IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

REGENERON PHARMACEUTICALS, INC. Plaintiff, v. SANDOZ INC., Defendant.	CASE NO.: JURY TRIAL DEMANDED

COMPLAINT

This is a patent case arising under the Biologics Price Competition and Innovation Act ("BPCIA"), a part of the Affordable Care Act that permits a drug company like the defendant, Sandoz, Inc. ("Sandoz"), to create a "biosimilar" copy of Regeneron's drug EYLEA® (aflibercept), the market-leading treatment for several serious eye diseases. That statute creates a "carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement."[1] By filing its abbreviated Biologics License Application ("aBLA") and failing to provide the statutorily mandated information as required by 42 U.S.C. § 262(*l*)(2), Sandoz has violated, and will continue to violate, this statute and infringe Regeneron's patent rights.

NATURE OF THE CASE

1. 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

[1] *Sandoz, Inc. v. Amgen Inc.*, 582 U.S. 1, 8 (2017).

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 for people with serious diseases, including cancer, atopic dermatitis, asthma, eye diseases, cardiovascular and metabolic diseases, Ebola, and COVID-19, which have been used across the country. Regeneron's cutting-edge scientific advances are supported, in large part, by its ophthalmic product, EYLEA®, which FDA approved in 2011.

2. 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 new 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 other serious disorders of the eye: macular edema following retinal vein occlusion and diabetic retinopathy. 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 new life-transforming medicines.

3. Enacted in 2010 as part of the Affordable Care Act, the BPCIA provides for a substantially 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.*, 137 S. Ct. 1664 (2017).

4. Sandoz filed with FDA an aBLA for SOK583 (aflibercept) or "ENZEEVU" pursuant to 42 U.S.C. § 262(*k*), the FDA accepted Sandoz's aBLA for review, and the FDA then granted approval of ENZEEVU. Given the FDA's approval of ENZEEVU, it is abundantly clear that well over 20 days have elapsed since FDA's acceptance of Sandoz's aBLA, yet Sandoz still has not provided the information to Regeneron that it is required to provide by 42 U.S.C. § 262(*l*)(2)(A). Sandoz's failure to provide this information is a violation of the BPCIA that authorizes Regeneron to bring claims for patent infringement against Sandoz under 28 U.S.C. §§ 2201-2202, pursuant to 42 U.S.C. § 262(*l*)(9)(C).

THE PARTIES, JURISDICTION, AND VENUE

5. Plaintiff Regeneron Pharmaceuticals, Inc. 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. Regeneron owns each of the patents asserted in this Complaint (collectively, the "asserted patents" or the "patents in suit"):

Patent	**First Named Inventor**
9,222,106	Gang Chen
9,315,281	Tikiri Jean Dissanayake
9,816,110	Ying Shen
10,182,969	Rachel Paige Arnott
10,415,055	Gang Chen
10,669,594	Serge Monpoeho
10,828,345	George D. Yancopoulos
10,905,786	Philip Stephen Shodder

Patent	First Named Inventor
10,918,754	Philip Stephen Shodder
10,927,342	Amy S. Johnson
11,053,280	Andrew Tustian
11,066,458	Eric Furfine
11,084,865	Eric Furfine
11,104,715	Shawn Lawrence
11,160,918	Andrew Cook
11,174,283	Andrew Tustian
11,268,109	Ying Shen
11,299,532	Andrew Tustian
11,312,936	Amy S. Johnson
11,332,771	Shadia Abike Oshodi
11,406,565	Rachel Paige Arnott
11,433,186	Sibgat Ulla
11,439,758	Trevor Langley
11,459,373	Andrew Tustian
11,459,374	Andrew Tustian
11,472,861	Shawn Lawrence
11,478,588	Bryan Grygus
11,535,663	Shawn Lawrence
11,548,932	Shunhai Wang
11,555,176	Wei Xue
11,577,025	Daniel B. Dix
11,732,025	Shunhai Wang
11,788,102	Ying Shen
11,793,926	Andrew Cook
11,850,407	Bryan Grygus
11,918,785	Daniel B. Dix
11,970,724	Shadia Abike Oshodi
11,975,045	George D. Yancopoulos
D858,754	Bryan Grygus
D906,102	Andrew Cook
D934,069	Andrew Cook
D961,376	Andrew Cook

Patent	First Named Inventor
D961,377	Andrew Cook
D1,024,321	Christopher Hunter
D1,028,224	Christopher Hunter
D1,035,436	Andrew Cook

6. On information and belief, Sandoz is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 100 College Road West, Princeton, NJ 08540. Sandoz is a biopharmaceutical company that specializes in research and development of copies of medicines invented by other companies, including biosimilars.

7. On information and belief, Sandoz, acting in concert with one or more of its subsidiaries, affiliates, or agents, develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state, either directly or indirectly.

8. This action arises under the BPCIA, 42 U.S.C. § 262(*l*), the Patent Laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1332, 1338, 2201(a), and 2202.

9. Sandoz maintains its principal place of business at 100 College Road West, Princeton, NJ 08540. Sandoz's office located at this address is a regular and established place of business within the forum.

10. Sandoz is listed with the State of New Jersey Department of the Treasury as an entity that is currently doing business in the State of New Jersey, and the New Jersey Department of the Treasury has assigned Sandoz the following business entity numbers: 0100097265 (1979); 0101056767 (2020). Sandoz is also registered with the New Jersey Department of Health as a manufacturer and wholesaler, and the New Jersey Department of Health has assigned Sandoz the

following wholesale drug and medical device registration number: 5003732. The New Jersey Department of Health registration listing for Sandoz states the physical address of Sandoz as 100 College Road West, Princeton, NJ 08540.

11. Sandoz is a corporate entity currently doing business in the State of New Jersey and having a regular established place of business within the forum, Sandoz purposefully engaged in activities that are directed at the forum, the 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. For at least this reason, the Court has jurisdiction over Sandoz in this action.

12. This Court has personal jurisdiction over Sandoz because Sandoz filed its aBLA for ENZEEVU with FDA, seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of ENZEEVU in the United States. Sandoz's product subsequently received FDA approval, and Sandoz thus intends to—by itself or through others—market, distribute, offer for sale, and/or sell it in the United States, deriving substantial revenue therefrom. This conduct is "suit-related," has "substantial connection" with New Jersey, and therefore satisfies the minimum contacts requirement. *Cf. Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 762 (Fed. Cir. 2016).

13. In addition, Sandoz has consented to jurisdiction in the District of New Jersey in one or more prior cases arising out of its manufacture, use, offer for sale, sale, and/or importation of Sandoz pharmaceutical products in the United States, including in the State of New Jersey. This includes cases Sandoz has initiated as the plaintiff.

14. Venue is proper in this District under 28 U.S.C. § 1391(b) because Sandoz resides in this District and a substantial part of the events and injury giving rise to Plaintiff's claims has and continues to occur in this district.

FACTUAL BASIS FOR RELIEF

15. The BPCIA provides a mechanism to obtain FDA approval for a biological product that is "biosimilar" to a previously licensed "reference product" such as EYLEA®. 42 U.S.C. § 262(*k*). In order to be approved, biosimilars must be "highly similar to the reference product notwithstanding minor differences in clinically inactive components," with "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." *Id.* § 262(*i*)(2)(A)-(B).

16. The BPCIA reduces substantially the time and expense otherwise required to gain FDA approval, by allowing a biosimilar applicant like Sandoz to rely on most of the prior clinical testing that Regeneron conducted to establish the safety and efficacy of the reference product (EYLEA®). Regeneron, the reference product sponsor, invested many years of effort into its design and development of EYLEA® and received numerous patents rewarding this research. 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 its patent dance.

17. In particular, the BPCIA provides that "[w]hen a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to [the reference product sponsor], subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant

determines, in its sole discretion, to be appropriate (referred to in this subsection as the 'confidential information')." 42 U.S.C. § 262(*l*)(1)(B).

18. The referenced paragraph (2) provides that "[n]ot later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

> (A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and
>
> (B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor." 42 U.S.C. § 262(*l*)(2).

19. On May 13, 2024, Regeneron sent Sandoz a letter asking it to confirm whether Sandoz had filed an aBLA for an aflibercept biosimilar and, if so, whether FDA had accepted that aBLA for review. Sandoz never responded.

20. Subsequently, on July 12, 2024, Regeneron sent Sandoz a second letter requesting that Sandoz confirm by July 24, 2024 that it had submitted an aBLA for ENZEEVU, and that 20 days had passed since the FDA accepted Sandoz's aBLA for ENZEEVU. Regeneron further notified Sandoz that, "[i]f Sandoz fails to confirm or deny these statements by July 24, Regeneron will interpret [Sandoz's] silence as confirmation that Regeneron's understanding is correct, that the provisions of 42 U.S.C § 262(*l*)(9)(C) apply, and that Sandoz understands that immediate patent litigation will follow as a result of Sandoz's decision not to abide by the BPCIA and not to respond to [Regeneron's] inquiries." Sandoz responded to the second letter on July 19, 2024, but did not confirm or deny Regeneron's statements at that time and never provided notice under § 262(*l*)(2).

21. Rather, on August 12, 2024, Sandoz announced via a press release that FDA granted approval for ENZEEVU in both vial and pre-filled syringe presentations. Exhibit 1. That

same day, Sandoz notified Regeneron of FDA's approval of ENZEEVU. Thus, on information and belief, Sandoz submitted its aBLA for ENZEEVU earlier in 2024. To comply with its obligations under the BPCIA, Sandoz was required to provide the information specified by 42 U.S.C. § 262(*l*)(2) (at least its aBLA and manufacturing information) to Regeneron no more than 20 days after FDA acceptance or, absent willingness to supply that information, provide notice to Regeneron that FDA accepted its application. Sandoz has wholly failed to comply with that obligation. This is not the first instance in which Sandoz has pushed the limits of non-compliance with the BPCIA.

22. In *Sandoz v. Amgen*, Sandoz provided timely actual notice to Amgen of FDA's acceptance, but Sandoz did not provide Amgen with either its aBLA or manufacturing information as set forth in § 262(*l*)(2)(A). *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 12 (2017). Sandoz took non-compliance to the next level in *Genentech v. Sandoz*. There, Sandoz merely provided constructive notice (albeit timely) of its aBLA acceptance via a press release. Complaint, *Genentech, Inc.et al. v. Sandoz Inc. et al.*, No. 1:17-cv-13507 (D.N.J.). Moreover, it did not timely provide Genentech with access to its aBLA, and did not provide Genentech with its manufacturing information at all. *Id.*

23. In those prior BPCIA cases, Sandoz at least timely announced publicly or notified the reference product sponsor directly that it had submitted an aBLA and the FDA had accepted the aBLA for review.[2] Here, Sandoz did not timely provide ***any notice***—constructive or actual—

[2] Timely notice (within 20 days of FDA acceptance) is a material underpinning to the patent resolution scheme under 42 U.S.C. § 262(*l*). Initial FDA regulatory review of an aBLA and communicated decision to the aBLA applicant typically occurs about ten months after aBLA acceptance. This regulatory review period is a window within which patent issues can be resolved ***prior to FDA approval***, and timely notice is critical to that.

that its aBLA had been accepted for review. Instead, Regeneron learned that FDA had accepted Sandoz's aBLA for filing on August 12, 2024—***the very day FDA announced that it had approved Sandoz's aBLA***. Through its actions here, Sandoz is attempting to stretch acceptable non-compliance with § 262(*l*) to a point where a reference product sponsor, like Regeneron, is deprived entirely of any ability to resolve patent issues before FDA approval of a biosimilar product, creating an unnecessary emergency for the Court. This is not an outcome consistent with the BPCIA nor with any decision interpreting it.

