquid ophthalmic formulation containing a VEGF antagonist without an excipient buffer, or (iii) the specification of the '099 Patent in any way described an aflibercept formulation without an excipient buffer. Yet, Regeneron's Counsel proceeded to petition for issuance of the '099 Patent. In summary, the following and foregoing facts support that the '099 Patent is unenforceable due to inequitable conduct.

272. **Individuals with a duty of candor**. Regeneron's Counsel and the named inventors are subject to a duty of candor to the USPTO.

273. **Material Misrepresentation.** Regeneron's Counsel misrepresented that the same inventors of the '865 Patent invented the subject matter claimed in the '099 Patent, which as written recite aflibercept formulations that do not include a buffer. Despite the court findings that the inventors of the '865 Patent did not disclose in the identical specification any buffer-free aflibercept formulation, and that Amgen "advanced the art" by developing such buffer-free formulations, Regeneron's Counsel misrepresented the inventors of the '865 Patent as the inventors of such buffer-free formulations. Regeneron's Counsel submitted an Application Data Sheet and re-submitted inventor declarations falsely identifying Eric Furfine, Daniel Dix, Kenneth Graham, and Kelly Frye as inventors of the subject matter claimed in the '099 Patent. Additionally, Regeneron's Counsel failed to disclose statements from the inventors confirming that they believed an excipient buffer was necessary to an aflibercept formulation. Regeneron's Counsel also falsely stated that the claim amendments presented in the application for the '099

Patent did not add new matter. But for these material misrepresentations, the USPTO would not have issued the '099 Patent.

274. **Specific intent to deceive**. Regeneron's Counsel acted with a specific intent to deceive the USPTO. Regeneron's Counsel filed the application for the '099 Patent under an accelerated examination program despite failing to pursue the claimed subject matter for over eighteen years after the filing of the earliest priority application. Upon information and belief, Regeneron's Counsel filed the application for the '099 Patent only after learning of Amgen's ABP 938 formulation and '463 Application relating to buffer-free aflibercept formulations. Additionally, Regeneron's Counsel filed the application for the '099 Patent only after receiving adverse decisions in the First Amgen Action. Regeneron's Counsel filed the application for the '099 Patent without an Information Disclosure Statement and without informing the USPTO of at least the adverse decisions from the First Amgen Action. Rather, Regeneron's Counsel waited until after obtaining a Notice of Allowance from the USPTO before disclosing the Order Denying PI, along with numerous other references. Further, Regeneron's Counsel did not disclose the Federal Circuit Order Affirming Denial of PI to the USPTO before paying the issue fee for the '099 Patent. Only after paying the issue fee did Regeneron's Counsel submit the Federal Circuit Order Affirming Denial of PI to the USPTO with a Quick Path Information Disclosure Statement, and even then Regeneron's Counsel buried the Federal Circuit Order Affirming Denial of PI with other more favorable orders that had already been disclosed to the USPTO. Regeneron's Counsel knew that the contents of the Federal Circuit Order Affirming Denial of PI are highly material to the patentability of the then-pending claims of the '099 Patent. These acts of delay and omission were intentional and performed with the specific intent

to mislead the USPTO into granting the claims of the ’099 Patent, without the benefit of the highly material information within the court orders.

275. In view of the foregoing, the ’099 Patent is unenforceable due to inequitable conduct.

276. An actual, substantial, and justiciable controversy exists between Amgen and Regeneron about the ’099 Patent is unenforceable due to inequitable conduct.

277. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

278. Amgen is entitled to a judicial declaration that the ’099 Patent is unenforceable.

FIFTH COUNTERCLAIM: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF U.S. PATENT NO. 12,331,099 (PATENT MISUSE)

279. Amgen incorporates by reference the foregoing paragraphs as if fully set forth herein.

280. Regeneron’s claims of patent infringement are barred, in whole or in part, by the doctrine of patent misuse.

281. As reflected in paragraphs 53-97 above, which are incorporated herein by reference, Regeneron engaged in inequitable conduct to procure the ’099 Patent. For at least the reasons relating to Regeneron’s egregious misconduct and abuse of the patent system by filing and prosecuting the ’099 Patent and the reasons relating to Regeneron’s inequitable conduct, Regeneron’s claims of patent infringement are barred in whole or in part by the doctrine of patent misuse.

