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

AMGEN INC. and AMGEN MANUFACTURING LIMITED LLC Plaintiffs, v. SHANGHAI HENLIUS BIOTECH, INC, SHANGHAI HENLIUS BIOLOGICS CO., LTD., ORGANON LLC, and ORGANON & CO. Defendants.	Civil Action No. **COMPLAINT & DEMAND FOR A JURY TRIAL** **Redacted Version**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Amgen Inc. and Amgen Manufacturing Limited LLC (together "Amgen" or "Plaintiffs"), by and through their undersigned attorneys, for their Complaint against Defendants Shanghai Henlius Biotech, Inc. ("Henlius Biotech"), Shanghai Henlius Biologics Co., Ltd. ("Henlius Biologics"), Organon LLC, and Organon & Co. (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the laws of the United States, Title 35 United States Code §§ 1, *et seq.*, including 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("the BPCIA"), Pub. L. No. 111-148, §§ 7001–03, 124 Stat. 119, 804–21 (2010), including 42 U.S.C. § 262(*l*), and the Declaratory Judgment Act of 1934, 28 U.S.C. §§ 2201–02.

2. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. 42 U.S.C. § 262(k). This abbreviated pathway allows a biosimilar applicant, such as [redacted], to rely on the prior licensure and approval status of the innovative biologic products that the biosimilar seeks to replicate.

3. This action arises out of Defendants' submission of abbreviated Biologic License Application ("BLA") No. [redacted] to the U.S. Food and Drug Administration ("FDA") on [redacted], pursuant to 42 U.S.C. § 262(k), seeking approval to manufacture and sell biosimilar versions of Amgen's Prolia® and XGEVA® drug products. This action further arises from Defendants' imminent and actual import, and imminent commercial manufacture, offer for sale, and sale of that proposed biosimilar product.

4. Prolia is prescribed to treat patients with a high risk of bone fracture in certain settings, such as patients suffering from osteoporosis. XGEVA is prescribed to prevent skeletal-related events (*e.g.*, fractures or spinal cord compression) in cancer patients whose cancer has spread to the bone, as well as to treat certain types of tumors. The active ingredient in these two drugs is an antibody called denosumab. Amgen's scientists and clinicians have spent decades elucidating the biology of bone remodeling, creating the denosumab antibody, and developing Prolia and XGEVA. Amgen's innovative work on Prolia and XGEVA has benefited a tremendous number of patients. To support its portfolio of complex biological products such as

Prolia and XGEVA, Amgen scientists have also made significant advancements in manufacturing processes that enhance product yield, consistency, and quality.

5. The asserted patents in this action cover the denosumab antibody and pharmaceutical compositions comprising denosumab (the active ingredient in Prolia and XGEVA), innovative methods of manufacturing therapeutic proteins, like denosumab, and denosumab products. The asserted patents (collectively, "the Patents-in-Suit") are as follows: U.S. Patent Nos. 7,364,736 (the "Boyle '736 Patent"); 7,888,101 (the "Crowell '101 Patent"); 7,928,205 (the "Dillon '205 Patent"); 8,053,236 (the "Morris '236 Patent"); 8,217,153 (the "Zhou '153 Patent"); 8,460,896 (the "Crowell '896 Patent"); 8,680,248 (the "Crowell '248 Patent"); 9,228,168 (the "Morris '168 Patent"); 9,359,435 (the "Wu '435 Patent"); 10,106,829 (the "Gupta '829 Patent"); 10,227,627 (the "Gupta '627 Patent"); 10,513,723 (the "Kang '723 Patent"); 10,583,397 (the "Gefroh '397 Patent"); 10,655,156 (the "Gupta '156 Patent"); 10,894,972 (the "Huang '972 Patent"); 11,077,404 (the "Gefroh '404 Patent"); 11,098,079 (the "Hoang '079 Patent"); 11,192,919 (the "Trejo '919 Patent"); 11,254,963 (the "Kang '963 Patent"); 11,319,568 (the "Wu '568 Patent"); 11,434,514 (the "Huang '514 Patent"); 11,459,595 (the "Wu '595 Patent"); 11,492,372 (the "Trejo '372 Patent")**;** 11,946,085 (the "Huang '085 Patent"); 11,952,605 (the "Wu '605 Patent"); 12,084,686 (the "Crowell '686 Patent").

6. On [redacted], Defendants informed Amgen that "[redacted]" Defendants' [redacted] letter stated that Defendants [redacted]

[redacted] On information and belief, Defendants submitted BLA No. [redacted] on [redacted].

7. On [redacted], Defendants informed Amgen that [redacted]

[redacted]

Defendants' BLA indicates Defendants are seeking approval to manufacture and sell biosimilar versions of Amgen's Prolia and XGEVA denosumab drug products, designated "HLX14."

8. Upon reviewing Defendants' document production from [redacted], Amgen determined that Defendants had not fully complied with the requirements set out in § 262(*l*)(2)(A) of the BPCIA, which requires disclosure of not only a copy of the BLA itself, but also "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A). Such information is critical for Amgen to achieve a fuller understanding of Defendants' manufacturing process, which is necessary for Amgen to participate in the pre-litigation exchange and negotiation contemplated by the BPCIA.

9. Since receiving the initial BLA production, Amgen has diligently evaluated the produced documents and repeatedly requested that Defendants correct or supplement their deficient production. On [redacted], and again on [redacted], Amgen informed Defendants of missing documents and information concerning the process used to manufacture HLX14. Although Defendants subsequently supplemented their production, the materials produced to Amgen remain deficient.

10. Amgen has participated in the pre-litigation exchange contemplated under the BPCIA to the best of its ability. Amgen's efforts, however, have been frustrated by Defendants'

initial and ongoing failure to comply with section 262(*l*)(2)(A) of the BPCIA, which states that a biosimilar applicant "shall provide" to the reference product sponsor both: "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." 42 U.S.C. § 262(*l*)(2)(A). Defendants have declined to fully resolve the deficiencies identified in Amgen's multiple letters.

11. Defendants' failure to produce the required information under section 262(*l*)(2)(A) has prejudiced and will continue to prejudice Amgen's efforts to conduct a complete patent infringement analysis under the BPCIA. After conducting an analysis to the best of its ability based on the limited information available, on [redacted], Amgen provided to Defendants a list of patents that could reasonably be asserted if the denosumab biosimilar product that is the subject of the BLA Henlius provided on [redacted] is made, used, offered for sale, or sold in, or imported into, the United States without a license from Amgen. All of the Patents-in-Suit were identified in Amgen's [redacted] letter and could have been identified in Amgen's list pursuant to 42. U.S.C. § 262(*l*)(2)(A) had Defendants complied with section 262(*l*)(2)(A). Despite producing this list of patents, Amgen informed Defendants that they had not complied with section 262(*l*)(2)(A), and that, accordingly, Amgen had no obligation to provide a patent list under section 262(*l*)(3)(A).

12. On [redacted], Defendants tendered to Amgen a purported "statement" in response to Amgen's list of patents. This statement did not provide additional information necessary for Amgen to verify Defendants' claims.

13. [redacted]

14. As alleged herein, Defendants' failure to comply with section 262(*l*)(2)(A) authorizes Amgen to file a suit for a declaration of infringement. 42 U.S.C. § 262(*l*)(9)(C); *see also Sandoz v. Amgen*, 137 S. Ct. 1664, 1667-68 (2017) ("§ 262(*l*)(9)(C) provides a remedy for an applicant's failure to turn over its application and manufacturing information" by authorizing the sponsor "to bring an immediate declaratory judgment action for artificial infringement.").

15. [redacted]

16. On information and belief—including based on the information available in Defendants' BLA and documents produced thus far—Defendants have infringed or will imminently infringe the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(C), as evidenced by Defendants' submitting a BLA seeking the FDA's approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, sale, or offer for sale of their denosumab biosimilar products before the expiration of the Patents-in-Suit.