24. Sandoz's submission of its aBLA is an act of infringement. 35 U.S.C. § 271(e)(2)(C). Because Sandoz did not timely provide the information specified in 42 U.S.C. § 262(*l*)(2) (indeed, FDA has already approved Sandoz's aBLA), the BPCIA authorizes Regeneron to bring suit on any patents that "could be identified pursuant to section 351(*l*)(3)(A)(i)." 35 U.S.C. § 271(e)(2)(C)(ii); *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 15 (2017) (holding that § 271(e)(2)(C)(ii) "assists in identifying which patents will be the subject of the artificial infringement suit" "where an applicant fails to disclose its application and manufacturing information altogether and the parties never prepare the § 262(*l*)(3) lists.").

25. Sandoz's failure to timely provide the information specified in 42 U.S.C. § 262(*l*)(2) authorizes Regeneron to "bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or use of a biological product." 42 U.S.C. § 262(*l*)(9)(C).

26. In view of Sandoz's refusal to timely provide Regeneron with the information set forth in 42 U.S.C. § 262(*l*)(2), Regeneron has been forced to guess which patents Sandoz might be infringing. *See Amgen Inc. v. Hospira, Inc.*, 866 F.3d 1355, 1360–61 (Fed. Cir. 2017) ("[I]f a

sponsor forms a belief based on an inquiry limited by an applicant's withholding of information, the sponsor has still satisfied Rule 11.").

CLAIMS FOR RELIEF

COUNT 1: VIOLATION OF THE BPCIA

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

28. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

29. The BPCIA is predicated on the notion that the biosimilar applicant will provide notice to the reference product sponsor of the acceptance of the biosimilar applicant's aBLA. While the Supreme Court has held that the biosimilar applicant may elect not to provide a copy of the aBLA to the reference product sponsor (and by so failing to do, trigger immediate patent litigation), the Supreme Court has never countenanced what Sandoz has done here: failure to provide notice of any kind. Notice by Sandoz to Regeneron is required by 42 U.S.C. § 262(*l*)(2)(A).

30. Accordingly, there is a real, substantial, and continuing case or controversy between Regeneron and Sandoz regarding Sandoz's failure to comply with the BPCIA.

31. Regeneron should be granted a declaratory judgment that Sandoz has not provided notice to Regeneron required under the BPCIA, and any equitable and monetary relief the Court deems just and appropriate.

COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 9,222,106 UNDER 35 U.S.C. § 271(e)

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

33. United States Patent No. 9,222,106 ("the '106 patent") (Exhibit 2 hereto), titled "Enhanced expression and stability regions," was duly and legally issued on December 29, 2015.

34. Regeneron is the owner of all right, title, and interest in the '106 patent.

35. The '106 patent has not yet expired.

36. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '106 patent, based on the information available to Regeneron, ENZEEVU infringes the '106 patent at least under § 271(e).

37. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '106 patent is an act of infringement of one or more claims of the '106 patent under 35 U.S.C. § 271(e)(2)(C)(i).

38. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 20 of the '106 patent.

39. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '106 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

40. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '106 patent

will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

41. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '106 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 3: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '106 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

43. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '106 patent, based on the information available to Regeneron, ENZEEVU infringes the '106 patent at least under §§ 271(b) and/or (g).

44. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '106 patent.

45. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '106 patent, which would constitute infringement of claims of the '106 patent under 35 U.S.C. § 271(g).

46. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '106 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '106 patent.

47. On information and belief, Sandoz has knowledge of and is aware of the '106 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '106 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '106 patent.

48. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '106 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the '106 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

49. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the '106 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the '106 patent.

50. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’106 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’106 patent, before the expiration of the ’106 patent.

COUNT 4: INFRINGEMENT OF U.S. PATENT NO. 9,315,281 UNDER 35 U.S.C. § 271(e)

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

52. United States Patent No. 9,315,281 (“the ’281 patent”) (Exhibit 3 hereto), titled “System and methods for use in dispensing biopharmaceutical materials,” was duly and legally issued on April 19, 2016.

53. Regeneron is the owner of all right, title, and interest in the ’281 patent.

54. The ’281 patent has not yet expired.

55. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’281 patent, based on the information available to Regeneron, ENZEEVU infringes the ’281 patent at least under § 271(e).

56. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into

the United States, of ENZEEVU before the expiration of the ’281 patent is an act of infringement of one or more claims of the ’281 patent under 35 U.S.C. § 271(e)(2)(C)(i).

57. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 13 of the ’281 patent.

58. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’281 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

59. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’281 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

60. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’281 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 5: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’281 PATENT UNDER 35 U.S.C. §§ 271 (a), (b), (g)

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

62. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the ’281 patent, based

on the information available to Regeneron, ENZEEVU infringes the ’281 patent at least under §§ 271 (a), (b) and/or (g).

63. Sandoz submitted its aBLA referencing Regeneron’s EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz’s ENZEEVU before the expiration of the ’281 patent.

64. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the ’281 patent, which would constitute infringement of claims of the ’281 patent under 35 U.S.C. § 271(g).

65. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to make, use, offer for sale, or sell within the United States, or import into the United States, a system for dispensing Sandoz’s ENZEEVU, which would constitute infringement of claims of the ’281 patent under 35 U.S.C. § 271(a).

66. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the ’281 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the ’281 patent.

67. On information and belief, Sandoz has knowledge of and is aware of the ’281 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’281 patent based on its active monitoring of Regeneron’s patents. On

information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’281 patent.

68. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’281 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’281 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

69. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’281 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’281 patent.

70. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’281 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’281 patent, before the expiration of the ’281 patent.

COUNT 6: INFRINGEMENT OF U.S. PATENT NO. 9,816,110 UNDER 35 U.S.C. § 271(e)

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

72. United States Patent No. 9,816,110 ("the '110 patent") (Exhibit 4 hereto), titled "CHO integration sites and uses thereof," was duly and legally issued on November 14, 2017.

73. Regeneron is the owner of all right, title, and interest in the '110 patent.

74. The '110 patent has not yet expired.

75. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '110 patent, based on the information available to Regeneron, ENZEEVU infringes the '110 patent at least under § 271(e).

76. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '110 patent is an act of infringement of one or more claims of the '110 patent under 35 U.S.C. § 271(e)(2)(C)(i).

77. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 18 of the '110 patent.

78. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '110 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

79. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '110 patent

will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

80. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '110 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 7: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '110 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

82. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '110 patent, based on the information available to Regeneron, ENZEEVU infringes the '110 patent at least under §§ 271(b) and/or (g).

83. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '110 patent.

84. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '110 patent, which would constitute infringement of claims of the '110 patent under 35 U.S.C. § 271(g).

85. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the ’110 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the ’110 patent.

86. On information and belief, Sandoz has knowledge of and is aware of the ’110 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’110 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’110 patent.

87. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’110 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’110 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

88. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’110 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’110 patent.

89. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’110 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’110 patent, before the expiration of the ’110 patent.

COUNT 8: INFRINGEMENT OF U.S. PATENT NO. 10,182,969 UNDER 35 U.S.C. § 271(e)

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

91. United States Patent No. 10,182,969 (“the ’969 patent”) (Exhibit 5 hereto), titled “Aseptic piercing system and method,” was duly and legally issued on January 22, 2019.

92. Regeneron is the owner of all right, title, and interest in the ’969 patent.

93. The ’969 patent has not yet expired.

94. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’969 patent, based on the information available to Regeneron, ENZEEVU infringes the ’969 patent at least under § 271(e).

95. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’969 patent is an act of infringement of one or more claims of the ’969 patent under 35 U.S.C. § 271(e)(2)(C)(i).

96. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’969 patent.

97. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’969 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

98. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’969 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

99. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’969 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 9: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’969 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

101. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the ’969 patent, based on the information available to Regeneron, ENZEEVU infringes the ’969 patent at least under §§ 271(a), (b), and/or (c).

102. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '969 patent.

103. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the '969 patent under 35 U.S.C. § 271(a).

104. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the '969 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 ENZEEVU.

105. On information and belief, Sandoz has knowledge of and is aware of the '969 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '969 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '969 patent.

106. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '969 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz

has infringed and/or will infringe one or more claims of the ’969 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

107. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’969 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’969 patent.

108. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’969 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’969 patent, before the expiration of the ’969 patent.

COUNT 10: INFRINGEMENT OF U.S. PATENT NO. 10,415,055 UNDER 35 U.S.C. § 271(e)

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

110. United States Patent No. 10,415,055 (“the ’055 patent”) (Exhibit 6 hereto), titled “Enhanced expression and stability regions,” was duly and legally issued on September 17, 2019.

111. Regeneron is the owner of all right, title, and interest in the ’055 patent.

112. The ’055 patent has not yet expired.

113. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’055

patent, based on the information available to Regeneron, ENZEEVU infringes the ’055 patent at least under § 271(e).

114. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’055 patent is an act of infringement of one or more claims of the ’055 patent under 35 U.S.C. § 271(e)(2)(C)(i).

115. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 23 of the ’055 patent.

116. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’055 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

117. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’055 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

118. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’055 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 11: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '055 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

120. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '055 patent, based on the information available to Regeneron, ENZEEVU infringes the '055 patent at least under §§ 271(b) and/or (g).

121. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '055 patent.

122. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '055 patent, which would constitute infringement of claims of the '055 patent under 35 U.S.C. § 271(g).

123. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '055 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '055 patent.

124. On information and belief, Sandoz has knowledge of and is aware of the ’055 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’055 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’055 patent.

125. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’055 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’055 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

126. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’055 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’055 patent.

127. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’055 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’055 patent, before the expiration of the ’055 patent.

COUNT 12: INFRINGEMENT OF U.S. PATENT NO. 10,669,594 UNDER 35 U.S.C. § 271(e)

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

129. United States Patent No. 10,669,594 ("the '594 patent") (Exhibit 7 hereto), titled "Compositions and methods for detecting a biological contaminant," was duly and legally issued on June 2, 2020.

130. Regeneron is the owner of all right, title, and interest in the '594 patent.

131. The '594 patent has not yet expired.

132. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '594 patent, based on the information available to Regeneron, ENZEEVU infringes the '594 patent at least under § 271(e).

133. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '594 patent is an act of infringement of one or more claims of the '594 patent under 35 U.S.C. § 271(e)(2)(C)(i).

134. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the '594 patent.

135. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '594 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C.

§ 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

136. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '594 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

137. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '594 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 13: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '594 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

139. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '594 patent, based on the information available to Regeneron, ENZEEVU infringes the '594 patent at least under §§ 271(b) and/or (g).

140. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '594 patent.

141. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '594 patent, which would constitute infringement of claims of the '594 patent under 35 U.S.C. § 271(g).

142. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '594 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '594 patent.

143. On information and belief, Sandoz has knowledge of and is aware of the '594 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '594 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '594 patent.

144. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '594 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the '594 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

145. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’594 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’594 patent.

146. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’594 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’594 patent, before the expiration of the ’594 patent.

COUNT 14: INFRINGEMENT OF U.S. PATENT NO. 10,828,345 UNDER 35 U.S.C. § 271(e)

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

148. United States Patent No. 10,828,345 (“the ’345 patent”) (Exhibit 8 hereto), titled “Use of a VEGF antagonist to treat angiogenic eye disorders,” was duly and legally issued on November 10, 2020.

149. Regeneron is the owner of all right, title, and interest in the ’345 patent.

150. The ’345 patent has not yet expired.

151. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’345 patent, based on the information available to Regeneron, use of ENZEEVU will infringe the ’345 patent at least under § 271(e).

152. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '345 patent is an act of infringement of one or more claims of the '345 patent under 35 U.S.C. § 271(e)(2)(C)(i).

153. For example, the sale of ENZEEVU pursuant to the ENZEEVU label will contribute to and induce infringement of, *inter alia*, claim 1 of the '345 patent.

154. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '345 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

155. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '345 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

156. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '345 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 15: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '345 PATENT UNDER 35 U.S.C. §§ 271(b), (c)

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

158. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and based on the information available to Regeneron, Sandoz's commercial marketing of ENZEEVU in accordance with its label will infringe the '345 patent at least under §§ 271(b) and/or (c).

159. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '345 patent.

160. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately infringe the '345 patent under 35 U.S.C. § 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, offer for sale, sale, use, or promotion of use of ENZEEVU.

161. On information and belief, Sandoz knows and/or is willfully blind to the fact that medical practitioners will administer and/or patients will use ENZEEVU, which will directly infringe one or more claims of the '345 patent.

162. On information and belief, Sandoz has knowledge of and is aware of the '345 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '345 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz knows and/or is willfully blind to the fact that the use of ENZEEVU will practice the methods prescribed in one or more claims of the '345 patent.

163. Sandoz has an affirmative intent to actively induce infringement by others of one or more claims of the '345 patent at least because it filed an aBLA that includes an approved label having directions that instruct medical practitioners to administer and/or patients to use ENZEEVU in a manner that infringes one or more claims of the '345 patent.

164. On information and belief, Sandoz knows or is willfully blind to the fact that it will aid and abet another's direct infringement of at least one of the claims of the '345 patent, either literally or under the doctrine of equivalents, at least by recommending such infringing acts in its label for the Sandoz aBLA product.

165. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the '345 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

166. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the '345 patent by actively inducing and/or contributing to the infringement of one or more claims of the '345 patent, before the expiration of the '345 patent.

167. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '345 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the '345 patent, before the expiration of the '345 patent.

COUNT 16: INFRINGEMENT OF U.S. PATENT NO. 10,905,786 UNDER 35 U.S.C. § 271(e)

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

169. United States Patent No. 10,905,786 ("the '786 patent") (Exhibit 9 hereto), titled "Sterilisation method," was duly and legally issued on February 2, 2021.

170. Regeneron is the owner of all right, title, and interest in the '786 patent.

171. The ’786 patent has not yet expired.

172. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’786 patent, based on the information available to Regeneron, ENZEEVU infringes the ’786 patent at least under § 271(e).

173. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’786 patent is an act of infringement of one or more claims of the ’786 patent under 35 U.S.C. § 271(e)(2)(C)(i).

174. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’786 patent.

175. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’786 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

176. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’786 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

177. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation

into the United States, of ENZEEVU before the expiration of the ’786 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 17: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’786 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

179. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the ’786 patent, based on the information available to Regeneron, ENZEEVU infringes the ’786 patent at least under §§ 271(b) and/or (g).

180. Sandoz submitted its aBLA referencing Regeneron’s EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz’s ENZEEVU before the expiration of the ’786 patent.

181. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the ’786 patent, which would constitute infringement of claims of the ’786 patent under 35 U.S.C. § 271(g).

182. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the ’786 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into

the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the ’786 patent.

183. On information and belief, Sandoz has knowledge of and is aware of the ’786 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’786 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’786 patent.

184. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’786 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’786 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

185. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’786 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’786 patent.

186. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’786 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or

contributing to the infringement of one or more claims of the ’786 patent, before the expiration of the ’786 patent.

COUNT 18: INFRINGEMENT OF U.S. PATENT NO. 10,918,754 UNDER 35 U.S.C. § 271(e)

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

188. United States Patent No. 10,918,754 (“the ’754 patent”) (Exhibit 10 hereto), titled “Sterilisation method,” was duly and legally issued on February 16, 2021.

189. Regeneron is the owner of all right, title, and interest in the ’754 patent.

190. The ’754 patent has not yet expired.

191. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’754 patent, based on the information available to Regeneron, ENZEEVU infringes the ’754 patent at least under § 271(e).

192. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’754 patent is an act of infringement of one or more claims of the ’754 patent under 35 U.S.C. § 271(e)(2)(C)(i).

193. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’754 patent.

194. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’754 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C.

§ 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

195. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '754 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

196. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '754 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 19: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '754 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

198. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '754 patent, based on the information available to Regeneron, ENZEEVU infringes the '754 patent at least under §§ 271(b) and/or (g).

199. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '754 patent.

200. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '754 patent, which would constitute infringement of claims of the '754 patent under 35 U.S.C. § 271(g).

201. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '754 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '754 patent.

202. On information and belief, Sandoz has knowledge of and is aware of the '754 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '754 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '754 patent.

203. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '754 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the '754 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

204. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’754 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’754 patent.

205. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’754 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’754 patent, before the expiration of the ’754 patent.

COUNT 20: INFRINGEMENT OF U.S. PATENT NO. 10,927,342 UNDER 35 U.S.C. § 271(e)

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

207. United States Patent No. 10,927,342 (“the ’342 patent”) (Exhibit 11 hereto), titled “Taurine supplemented cell culture medium and methods of use,” was duly and legally issued on February 23, 2021.

208. Regeneron is the owner of all right, title, and interest in the ’342 patent.

209. The ’342 patent has not yet expired.

210. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’342 patent, based on the information available to Regeneron, ENZEEVU infringes the ’342 patent at least under § 271(e).

211. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '342 patent is an act of infringement of one or more claims of the '342 patent under 35 U.S.C. § 271(e)(2)(C)(i).

212. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the '342 patent.

213. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '342 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

214. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '342 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

215. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '342 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 21: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '342 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

217. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '342 patent, based on the information available to Regeneron, ENZEEVU infringes the '342 patent at least under §§ 271(b) and/or (g).

218. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '342 patent.

219. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '342 patent, which would constitute infringement of claims of the '342 patent under 35 U.S.C. § 271(g).

220. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '342 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '342 patent.

221. On information and belief, Sandoz has knowledge of and is aware of the '342 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '342 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries,

affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’342 patent.

222. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’342 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’342 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

223. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’342 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’342 patent.

224. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’342 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’342 patent, before the expiration of the ’342 patent.

COUNT 22: INFRINGEMENT OF U.S. PATENT NO. 11,053,280 UNDER 35 U.S.C. § 271(e)

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

226. United States Patent No. 11,053,280 ("the '280 patent") (Exhibit 12 hereto), titled "Anti-VEGF protein compositions and methods for producing the same," was duly and legally issued on July 6, 2021.

227. Regeneron is the owner of all right, title, and interest in the '280 patent.

228. The '280 patent has not yet expired.

229. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '280 patent, based on the information available to Regeneron, ENZEEVU infringes the '280 patent at least under § 271(e).

230. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the '280 patent.

231. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '280 patent is an act of infringement of one or more claims of the '280 patent under 35 U.S.C. § 271(e)(2)(C)(i).

232. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '280 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

233. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '280 patent

will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

234. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '280 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 23: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '280 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

236. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '280 patent, based on the information available to Regeneron, ENZEEVU infringes the '280 patent at least under §§ 271(b) and/or (g).

237. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '280 patent.

238. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '280 patent, which would constitute infringement of claims of the '280 patent under 35 U.S.C. § 271(g).

239. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the ’280 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the ’280 patent.

240. On information and belief, Sandoz has knowledge of and is aware of the ’280 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’280 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’280 patent.

241. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’280 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’280 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

242. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’280 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’280 patent.

243. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’280 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’280 patent, before the expiration of the ’280 patent.

COUNT 24: INFRINGEMENT OF U.S. PATENT NO. 11,066,458 UNDER 35 U.S.C. § 271(e)

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

245. United States Patent No. 11,066,458 (“the ’458 patent”) (Exhibit 13 hereto), titled “VEGF antagonist formulations suitable for intravitreal administration,” was duly and legally issued on July 20, 2021.

246. Regeneron is the owner of all right, title, and interest in the ’458 patent.

247. The ’458 patent has not yet expired.

248. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’458 patent, based on the information available to Regeneron, ENZEEVU infringes the ’458 patent at least under § 271(e).

249. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’458 patent is an act of infringement of one or more claims of the ’458 patent under 35 U.S.C. § 271(e)(2)(C)(i).

250. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’458 patent.

251. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’458 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

252. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’458 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

253. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’458 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 25: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’458 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

255. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the ’458 patent, based on the information available to Regeneron, ENZEEVU infringes the ’458 patent at least under §§ 271(a), (b), and/or (c).

256. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '458 patent.

257. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the '458 patent under 35 U.S.C. § 271(a).

258. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '458 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 sale, offer for sale, sale, marketing, distributing and/or importing of ENZEEVU.

259. On information and belief, Sandoz has knowledge of and is aware of the '458 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '458 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '458 patent.

260. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '458 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz

has infringed and/or will infringe one or more claims of the ’458 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

261. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’458 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’458 patent.

262. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’458 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’458 patent, before the expiration of the ’458 patent.

COUNT 26: INFRINGEMENT OF U.S. PATENT NO. 11,084,865 UNDER 35 U.S.C. § 271(e)

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

264. United States Patent No. 11,084,865 (“the ’865 patent”) (Exhibit 14 hereto), titled “VEGF antagonist formulations suitable for intravitreal administration” was duly and legally issued on August 10, 2021.

265. Regeneron is the owner of all right, title, and interest in the ’865 patent.

266. The ’865 patent has not yet expired.

267. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’865

patent, based on the information available to Regeneron, ENZEEVU infringes the '865 patent at least under § 271(e).

268. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '865 patent is an act of infringement of one or more claims of the '865 patent under 35 U.S.C. § 271(e)(2)(C)(i).

269. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the '865 patent.

270. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '865 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

271. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '865 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

272. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '865 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 27: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '865 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

274. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '865 patent, based on the information available to Regeneron, ENZEEVU infringes the '865 patent at least under §§ 271(a), (b), and/or (c).

275. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '865 patent.

276. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the '865 patent under 35 U.S.C. § 271(a).

277. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '865 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 sale, offer for sale, sale, marketing, distributing and/or importing of ENZEEVU.

278. On information and belief, Sandoz has knowledge of and is aware of the '865 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '865 patent based on its active monitoring of Regeneron's patents. On

information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '865 patent.

279. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '865 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the '865 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

280. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the '865 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the '865 patent.

281. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the '865 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the '865 patent, before the expiration of the '865 patent.

COUNT 28: INFRINGEMENT OF U.S. PATENT NO. 11,104,715 UNDER 35 U.S.C. § 271(e)

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

283. United States Patent No. 11,104,715 ("the '715 patent") (Exhibit 15 hereto), titled "Methods for producing aflibercept in chemically defined media having reduced aflibercept variants," was duly and legally issued on August 31, 2021.

284. Regeneron is the owner of all right, title, and interest in the '715 patent.

285. The '715 patent has not yet expired.

286. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '715 patent, based on the information available to Regeneron, ENZEEVU infringes the '715 patent at least under § 271(e).

287. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '715 patent is an act of infringement of one or more claims of the '715 patent under 35 U.S.C. § 271(e)(2)(C)(i).

288. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the '715 patent.

289. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '715 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

290. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '715 patent

will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

291. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '715 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 29: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '715 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

293. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '715 patent, based on the information available to Regeneron, ENZEEVU infringes the '715 patent at least under §§ 271(b) and/or (g).

294. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '715 patent.

295. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '715 patent, which would constitute infringement of claims of the '715 patent under 35 U.S.C. § 271(g).

296. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '715 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '715 patent.

297. On information and belief, Sandoz has knowledge of and is aware of the '715 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '715 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '715 patent.

298. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '715 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the '715 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

299. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the '715 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the '715 patent.

300. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’715 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’715 patent, before the expiration of the ’715 patent.

COUNT 30: INFRINGEMENT OF U.S. PATENT NO. 11,160,918 UNDER 35 U.S.C. § 271(e)

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

302. United States Patent No. 11,160,918 (“the ’918 patent”) (Exhibit 16 hereto), titled “Medical device packaging and related methods,” was duly and legally issued on November 2, 2021.

303. Regeneron is the owner of all right, title, and interest in the ’918 patent.

304. The ’918 patent has not yet expired.

305. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’918 patent, based on the information available to Regeneron, ENZEEVU infringes the ’918 patent at least under § 271(e).

306. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’918 patent is an act of infringement of one or more claims of the ’918 patent under 35 U.S.C. § 271(e)(2)(C)(i).

307. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’918 patent.

308. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’918 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

309. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’918 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

310. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’918 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 31: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’918 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

312. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the ’918 patent, based on the information available to Regeneron, ENZEEVU infringes the ’918 patent at least under §§ 271(a), (b), and/or (c).

313. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '918 patent.

314. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the '918 patent under 35 U.S.C. § 271(a).

315. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the '918 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 ENZEEVU.

316. On information and belief, Sandoz has knowledge of and is aware of the '918 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '918 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '918 patent.

317. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '918 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz

has infringed and/or will infringe one or more claims of the ’918 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

318. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’918 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’918 patent.

319. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’918 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’918 patent, before the expiration of the ’918 patent.

COUNT 32: INFRINGEMENT OF U.S. PATENT NO. 11,174,283 UNDER 35 U.S.C. § 271(e)

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

321. United States Patent No. 11,174,283 (“the ’283 patent”) (Exhibit 17 hereto), titled “Anti-VEGF protein compositions and methods for producing the same,” was duly and legally issued on November 16, 2021.

322. Regeneron is the owner of all right, title, and interest in the ’283 patent.

323. The ’283 patent has not yet expired.

324. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’283

patent, based on the information available to Regeneron, ENZEEVU infringes the ’283 patent at least under § 271(e).

325. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’283 patent is an act of infringement of one or more claims of the ’283 patent under 35 U.S.C. § 271(e)(2)(C)(i).

326. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’283 patent.

327. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’283 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

328. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’283 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

329. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’283 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 33: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '283 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

331. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '283 patent, based on the information available to Regeneron, ENZEEVU infringes the '283 patent at least under §§ 271(b), and/or (g).

332. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '283 patent.

333. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '283 patent, which would constitute infringement of claims of the '283 patent under 35 U.S.C. § 271(g).

334. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '283 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '283 patent.

335. On information and belief, Sandoz has knowledge of and is aware of the ’283 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’283 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’283 patent.

336. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’283 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’283 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

337. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’283 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’283 patent.

338. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’283 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’283 patent, before the expiration of the ’283 patent.

COUNT 34: INFRINGEMENT OF U.S. PATENT NO. 11,268,109 UNDER 35 U.S.C. § 271(e)

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

340. United States Patent No. 11,268,109 ("the '109 patent") (Exhibit 18 hereto), titled "CHO integration sites and uses thereof," was duly and legally issued on March 8, 2022.

341. Regeneron is the owner of all right, title, and interest in the '109 patent.

342. The '109 patent has not yet expired.

343. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '109 patent, based on the information available to Regeneron, ENZEEVU infringes the '109 patent at least under § 271(e).

344. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '109 patent is an act of infringement of one or more claims of the '109 patent under 35 U.S.C. § 271(e)(2)(C)(i).

345. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 15 of the '109 patent.

346. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '109 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

347. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '109 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

348. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '109 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 35: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '109 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

350. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '109 patent, based on the information available to Regeneron, ENZEEVU infringes the '109 patent at least under §§ 271(b) and/or (g).

351. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '109 patent.

352. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly,

ENZEEVU manufactured by the process patented in one or more claims of the '109 patent, which would constitute infringement of claims of the '109 patent under 35 U.S.C. § 271(g).

353. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '109 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '109 patent.

354. On information and belief, Sandoz has knowledge of and is aware of the '109 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '109 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '109 patent.

355. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '109 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the '109 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

356. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the '109 patent by using, offering to sell, and/or selling within the United

States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the '109 patent.

357. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the '109 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the '109 patent, before the expiration of the '109 patent.

COUNT 36: INFRINGEMENT OF U.S. PATENT NO. 11,299,532 UNDER 35 U.S.C. § 271(e)

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

359. United States Patent No. 11,299,532 ("the '532 patent") (Exhibit 19 hereto), titled "Anti-VEGF protein compositions and methods for producing the same," was duly and legally issued on April 12, 2022.

360. Regeneron is the owner of all right, title, and interest in the '532 patent.

361. The '532 patent has not yet expired.

362. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '532 patent, based on the information available to Regeneron, ENZEEVU infringes the '532 patent at least under § 271(e).

363. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into

the United States, of ENZEEVU before the expiration of the ’532 patent is an act of infringement of one or more claims of the ’532 patent under 35 U.S.C. § 271(e)(2)(C)(i).

364. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1of the ’532 patent.

365. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’532 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

366. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’532 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

367. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’532 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 37: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’532 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

369. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the ’532 patent, based

on the information available to Regeneron, ENZEEVU infringes the ’532 patent at least under §§ 271(b) and/or (g).

370. Sandoz submitted its aBLA referencing Regeneron’s EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz’s ENZEEVU before the expiration of the ’532 patent.

371. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the ’532 patent, which would constitute infringement of claims of the ’532 patent under 35 U.S.C. § 271(g).

372. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the ’532 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the ’532 patent.

373. On information and belief, Sandoz has knowledge of and is aware of the ’532 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’532 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’532 patent.

374. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '532 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the '532 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

375. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the '532 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the '532 patent.

376. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the '532 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the '532 patent, before the expiration of the '532 patent.

COUNT 38: INFRINGEMENT OF U.S. PATENT NO. 11,312,936 UNDER 35 U.S.C. § 271(e)

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

378. United States Patent No. 11,312,936 ("the '936 patent") (Exhibit 20 hereto), titled "Taurine supplemented cell culture medium and methods of use," was duly and legally issued on April 26, 2022.

379. Regeneron is the owner of all right, title, and interest in the ’936 patent.

380. The ’936 patent has not yet expired.

381. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’936 patent, based on the information available to Regeneron, ENZEEVU infringes the ’936 patent at least under § 271(e).

382. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’936 patent is an act of infringement of one or more claims of the ’936 patent under 35 U.S.C. § 271(e)(2)(C)(i).

383. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’936 patent.

384. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’936 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

385. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’936 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

386. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '936 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 39: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '936 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

388. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '936 patent, based on the information available to Regeneron, ENZEEVU infringes the '936 patent at least under §§ 271(b) and/or (g).

389. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '936 patent.

390. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '936 patent, which would constitute infringement of claims of the '936 patent under 35 U.S.C. § 271(g).

391. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '936 patent under 35 U.S.C.

§ 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the ’936 patent.

392. On information and belief, Sandoz has knowledge of and is aware of the ’936 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’936 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’936 patent.

393. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’936 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’936 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

394. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’936 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’936 patent.

395. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’936 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the

United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’936 patent, before the expiration of the ’936 patent.

COUNT 40: INFRINGEMENT OF U.S. PATENT NO. 11,332,771 UNDER 35 U.S.C. § 271(e)

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

397. United States Patent No. 11,332,771 (“the ’771 patent”) (Exhibit 21 hereto), titled “Serum-free cell culture medium,” was duly and legally issued on May 17, 2022.

398. Regeneron is the owner of all right, title, and interest in the ’771 patent.

399. The ’771 patent has not yet expired.

400. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’771 patent, based on the information available to Regeneron, ENZEEVU infringes the ’771 patent at least under § 271(e).

401. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’771 patent is an act of infringement of one or more claims of the ’771 patent under 35 U.S.C. § 271(e)(2)(C)(i).

402. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’771 patent.

403. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’771 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

404. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’771 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

405. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’771 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 41: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’771 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

407. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the ’771 patent, based on the information available to Regeneron, ENZEEVU infringes the ’771 patent at least under §§ 271(b) and/or (g).

408. Sandoz submitted its aBLA referencing Regeneron’s EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale,

and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '771 patent.

409. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '771 patent, which would constitute infringement of claims of the '771 patent under 35 U.S.C. § 271(g).

410. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '771 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '771 patent.

411. On information and belief, Sandoz has knowledge of and is aware of the '771 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '771 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '771 patent.

412. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '771 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz

has infringed and/or will infringe one or more claims of the ’771 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

413. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’771 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’771 patent.

414. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’771 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’771 patent, before the expiration of the ’771 patent.

COUNT 42: INFRINGEMENT OF U.S. PATENT NO. 11,406,565 UNDER 35 U.S.C. § 271(e)

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

416. United States Patent No. 11,406,565 (“the ’565 patent”) (Exhibit 22 hereto), titled “Aseptic piercing system and method,” was duly and legally issued on August 9, 2022.