282. Regeneron’s claims of infringement of the ’099 Patent are barred in whole or in part under the doctrine of patent misuse because Regeneron impermissibly broadened the scope of the ’099 Patent to include claims that Regeneron knew to be invalid. Regeneron

impermissibly broadened the scope of the application for the ’099 Patent by filing a preliminary amendment on October 23, 2024 that presented claims allegedly encompassing Amgen’s novel buffer-free formulation, which is not described in the patent specification and was not invented by the individuals named as inventors. Regeneron prosecuted those claims to issuance despite knowing they are invalid. Regeneron filed the Complaint in this matter in bad faith to harass and further attempt to deter Amgen, and other potential competitors, as part of an egregious misuse of the patent system. Regeneron is seeking to enforce the ’099 Patent—a patent Regeneron knows is not valid—for the improper purpose of attempting to remove Amgen’s competitive product from the market and forcing Amgen to commit time and resources to defending a baseless allegation of patent infringement.

283. Regeneron unreasonably and inexcusably delayed pursuing the claims of the ’099 Patent for over eighteen years after filing the earliest claimed priority application, the ’484 Provisional filed June 16, 2006. Regeneron and Regeneron’s Counsel filed the application for the ’099 Patent seeking claims allegedly encompassing buffer-free ophthalmic formulations only after: (i) Amgen invested significant resources into the development of a buffer-free aflibercept formulation; (ii) upon information and belief, Regeneron’s counsel became aware of the components of Amgen’s PAVBLU formulation and Amgen’s ’463 Application disclosing buffer-free aflibercept formulations; (iii) the United States District Court for the Northern District of West Virginia issued the Order Denying PI involving the related ’865 Patent; and (iv) the Federal Circuit issued the Order Denying PI Pending Appeal.

284. Upon information and belief, Regeneron’s Counsel pursued claims allegedly encompassing a buffer-free aflibercept formulation despite knowing that (i) the listed inventors

on the ’099 Patent did not invent buffer-free ophthalmic formulations comprising a VEGF antagonist; and (ii) the specification contains no disclosures supporting such an invention.

285. Upon information and belief, Regeneron and Regeneron’s Counsel were aware that the claims of the ’099 Patent are invalid and never should have been issued by the USPTO because the claims fail to meet the requirements of at least 35 U.S.C. § 112 for lack of written description support and lack of enablement.

286. As set forth in paragraphs 49-50, Regeneron’s and Regeneron’s Counsel’s delay in filing the application for ’099 Patent and Regeneron’s Counsel’s deceptive conduct during prosecution constitute an egregious misuse of the statutory patent system. As courts have recognized, facts giving rise to prosecution laches “constitutes an egregious misuse of the statutory patent system.” *Personalized Media Comm’ns, LLC v. Apple Inc.*, 57 F.4th 1346, 1354 (Fed. Cir. 2023); *see also Miracor Medical SA v. Abbott Labs.*, No. 23-cv-16257, 2024 WL 4487294, at *2 (N.D. Ill. Oct. 7, 2024) (“[T]he patents are barred by prosecution laches based on an unreasonable and unexplained delay of over ten years in the prosecution process with the United States Patent and Trademark Office (USPTO) constituting an egregious misuse of the statutory patent system.”).

287. As of June 16, 2006, when the ’484 Provisional was filed at the USPTO, the listed inventors of the ’099 Patent had neither invented nor possessed any buffer-free ophthalmic formulations comprising a VEGF antagonist. The specification of the ’099 Patent includes no disclosure that would inform the person of ordinary skill in the art that the inventors possessed the claimed buffer-free aflibercept formulations. Likewise, without any guidance in the specification or in the art about how to make buffer-free protein formulations, the person of ordinary skill in the art would have had to engage in undue experimentation to make a buffer-

free liquid ophthalmic formulation of a VEGF antagonist that is able to maintain the claimed pH range and stability.