17. As further alleged herein, on information and belief, Defendants have infringed or will imminently infringe one or more claims of the Patents-in-Suit under at least 35 U.S.C. § 271(a), (b), and/or (g) by making, using, offering for sale, or selling within the United States, or importing into the United States, one or more of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit.

THE PARTIES

A. Plaintiffs

18. Amgen Inc. is the sponsor of the reference products, Prolia and XGEVA, which the FDA has approved for a number of different therapeutic uses (termed "indications"). Amgen Inc. is the owner of all rights, title, and interest in each of the Patents-in-Suit. Amgen Manufacturing Limited LLC is the exclusive licensee of the Patents-in-Suit in the United States and its territories for commercialization of Prolia and XGEVA.

19. Amgen Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

20. Amgen Manufacturing Limited LLC ("AML") is a corporation existing under the laws of the Commonwealth of Puerto Rico, with its principal place of business at Road 31 km 24.6, Juncos, Puerto Rico 00777. AML is a wholly owned subsidiary of Amgen Inc.

21. Amgen is one of the world's leading biopharmaceutical companies and is dedicated to using discoveries in human biology to invent, develop, manufacture, and sell innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry for the benefit of patients suffering from serious illness. To that end, Amgen has invested billions of dollars into its research and development efforts. The two denosumab biological drug products that Defendants now seek to copy, Prolia and XGEVA, are the result of Amgen's innovations. Amgen brings this action to redress and halt the Defendants' actual and intended infringement of the Patents-in-Suit.

B. Defendants

22. Henlius Biotech is a corporation organized and existing under the laws of the People's Republic of China ("China"), with, on information and belief, its principal place of

business at Room 901, 9th Floor, Building 1, No. 367 Shengrong Road, China (Shanghai) Pilot Free Trade Zone, 201210.

23. Henlius Biologics is a corporation organized and existing under the laws of China, with, on information and belief, its principal place of business at No. 182 Wenjun Road, Sonjiang District, Shanghai, China 201616. On information and belief, Henlius Biologics is a wholly-owned subsidiary of Henlius Biotech.[1]

24. Organon & Co. is a corporation organized and existing under the laws of Delaware, with, on information and belief, its principal place of business at 30 Hudson Street, Floor 33, Jersey City, New Jersey 07302.

25. Organon LLC is a corporation organized and existing under the laws of Delaware, with, on information and belief, its principal place of business in Jersey City, New Jersey 07302. According to Organon & Co.'s 2024 10-K filing with the SEC, Organon LLC is a subsidiary of Organon & Co.[2]

26. [redacted] submitting BLA No. [redacted] (which references Amgen's BLA No. 125320 for Prolia and XGEVA) to the FDA for review.

27. [redacted] submitting BLA No. [redacted].

[redacted]

[1] Shanghai Henlius Biotech, Inc., *2023 Annual Report* at 105, https://www.henlius.com/upload/202404/17/2023AnnualReport.pdf (last accessed June 20, 2025).

[2] Organon & Co., *2024 Form 10-K* at Ex. 21.1 (Feb. 28, 2025), https://d18rn0p25nwr6d.cloudfront.net/CIK-0001821825/fa11c4b8-abe3-4eb5-82b5-f14386bffc03.pdf (last accessed June 20, 2025).

28. [redacted]

29. BPD meetings are "formal meetings between the Food and Drug Administration (FDA) and sponsors or applicants relating to the development and review of biosimilar or interchangeable biosimilar products."[3] A BPD Type 2a meeting is "focused on a narrow set of issues . . . requiring input from no more than three disciplines or review divisions"; a BPD Type 4 meeting is a "pre-submission meeting to discuss the format and content of a . . . supplement submitted under 351(k) of the PHS Act for a biosimilar or interchangeable biosimilar product."[4]

[3] FDA, *Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products: Draft Guidance* at 1 (Aug. 2023), https://www.fda.gov/media/113913/download; *see also* Center for Biologics Evaluation and Research, SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products at 1-2 (July 17, 2024), https://www.fda.gov/media/84040/download (last accessed June 20, 2025).

[4] FDA, *Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products: Draft Guidance* at 5-6 (Aug. 2023); *see also* Center for Biologics Evaluation and Research, SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological

30. On information and belief, Henlius Biotech, acting in concert with Henlius Biologics, Organon LLC and Organon & Co., is in the business of developing, manufacturing, and seeking regulatory approval for developing, manufacturing, importing, marketing, distributing, using, offering to sell, and/or selling biopharmaceutical products (including products intended to be sold as biosimilar versions of successful biopharmaceutical products developed by others) in New Jersey and throughout the United States, through its own actions and through the actions of its agents.

31. On information and belief, Henlius Biotech, in concert with Henlius Biologics, Organon LLC and Organon & Co., intends to develop, manufacture, import, market, distribute, offer for sale, and/or sell in New Jersey and across the United States biosimilar versions of Amgen's Prolia and XGEVA upon FDA approval and, in doing so, will improperly exploit Amgen's intellectual property surrounding these important medicines.

32. On information and belief, Organon & Co. entered into a global (excluding China) license agreement with Henlius, which secured for Organon & Co. U.S. commercialization rights related to the Henlius BLA for denosumab. Organon & Co.'s 2024 10-K filing with the SEC states: "We have worldwide commercialization rights to HXL14 in countries except for China (including Hong Kong, Macau and Taiwan)," and that "Henlius is responsible for development of this product and, if approved, will supply the products to us."[5]

33. On information and belief, Organon LLC, working in concert with Organon & Co., will serve as the distributor for Defendants' proposed biosimilar products in the United

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Products at 3 (July 17, 2024), https://www.fda.gov/media/84040/download (last accessed June 20, 2025).

[5] Organon & Co., *2024 Form 10-K* at 6, 9 (Feb. 28, 2025), https://d18rn0p25nwr6d.cloudfront.net/CIK-0001821825/fa11c4b8-abe3-4eb5-82b5-f14386bffc03.pdf (last accessed June 20, 2025).

States. On June 13, 2022, "Organon[], a global women's health company with deep expertise in biosimilar commercialization, . . . announced that it has entered into an agreement with Shanghai Henlius Biotech, Inc. (2696.HK), whereby Organon will license commercialization rights for biosimilar candidates referencing Perjeta® (pertuzumab, HLX11) and Prolia®/Xgeva® (denosumab, HLX14)."[6] Specifically, it was announced that "Organon will acquire exclusive global commercialization rights except for China; including Hong Kong, Macau and Taiwan." On October 30, 2024, "Shanghai Henlius Biotech, Inc. (2696.HK) and Organon (NYSE: OGN) announced that the US Food and Drug Administration (FDA) has accepted the Biologic License Application (BLA) for HLX14, an investigational biosimilar of PROLIA/XGEVA (denosumab)."[7] [redacted] The website for "Organon" lists 1-844-674-3200 as the contact information for

[6] Organon, *Organon Enters into Global License Agreement to Commercialize Henlius' Investigational Perjeta® (Pertuzumab) and Prolia®/Xgeva® (Denosumab) Biosimilar Candidates* (June 13, 2022), https://www.organon.com/news/organon-enters-into-global-license-agreement-to-commercialize-henlius-investigational-perjeta-pertuzumab-and-prolia-xgeva-denosumab-biosimilar-candidates/ (last accessed June 20, 2025).

[7] Henlius, *US FDA Accepts Biologics License Application (BLA) for HLX14, Biosimilar Candidate of PROLIA/XGEVA (denosumab)* (Oct. 30, 2024), https://www.henlius.com/en/NewsDetails-4739-26.html (last accessed June 20, 2025).

"reporting of an Adverse Event or Product Quality Complaint with a specific Organon product" with "the Organon Service Center."[8]

JURISDICTION AND VENUE

A. Subject-Matter Jurisdiction

34. This action arises under the patent laws of the United States, Title 35 of the United States Code, Title 42 of the United States Code, and under the Declaratory Judgment Act of 1934 (28 U.S.C. §§ 2201–02), Title 28 of the United States Code.