417. Regeneron is the owner of all right, title, and interest in the ’565 patent.

418. The ’565 patent has not yet expired.

419. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’565

patent, based on the information available to Regeneron, ENZEEVU infringes the ’565 patent at least under § 271(e).

420. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’565 patent is an act of infringement of one or more claims of the ’565 patent under 35 U.S.C. § 271(e)(2)(C)(i).

421. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’565 patent.

422. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’565 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

423. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’565 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

424. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’565 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 43: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '565 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

426. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '565 patent, based on the information available to Regeneron, ENZEEVU infringes the '565 patent at least under §§ 271(b) and/or (g).

427. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '565 patent.

428. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '565 patent, which would constitute infringement of claims of the '565 patent under 35 U.S.C. § 271(g).

429. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '565 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '565 patent.

430. On information and belief, Sandoz has knowledge of and is aware of the ’565 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’565 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’565 patent.

431. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’565 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’565 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

432. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’565 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’565 patent.

433. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’565 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’565 patent, before the expiration of the ’565 patent.

COUNT 44: INFRINGEMENT OF U.S. PATENT NO. 11,433,186 UNDER 35 U.S.C. § 271(e)

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

435. United States Patent No. 11,433,186 ("the '186 patent") (Exhibit 23 hereto), titled "Devices and methods for precision dose delivery," was duly and legally issued on September 6, 2022.

436. Regeneron is the owner of all right, title, and interest in the '186 patent.

437. The '186 patent has not yet expired.

438. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '186 patent, based on the information available to Regeneron, ENZEEVU infringes the '186 patent at least under § 271(e).

439. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '186 patent is an act of infringement of one or more claims of the '186 patent under 35 U.S.C. § 271(e)(2)(C)(i).

440. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the '186 patent.

441. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '186 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C.

§ 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

442. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '186 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

443. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '186 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 45: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '186 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

445. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '186 patent, based on the information available to Regeneron, ENZEEVU infringes the '186 patent at least under §§ 271(a), (b), and/or (c).

446. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '186 patent.

447. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the '186 patent under 35 U.S.C. § 271(a).

448. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the '186 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 ENZEEVU.

449. On information and belief, Sandoz has knowledge of and is aware of the '186 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '186 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '186 patent.

450. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '186 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the '186 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

451. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the '186 patent by using, offering to sell, and/or selling within the United

States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the '186 patent.

452. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the '186 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the '186 patent, before the expiration of the '186 patent.

COUNT 46: INFRINGEMENT OF U.S. PATENT NO. 11,439,758 UNDER 35 U.S.C. § 271(e)

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

454. United States Patent No. 11,439,758 ("the '758 patent") (Exhibit 24 hereto), titled "Devices and methods for precision dose delivery," was duly and legally issued on September 13, 2022.

455. Regeneron is the owner of all right, title, and interest in the '758 patent.

456. The '758 patent has not yet expired.

457. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '758 patent, based on the information available to Regeneron, ENZEEVU infringes the '758 patent at least under § 271(e).

458. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into

the United States, of ENZEEVU before the expiration of the ’758 patent is an act of infringement of one or more claims of the ’758 patent under 35 U.S.C. § 271(e)(2)(C)(i).

459. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’758 patent.

460. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’758 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

461. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’758 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

462. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’758 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 47: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’758 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

464. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the ’758 patent, based

on the information available to Regeneron, ENZEEVU infringes the ’758 patent at least under §§ 271(a), (b), and/or (c).

465. Sandoz submitted its aBLA referencing Regeneron’s EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz’s ENZEEVU before the expiration of the ’758 patent.

466. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz’s ENZEEVU, which would constitute infringement of claims of the ’758 patent under 35 U.S.C. § 271(a).

467. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the ’758 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 ENZEEVU.

468. On information and belief, Sandoz has knowledge of and is aware of the ’758 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’758 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’758 patent.

469. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United

States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’758 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’758 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

470. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’758 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’758 patent.

471. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’758 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’758 patent, before the expiration of the ’758 patent.

COUNT 48: INFRINGEMENT OF U.S. PATENT NO. 11,459,373 UNDER 35 U.S.C. § 271(e)

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

473. United States Patent No. 11,459,373 (“the ’373 patent”) (Exhibit 25 hereto), titled “Anti-VEGF protein compositions and methods for producing the same,” was duly and legally issued on October 4, 2022.

474. Regeneron is the owner of all right, title, and interest in the ’373 patent.

475. The ’373 patent has not yet expired.

476. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '373 patent, based on the information available to Regeneron, ENZEEVU infringes the '373 patent at least under § 271(e).

477. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '373 patent is an act of infringement of one or more claims of the '373 patent under 35 U.S.C. § 271(e)(2)(C)(i).

478. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the '373 patent.

479. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '373 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

480. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '373 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

481. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation

into the United States, of ENZEEVU before the expiration of the ’373 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 49: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’373 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

483. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the ’373 patent, based on the information available to Regeneron, ENZEEVU infringes the ’373 patent at least under §§ 271(b) and/or (g).

484. Sandoz submitted its aBLA referencing Regeneron’s EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz’s ENZEEVU before the expiration of the ’373 patent.

485. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the ’373 patent, which would constitute infringement of claims of the ’373 patent under 35 U.S.C. § 271(g).

486. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the ’373 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into

the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the ’373 patent.

487. On information and belief, Sandoz has knowledge of and is aware of the ’373 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’373 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’373 patent.

488. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’373 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’373 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

489. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’373 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’373 patent.

490. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’373 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or

contributing to the infringement of one or more claims of the ’373 patent, before the expiration of the ’373 patent.

COUNT 50: INFRINGEMENT OF U.S. PATENT NO. 11,459,374 UNDER 35 U.S.C. § 271(e)

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

492. United States Patent No. 11,459,374 (“the ’374 patent”) (Exhibit 26 hereto), titled “Anti-VEGF protein compositions and methods for producing the same,” was duly and legally issued on October 4, 2022.

493. Regeneron is the owner of all right, title, and interest in the ’374 patent.

494. The ’374 patent has not yet expired.

495. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’374 patent, based on the information available to Regeneron, ENZEEVU infringes the ’374 patent at least under § 271(e).

496. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’374 patent is an act of infringement of one or more claims of the ’374 patent under 35 U.S.C. § 271(e)(2)(C)(i).

497. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’374 patent.

498. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’374 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

499. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’374 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

500. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’374 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 51: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’374 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

502. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the ’374 patent, based on the information available to Regeneron, ENZEEVU infringes the ’374 patent at least under §§ 271(b) and/or (g).

503. Sandoz submitted its aBLA referencing Regeneron’s EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale,

and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '374 patent.

504. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '374 patent, which would constitute infringement of claims of the '374 patent under 35 U.S.C. § 271(g).

505. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '374 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '374 patent.

506. On information and belief, Sandoz has knowledge of and is aware of the '374 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '374 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '374 patent.

507. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '374 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz

has infringed and/or will infringe one or more claims of the ’374 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

508. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’374 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’374 patent.

509. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’374 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’374 patent, before the expiration of the ’374 patent.

COUNT 52: INFRINGEMENT OF U.S. PATENT NO. 11,472,861 UNDER 35 U.S.C. § 271(e)

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

511. United States Patent No. 11,472,861 (“the ’861 patent”) (Exhibit 27 hereto), titled “Methods for producing aflibercept in chemically defined media having reduced aflibercept variants,” was duly and legally issued on October 18, 2022.

512. Regeneron is the owner of all right, title, and interest in the ’861 patent.

513. The ’861 patent has not yet expired.

514. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’861

patent, based on the information available to Regeneron, ENZEEVU infringes the ’861 patent at least under § 271(e).

515. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’861 patent is an act of infringement of one or more claims of the ’861 patent under 35 U.S.C. § 271(e)(2)(C)(i).

516. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’861 patent.

517. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’861 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

518. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’861 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

519. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’861 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 53: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '861 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

521. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '861 patent, based on the information available to Regeneron, ENZEEVU infringes the '861 patent at least under §§ 271(b) and/or (g).

522. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '861 patent.

523. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '861 patent, which would constitute infringement of claims of the '861 patent under 35 U.S.C. § 271(g).

524. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '861 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '861 patent.

525. On information and belief, Sandoz has knowledge of and is aware of the ’861 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’861 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’861 patent.

526. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’861 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’861 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

527. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’861 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’861 patent.

528. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’861 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’861 patent, before the expiration of the ’861 patent.

COUNT 54: INFRINGEMENT OF U.S. PATENT NO. 11,478,588 UNDER 35 U.S.C. § 271(e)

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

530. United States Patent No. 11,478,588 ("the '588 patent") (Exhibit 28 hereto), titled "Needle shield grip devices and related methods," was duly and legally issued on October 25, 2022.

531. Regeneron is the owner of all right, title, and interest in the '588 patent.

532. The '588 patent has not yet expired.

533. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '588 patent, based on the information available to Regeneron, ENZEEVU infringes the '588 patent at least under § 271(e).

534. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '588 patent is an act of infringement of one or more claims of the '588 patent under 35 U.S.C. § 271(e)(2)(C)(i).

535. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the '588 patent.

536. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '588 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C.

§ 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

537. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '588 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

538. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '588 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 55: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '588 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

540. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '588 patent, based on the information available to Regeneron, ENZEEVU infringes the '588 patent at least under §§ 271(a), (b), and/or (c).

541. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '588 patent.

542. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the '588 patent under 35 U.S.C. § 271(a).

543. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the '588 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 ENZEEVU.

544. On information and belief, Sandoz has knowledge of and is aware of the '588 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '588 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '588 patent.

545. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '588 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the '588 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

546. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the '588 patent by using, offering to sell, and/or selling within the United

States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the '588 patent.

547. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the '588 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the '588 patent, before the expiration of the '588 patent.

COUNT 56: INFRINGEMENT OF U.S. PATENT NO. 11,535,663 UNDER 35 U.S.C. § 271(e)

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

549. United States Patent No. 11,535,663 ("the '663 patent") (Exhibit 29 hereto), titled "Methods for producing aflibercept in chemically defined media having reduced aflibercept variants," was duly and legally issued on December 27, 2022.

550. Regeneron is the owner of all right, title, and interest in the '663 patent.

551. The '663 patent has not yet expired.

552. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '663 patent, based on the information available to Regeneron, ENZEEVU infringes the '663 patent at least under § 271(e).

553. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into

the United States, of ENZEEVU before the expiration of the ’663 patent is an act of infringement of one or more claims of the ’663 patent under 35 U.S.C. § 271(e)(2)(C)(i).

554. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’663 patent.

555. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’663 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

556. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’663 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

557. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’663 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 57: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’663 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

559. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the ’663 patent, based

on the information available to Regeneron, ENZEEVU infringes the ’663 patent at least under §§ 271(b) and/or (g).

560. Sandoz submitted its aBLA referencing Regeneron’s EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz’s ENZEEVU before the expiration of the ’663 patent.

561. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the ’663 patent, which would constitute infringement of claims of the ’663 patent under 35 U.S.C. § 271(g).

562. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the ’663 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the ’663 patent.

563. On information and belief, Sandoz has knowledge of and is aware of the ’663 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’663 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’663 patent.

564. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '663 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the '663 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

565. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the '663 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the '663 patent.

566. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the '663 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the '663 patent, before the expiration of the '663 patent.

COUNT 58: INFRINGEMENT OF U.S. PATENT NO. 11,548,932 UNDER 35 U.S.C. § 271(e)

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

568. United States Patent No. 11,548,932 ("the '932 patent") (Exhibit 30 hereto), titled "Anti-VEGF protein compositions and methods for producing the same," was duly and legally issued on January 10, 2023.

569. Regeneron is the owner of all right, title, and interest in the ’932 patent.

570. The ’932 patent has not yet expired.

571. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’932 patent, based on the information available to Regeneron, ENZEEVU infringes the ’932 patent at least under § 271(e).

572. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’932 patent is an act of infringement of one or more claims of the ’932 patent under 35 U.S.C. § 271(e)(2)(C)(i).

573. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’932 patent.

574. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’932 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

575. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’932 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

576. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '932 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 59: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '932 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

578. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '932 patent, based on the information available to Regeneron, ENZEEVU infringes the '932 patent at least under §§ 271(b) and/or (g).

579. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '932 patent.

580. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '932 patent, which would constitute infringement of claims of the '932 patent under 35 U.S.C. § 271(g).

581. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '932 patent under 35 U.S.C.

§ 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the ’932 patent.

582. On information and belief, Sandoz has knowledge of and is aware of the ’932 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’932 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’932 patent.

583. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’932 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’932 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

584. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’932 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’932 patent.

585. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’932 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the

United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’932 patent, before the expiration of the ’932 patent.

COUNT 60: INFRINGEMENT OF U.S. PATENT NO. 11,555,176 UNDER 35 U.S.C. § 271(e)

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

587. United States Patent No. 11,555,176 (“the ’176 patent”) (Exhibit 31 hereto), titled “Cell culture medium for eukaryotic cells,” was duly and legally issued on January 17, 2023.

588. Regeneron is the owner of all right, title, and interest in the ’176 patent.

589. The ’176 patent has not yet expired.

590. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’176 patent, based on the information available to Regeneron, ENZEEVU infringes the ’176 patent at least under § 271(e).

591. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’176 patent is an act of infringement of one or more claims of the ’176 patent under 35 U.S.C. § 271(e)(2)(C)(i).

592. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’176 patent.

593. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '176 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

594. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '176 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

595. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '176 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 61: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '176 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

597. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '176 patent, based on the information available to Regeneron, ENZEEVU infringes the '176 patent at least under §§ 271(b) and/or (g).

598. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale,

and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '176 patent.

599. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '176 patent, which would constitute infringement of claims of the '176 patent under 35 U.S.C. § 271(g).

600. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '176 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '176 patent.

601. On information and belief, Sandoz has knowledge of and is aware of the '176 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '176 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '176 patent.

602. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '176 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz

has infringed and/or will infringe one or more claims of the ’176 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

603. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’176 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’176 patent.

604. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’176 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’176 patent, before the expiration of the ’176 patent.

COUNT 62: INFRINGEMENT OF U.S. PATENT NO. 11,577,025 UNDER 35 U.S.C. § 271(e)

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

606. United States Patent No. 11,577,025 (“the ’7,025 patent”) (Exhibit 32 hereto), titled “Devices and methods for overfilling drug containers,” was duly and legally issued on February 14, 2023.

607. Regeneron is the owner of all right, title, and interest in the ’7,025 patent.

608. The ’7,025 patent has not yet expired.

609. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’7,025

patent, based on the information available to Regeneron, ENZEEVU infringes the ’7,025 patent at least under § 271(e).

610. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’7,025 patent is an act of infringement of one or more claims of the ’7,025 patent under 35 U.S.C. § 271(e)(2)(C)(i).

611. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’7,025 patent.

612. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’7,025 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

613. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’7,025 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

614. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’7,025 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 63: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '7,025 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

616. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '7,025 patent, based on the information available to Regeneron, ENZEEVU infringes the '7,025 patent at least under §§ 271(b) and/or (g).

617. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '7,025 patent.

618. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '7,025 patent, which would constitute infringement of claims of the '7,025 patent under 35 U.S.C. § 271(g).

619. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '7,025 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '7,025 patent.

620. On information and belief, Sandoz has knowledge of and is aware of the ’7,025 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’7,025 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’7,025 patent.

621. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’7,025 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’7,025 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

622. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’7,025 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’7,025 patent.

623. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’7,025 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or

contributing to the infringement of one or more claims of the ’7,025 patent, before the expiration of the ’7,025 patent.

COUNT 64: INFRINGEMENT OF U.S. PATENT NO. 11,732,025 UNDER 35 U.S.C. § 271(e)

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

625. United States Patent No. 11,732,025 (“the ’2,025 patent”) (Exhibit 33 hereto), titled “Anti-VEGF protein compositions and methods for producing the same,” was duly and legally issued on August 22, 2023.

626. Regeneron is the owner of all right, title, and interest in the ’2,025 patent.

627. The ’2,025 patent has not yet expired.

628. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’2,025 patent, based on the information available to Regeneron, ENZEEVU infringes the ’2,025 patent at least under § 271(e).

629. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’2,025 patent is an act of infringement of one or more claims of the ’2,025 patent under 35 U.S.C. § 271(e)(2)(C)(i).

630. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the ’2,025 patent.

631. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’2,025 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

632. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’2,025 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

633. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’2,025 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 65: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’2,025 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

635. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the ’2,025 patent, based on the information available to Regeneron, ENZEEVU infringes the ’2,025 patent at least under §§ 271(b) and/or (g).

636. Sandoz submitted its aBLA referencing Regeneron’s EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale,

and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '2,025 patent.

637. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '2,025 patent, which would constitute infringement of claims of the '2,025 patent under 35 U.S.C. § 271(g).

638. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '2,025 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '2,025 patent.

639. On information and belief, Sandoz has knowledge of and is aware of the '2,025 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '2,025 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '2,025 patent.

640. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '2,025 patent. An actual controversy has also arisen and now exists between the parties concerning whether

Sandoz has infringed and/or will infringe one or more claims of the ’2,025 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

641. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’2,025 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’2,025 patent.

642. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’2,025 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’2,025 patent, before the expiration of the ’2,025 patent.

COUNT 66: INFRINGEMENT OF U.S. PATENT NO. 11,788,102 UNDER 35 U.S.C. § 271(e)

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

644. United States Patent No. 11,788,102 (“the ’102 patent”) (Exhibit 34 hereto), titled “CHO integration sites and uses thereof,” was duly and legally issued on October 17, 2023.

645. Regeneron is the owner of all right, title, and interest in the ’102 patent.

646. The ’102 patent has not yet expired.

647. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’102

patent, based on the information available to Regeneron, ENZEEVU infringes the ’102 patent at least under § 271(e).

648. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’102 patent is an act of infringement of one or more claims of the ’102 patent under 35 U.S.C. § 271(e)(2)(C)(i).

649. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 21 of the ’102 patent.

650. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’102 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

651. Sandoz’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’102 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

652. The submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the ’102 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 67: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '102 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

654. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '102 patent, based on the information available to Regeneron, ENZEEVU infringes the '102 patent at least under §§ 271(b) and/or (g).

655. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '102 patent.

656. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '102 patent, which would constitute infringement of claims of the '102 patent under 35 U.S.C. § 271(g).

657. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '102 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '102 patent.

658. On information and belief, Sandoz has knowledge of and is aware of the ’102 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’102 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’102 patent.

659. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’102 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’102 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

660. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’102 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’102 patent.

661. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’102 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’102 patent, before the expiration of the ’102 patent.

COUNT 68: INFRINGEMENT OF U.S. PATENT NO. 11,793,926 UNDER 35 U.S.C. § 271(e)

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

663. United States Patent No. 11,793,926 ("the '926 patent") (Exhibit 35 hereto), titled "Medical device packaging and related methods," was duly and legally issued on October 24, 2023.

664. Regeneron is the owner of all right, title, and interest in the '926 patent.

665. The '926 patent has not yet expired.

666. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '926 patent, based on the information available to Regeneron, ENZEEVU infringes the '926 patent at least under § 271(e).

667. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '926 patent is an act of infringement of one or more claims of the '926 patent under 35 U.S.C. § 271(e)(2)(C)(i).

668. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 11 of the '926 patent.

669. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '926 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C.

§ 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

670. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '926 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

671. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '926 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 69: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '926 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c), (g)

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

673. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '926 patent, based on the information available to Regeneron, ENZEEVU infringes the '926 patent at least under §§ 271(a), (b), (c), and/or (g).

674. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '926 patent.

675. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the '926 patent under 35 U.S.C. § 271(a).

676. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the '926 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 ENZEEVU.

677. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '926 patent, which would constitute infringement of claims of the '926 patent under 35 U.S.C. § 271(g).

678. On information and belief, Sandoz has knowledge of and is aware of the '926 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '926 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '926 patent.

679. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the '926 patent. An

actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’926 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

680. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’926 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’926 patent.

681. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’926 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’926 patent, before the expiration of the ’926 patent.

COUNT 70: INFRINGEMENT OF U.S. PATENT NO. 11,850,407 UNDER 35 U.S.C. § 271(e)

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

683. United States Patent No. 11,850,407 (“the ’407 patent”) (Exhibit 36 hereto), titled “Needle shield grip devices and related methods,” was duly and legally issued on December 26, 2023.

684. Regeneron is the owner of all right, title, and interest in the ’407 patent.

685. The ’407 patent has not yet expired.

686. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate

whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '407 patent, based on the information available to Regeneron, ENZEEVU infringes the '407 patent at least under § 271(e).

687. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '407 patent is an act of infringement of one or more claims of the '407 patent under 35 U.S.C. § 271(e)(2)(C)(i).

688. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the '407 patent.

689. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '407 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

690. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '407 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

691. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '407 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 71: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '407 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

693. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '407 patent, based on the information available to Regeneron, ENZEEVU infringes the '407 patent at least under §§ 271(a), (b), and/or (c).

694. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '407 patent.

695. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the '407 patent under 35 U.S.C. § 271(a).

696. On information and belief, in view of the FDA approval, Sandoz intends to and will immediately begin to infringe the '407 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 ENZEEVU.

697. On information and belief, Sandoz has knowledge of and is aware of the '407 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '407 patent based on its active monitoring of Regeneron's patents. On

information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’407 patent.

698. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’407 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’407 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

699. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’407 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’407 patent.

700. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’407 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’407 patent, before the expiration of the ’407 patent.

COUNT 72: INFRINGEMENT OF U.S. PATENT NO. 11,918,785 UNDER 35 U.S.C. § 271(e)

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

702. United States Patent No. 11,918,785 ("the '785 patent") (Exhibit 37 hereto), titled "Devices and methods for overfilling drug containers," was duly and legally issued on March 5, 2024.