288. As such, by prosecuting the claims of the '099 Patent, Regeneron and its Regeneron's Counsel impermissibly broadened the scope of the '099 Patent to include claims that they knew to be invalid and unenforceable. *See Bayer CropSci. AG v. Dow AgroSci. LLC*, No. 10-cv-1045, 2011 WL 6934557, at *4 (D. Del. Dec. 30, 2011) ("all Defendant [is] required to allege" to maintain a patent misuse claim at the pleading stage is that plaintiff "was enforcing a patent it knew was invalid, unenforceable, and/or not infringed"); *CMC Materials, LLC v. DuPont de Nemours, Inc.*, No. 20-738-GBW, Dkt. 218 at 19 (D. Del. Nov. 13, 2023) (denying motion to dismiss patent misuse because defendant adequately alleged "that the [asserted] Patent was fraudulently procured and invalid, and that CMC knew of the fraud").

289. Regeneron's infringement claims are also "objectively baseless" because "no reasonable litigant could realistically expect success on the merits." *See Nalco Co. v. Turner Designs, Inc.*, No. 13-cv-02727, 2014 WL 645365, at *10 (N.D. Cal. Feb. 19, 2024) (quoting *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993)).

290. No reasonable litigant could conclude that Regeneron's infringement claim is reasonably likely to succeed, at least because the claims of the '099 Patent lack written description support and are not enabled, which is confirmed by the Order Denying PI and the Federal Circuit Order Affirming Denial of PI. *See Miracor Med. SA v. Abbott Labs.*, No. 23-cv-16257, 2024 WL 4487294, at *3 (N.D. Ill. Oct. 7, 2024) (denying motion to strike patent misuse defense where "Defendants assert that Plaintiff improperly drafted the six Asserted Patents to cover Defendants' [] device" and "Defendants contend that Plaintiff knew the Asserted Patents were invalid and pursued them anyway in bad faith"). Further, no reasonable litigant could

conclude that Regeneron's infringement claim is reasonably likely to succeed, because the claims are unenforceable against Amgen under the doctrine of prosecution laches.

291. On information and belief, Regeneron brought its infringement claim to harass Amgen, and obtain another opportunity to remove Amgen's PAVBLU product from the market. Regeneron knows, knew, or should have known that the claims of the '099 Patent are invalid and/or unenforceable, and nevertheless brought this action against Amgen in bad faith for the improper purpose of obtaining another opportunity to exclude Amgen from the market and restrict rightful competition. Regeneron's enforcement of the '099 Patent against Amgen is an egregious misuse of the statutory patent system.

292. An actual, substantial, and justiciable controversy exists between Amgen and Regeneron about whether the '099 Patent is unenforceable under the doctrine of patent misuse.

293. Amgen is entitled to a judicial declaration that the '099 Patent is unenforceable under the doctrine of patent misuse.

SIXTH COUNTERCLAIM: SHERMAN ACT VIOLATION (15 U.S.C. § 2) MONOPOLIZATION THROUGH *WALKER PROCESS* FRAUD

294. Amgen restates, realleges, and incorporates by reference each of the allegations set forth above as if fully set forth herein.

295. There is a relevant market comprised of sales of 2 mg aflibercept-based anti-VEGF treatments in the United States (the "Relevant Market").

296. Regeneron at all relevant times has had monopoly power within the Relevant Market. Before PAVBLU's launch in October 2024, Regeneron held 100% of the Relevant Market. In the year since its launch, PAVBLU has made significant inroads and continues to grow as a competitive presence in the Relevant Market. Nonetheless, Regeneron today

continues to hold at least approximately 70% of the Relevant Market while continuing to charge supracompetitive prices and earn supracompetitive margins for EYLEA.

297. Regeneron is willfully maintaining its monopoly power in the Relevant Market through (1) the assertion of fraudulently-procured patents in the 2024 Litigation against Amgen and (2) the assertion of the fraudulently-procured '099 Patent in the instant Action against Amgen, each with the intent to prevent Amgen from continuing to compete against EYLEA and to protect and maintain EYLEA's monopoly position in the Relevant Market, and each constituting a separate, anticompetitive act of monopolization.

