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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

REGENERON PHARMACEUTICALS, INC., a New York Corporation, Plaintiff v. AMGEN INC., a Delaware corporation, Defendant.	Case No. 2:25-cv-5499 **COMPLAINT** **DEMAND FOR JURY TRIAL**

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COMPLAINT

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") brings this Complaint against Defendant Amgen Inc. ("Amgen") for infringement of U.S. Patent No. 12,331,099 (the "'099 Patent").

INTRODUCTION

1. Regeneron invented, developed, and sells EYLEA®, the market-leading treatment for several serious eye diseases. Amgen 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," a biosimilar of EYLEA®. Following FDA approval, Amgen has made, used, offered to sell, or sold ABP 938 in vials and pre-filled syringes under the market name Pavblu® in the United States. Regeneron owns the '099 Patent, which is the patent asserted in this Complaint and which is infringed by Amgen's Pavblu®. To vindicate its patent rights, Regeneron brings this Complaint against Amgen pursuant to 35 U.S.C. §§ 271(a), (b), and (c), seeking relief.

2. Regeneron is a leading science-based American biotechnology company. With a focus on patient access and fair drug pricing, Regeneron is dedicated to innovation, improving human health, and tackling the most urgent medical issues facing the Nation. Founded and led for over 30 years by physician-scientists, Regeneron has developed life-transforming medicines that have been used across the country to treat serious diseases, including cancer, atopic dermatitis, asthma, eye diseases, cardiovascular and metabolic diseases, Ebola, and COVID-19. Regeneron's cutting-edge scientific advances are supported, in large part, by its groundbreaking ophthalmic product EYLEA®.

3. EYLEA® has been administered millions of times to treat certain ophthalmic disorders that, if left untreated, can lead to permanent blindness. Its active ingredient is a genetically engineered fusion protein called aflibercept. It works by blocking the overproduction of a naturally occurring protein in the eye that can cause the formation of excess blood vessels, leading to vision loss. Based on extensive clinical

testing by Regeneron, FDA approved EYLEA® in 2011 to treat an ophthalmic disorder called neovascular (wet) age-related macular degeneration ("wAMD"), and in 2014 to treat diabetic macular edema ("DME"). As a result of Regeneron's additional clinical testing, EYLEA® is now also approved for use in treating macular edema following retinal vein occlusion and diabetic retinopathy, two other serious disorders of the eye. Most recently, FDA granted approval for EYLEA® to treat retinopathy of prematurity in preterm infants, which is the leading cause of childhood blindness worldwide. In addition to benefitting the many patients it has been used to treat, EYLEA® is also a critical source of research and development funding for Regeneron to develop other life-transforming medicines.

PLAINTIFF

4. Plaintiff Regeneron is a 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. Regeneron is dedicated to discovering, developing, and commercializing medicines to treat patients with debilitating and life-threatening diseases.

DEFENDANT

5. Defendant Amgen is a corporation organized under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen is, among other things, engaged in the development and commercialization of biosimilar drugs, including a biosimilar version of Regeneron's EYLEA®, called ABP 938.

6. On information and belief, Amgen directly—or via its subsidiaries, affiliates, or other agents—develops, distributes, or sells within the United States or imports into the United States Amgen's drug products, under the general direction and control of Amgen. On information and belief, Amgen, directly or indirectly, manufactures, sells, and offers to sell its drug products, including ABP 938, within the United States.

7. On information and belief, Amgen and its subsidiaries, affiliates, and agents function as an integrated organization and a single business enterprise in the manufacture of ABP 938, the importation of ABP 938 into the United States, and/or the sale or offer for sale of ABP 938 in the United States.

8. On information and belief, Amgen and its subsidiaries, affiliates, and agents develop, manufacture, distribute, sell, and/or import drug products for the entire United States market and do business in every state, including California, either directly or indirectly.

JURISDICTION AND VENUE

9. This action arises under the Patent Laws of the United States, Title 35 of the United States Code, and the BPCIA, 42 U.S.C. § 262(*l*). This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1332, and 1338.