35. This Court has subject-matter jurisdiction over Amgen's claims under 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

B. Venue and Personal Jurisdiction

36. Venue as to Henlius Biotech is proper in this District pursuant to 28 U.S.C. § 1391(c)(3) because it is a foreign corporation and is therefore subject to suit in any judicial district.[9]

37. Venue as to Henlius Biologics is proper in this District pursuant to 28 U.S.C. § 1391(c)(3) because it is a foreign corporation and is therefore subject to suit in any judicial district.

38. Venue as to Organon LLC is proper in this District pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Organon LLC has systematic and continuous contacts with New Jersey; has a regular and established place of business in New Jersey; has its headquarters and principal place of business in Jersey City, NJ 07302; and, in particular, on information and belief, Organon LLC has committed an act of patent infringement under 35

[8] Organon, *Contact Us*, https://www.organon.com/contact-us/ (last accessed June 20, 2025).

[9] *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 713-14 (1972); *In re HTC Corp.*, 889 F.3d 1349, 1357-58 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 1271 (2019).

U.S.C. § 271(e)(2)(C) by preparing and submitting Defendants' BLA for a proposed denosumab biosimilar in and from New Jersey, and receiving correspondence with the FDA regarding Defendants' BLA at its office in New Jersey, and attending FDA pre-investigational meetings virtually from its office in New Jersey and/or preparing for such FDA pre-investigational meetings from its office in New Jersey.

39. Venue as to Organon & Co. is proper in this District pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Organon & Co. has systematic and continuous contacts with New Jersey; has a regular and established place of business in New Jersey; has its headquarters and principal place of business at 30 Hudson Street, Floor 33, Jersey City, NJ 07302; and, in particular, on information and belief, Organon & Co. has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(C) by preparing and submitting Defendants' BLA for a proposed denosumab biosimilar in and from New Jersey, and receiving correspondence with the FDA regarding Defendants' BLA at its office in New Jersey, and attending FDA pre-investigational meetings virtually from its office in New Jersey and/or preparing for such FDA pre-investigational meetings from its office in New Jersey.

40. On information and belief, Henlius Biotech develops, manufactures, seeks regulatory approval for, markets, distributes, and sells pharmaceutical products, for use throughout the United States, including in this District.

41. On information and belief, Henlius Biologics collaborated with Henlius Biotech, Organon LLC, and Organon & Co. to develop, manufacture, seek regulatory approval for, market, distribute, and sell pharmaceutical products, for use throughout the United States, including in this District.

42. On information and belief, Organon LLC collaborated with Henlius Biotech, Henlius Biologics, and Organon & Co. to develop, manufacture, seek regulatory approval for, market, distribute, and sell pharmaceutical products, for use throughout the United States, including in this District.

43. On information and belief, Organon & Co. collaborated with Henlius Biotech, Henlius Biologics, and Organon LLC to develop, manufacture, seek regulatory approval for, market, distribute, and sell pharmaceutical products, for use throughout the United States, including in this District.

44. On information and belief, Henlius Biologics, Organon LLC, and Organon & Co. collaborated with Henlius Biotech to take substantial steps to prepare for and undertake the filing of a BLA for their proposed denosumab biosimilar products. On information and belief, such steps included preparing and submitting the BLA and sending and receiving correspondence with the FDA regarding Defendants' BLA.

45. Venue is proper and this Court also has personal jurisdiction over each of the Defendants for the reasons set forth below.

C. Henlius Biotech

46. This Court has personal jurisdiction over Henlius Biotech because, among other reasons, Henlius Biotech, itself and through its collaboration with Organon LLC and Organon & Co., has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court.

47. On information and belief, Henlius Biotech develops, manufactures, and imports generic and biosimilar drugs throughout the United States, including in the State of New Jersey.

48. This Court has personal jurisdiction over Henlius Biotech by virtue of the fact that it took the significant step to prepare and file Defendants' BLA seeking approval from the FDA

to engage in the importation, use, offer of sale, or sale of the Defendants' biosimilar products in New Jersey and throughout the United States, which directly gives rise to Amgen's claims of patent infringement.

49. On information and belief, Henlius Biotech intends to participate in the commercial manufacturing and supply of Defendants' proposed denosumab biosimilar products, for sale in New Jersey and in the United States, upon FDA approval. On information and belief, Organon LLC and Organon & Co. are responsible for importing and conducting sales, marketing, and distribution activities for biosimilars manufactured by and for Henlius Biotech. On information and belief, Henlius Biotech will accordingly benefit commercially and be financially compensated for its active involvement in the use or sale of Defendants' proposed denosumab biosimilar products in New Jersey and in the United States.

50. On information and belief, the exercise of personal jurisdiction over Henlius Biotech in this federal judicial district would not unfairly burden Henlius Biotech.

51. Additionally, and in the alternative, this Court has personal jurisdiction over Henlius Biotech under Federal Rule of Civil Procedure 4(k)(2) because Amgen's claims arise under federal law; Henlius Biotech is a foreign defendant that is not subject to general personal jurisdiction in any state; and, on information and belief, Henlius Biotech has sufficient contacts with the United States as a whole, including but not limited to, filing BLAs with the FDA and manufacturing and selling generic or biosimilar pharmaceutical products through its U.S. affiliates and agents for distribution throughout the United States, such that this Court's exercise of jurisdiction over Henlius Biotech satisfies due process.

D. Henlius Biologics

52. Henlius Biologics is subject to personal jurisdiction in New Jersey because, among other reasons, through its parent Henlius Biotech and its collaboration with Organon LLC

and Organon & Co., Henlius Biologics has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court.

53. On information and belief, Henlius Biologics worked in concert with Henlius Biotech, Organon LLC, and Organon & Co. to take the significant step to prepare and file Defendants' BLA seeking approval from the FDA to engage in the importation, use, offer for sale, or sale of Defendants' proposed denosumab biosimilar products in New Jersey and throughout the United States. Henlius Biologics specifically helped develop HLX14 by manufacturing both HLX14 drug substance and HLX14 drug product.

54. On information and belief, Henlius Biologics intends to participate in the commercial manufacturing and supply of Defendants' proposed denosumab biosimilar products, for sale in New Jersey and in the United States, upon FDA approval. On information and belief, Organon LLC and Organon & Co. are responsible for importing and conducting sales, marketing, and distribution activities for biosimilars manufactured by Henlius Biologics. On information and belief, Henlius Biologics will accordingly benefit commercially and be financially compensated for its active involvement in the use or sale of Defendants' proposed denosumab biosimilar products in New Jersey and in the United States.

55. On information and belief, the exercise of personal jurisdiction over Henlius Biologics in this federal judicial district would not unfairly burden Henlius Biologics.

56. Additionally, and in the alternative, this Court has personal jurisdiction over Henlius Biologics under Federal Rule of Civil Procedure 4(k)(2) because Amgen's claims arise under federal law; Henlius Biologics is a foreign defendant that is not subject to general personal jurisdiction in any state; and, on information and belief, Henlius Biologics has sufficient contacts with the United States as a whole, including but not limited to, sponsoring the clinical trials for

potential biosimilar pharmaceutical products intended to be sold through its U.S. affiliates and agents that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Henlius Biologics satisfies due process.

E. Organon LLC

57. Organon LLC is subject to personal jurisdiction in New Jersey because it maintains its principal place of business in New Jersey. On information and belief, Organon LLC markets, distributes, offers for sale, and sells biopharmaceuticals for sale and use throughout the United States, including in New Jersey and this federal judicial district, and therefore transacts or intends to transact business within the State of New Jersey related to Amgen's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. Organon LLC has thus purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court, and this Court's exercise of jurisdiction over Organon LLC satisfies due process.

58. On information and belief, Organon LLC worked in concert with Henlius Biotech, Henlius Biologics, and Organon & Co. to take the significant step to prepare and file Defendants' BLA seeking approval from the FDA to engage in the importation, use, offer for sale, or sale of Defendants' proposed denosumab biosimilar products in New Jersey and throughout the United States.