703. Regeneron is the owner of all right, title, and interest in the '785 patent.

704. The '785 patent has not yet expired.

705. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '785 patent, based on the information available to Regeneron, ENZEEVU infringes the '785 patent at least under § 271(e).

706. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '785 patent is an act of infringement of one or more claims of the '785 patent under 35 U.S.C. § 271(e)(2)(C)(i).

707. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the '785 patent.

708. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '785 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

709. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '785 patent

will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

710. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '785 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 73: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '785 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

712. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '785 patent, based on the information available to Regeneron, ENZEEVU infringes the '785 patent at least under §§ 271(b) and/or (g).

713. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '785 patent.

714. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '785 patent, which would constitute infringement of claims of the '785 patent under 35 U.S.C. § 271(g).

715. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the ’785 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the ’785 patent.

716. On information and belief, Sandoz has knowledge of and is aware of the ’785 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the ’785 patent based on its active monitoring of Regeneron’s patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’785 patent.

717. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’785 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’785 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

718. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’785 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’785 patent.

719. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’785 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’785 patent, before the expiration of the ’785 patent.

COUNT 74: INFRINGEMENT OF U.S. PATENT NO. 11,970,724 UNDER 35 U.S.C. § 271(e)

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

721. United States Patent No. 11,970,724 (“the ’724 patent”) (Exhibit 38 hereto), titled “Serum-free cell culture medium,” was duly and legally issued on April 30, 2024.

722. Regeneron is the owner of all right, title, and interest in the ’724 patent.

723. The ’724 patent has not yet expired.

724. In view of Sandoz’s failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz’s Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the ’724 patent, based on the information available to Regeneron, ENZEEVU infringes the ’724 patent at least under § 271(e).

725. On information and belief, the submission of Sandoz’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the ’724 patent is an act of infringement of one or more claims of the ’724 patent under 35 U.S.C. § 271(e)(2)(C)(i).

726. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the '724 patent.

727. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '724 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

728. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '724 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

729. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '724 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 75: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '724 PATENT UNDER 35 U.S.C. §§ 271(b), (g)

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

731. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the '724 patent, based on the information available to Regeneron, ENZEEVU infringes the '724 patent at least under §§ 271(b) and/or (g).

732. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '724 patent.

733. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, ENZEEVU manufactured by the process patented in one or more claims of the '724 patent, which would constitute infringement of claims of the '724 patent under 35 U.S.C. § 271(g).

734. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will induce infringement of one or more claims of the '724 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States ENZEEVU manufactured by the process patented in one or more claims of the '724 patent.

735. On information and belief, Sandoz has knowledge of and is aware of the '724 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '724 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '724 patent.

736. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United

States, of ENZEEVU has infringed and/or will infringe one or more claims of the ’724 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’724 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

737. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’724 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz’s ENZEEVU, before the expiration of the ’724 patent.

738. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the ’724 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’724 patent, before the expiration of the ’724 patent.

COUNT 76: INFRINGEMENT OF U.S. PATENT NO. 11,975,045 UNDER 35 U.S.C. § 271(e)

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

740. United States Patent No. 11,975,045 (“the ’045 patent”) (Exhibit 39 hereto), titled “Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders,” was duly and legally issued on May 7, 2024.

741. Regeneron is the owner of all right, title, and interest in the ’045 patent.

742. The ’045 patent has not yet expired.

743. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the '045 patent, based on the information available to Regeneron, use of ENZEEVU will infringe the '045 patent at least under § 271(e).

744. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the '045 patent is an act of infringement of one or more claims of the '045 patent under 35 U.S.C. § 271(e)(2)(C)(i).

745. For example, the sale of ENZEEVU pursuant to the ENZEEVU label will contribute to and induce infringement of, *inter alia*, claim 1 of the '045 patent.

746. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the '045 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

747. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '045 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

748. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the '045 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 77: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '045 PATENT UNDER 35 U.S.C. §§ 271(b), (c)

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

750. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and based on the information available to Regeneron, Sandoz's commercial marketing of ENZEEVU in accordance with its label will infringe the '045 patent at least under §§ 271(b) and/or (c).

751. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the '045 patent.

752. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately infringe the '045 patent under 35 U.S.C. § 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, offer for sale, sale, use, or promotion of use of ENZEEVU.

753. On information and belief, Sandoz knows and/or is willfully blind to the fact that medical practitioners will administer and/or patients will use ENZEEVU, which will directly infringe one or more claims of the '045 patent.

754. On information and belief, Sandoz has knowledge of and is aware of the '045 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the '045 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz knows and/or is willfully blind to the fact that the use of ENZEEVU will practice the methods prescribed in one or more claims of the '045 patent.

755. Sandoz has an affirmative intent to actively induce infringement by others of one or more claims of the ’045 patent at least because it filed an aBLA that includes an approved label having directions that instruct medical practitioners to administer and/or patients to use ENZEEVU in a manner that infringes one or more claims of the ’045 patent.

756. On information and belief, Sandoz knows or is willfully blind to the fact that it will aid and abet another’s direct infringement of at least one of the claims of the ’045 patent, either literally or under the doctrine of equivalents, at least by recommending such infringing acts in its label for the Sandoz aBLA product.

757. In view of Sandoz’s submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the ’045 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

758. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the ’045 patent by actively inducing and/or contributing to the infringement of one or more claims of the ’045 patent, before the expiration of the ’045 patent.

759. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the ’045 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the ’045 patent, before the expiration of the ’045 patent.

COUNT 78: INFRINGEMENT OF U.S. PATENT NO. D858,754 UNDER 35 U.S.C. § 271(e)

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

761. United States Patent No. D858,754 ("the D754 patent") (Exhibit 40 hereto), titled "Syringe cap," was duly and legally issued on September 3, 2019.

762. Regeneron is the owner of all right, title, and interest in the D754 patent.

763. The D754 patent has not yet expired.

764. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the D754 patent, based on the information available to Regeneron, ENZEEVU infringes the D754 patent at least under § 271(e).

765. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the D754 patent is an act of infringement of one or more claims of the D754 patent under 35 U.S.C. § 271(e)(2)(C)(i).

766. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, inter alia, claim 1 of the D754 patent.

767. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the D754 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

768. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D754 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

769. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D754 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 79: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE D754 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

771. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the D754 patent, based on the information available to Regeneron, ENZEEVU infringes the D754 patent at least under §§ 271(a), (b), and/or (c).

772. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the D754 patent.

773. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell

within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the D754 patent under 35 U.S.C. § 271(a).

774. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the D754 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 ENZEEVU.

775. On information and belief, Sandoz has knowledge of and is aware of the D754 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the D754 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the D754 patent.

776. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the D754 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the D754 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

777. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the D754 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the D754 patent.

778. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the D754 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the D754 patent, before the expiration of the D754 patent.

COUNT 80: INFRINGEMENT OF U.S. PATENT NO. D906,102 UNDER 35 U.S.C. § 271(e)

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

780. United States Patent No. D906,102 ("the D102 patent") (Exhibit 41 hereto), titled "Packaging," was duly and legally issued on December 29, 2020.

781. Regeneron is the owner of all right, title, and interest in the D102 patent.

782. The D102 patent has not yet expired.

783. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the D102 patent, based on the information available to Regeneron, ENZEEVU infringes the D102 patent at least under § 271(e).

784. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the D102 patent is an act of infringement of one or more claims of the D102 patent under 35 U.S.C. § 271(e)(2)(C)(i).

785. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the D102 patent.

786. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the D102 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

787. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D102 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

788. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D102 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 81: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE D102 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

790. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the D102 patent, based on the information available to Regeneron, ENZEEVU infringes the D102 patent at least under §§ 271(a), (b), and/or (c).

791. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the D102 patent.

792. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the D102 patent under 35 U.S.C. § 271(a).

793. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the D102 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 ENZEEVU.

794. On information and belief, Sandoz has knowledge of and is aware of the D102 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the D102 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the D102 patent.

795. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the D102 patent. An actual controversy has also arisen and now exists between the parties concerning whether

Sandoz has infringed and/or will infringe one or more claims of the D102 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

796. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the D102 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the D102 patent.

797. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the D102 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the D102 patent, before the expiration of the D102 patent.

COUNT 82: INFRINGEMENT OF U.S. PATENT NO. D934,069 UNDER 35 U.S.C. § 271(e)

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

799. United States Patent No. D934,069 ("the D069 Patent") (Exhibit 42 hereto), titled "Packaging," was duly and legally issued on October 26, 2021.

800. Regeneron is the owner of all right, title, and interest in the D069 patent.

801. The D069 patent has not yet expired.

802. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the D069

patent, based on the information available to Regeneron, ENZEEVU infringes the D069 patent at least under § 271(e).

803. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the D069 patent is an act of infringement of one or more claims of the D069 patent under 35 U.S.C. § 271(e)(2)(C)(i).

804. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the D069 patent.

805. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the D069 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

806. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D069 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

807. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D069 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 83: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE D069 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

809. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the D069 patent, based on the information available to Regeneron, ENZEEVU infringes the D069 patent at least under §§ 271(a), (b), and/or (c).

810. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the D069 patent.

811. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the D069 patent under 35 U.S.C. § 271(a).

812. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the D069 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 ENZEEVU.

813. On information and belief, Sandoz has knowledge of and is aware of the D069 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the D069 patent based on its active monitoring of Regeneron's patents. On

information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the D069 patent.

814. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the D069 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the D069 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

815. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the D069 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the D069 patent.

816. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the D069 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the D069 patent, before the expiration of the D069 patent.

COUNT 84: INFRINGEMENT OF U.S. PATENT NO. D961,376 UNDER 35 U.S.C. § 271(e)

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

818. United States Patent No. D961,376 ("the D376 patent") (Exhibit 43 hereto), titled "Packaging," was duly and legally issued on August 23, 2022.

819. Regeneron is the owner of all right, title, and interest in the D376 patent.

820. The D376 patent has not yet expired.

821. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the D376 patent, based on the information available to Regeneron, ENZEEVU infringes the D376 patent at least under § 271(e).

822. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the D376 patent is an act of infringement of one or more claims of the D376 patent under 35 U.S.C. § 271(e)(2)(C)(i).

823. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the D376 patent.

824. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the D376 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

825. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D376

patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

826. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D376 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 85: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE D376 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

828. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the D376 patent, based on the information available to Regeneron, ENZEEVU infringes the D376 patent at least under §§ 271(a), (b), and/or (c).

829. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the D376 patent.

830. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the D376 patent under 35 U.S.C. § 271(a).

831. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the D376 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 ENZEEVU.

832. On information and belief, Sandoz has knowledge of and is aware of the D376 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the D376 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the D376 patent.

833. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the D376 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the D376 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

834. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the D376 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the D376 patent.

835. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the D376 patent. Regeneron does not have an adequate remedy at law and is entitled to

injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the D376 patent, before the expiration of the D376 patent.