298. First, Regeneron procured the following aflibercept-based patents by fraud on the USPTO, and is attempting to assert those patents against Amgen in the 2024 Litigation, upon information and belief, with knowledge of their fraudulent procurement: the '338, '681, '345, '601, '572, '564, '506, '135, '593, '317, '459, and '374 Patents. As described above in paragraphs 39-116, which are incorporated herein by reference, for each of these fraudulently-procured patents, Regeneron made false representations and/or deliberate omissions of material facts to patentability, upon information and belief, knowingly and willfully with the intent to deceive the USPTO in order to obtain a patent that would not have otherwise issued but for Regeneron's fraud, and the USPTO justifiably relied on those material misstatements and/or omissions in incorrectly issuing each of those patents.

299. Second, Regeneron procured the '099 Patent by fraud and is attempting to assert the fraudulently-procured '099 Patent in this Action, upon information and belief, with knowledge of its fraudulent procurement. Regeneron made a series of material misrepresentations before the USPTO and then covered up their misconduct by delaying, and burying, the submission of key documents fatal to their patent application. Upon information

and belief, at the time the application for the ’099 Patent was filed, Regeneron knew that Amgen invented the buffer-free formulation. Nonetheless, Regeneron fraudulently misrepresented to the USPTO that Eric Furfine, Daniel Dix, Kenneth Graham, and Kelly Frye were the true inventors of the buffer-free formulation. When Regeneron filed its first response to the USPTO Office Action, it failed to disclose documents material to patentability. Instead, it waited until after a Notice of Allowance was issued and submitted those documents—including the MDL Opinion denying Regeneron’s motion for a PI that was issued nearly five months prior—with over 600 other documents.

300. Regeneron’s assertion of fraudulently-procured patents in the 2024 Litigation, and Regeneron’s assertion of the fraudulently-procured ’099 Patent in the instant Action, each constitute an unlawful attempt to remove PAVBLU from the market on the basis of one or more patents procured by fraud, and each is an act by Regeneron designed to maintain, and, if successful, that would have the effect of maintaining, PAVBLU’s monopoly in the Relevant Market. If PAVBLU were enjoined from competing in the Relevant Market, the only competitor challenging EYLEA’s dominant market position in the Relevant Market will have been removed, and no other future entrant would be likely to replace the competitive constraint imposed by PAVBLU on EYLEA—competition that today is benefitting patients and providers.

301. Each anticompetitive act has directly and proximately injured Amgen, including by causing Amgen to incur substantial costs defending against Regeneron’s assertions of fraudulently-procured patents in the 2024 Action and Regeneron’s assertion of the fraudulently procured ’099 Patent in the instant Action. Additionally, the extent litigation continues on the basis of fraudulently-procured patent(s), Amgen may suffer a loss of PAVBLU sales due to any uncertainty that providers and physicians may have about the continued future availability of

PAVBLU. Each of these injuries that have been and will be suffered by Amgen as a result of Regeneron's anticompetitive actions are of the type the antitrust laws are intended to prevent and flow directly from Regeneron's anticompetitive, unlawful conduct described herein.

302. Regeneron's assertion of fraudulently-procured patents in the 2024 Litigation, and Regeneron's assertion of the fraudulently-procured '099 Patent in the instant Action, each lacks a non-pretextual procompetitive justification that offsets the harm caused by such anticompetitive conduct.

303. Regeneron's assertion of fraudulently-procured patents in the 2024 Litigation, and Regeneron's assertion of the fraudulently-procured '099 Patent in the instant Action, each constitutes a violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

304. Amgen is entitled to injunctive relief, actual damages, trebled, plus interest, as well as attorneys' fees and costs under Section 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

SEVENTH COUNTERCLAIM: SHERMAN ACT (15 U.S.C. § 2)
ATTEMPTED MONOPOLIZATION THROUGH *WALKER PROCESS* FRAUD

305. Amgen restates, realleges, and incorporates by reference each of the allegations set forth above as if fully set forth herein.

306. There is a relevant market comprised of sales of 2 mg aflibercept-based anti-VEGF treatments in the United States (the "Relevant Market").