59. On information and belief, if Defendants' BLA is approved, Organon LLC will import, market, distribute, offer for sale, and/or sell Defendants' proposed denosumab biosimilar products within the United States, including in New Jersey, consistent with Organon LLC's practices for the marketing and distribution of other biopharmaceutical products. On information and belief, Organon LLC regularly conducts business in New Jersey, and its practices with other biopharmaceutical products have involved placing those products into the stream of commerce

for distribution throughout the United States, including in New Jersey. On information and belief, Organon LLC's pharmaceutical products are used and consumed within and throughout the United States, including in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the Patents-in-Suit in the event that one or more of Defendants' proposed denosumab biosimilar products are approved before the Patents-in-Suit expire.

60. On information and belief, Organon LLC is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0600467987.

61. On information and belief, the exercise of personal jurisdiction over Organon LLC in this federal judicial district would not unfairly burden Organon LLC, which maintains its principal office in this judicial district.

F. Organon & Co.

62. Organon & Co. is subject to personal jurisdiction in New Jersey because it maintains its principal place of business in New Jersey. On information and belief, Organon & Co. markets, distributes, offers for sale, and sells biopharmaceuticals for sale and use throughout the United States, including in New Jersey and this federal judicial district, and therefore transacts or intends to transact business within the State of New Jersey related to Amgen's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. Organon & Co. has thus purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court, and this Court's exercise of jurisdiction over Organon & Co. satisfies due process.

63. On information and belief, Organon & Co. worked in concert with Henlius Biotech, Henlius Biologics, and Organon LLC to take the significant step to prepare and file

Defendants' BLA seeking approval from the FDA to engage in the importation, use, offer for sale, or sale of Defendants' proposed denosumab biosimilar products in New Jersey and throughout the United States.

64. On information and belief, if Defendants' BLA is approved, Organon & Co. will import, market, distribute, offer for sale, and/or sell Defendants' proposed denosumab biosimilar products within the United States, including in New Jersey, consistent with Organon & Co.'s practices for the marketing and distribution of other biopharmaceutical products. On information and belief, Organon & Co. regularly conducts business in New Jersey, and its practices with other biopharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. On information and belief, Organon & Co.'s pharmaceutical products are used and consumed within and throughout the United States, including in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the Patents-in-Suit in the event that one or more of Defendants' proposed denosumab biosimilar products are approved before the Patents-in-Suit expire.

65. On information and belief, Organon & Co. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0101057626.

66. On information and belief, the exercise of personal jurisdiction over Organon & Co. in this federal judicial district would not unfairly burden Organon & Co., which maintains its principal office in this judicial district.

THE PROLIA AND XGEVA DRUG PRODUCTS

A. Bone Metabolism and RANKL

67. Human bones undergo a lifelong cycle of growth and resorption (*i.e.*, destruction) that is essential to preserving bone integrity. This bone remodeling cycle involves a series of coordinated steps carefully regulated by complex signaling pathways in the body.

68. All tissues in the body express, or produce, proteins. Among those proteins is receptor activator of nuclear factor kappa-β (also known as "RANK"), which is found on the surface of cells called osteoclast precursors. RANK selectively binds to another protein—its binding partner or "ligand"—called RANK ligand ("RANKL").[10] When RANKL binds to RANK on the surface of osteoclast precursors, the interaction stimulates the precursor cell to transform into a mature osteoclast cell. Mature osteoclasts carry out bone resorption, *i.e.* the breakdown of bone. A different type of cell in the bone environment is called an "osteoblast." It performs the opposite function as the osteoclast—it forms new bone.

69. Normally, bone resorption is carried out in balance with bone formation. However, imbalances between bone formation and bone resorption can occur. Imbalances can result, for example, from menopause in women, glucocorticoid medications, androgen deprivation therapy for prostate cancer, adjuvant aromatase inhibitor therapy for breast cancer, hyperparathyroidism, rheumatoid arthritis, and certain forms of bone cancer. A common consequence of this imbalance is excess bone loss, putting patients at higher risk for bone fractures.

[10] RANK and RANKL are also sometimes referred to as osteoclast differentiation and activation receptor ("ODAR") and osteoprotegerin ligand ("OPGL") respectively.

B. Amgen's Invention of Prolia and XGEVA

70. Amgen developed Prolia and XGEVA after years of groundbreaking research into the bone remodeling pathway. This research dates back to the late 1990s, when studies by Amgen Inc. scientists identified the relationship between the protein RANKL (what they originally called "OPGL") and bone resorption. Amgen devoted significant resources to developing a treatment for diseases mediated by this mechanism, such as osteoporosis and disease states characterized by weakened bones, and invented novel pharmaceutical compositions that could be used in the treatment of such diseases.

71. An Amgen team led by named inventor Dr. William Boyle pursued several avenues to create a biologic treatment that would interfere with interactions between RANKL and RANK and thereby reduce the rate of bone resorption in a patient. Among these efforts was a collaboration with Abgenix, Inc. using the latter's XenoMouse™ transgenic mouse platform. In collaboration with co-inventors at Abgenix, Dr. Boyle and his team used the XenoMouse to create a fully human antibody with superior and surprising qualities. This antibody is known today as denosumab.

72. Denosumab, the active ingredient in Prolia and XGEVA, is a human IgG2 monoclonal antibody with affinity and specificity for human RANKL.

73. Denosumab binds to RANKL, preventing it from interacting with RANK. By preventing the RANKL/RANK interaction, denosumab can inhibit osteoclast activation and thus inhibit the breakdown of bone. By administering denosumab to a patient, bone breakdown can be decreased, thereby increasing bone mineral density and reducing the risk of bone fracture.

74. In 2001, Dr. Boyle and his co-inventors filed U.S. Provisional Patent Application No. 60/301,172 (the "'172 Application"). The Boyle '736 Patent claims priority to the '172 Application. The '172 Application (and the Boyle '736 Patent) discloses and describes

denosumab, including the specific heavy and light chain amino acid sequences of denosumab. The specification also discloses the particular heavy chain variable region sequence (SEQ ID NO: 13) and light chain variable region sequence (SEQ ID NO: 14) that form denosumab's antigen binding site and confer its unique binding properties for RANKL. The Boyle '736 Patent claims the denosumab antibody, as well as novel pharmaceutical compositions containing denosumab.

C. Amgen's Investment in Prolia and XGEVA

75. Today, denosumab is the active ingredient in two medicines that Amgen sells under two different brand names: Prolia and XGEVA. Prolia is indicated for the treatment of osteoporosis and other conditions associated with bone loss. XGEVA is indicated to treat bone cancers and to prevent fractures in cancer patients with bone metastases. On information and belief, the Defendants intend to market biosimilar versions of both products in the United States.

76. At the time Dr. Boyle and his team were researching biologic treatments for bone loss, osteoporosis treatments largely consisted of bisphosphonates—small molecule (*i.e.*, chemical) drugs that needed to be taken frequently, had significant side effects, and low patient adherence. Few believed that a biologic could achieve a safety and efficacy profile that would make it a successful therapeutic for treating chronic bone loss. Dr. Boyle and his team developed denosumab and its pharmaceutical composition despite this skepticism and made a surprising discovery: denosumab for osteoporosis (which eventually was named Prolia) needed only to be given to osteoporosis patients every 6 *months*, thereby substantially improving patient adherence over existing treatments like bisphosphonates—and clinical trials showed that it was well-tolerated over long-term administration.

77. Based on the results of extensive clinical testing, Amgen filed Biologic BLA No. 125320 in December 2008. In June 2010, the FDA first approved Prolia (active ingredient

denosumab, formulated in combination with sorbitol and acetate), pursuant to BLA No. 125320, for treating postmenopausal women with osteoporosis at high risk for fracture. Prolia was the first biologic ever approved to treat osteoporosis.

78. Amgen's subsequent investigations identified additional uses for denosumab, including using denosumab to treat cancer patients. In November 2010, the FDA approved—via a supplement to BLA No. 125320—XGEVA (active ingredient denosumab, formulated in combination with sorbitol and acetate) for the prevention of skeletal-related events in patients with bone metastases from solid tumors. The XGEVA product is administered more frequently, and in higher doses, to patients given the acute nature of the disease being treated (*i.e.*, cancer, such as bone cancer where patients may have an over-expression of RANKL).