COUNT 86: INFRINGEMENT OF U.S. PATENT NO. D961,377 UNDER 35 U.S.C. § 271(e)

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

837. United States Patent No. D961,377 ("the D377 patent") (Exhibit 44 hereto), titled "Packaging," was duly and legally issued on August 23, 2022.

838. Regeneron is the owner of all right, title, and interest in the D377 patent.

839. The D377 patent has not yet expired.

840. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the D377 patent, based on the information available to Regeneron, ENZEEVU infringes the D377 patent at least under § 271(e).

841. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the D377 patent is an act of infringement of one or more claims of the D377 patent under 35 U.S.C. § 271(e)(2)(C)(i).

842. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the D377 patent.

843. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the D377 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

844. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D377 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

845. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D377 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 87: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE D377 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

847. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the D377 patent, based on the information available to Regeneron, ENZEEVU infringes the D377 patent at least under §§ 271(a), (b), and/or (c).

848. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale,

and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the D377 patent.

849. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the D377 patent under 35 U.S.C. § 271(a).

850. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the D377 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 ENZEEVU.

851. On information and belief, Sandoz has knowledge of and is aware of the D377 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the D377 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the D377 patent.

852. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the D377 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the D377 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

853. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the D377 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the D377 patent.

854. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the D377 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the D377 patent, before the expiration of the D377 patent.

COUNT 88: INFRINGEMENT OF U.S. PATENT NO. D1,024,321 UNDER 35 U.S.C. § 271(e)

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

856. United States Patent No. D1,024,321 ("the D321 patent") (Exhibit 45 hereto), titled "Retainer adapter assembly," was duly and legally issued on April 23, 2024.

857. Regeneron is the owner of all right, title, and interest in the D321 patent.

858. The D321 patent has not yet expired.

859. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the D321 patent, based on the information available to Regeneron, ENZEEVU infringes the D321 patent at least under § 271(e).

860. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the D321 patent is an act of infringement of one or more claims of the D321 patent under 35 U.S.C. § 271(e)(2)(C)(i).

861. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the D321 patent.

862. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the D321 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

863. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D321 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

864. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D321 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 89: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE D321 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

866. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the D321 patent, based on the information available to Regeneron, ENZEEVU infringes the D321 patent at least under §§ 271(a), (b), and/or (c).

867. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the D321 patent.

868. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the D321 patent under 35 U.S.C. § 271(a).

869. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the D321 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 ENZEEVU.

870. On information and belief, Sandoz has knowledge of and is aware of the D321 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the D321 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the D321 patent.

871. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the D321 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the D321 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

872. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the D321 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the D321 patent.

873. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the D321 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the D321 patent, before the expiration of the D321 patent.

COUNT 90: INFRINGEMENT OF U.S. PATENT NO. D1,028,224 UNDER 35 U.S.C. § 271(e)

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

875. United States Patent No. D1,028,224 ("the D224 patent") (Exhibit 46 hereto), titled "Retainer adapter assembly," was duly and legally issued May 21, 2024.

876. Regeneron is the owner of all right, title, and interest in the D224 patent.

877. The D224 patent has not yet expired.

878. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the D224 patent, based on the information available to Regeneron, ENZEEVU infringes the D224 patent at least under § 271(e).

879. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the D224 patent is an act of infringement of one or more claims of the D224 patent under 35 U.S.C. § 271(e)(2)(C)(i).

880. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the D224 patent.

881. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the D224 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

882. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D224 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

883. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation

into the United States, of ENZEEVU before the expiration of the D224 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 91: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE D224 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

885. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the D224 patent, based on the information available to Regeneron, ENZEEVU infringes the D224 patent at least under §§ 271(a), (b), and/or (c).

886. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the D224 patent.

887. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the D224 patent under 35 U.S.C. § 271(a).

888. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the D224 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 ENZEEVU.

889. On information and belief, Sandoz has knowledge of and is aware of the D224 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the D224 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the D224 patent.

890. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the D224 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the D224 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

891. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the D224 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the D224 patent.

892. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the D224 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the D224 patent, before the expiration of the D224 patent.

COUNT 92: INFRINGEMENT OF U.S. PATENT NO. D1,035,436 UNDER 35 U.S.C. § 271(e)

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

894. United States Patent No. D1,035,436 ("the D436 patent") (Exhibit 47 hereto), titled "Packaging," was duly and legally issued on July 16, 2024.

895. Regeneron is the owner of all right, title, and interest in the D436 patent.

896. The D436 patent has not yet expired.

897. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the necessary information to adequately evaluate whether Sandoz's Eylea biosimilar, ENZEEVU, has infringed and/or would infringe the D436 patent, based on the information available to Regeneron, ENZEEVU infringes the D436 patent at least under § 271(e).

898. On information and belief, the submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ENZEEVU before the expiration of the D436 patent is an act of infringement of one or more claims of the D436 patent under 35 U.S.C. § 271(e)(2)(C)(i).

899. For example, based on the information available to Regeneron, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU will infringe, *inter alia*, claim 1 of the D436 patent.

900. Regeneron will be irreparably harmed if Sandoz is not enjoined from infringing one or more claims of the D436 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Sandoz from any further infringement. Regeneron has no adequate remedy at law.

901. Sandoz's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D436 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

902. The submission of Sandoz's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ENZEEVU before the expiration of the D436 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 93: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE D436 PATENT UNDER 35 U.S.C. §§ 271(a), (b), (c)

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

904. In view of Sandoz's failure to comply with its obligations under § 262(*l*)(2)(A) and its persistent refusal to provide Regeneron with the required and necessary information to adequately evaluate whether ENZEEVU has infringed and/or would infringe the D436 patent, based on the information available to Regeneron, ENZEEVU infringes the D436 patent at least under §§ 271(a), (b), and/or (c).

905. Sandoz submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(*k*) to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of Sandoz's ENZEEVU before the expiration of the D436 patent.

906. Sandoz received FDA approval of ENZEEVU on August 12, 2024, and on information and belief, Sandoz intends to and will immediately begin to use, offer for sale, or sell

within the Unites States, or import into the United States, Sandoz's ENZEEVU, which would constitute infringement of claims of the D436 patent under 35 U.S.C. § 271(a).

907. On information and belief, in view of the FDA approval of ENZEEVU, Sandoz intends to and will immediately begin to infringe the D436 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 ENZEEVU.

908. On information and belief, Sandoz has knowledge of and is aware of the D436 patent at least due to the filing of this Complaint. On information and belief, Sandoz has also had knowledge of the D436 patent based on its active monitoring of Regeneron's patents. On information and belief, Sandoz will provide ENZEEVU to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the D436 patent.

909. In view of Sandoz's submission and FDA approval of its aBLA, an actual controversy has arisen and now exists between the parties concerning whether Sandoz's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of ENZEEVU has infringed and/or will infringe one or more claims of the D436 patent. An actual controversy has also arisen and now exists between the parties concerning whether Sandoz has infringed and/or will infringe one or more claims of the D436 patent by actively inducing and/or contributing to the manufacture, use, offer to sell, and/or sale of ENZEEVU.

910. Regeneron is entitled to a declaratory judgment that Sandoz has infringed and/or would infringe claims of the D436 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or by actively inducing and/or contributing to the infringement of Sandoz's ENZEEVU, before the expiration of the D436 patent.

911. Regeneron would be irreparably harmed if Sandoz is not enjoined from infringing claims of the D436 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Sandoz from making, using, offering to sell, and/or selling within the United States, or importing into the United States, ENZEEVU, or actively inducing and/or contributing to the infringement of one or more claims of the D436 patent, before the expiration of the D436 patent.

PRAYER FOR RELIEF

WHEREFORE, Regeneron requests the following relief:

(a) a declaratory judgment that Sandoz has failed to provide to Regeneron the notice required by the BPCIA;

(b) any equitable or monetary relief that the Court deems just and proper to remedy Sandoz's violation of the BPCIA, including but not limited to, ordering Sandoz to withdraw its aBLA, refile the aBLA, and provide notice as contemplated under 42 U.S.C. § 262(*l*)(2)(A), and/or issuing a scheduling order that allows for immediate and expansive discovery from Sandoz and facilitates swift resolution prior to any launch by Sandoz;

(c) a judgment that Sandoz has infringed the patents in suit;

(d) Preliminary and/or permanent equitable relief, including pursuant to 35 U.S.C. § 271(e)(4)(B), including but not limited to a preliminary and permanent injunction that enjoins Sandoz, 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 patents in suit, 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 any current or future versions of a product that infringes, or the use or manufacturing of which infringes, the patents in suit;

(e) Statutory relief under 35 U.S.C. § 271(e)(4)(D), including but not limited to a permanent injunction prohibiting Sandoz, 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 patents in suit, 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 any current or future versions of a product that infringes, or the use or manufacturing of which infringes, the patents in suit;

(f) Damages pursuant to 35 U.S.C. § 271(e)(4)(C), if applicable, in the form of lost profits but in no event less than a reasonable royalty;

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

(h) An award for an accounting of damages from Sandoz's infringement;

(i) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285 and 35 U.S.C. § 271(e)(4);

(j) An award of Regeneron's costs and expenses in this action; and

(k) Such further relief as this court may deem just and proper.

Date: August 26, 2024

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Attorneys for Plaintiff Regeneron Pharmaceuticals, Inc.

CERTIFICATE PURSUANT TO RULES 11.2 AND 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, except for the multidistrict litigation entitled *In re: Aflibercept Patent Litigation*, C.A. No. 1:24-md-03103-TSK (N.D.W. Va.) ("MDL") and the following pending matters in other judicial districts:

· C.D. Cal.

o *Regeneron Pharmaceuticals, Inc. v. Amgen, Inc.*, No. 2:24-cv-00264

· N.D.W. Va.

o *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc.*, No. 1:22-cv-00061

o *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, No. 1:23-cv-00089

o *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis, Co., Ltd.*, No. 1:23-cv-00094

o *Regeneron Pharmaceuticals, Inc. v. Formycon AG*, No. 1:23-cv-00097

o *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*, No. 1:23-cv-00106

o *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, No. 1:24-cv-00053

· Fed. Cir.

o *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc.*, Nos. 24-1965, 24-1966, 24-2082, 24-2083 – consolidated appeals from Bioepis, from MDL and related to No. 1:23-cv-00094 (N.D.W. Va.) and No. 1:23-cv-00106 (N.D.W. Va.) above

o *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc.*, No. 24-2002 – appeal from Mylan and Biocon, from MDL and related to No. 1:22-cv-00061 (N.D.W. Va.) above

o *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc.*, Nos. 24-2009, 24-2019, 24-2156 – consolidated appeals from Formycon, from MDL and related to No. 1:23-cv-00097 (N.D.W. Va.) above

o *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc.*, Nos. 24-2058, 24-2147 – appeals from Celltrion, from MDL and related to No. 1:23-cv-00089 (N.D.W. Va.) and No. 1:24-cv-00053 (N.D.W. Va.) above

Further, there are not any non-parties known to Plaintiff that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: August 26, 2024

Respectfully Submitted,

s/ Keith J. Miller

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