307. Before PAVBLU's launch in October 2024, Regeneron held 100% of the Relevant Market and possessed monopoly power in the Relevant Market. In the year since its launch, PAVBLU has made significant inroads and continues to grow as a competitive presence in the Relevant Market. Nonetheless, Regeneron today continues to hold at least approximately

70% of the Relevant Market while continuing to charge supracompetitive prices and earn supracompetitive margins for EYLEA.

308. To the extent Regeneron can be said to no longer have monopoly power in the Relevant Market, it has a dangerous probability of reclaiming it given its position as the long-standing, dominant incumbent with at least 70% share. Regeneron is willfully attempting to reclaim its monopoly power in the Relevant Market through (1) the assertion of fraudulently-procured patents in the 2024 Litigation against Amgen and (2) the assertion of the fraudulently-procured '099 Patent in the instant Action against Amgen, each with the intent to prevent Amgen from continuing to compete against EYLEA and to protect and maintain EYLEA's monopoly position in the Relevant Market, and each constituting a separate, anticompetitive act of attempted monopolization.

309. First, Regeneron procured the following aflibercept-based patents by fraud on the USPTO, and is attempting to assert those patents against Amgen in the 2024 Litigation, upon information and belief, with knowledge of their fraudulent procurement: the '338, '681, '345, '601, '572, '564, '506, '135, '593, '317, '459, and '374 Patents. As described above in paragraphs 39-116, which are incorporated herein by reference, for each of these fraudulently-procured patents, Regeneron made false representations and/or deliberate omissions of material facts to patentability, upon information and belief, knowingly and willfully with the intent to deceive the USPTO in order to obtain a patent that would not have otherwise issued but for Regeneron's fraud, and the USPTO justifiably relied on those material misstatements and/or omissions in incorrectly issuing each of those patents.

310. Second, Regeneron procured the '099 Patent by fraud and is attempting to assert the fraudulently-procured '099 Patent in this Action, upon information and belief, with

knowledge of its fraudulent procurement. Regeneron made a series of material misrepresentations before the USPTO and then covered up their misconduct by delaying, and burying, the submission of key documents fatal to their patent application. Upon information and belief, at the time the application for the '099 Patent was filed, Regeneron knew that Amgen invented the buffer-free formulation. Nonetheless, Regeneron fraudulently misrepresented to the USPTO that Eric Furfine, Daniel Dix, Kenneth Graham, and Kelly Frye were the true inventors of the buffer-free formulation. When Regeneron filed its first response to the USPTO Office Action, it failed to disclose documents material to patentability. Instead, it waited until after a Notice of Allowance was issued and submitted those documents—including the MDL Opinion denying Regeneron's motion for a PI that was issued nearly five months prior—with over 600 other documents.

311. Regeneron's assertion of fraudulently-procured patents in the 2024 Litigation, and Regeneron's assertion of the fraudulently-procured '099 Patent in the instant Action, each constitute an unlawful attempt to remove PAVBLU from the market on the basis of one or more patents procured by fraud, and each is an act by Regeneron designed to reclaim, and, if successful, that would have the effect of reclaiming, PAVBLU's monopoly in the Relevant Market. If PAVBLU were enjoined from competing in the Relevant Market, the only competitor challenging EYLEA's dominant market position in the Relevant Market will have been removed, and no other future entrant would be likely to replace the competitive constraint imposed by PAVBLU on EYLEA—competition that today is benefitting patients and providers with more choice and lower prices.

312. Each anticompetitive act has directly and proximately injured Amgen, including by causing Amgen to incur substantial costs defending against Regeneron's assertions of

fraudulently-procured patents in the 2024 Action and Regeneron's assertion of the fraudulently procured '099 Patent in the instant Action. Additionally, as and to the extent litigation continues on the basis of fraudulently-procured patent(s), Amgen may suffer a loss of PAVBLU sales due to any uncertainty that providers and physicians may have about the continued future availability of PAVBLU. Each of these injuries that have been and will be suffered by Amgen as a result of Regeneron's anticompetitive actions are of the type the antitrust laws are intended to prevent and flow directly from Regeneron's anticompetitive, unlawful conduct described herein.