79. Amgen's continued clinical testing revealed that denosumab was safe and effective to treat additional conditions beyond osteoporosis and skeletal-related events (*i.e.*, events that occur due to bone instability) in certain cancer patients. In September 2011, the FDA approved Prolia for the treatment of women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer and for the treatment of men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In September 2012, the FDA approved Prolia for treatment to increase bone mass in men with osteoporosis at high risk for fracture. In June 2013, the FDA approved XGEVA for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone. In December 2014, the FDA approved XGEVA for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. In May 2018, the FDA approved Prolia for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture.

D. Amgen's Further Innovations in Antibody Manufacturing

80. Amgen's further investments in research led to the development of novel manufacturing processes related to denosumab and the larger field of commercial manufacturing of antibody therapeutics for humans. Amgen's efforts in this field yielded advancements in several key areas of manufacturing, such as cell culture and purification methods, to improve and maintain product quality, consistency, safety, and effectiveness. Amgen obtained patent protection over many of these advancements, some of which are reflected in the Patents-in-Suit.

E. The Defendants' Knowledge of the Patents-in-Suit

81. As alleged herein, the Boyle '736 Patent issued on April 29, 2008. The Boyle '736 Patent was identified in Amgen's patent marking for Prolia and XGEVA before Defendants filed the BLA for their denosumab biosimilar product, and before Organon & Co. entered into a global license agreement with Henlius for Henlius's proposed denosumab biosimilar product. At least as early as May 24, 2023, at least one of the Patents-in-Suit, United States Patent No. 7,364,736, was identified on the FDA's publication entitled *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluation* ("the Purple Book").[11] Thus, the Defendants had constructive notice of and were aware of at minimum one of Amgen's patents before the filing of the BLA. *See* 35 U.S.C. § 287.

82. On information and belief, the Defendants, by the nature of being involved in the business of developing and distributing biosimilars, monitor the patent filings and patent ownership of reference product sponsors, including Amgen, and were thus aware of the Patents-in-Suit and their applicability to the Defendants' denosumab biosimilar products before the filing

[11] US FDA, *Purple Book Database of Licensed Biological Products*, https://web.archive.org/web/20230524143320/https://purplebooksearch.fda.gov/patent-list (last accessed June 20, 2025).

of the BLA or entering into a global license agreement related to the denosumab biosimilar proposed therein.

83. Further, as alleged herein, Amgen sent a letter to Defendants identifying the Patents-in-Suit on [redacted]. Defendants were thus aware of the Patents-in-Suit at least as of [redacted].

DEFENDANTS' FAILURE TO COMPLY WITH THE BPCIA AND IMPORTATION OF INFRINGING MATERIAL

A. The BPCIA's Framework for Confidential Information Exchange

84. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. Subject to certain conditions, the abbreviated pathway (also known as "the section (k) pathway") permits a biosimilar applicant, here Defendants, to rely on the prior clinical tests, data, and results, and the prior licensure and approval status, of the innovative (or "reference") biological product, here, Prolia and XGEVA, to secure licensing of a biosimilar version of the reference biological product.

85. The BPCIA 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 "shall provide to the reference product sponsor [1] a copy of the application submitted to the Secretary under subsection (k), and [2] such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2) (numeration added).

86. The initial disclosure contemplated by section 262(*l*)(2) enables the reference product sponsor (here, Amgen) to prepare and provide "[n]ot later than 60 days after the receipt of the application and information under paragraph (2)," a "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted

by the reference product sponsor . . . .” 42 U.S.C. § 262(*l*)(3). This is known colloquially as a “3A List,” and helps facilitate an efficient resolution of patent claims by enabling the product sponsor to “identify relevant patents and to flesh out the legal arguments that they might raise in future litigation.” *Sandoz v. Amgen*, 582 U.S. 1, 4 (2017).

87. However, if a subsection (k) applicant (here, Defendants) fails to comply with the initial disclosure requirements of section 262(*l*)(2)(A) by failing “to provide the application and information required,” then the reference product sponsor (here, Amgen) is permitted to file an action for declaratory judgment of patent infringement, validity, or enforceability pursuant to 42 U.S.C. § 262(*l*)(9)(C).

88. In the event the subsection (k) applicant complies with section 262(*l*)(2)(A), and the reference product sponsor tenders a timely 3A List, the subsection (k) applicant is required to provide, within 60 days of receiving the 3A List:

> (I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent [included in Amgen’s list] is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or
>
> (II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires . . . .

42 U.S.C. § 262(*l*)(3)(B)(ii).

89. This “detailed statement” is colloquially referred to as a “3B Statement.” The next step in the BPCIA’s information exchange is for the reference product sponsor to provide, within 60 days, a “3C Statement” responding to the applicant’s 3B Statement. 42 U.S.C. § 262(*l*)(3)(C).

B. Defendants' Non-Compliance with the BPCIA's Disclosure Provisions

90. Defendants submitted the BLA to the FDA pursuant to 42 U.S.C. § 262(k) in order to obtain approval to commercially manufacture, offer to sell, sell, and/or import in or into the United States Defendants' proposed denosumab biosimilar products. Defendants' BLA references Amgen's Prolia and XGEVA products bearing BLA license No. 125320.

91. On information and belief, the FDA accepted for review Defendants' BLA No. [redacted] on or before October 30, 2024.[12]

92. On [redacted], Defendants informed Amgen that it was [redacted] Defendants' [redacted] production did not purport to include "such other information that describes the process or processes used to manufacture the biological product that is the subject of that application," as contemplated by the second prong of section 262(*l*)(2)(A).

93. Upon reviewing Defendants' initial production of BLA documents, Amgen determined Defendants had not fully complied with section 262(*l*)(2)(A). Since receiving Defendants' initial production, Amgen has diligently evaluated the material provided and requested Defendants supplement their deficient production with manufacturing information.

94. On [redacted], Amgen sent Defendants a deficiency letter identifying missing documents and information concerning the process used to manufacture HLX14, as well as several illegible documents. Amgen explained that these deficiencies have hindered Amgen's ability to conduct the patent analysis contemplated by the BPCIA. The missing information

[12] Henlius, *US FDA Accepts Biologics License Application (BLA) for HLX14, Biosimilar Candidate of PROLIA/XGEVA (denosumab)* (Oct. 30, 2024), https://www.henlius.com /en/NewsDetails-4739-26.html (last accessed June 20, 2025).

included, but was not limited to [redacted] described in Defendants' production at HENLIUS_000005736-37.

95. Defendants disclosed additional documents on [redacted], including what Defendants described as [redacted] Defendants produced additional documents on [redacted]. However, Defendants' production remained deficient with respect to manufacturing information.

96. Amgen sent a second deficiency letter on [redacted] Defendants produced additional documents on [redacted] and [redacted], but remained deficient with respect to manufacturing information.

97. After conducting an analysis to the best of its ability based on the limited information available, Amgen provided to Defendants on [redacted] a list of patents that could reasonably be asserted if the denosumab biosimilar product that is the subject of the BLA Henlius provided on [redacted] is made, used, offered for sale, or sold in, or

imported into, the United States without a license from Amgen. In this letter, Amgen maintained its position that Defendants had not complied with section 262(*l*)(2)(A). All of the Patents-in-Suit were identified in Amgen's [redacted] letter and could have been identified in Amgen's list pursuant to 42. U.S.C. § 262(*l*)(2)(A) had Defendants complied with § 262(*l*)(2)(A).

98. On [redacted], Defendants tendered to Amgen a purported "statement" in response to Amgen's [redacted] letter. Defendants produced only six additional documents in connection with the statement, but Defendants' provision of manufacturing information remained deficient. This unremedied deficiency failed to provide Amgen sufficient information to meaningfully evaluate Defendants' position on the patents included in Amgen's [redacted] letter.