10. Amgen is a corporation organized and existing under the laws of the State of Delaware and has its corporate headquarters located at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen's office located at this address is a regular and established place of business within the forum.

11. Amgen is listed with the Office of the California Secretary of State as an entity that is currently doing business in the State of California, and the Office of the California Secretary of State has assigned Amgen the following business entity number: C1579467. The Office of the California Secretary of State business listing for Amgen states that its physical address is One Amgen Center Drive, Thousand Oaks, California 91320.

12. Amgen is a corporate entity currently doing business in the State of California and having a regular established place of business within the forum, Amgen purposefully engaged in activities that are directed at the forum, this action arises out of or relates to those activities, and the assertion of personal jurisdiction in the forum comports with traditional notions of fair play and substantial justice. The Court therefore has jurisdiction over Amgen in this action.

13. This Court also has personal jurisdiction over Amgen because Amgen sought and obtained approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of ABP 938 in the United States, including in the State of California; and because Amgen has begun to market, distribute, offer for sale, and/or sell ABP 938 under the market name Pavblu® in the United States, including in the State of California, deriving substantial revenue therefrom.

14. Venue is proper in the Central District of California under 28 U.S.C. § 1400(b) because Amgen resides in the Central District of California and a substantial part of the events and injury giving rise to Plaintiff's claims has and continues to occur in the Central District of California.

FACTUAL ALLEGATIONS

15. Enacted in 2010 as part of the Affordable Care Act, the BPCIA provides for an abbreviated regulatory approval pathway for biosimilars by letting applicants rely on the extensive clinical testing previously conducted, at great expense, by the innovator company that developed the medicine the applicant wants to copy. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1 (2017). In exchange for this accelerated and far less expensive application process, the BPCIA obligates a biosimilar applicant to address a reference product sponsor's relevant patents in a manner that permits adjudication of patent rights before commercialization of the biosimilar product. The BPCIA does so, *inter alia*, through a set of pre-litigation exchanges or steps outlined in 42 U.S.C. § 262(*l*) (the "Patent Dance").

16. On October 31, 2023, Amgen publicly announced that FDA had accepted its aBLA for ABP 938, a biosimilar copy of EYLEA®.

17. Amgen initiated the Patent Dance procedure with Regeneron in 2023, which the parties completed in 2024. The parties agreed to a list of Regeneron patents with respect to which Regeneron shall bring an action for patent infringement. *See* 42 U.S.C. § 262(*l*)(4)(A). Accordingly, on January 10, 2024, Regeneron brought an action (the "First Amgen Action") against Amgen in the Central District of California, alleging

that Amgen's submission of the aBLA for ABP 938 infringed the agreed-upon Regeneron patents under 35 U.S.C. § 271(e). *Regeneron Pharm., Inc. v. Amgen, Inc.*, Case No. 2:24-cv-264 (C.D. Cal.), Dkt. 1.

18. On April 11, 2024, pursuant to 28 U.S.C. § 1407, the U.S. Judicial Panel on Multidistrict Litigation instituted a multidistrict litigation in the Northern District of West Virginia ("MDL Court") for coordinated or consolidated pretrial proceedings of the First Amgen Action and other patent infringement actions Regeneron had brought against other manufacturers of EYLEA® biosimilars. *In re Aflibercept Patent Litig.*, Case No. 1:24-md-3103 (N.D.W. Va.), Dkt. 1. On June 7, 2024, Regeneron filed a motion for preliminary injunction. *Id.*, Dkt. 157.

19. Pursuant to 42 U.S.C. § 262(k)(7)(A), a biosimilar application may not be made effective until the reference product's regulatory exclusivity expires. EYLEA®'s regulatory exclusivity expired on May 18, 2024, and thus in accordance with § 262(k)(7)(A), FDA approved Amgen's aBLA on August 23, 2024 under the market name Pavblu®.[1] On September 23, 2024, the MDL Court denied Regeneron's motion for preliminary injunction against Amgen. *In re Aflibercept Patent Litig.*, Case No. 1:24-md-3103 (N.D.W. Va.), Dkt. 343. Shortly thereafter, Amgen launched its product and ever since has been making, using, offering to sell, or selling ABP 938 under the market name Pavblu® in the United States. Exhibit 1 (Amgen reporting $99 million in net sales of Pavblu® in Q1 of 2025); Exhibit 2 (Pavblu® ordering and distributor information); Exhibit 3 (Pavblu® website stating that "PAVBLU™ is a trademark of Amgen, Inc.").