313. Regeneron's assertion of fraudulently-procured patents in the 2024 Litigation, and Regeneron's assertion of the fraudulently-procured '099 Patent in the instant Action, each lacks a non-pretextual procompetitive justification that offsets the harm caused by such anticompetitive conduct.

314. Regeneron's assertion of fraudulently-procured patents in the 2024 Litigation, and Regeneron's assertion of the fraudulently-procured '099 Patent in the instant Action, each constitutes anticompetitive conduct taken with the specific intent to monopolize the Relevant Market. Furthermore, there is a dangerous probability of Regeneron reclaiming its monopoly in the Relevant Market through its anticompetitive actions, given that, if Regeneron were successful in its attempt to enforce any of the fraudulently-procured patents, it would remove the only competitor to EYLEA in the Relevant Market. Furthermore, upon information and belief, there is no near-term entrant ready to enter the Relevant Market, and any future entry is unlikely to come close to replicating the competition created by PAVBLU's presence in the market given PAVBLU's advantages from having been present in the market for nearly a year and counting, during which period, through great effort, expense and time, PAVBLU has been able to make significant and difficult-to-replicate inroads in competing against EYLEA.

315. Regeneron's assertion of fraudulently-procured patents in the 2024 Litigation, and Regeneron's assertion of the fraudulently-procured '099 Patent in the instant Action, each constitute a violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

316. Amgen is entitled to injunctive relief, actual damages, trebled, plus interest, as well as attorneys' fees and costs under Section 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

EIGHTH COUNTERCLAIM: CALIFORNIA UNFAIR COMPETITION LAW UNLAWFUL AND UNFAIR PRACTICES

317. Amgen restates, realleges, and incorporates by reference each of the allegations set forth above as if fully set forth herein.

318. Regeneron's conduct, as described above, violates California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, et seq., which prohibits any unlawful, unfair or fraudulent business act or practice.

319. Amgen has standing to bring this claim because it has suffered injury in fact and lost money as a result of Regeneron's unlawful and unfair business practices.

320. Amgen develops and markets aflibercept-based products administered via intravitreal injections, and Regeneron's conduct has unreasonably restricted Amgen's ability to fairly compete in the relevant market with these products.

321. Regeneron's conduct violates the Sherman Act and thus constitutes unlawful conduct under § 17200.

322. Regeneron's conduct is also "unfair" within the meaning of the Unfair Competition Law.

323. Regeneron's conduct harms Amgen which, as a direct result of Regeneron's anti-competitive conduct, is unreasonably prevented from freely competing in the relevant market and forfeits the money it would make absent Regeneron's conduct.

324. Amgen is entitled to injunctive relief and actual damages, plus interest.

VII. PRAYER FOR RELIEF AND DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Amgen demands a trial by jury of all the claims asserted in this complaint that are so triable.

WHEREFORE, Defendant respectfully requests that the Court enter judgment in favor of Amgen and against Plaintiff:

(1) Declaring that Amgen has not, does not, and will not infringe one or more of the claims of the '099 Patent;

(2) Declaring that one or more of the claims of the '099 Patent are invalid;

(3) Declaring that the '099 Patent is unenforceable;

(4) Declaring that Regeneron's assertion of fraudulently-procured patents, including the '099 Patent, as described herein is in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2;

(5) Awarding a declaration that the restraints complained of herein are unlawful and unenforceable, including but not limited to the '099 Patent;

(6) Awarding as monetary relief, compensatory, consequential, and punitive (including treble) damages for injuries directly and proximately caused to Amgen by Regeneron, as described herein, according to proof;

(7) Enjoining the unlawful conduct and awarding any other equitable relief necessary to prevent and remedy Regeneron's anticompetitive, unfair and/or unlawful conduct;

(8) Declaring that this is an exceptional case and awarding to Amgen its attorneys' fees and costs pursuant to 35 U.S.C. § 285;

(9) Awarding attorneys' fees and costs, including the costs of suit incurred herein; and

(10) Granting such other and further relief as the Court deems just and proper.

Dated: September 12, 2025

/s/ *John R. Labbe*

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