99. Nevertheless, on [redacted], Amgen provided a response to address Defendants' non-infringement conclusions and to provide additional information to Defendants regarding the factual and legal basis of Amgen's opinion that each patent identified in Amgen's [redacted] letter has been or will be infringed by Defendants' proposed denosumab biosimilar products. Amgen maintained its position that Defendants had, by withholding information, necessarily limited Amgen's ability to fully assess patent infringement.

100. Amgen has participated in the pre-litigation exchange contemplated under the BPCIA to the best of its ability. Amgen's efforts, however, have been frustrated by Defendants' initial and ongoing failure to comply with subsection 262(*l*)(2)(A) of the BPCIA. Defendants' failure to produce the manufacturing information required by subsection 262(*l*)(2)(A) has and will continue to prejudice Amgen's efforts to conduct a complete patent infringement analysis.

101. Defendants' failure to comply with section 262(*l*)(2)(A) authorizes Amgen to file an action for declaratory judgment of patent infringement, validity, or enforceability. *See* 42 U.S.C. § 262(*l*)(9)(C).

102. On information and belief, Defendants' proposed denosumab biosimilar products are manufactured by methods that utilize Amgen inventions related to various manufacturing processes, and on information and belief, Defendants, alone or in concert with others acting on behalf of Defendants or their affiliates, will manufacture these proposed denosumab biosimilar products. The full extent of Defendants' utilization of Amgen's manufacturing processes cannot yet be ascertained because of Defendants' failure to provide complete information.

C. [redacted]

103. [redacted]

104. The FDA has stated publicly that the agency's goal is to act on the majority of subsection (k) applications within 10 months of an application's 60-day filing date.[13] This 10-

[13] *See* US FDA, *Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027*, https://www.fda.gov/media/152279/download?attachment (last accessed June 20, 2025) ("Review performance goals . . . Review and act on 90 percent of original 351(k) BLA submissions within 10 months of the 60 day filing date."); *see also* US FDA, *BsUFA III: Fiscal Years 2023-2027*, https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027 (last accessed June 20, 2025).

month date is sometimes called a "BsUFA III date," which is an abbreviation for Biosimilar User Fee Act III date. According to Organon & Co.'s 2024 10-K filing with the SEC, "[o]n October 30, 2024, the U.S. Food and Drug Administration accepted the biologic license application for HLX14."[14] [redacted]

105. [redacted]

D. Defendants' Importation of Infringing Material

106. On information and belief, Defendants, acting in concert with their affiliates, have imported into and/or will import into the United States Defendants' proposed denosumab biosimilar product(s). The full extent of Defendants' importation of denosumab products cannot yet be ascertained due to Defendants' failure to provide complete information.

107. According to the publicly available FDA Dashboard, Henlius Biotech has imported at least five shipments of infringing products from China into the United States.[16] On

[14] Organon & Co., *2024 Form 10-K* at 70 (Feb. 28, 2025), https://d18rn0p25nwr6d.cloudfront.net/CIK-0001821825/fa11c4b8-abe3-4eb5-82b5-f14386bffc03.pdf (last accessed June 20, 2025).

[15] *See* Henlius, *US FDA Accepts Biologics License Application (BLA) for HLX14, Biosimilar Candidate of PROLIA/XGEVA (denosumab)* (Oct. 30, 2024), https://www.henlius.com/en/NewsDetails-4739-26.html (announcing on October 30, 2024 that the "US Food and Drug Administration (FDA) has accepted the Biologic License Application (BLA) for HLX14") (last accessed June 20, 2025).

[16] *See, e.g.*, US FDA, *FDA Data Dashboard*, https://datadashboard.fda.gov/ora/cd/impentry-table.htm (using search with "Henlius" as the Manufacturer Legal Name, and selecting "Download Dataset") (last accessed June 20, 2025).

February 2, 2024, Henlius Biotech imported two shipments from China into the United States that were labeled "RECOMBINANT ANTI-RANKL FULLY HUMAN MONOCLONAL ANTIBODY IN.[17] On August 28, 2024, Henlius Biotech imported three shipments from China into the United States that also were labeled "RECOMBINANT ANTI-RANKL FULLY HUMAN MONOCLONAL ANTIBODY IN."[18]

108. On information and belief, Defendants have not conducted a clinical trial for their denosumab biosimilar in the United States.

109. Furthermore, on information and belief, Defendants, acting in concert with their affiliates, including [redacted], have imported into the United States, and made use of in the United States, [redacted]. According to Defendants' submissions to the FDA, a [redacted]

THE PATENTS-IN-SUIT

A. The Boyle '736 Patent

110. The United States Patent and Trademark Office ("USPTO") duly and legally issued the Boyle '736 Patent, titled "Antibodies to OPGL," on April 29, 2008. The Boyle '736

[17] *See, e.g.*, US FDA, *FDA Data Dashboard*, Entry No.: SCS-2627731-3, https://www.access.fda.gov/itacs/#/ (using search for Entry Number "SCS-2627731-3") (last accessed June 20, 2025).

[18] *See, e.g.*, US FDA, *FDA Data Dashboard*, Entry No. SCS-6062699-5, https://www.access.fda.gov/itacs/#/ (using search for Entry Number "SCS-6062699-5") (last accessed June 20, 2025).

Patent discloses and claims denosumab. The Boyle '736 Patent is and has been identified on the label for XGEVA and Prolia.[19]

111. The Boyle '736 Patent is assigned to Amgen Inc. AML has a license to the Boyle '736 Patent that is exclusive with respect to Prolia and XGEVA. The Boyle '736 Patent was identified in the letter Amgen Inc. sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar products.

B. The Crowell '248, '896, and '101 Patents

112. The USPTO duly and legally issued the Crowell '248 Patent, titled "Host Cells Comprising Alpha 1,2 Mannosidase and Culture Methods Thereof," on March 25, 2014. The Crowell '248 Patent as a general matter discloses and claims a glycoprotein product produced by a process of culturing an isolated host cell engineered to overexpress alpha 1,2 mannosidase native to the host cell, and a glycoprotein of interest.

113. The USPTO duly and legally issued the Crowell '896 Patent, titled "Host Cells and Culture Methods," on June 11, 2013. The Crowell '896 Patent as a general matter discloses and claims methods of producing glycoproteins of interest by culturing an isolated host cell engineered to overexpress alpha 1,2 mannosidase native to the host cell, and a glycoprotein of interest.

114. The USPTO duly and legally issued the Crowell '101 Patent, titled "Host Cells Comprising Alpha 1,2 Mannosidase and Culture Methods Thereof," on February 15, 2011. The

[19] *See* https://pat.amgen.com/pdf/pat.amgen.com_Prolia.pdf ('736 Patent listed in "Version 2023.03.03"); https://pat.amgen.com/pdf/pat.amgen.com_Xgeva.pdf (same) (last accessed June 20, 2025).

Crowell ’101 Patent as a general matter discloses and claims methods of producing glycoproteins of interest by culturing an isolated host cell engineered to overexpress alpha 1,2 mannosidase native to the host cell, and a glycoprotein of interest.

115. The Crowell ’248, Crowell ’896, and Crowell ’101 Patents are assigned to Amgen Inc. AML has a license to the Crowell ’248, Crowell ’896, and Crowell ’101 Patents that is exclusive with respect to Prolia and XGEVA. The Crowell ’248, Crowell ’896, and Crowell ’101 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] as patents for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

C. The Crowell ’686 Patent

116. The USPTO duly and legally issued the Crowell ’686 Patent, titled “Antibodies with Modulated Glycan Profiles,” on September 10, 2024. The Crowell ’686 Patent as a general matter discloses and claims methods for modulating glycan profiles of denosumab molecules.

117. The Crowell ’686 Patent is assigned to Amgen Inc. AML has a license to the Crowell ’686 Patent that is exclusive with respect to Prolia and XGEVA. The Crowell ’686 Patent was identified in the letter Amgen Inc. sent to Defendants on [redacted] as patents for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

D. The Dillon ’205 Patent

118. The USPTO duly and legally issued the Dillon ’205 Patent, titled “Methods for Refolding of Recombinant Antibodies,” on April 19, 2011. The Dillon ’205 Patent as a general

matter discloses and claims methods of producing IgG2 antibodies by using a reduction/oxidation coupling reagent and optionally a chaotropic agent.