20. On June 17, 2025, the U.S. Patent and Trademark Office duly and legally issued the '099 Patent, entitled "VEGF Antagonist Formulations Suitable for Intravitreal Administration." Because the '099 Patent issued after the deadline to amend the

[1] Letter from William Boyd, U.S. Food & Drug Admin., to Amanda Santoro, Amgen, Inc. (Aug. 23, 2024), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/761298Orig1s000ltr.pdf.

complaint without leave in the First Amgen Action, Regeneron brings this action separate from the First Amgen Action. *See* Fed. R. Civ. P. 15.

21. Promptly upon filing of this action, Regeneron will petition the U.S. Judicial Panel on Multidistrict Litigation to transfer this action to the Northern District of West Virginia and consolidate with MDL No. 1:24-md-3103-TSK for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407.

CLAIM FOR RELIEF

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 12,331,099 UNDER 35 U.S.C. §§ 271(a), (b), and (c)

22. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

23. United States Patent No. 12,311,099 (the "'099 Patent") (Exhibit 4 hereto), was duly and legally issued on June 17, 2025.

24. Regeneron is the owner of all right, title, and interest in the '099 Patent.

25. The '099 Patent has not yet expired.

26. Amgen has engaged in the commercial 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® before the expiration of the '099 Patent. On information and belief, Amgen has infringed, literally and/or under the doctrine of equivalents. On information and belief, Amgen—itself or through its subsidiaries, affiliates, or agents—makes, uses, offers for sale, or sells within the United States, or imports into the United States, ABP 938, which constitutes infringement of one or more claims of the '099 Patent under 35 U.S.C. § 271(a). For example, Amgen's ABP 938 infringes at least claims 11-13, 21, 26, and 27. Claim 21, which depends from Claim 11, is reproduced below:

> A liquid ophthalmic formulation comprising:
>
> 40 mg/ml of a glycosylated vascular endothelial growth factor (VEGF) antagonist fusion protein comprising amino acids 27-

457 of SEQ ID NO: 4;

water;

an organic co-solvent comprising polysorbate; and

a stabilizing agent,

wherein the liquid ophthalmic formulation has a pH of between [6.2 to 6.3],

wherein the liquid ophthalmic formulation is suitable for intravitreal administration,

wherein at least 98% of the VEGF antagonist fusion protein is present in native conformation following storage at 5° C for two months as measured by size exclusion chromatography.

27. Pavblu® meets each and every limitation of at least claim 21 of the '099 Patent either literally and/or under the doctrine of equivalents, as shown in the table below, which is exemplary and non-limiting:

Claim 21 Limitation	Exemplary Evidence
[11.pre] A liquid ophthalmic formulation comprising:	"PAVBLU … is supplied as an aqueous solution for intravitreal injection." Exhibit 5 at 15. Pavblu® is indicated for treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration, Macular Edema Following Retinal Vein Occlusion, Diabetic Macular Edema, and Diabetic Retinopathy, which are all ophthalmic conditions. *Id.* at 1.
[11.a] 40 mg/ml of a glycosylated vascular endothelial growth factor (VEGF) antagonist fusion protein comprising amino acids 27-457 of SEQ ID NO: 4;	Pavblu®'s active ingredient is aflibercept, which is a VEGF antagonist, and is present at a concentration of 40 mg/mL. *Id.* at 14-15. Amgen's label describes the aflibercept in Pavblu® as "a recombinant fusion protein" that "contains glycosylation." *Id.*

Claim 21 Limitation	Exemplary Evidence
	On information and belief, the aflibercept in Pavblu® comprises amino acids 27-457 of SEQ ID NO: 4.
[11.b] water;	The formulation described in Amgen's Pavblu® label contains water for injection. *Id.* at 15.
[11.c] an organic co-solvent comprising polysorbate; and	The formulation described in Amgen's Pavblu® label contains polysorbate 80. *Id.*
[11.d] a stabilizing agent,	The formulation described in Amgen's Pavblu® label contains sucrose and trehalose. *Id.*
[11.e] wherein the liquid formulation has a pH of between 5.8 to 7.0,	The formulation described in Amgen's Pavblu® label is an aqueous solution having a pH of 6.2. *Id.*
[11.f] wherein the liquid formulation is suitable for intravitreal administration,	"PAVBLU … is supplied as an aqueous solution for intravitreal injection." *Id.*
[11.g] wherein at least 98% of the VEGF antagonist fusion protein is present in native conformation following storage at 5°C for two months as measured by size exclusion chromatography.	On information and belief, at least 98% of the VEGF antagonist fusion protein in Pavblu® is present in native conformation following storage at 5° C for two months as measured by size exclusion chromatography.
[21] The liquid ophthalmic formulation of claim 11, wherein the liquid ophthalmic formulation has a pH of between 6.2 to 6.3.	The formulation described in Amgen's Pavblu® label is an aqueous solution having a pH of 6.2. *Id.*

28. On information and belief, Amgen infringes the '099 Patent under 35 U.S.C. §§ 271(b) and/or (c) by inducing others, including its subsidiaries, affiliates, agents, and physicians, to engage in the use, offer for sale, sale, marketing, distributing and/or importing of ABP 938.

29. Amgen has knowledge of and is aware of the ’099 Patent at least due to the filing of this action. On information and belief, Amgen has also had knowledge of the ’099 Patent based on its active monitoring of Regeneron’s patents and patent applications, including those in the same family as the patents that Regeneron has already asserted against Amgen’s ABP 938. Amgen knows and/or is willfully blind to the fact that ABP 938 comprises a formulation covered by one or more claims of the ’099 Patent at least as of June 17, 2025.

30. Amgen has an affirmative intent to actively induce infringement by others of one or more claims of the ’099 Patent at least because, on information and belief, it manufactures, directly or indirectly, ABP 938, which meets every limitation of one or more claims of the ’099 Patent, and provides ABP 938 to its subsidiaries, affiliates, agents, and/or physicians who import, offer to sell, sell, and/or use ABP 938 in a manner that directly infringes one or more claims of the ’099 Patent.

31. On information and belief, Amgen knows or should know that it aids and abets another’s direct infringement of at least one of the claims of the ’099 Patent at least by providing its FDA-approved label with instructions to use ABP 938.

32. On information and belief, Amgen has profited from and will continue to profit from its infringement of the ’099 Patent. Regeneron is thus entitled to compensatory damages under 35 U.S.C. § 284, including, but not limited to, lost profits and/or a reasonable royalty, with interest and costs.

33. Amgen’s infringement of the ’099 Patent has been, and continues to be, willful and deliberate, entitling Regeneron to enhanced damages pursuant to 35 U.S.C. § 284.

34. Amgen’s willful and deliberate infringement of the ’099 Patent renders this case exceptional, and Regeneron is entitled to an award of attorney’s fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Regeneron requests the following relief:

(a) A judgment that Amgen has infringed the ’099 Patent;

(b) Damages pursuant to 35 U.S.C. § 284 in the form of lost profits but in no event less than a reasonable royalty;

(c) Injunctive relief, pursuant to 35 U.S.C. § 283, prohibiting Amgen, its officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns from infringing the ’099 Patent, or contributing to the same, or actively inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of ABP 938 and any other current or future versions of a product that infringes, or the use or manufacturing of which infringes, the ’099 Patent;

(d) A judgment that the infringement has been willful and an enhancement of damages;

(e) An award for an accounting of damages from Amgen’s infringement;

(f) A declaration that this is an exceptional case and an award of attorneys’ fees, pursuant to 35 U.S.C. § 285;

(g) An award of Regeneron’s costs and expenses in this action; and

(h) Such further relief as this Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: June 17, 2025

Respectfully submitted,

/s/ *Matthew Donald Umhofer*
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