119. The Dillon ’205 Patent is assigned to Amgen Inc. AML has a license to the Dillon ’205 Patent that is exclusive with respect to Prolia and XGEVA. The Dillon ’205 Patent was identified in the letter Amgen Inc. sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

E. <u>The Huang ’972, ’514, and ’085 Patents</u>

120. The USPTO duly and legally issued the Huang ’972 Patent, titled “Methods for Increasing Mannose Content of Recombinant Proteins” on January 19, 2021. The Huang ’972 Patent as a general matter discloses and claims methods of influencing the high mannose glycoform content of a recombinant protein during a mammalian cell culture by adding mannose sugars after establishing the cell culture, and manipulating the mannose to total hexose ratio in the cell culture and feed media.

121. The USPTO duly and legally issued the Huang ’514 Patent, titled “Methods for Increasing Mannose Content of Recombinant Proteins” on September 6, 2022. The Huang ’514 Patent as a general matter discloses and claims methods of influencing the high mannose glycoform content of denosumab during a mammalian cell culture by adding mannose sugars during a production phase and manipulating the mannose to total hexose ratio in the cell culture and feed media.

122. The USPTO duly and legally issued the Huang ’085 Patent, titled “Methods for Increasing Mannose Content of Recombinant Proteins,” on April 2, 2024. The Huang ’085 Patent as a general matter discloses and claims methods for controlling mannose-5 glycoform

content of denosumab molecules by adding mannose and glucose sugars and manipulating the mannose to total hexose ratio in the cell culture media.

123. The Huang ’972, Huang ’514, and Huang ’085 Patents are assigned to Amgen Inc. AML has a license to the Huang ’972, Huang ’514, and Huang ’085 Patents that is exclusive with respect to Prolia and XGEVA. The Huang ’972, Huang ’514, and Huang ’085 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] as patents for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

F. <u>The Gupta ’829, ’627, and ’156 Patents</u>

124. The USPTO duly and legally issued the Gupta ’829 Patent, titled “Overexpression of N-Glycosylation Pathway Regulators to Modulate Glycosylation of Recombinant Proteins,” on October 23, 2018. The Gupta ’829 Patent as a general matter discloses and claims methods of regulating the high mannose glycoform content of recombinant proteins during a mammalian cell culture process.

125. The USPTO duly and legally issued the Gupta ’627 Patent, titled “Overexpression of N-Glycosylation Pathway Regulators to Modulate Glycosylation of Recombinant Proteins,” on March 12, 2019. The Gupta ’627 Patent as a general matter discloses and claims methods of regulating the high mannose glycoform content of recombinant proteins during a mammalian cell culture process.

126. The USPTO duly and legally issued the Gupta ’156 Patent, titled “Overexpression of N-Glycosylation Pathway Regulators to Modulate Glycosylation of Recombinant Proteins,” on May 19, 2020. The Gupta ’156 Patent as a general matter discloses and claims methods of

regulating the high mannose glycoform content of recombinant proteins during a mammalian cell culture process.

127. The Gupta ’829, Gupta ’627, and Gupta ’156 Patents are assigned to Amgen Inc. AML has a license to the Gupta ’829, Gupta ’627, and Gupta ’156 Patents that is exclusive with respect to Prolia and XGEVA. The Gupta ’829, Gupta ’627, and Gupta ’156 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] a patents for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

G. The Kang ’723 and ’963 Patents

128. The USPTO duly and legally issued the Kang ’723 Patent, titled “Decreasing Ornithine Production to Decrease High Mannose Glycoform Content of Recombinant Proteins,” on December 24, 2019. The Kang ’723 Patent as a general matter discloses and claims methods of influencing the high mannose glycoform content of a recombinant protein.

129. The USPTO duly and legally issued the Kang ’963 Patent, titled “Increasing Ornithine Accumulation to Increase High Mannose Glycoform Content of Recombinant Proteins,” on February 22, 2022. The Kang ’963 Patent as a general matter discloses and claims methods of influencing the high mannose glycoform content of a recombinant protein.

130. The Kang ’723 and Kang ’963 Patents are assigned to Amgen Inc. AML has a license to the Kang ’723 and Kang ’963 Patents that is exclusive with respect to Prolia and XGEVA. The Kang ’723 and Kang ’963 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering

to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar products.

H. The Gefroh '397 and '404 Patent

131. The USPTO duly and legally issued the Gefroh '397 Patent, titled "Process Control Systems and Methods for Use with Filters and Filtration Processes," on March 10, 2020. The Gefroh '397 Patent as a general matter discloses and claims systems and methods used to control flow filtration in the production and/or purification of recombinant proteins.

132. The USPTO duly and legally issued the Gefroh '404 Patent, titled "Process control systems and methods for use with filters and filtration processes," on August 3, 2021. The Gefroh '404 Patent as a general matter discloses and claims systems and methods used to control flow filtration in the production and/or purification of recombinant proteins.

133. The Gefroh '397 and Gefroh '404 Patents are assigned to Amgen Inc. AML has a license to the Gefroh '397 and Gefroh '404 Patents that is exclusive with respect to Prolia and XGEVA. The Gefroh '397 and Gefroh '404 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] as patents for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar products.

I. The Hoang '079 Patent

134. The USPTO duly and legally issued the Hoang '079 Patent, titled "Charging Depth Filtration of Antigen-Binding Proteins," on August 24, 2021. The Hoang '079 Patent as a general matter discloses and claims methods of using a charged depth filter to purify an antigen-binding protein.

135. The Hoang ’079 Patent is assigned to Amgen Inc. AML has a license to the’079 Patent that is exclusive with respect to Prolia and XGEVA. The Hoang ’079 Patent was identified in the letter Amgen Inc. sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

J. The Trejo ’919 and ’372 Patents

136. The USPTO duly and legally issued the Trejo ’919 Patent, titled “Removal of Leaked Affinity Purification Ligand,” on December 7, 2021. The Trejo ’919 Patent as a general matter discloses and claims methods for purifying a recombinant protein from a sample containing the recombinant protein and a second protein that binds to the protein, using a tentacle anion exchange matrix chromatography medium.

137. The USPTO duly and legally issued the Trejo ’372 Patent, titled “Removal of Leaked Affinity Purification Ligand,” on November 8, 2022. The Trejo ’372 Patent as a general matter discloses and claims methods for purifying an antibody from a sample containing the antibody and a second protein that binds to the antibody, using a tentacle anion exchange matrix chromatography medium.

138. The Trejo ’919 and Trejo ’372 Patents are assigned to Amgen Inc. AML has a license to the Trejo ’919 and Trejo ’372 Patents that is exclusive with respect to Prolia and XGEVA. The Trejo ’919 and Trejo ’372 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] as patents for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

K. The Morris ’236 and ’168 Patents

139. The USPTO duly and legally issued the Morris ’236 Patent, titled “Feed Media,” on November 8, 2011. The Morris ’236 Patent as a general matter discloses and claims feed media and methods for stabilizing feed media, where the feed media contains certain concentrations of particular components.

140. The USPTO duly and legally issued the Morris ’168 Patent, titled “Feed media,” on January 5, 2016. The Morris ’168 Patent as a general matter discloses and claims methods for stabilizing feed media for culturing mammalian cells by adding pyruvate.

141. The Morris ’236 and Morris ’168 Patents are assigned to Amgen Inc. AML has a license to the Morris ’236 and Morris ’168 Patents that is exclusive with respect to Prolia and XGEVA. The Morris ’236 and Morris ’168 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] as patents for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

L. The Wu ’435 Patent

142. The USPTO duly and legally issued the Wu ’435 Patent, titled “Methods for Modulating Mannose Content of Recombinant Proteins,” on June 7, 2016. The Wu ’435 Patent as a general matter discloses and claims methods of modulating the high-mannose glycoform content of a recombinant protein during a mammalian cell culture.

143. The Wu ’435 Patent is assigned to Amgen Inc. AML has a license to the Wu ’435 Patent that is exclusive with respect to Prolia and XGEVA. The Wu ’435 Patent was identified in the letter Amgen Inc. sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged

in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar products.

M. The Wu '568, '595, and '605 Patents

144. The USPTO duly and legally issued the Wu '568 Patent, titled "Methods for Increasing Mannose Content of Recombinant Proteins," on May 3, 2022. The Wu '568 Patent as a general matter discloses and claims methods for modulating mannose 5 on recombinant proteins during a mammalian cell culture process.

145. The USPTO duly and legally issued the Wu '595 Patent, titled "Methods for Increasing Mannose Content of Recombinant Proteins," on October 4, 2022. The Wu '595 Patent as a general matter discloses and claims methods for modulating mannose 5 on an immunoglobulin molecule during a mammalian cell culture process.

146. The USPTO duly and legally issued the Wu '605 Patent, titled "Methods for Increasing Mannose Content of Recombinant Proteins," on April 9, 2024. The Wu '605 Patent as a general matter discloses and claims methods of modulating the amount of the mannose-5 glycoform of an IgG2 molecule in an IgG2 composition, as well as methods of producing IgG2 compositions, by a Chinese Hamster Ovary cell culture.

147. The Wu '568, Wu '595, and Wu '605 Patents are assigned to Amgen Inc. AML has a license to the Wu '568, Wu '595, and Wu '605 Patents that is exclusive with respect to Prolia and XGEVA. The Wu '568, Wu '595, and Wu '605 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] as patents for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar products.

N. The Zhou ’153 Patent

148. The USPTO duly and legally issued the Zhou ’153 Patent, titled “Methods and Systems for Isolating Target Molecules from Complex Solutions by Column-Chromatography Using Wash Solutions Containing Organic Solvents,” on July 12, 2012. The Zhou ’153 Patent as a general matter discloses and claims methods for purifying protein-A-selected target molecules from a complex solution by affinity column chromatography.

149. The Zhou ’153 Patent is assigned to Amgen Inc. AML has a license to the Zhou ’153 Patent that is exclusive with respect to Prolia and XGEVA. The Zhou ’153 Patent was identified in the letter Amgen Inc. sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

COUNT 1: INFRINGEMENT OF THE BOYLE ’736 PATENT

150. Paragraphs 1–149 are incorporated by reference as if fully set forth herein.

151. Based on information presently available to Amgen, Defendants have infringed the Boyle ’736 Patent under at least 35 U.S.C. §§ 271(a), (b), and (e).

152. On information and belief, based on information presently available to Amgen, the submission of Defendants’ BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants’ proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Boyle ’736 Patent, including at least claim 3.

153. On information and belief, Defendants' proposed denosumab biosimilar products infringe, either literally or under the doctrine of equivalents, one or more claims of the Boyle '736 Patent, including at least claim 3.

154. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Boyle '736 Patent, including at least claim 3. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Boyle '736 Patent, constitutes willful infringement.

155. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Boyle '736 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

COUNT 2: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE BOYLE '736 PATENT

156. Paragraphs 1–155 are incorporated by reference as if fully set forth herein.

157. Based on information presently available to Amgen, on information and belief, the Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Boyle '736 Patent, including at least claim 3, under at least 35 U.S.C. §§ 271(a) and (b). On information and belief, Defendants have imported into the United States, or, used,

offered for sale, or sold within the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Boyle '736 Patent.

158. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Boyle '736 Patent, infringes one or more claims of the Boyle '736 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

159. Amgen is entitled to a declaratory judgment that Defendants infringed one or more claims of the Boyle '736 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Boyle '736 Patent.

COUNT 3: INFRINGEMENT OF THE CROWELL '248 PATENT

160. Paragraphs 1–159 are incorporated by reference as if fully set forth herein.

161. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Crowell '248 Patent has been or will be infringed, the Defendants have infringed the Crowell '248 Patent under at least 35 U.S.C. §§ 271(a), (b), and (e).

162. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of

infringement, either literally or under the doctrine of equivalents, of one or more claims of the Crowell ’248 Patent, including at least claim 1.

163. On information and belief, Defendants’ proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Crowell ’248 Patent, including at least claim 1, and Defendants’ denosumab is the essential active ingredient of Defendants’ proposed denosumab biosimilar products.

164. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants’ past imports of denosumab from China into the United States, Defendants’ importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants’ proposed denosumab biosimilar products, or Defendants’ active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Crowell ’248 Patent, including at least claim 1. On information and belief, Defendants’ importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants’ proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Crowell ’248 Patent, constitutes willful infringement.

165. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Crowell ’248 Patent. Amgen has been injured by Defendants’ infringement and is entitled to damages.

166. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants’ proposed denosumab biosimilar products. Amgen does not

have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Crowell ’248 Patent.

COUNT 4: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL ’248 PATENT

167. Paragraphs 1–166 are incorporated by reference as if fully set forth herein.

168. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Crowell ’248 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Crowell ’248 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(a) and (b). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants’ proposed denosumab biosimilar products before expiration of the Crowell ’248 Patent, or will actively induce such activities.

169. On information and belief, based on information presently available to Amgen, Defendants’ proposed denosumab biosimilar products infringe, either literally or under the doctrine of equivalents, one or more claims of the Crowell ’248 Patent, including at least claim 1, and Defendants’ denosumab is the essential active ingredient of Defendants’ proposed denosumab biosimilar products.

170. An actual controversy has arisen and now exists between the parties concerning whether the Defendants’ making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Crowell ’248 Patent, will infringe one or more claims of the Crowell ’248 Patent. A judicial determination of infringement is necessary and appropriate to resolve this

controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

171. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Crowell '248 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Crowell '248 Patent.

172. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Crowell '248 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Crowell '248 Patent.

COUNT 5: INFRINGEMENT OF THE CROWELL '896 PATENT

173. Paragraphs 1–172 are incorporated by reference as if fully set forth herein.

174. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Crowell '896 Patent has been or will be infringed, the Defendants have infringed the Crowell '896 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

175. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of

infringement, either literally or under the doctrine of equivalents, of one or more claims of the Crowell ’896 Patent, including at least claim 1.

176. On information and belief, Defendants’ proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Crowell ’896 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants’ proposed denosumab biosimilar products.

177. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants’ past imports of denosumab from China into the United States, Defendants’ importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants’ proposed denosumab biosimilar products, or Defendants’ active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Crowell ’896 Patent, including at least claim 1. On information and belief, Defendants’ importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants’ proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Crowell ’896 Patent, constitutes willful infringement.

178. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Crowell ’896 Patent. Amgen has been injured by Defendants’ infringement and is entitled to damages.

179. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants’ proposed denosumab biosimilar products. Amgen does not

have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Crowell '896 Patent.

COUNT 6: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '896 PATENT

180. Paragraphs 1–179 are incorporated by reference as if fully set forth herein.

181. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Crowell '896 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Crowell '896 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Crowell '896 Patent, or will actively induce such activities.

182. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Crowell '896 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

183. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Crowell '896 Patent, will infringe one or more claims of the Crowell '896 Patent. A judicial determination of infringement is necessary and appropriate to resolve this

controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. See 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

184. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Crowell '896 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Crowell '896 Patent.

185. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Crowell '896 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Crowell '896 Patent.

COUNT 7: INFRINGEMENT OF THE CROWELL '101 PATENT

186. Paragraphs 1–185 are incorporated by reference as if fully set forth herein.

187. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Crowell '101 Patent has been or will be infringed, the Defendants have infringed the Crowell '101 Patent under at least 35 U.S.C. §§ 271(a), (b), (e), and (g).

188. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of

infringement, either literally or under the doctrine of equivalents, of one or more claims of the Crowell '101 Patent, including at least claim 15.

189. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Crowell '101 Patent, including at least claim 15, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

190. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' past importation [redacted] Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Crowell '101 Patent, including at least claim 15. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products or [redacted], or active inducement thereof, despite knowledge of the Crowell '101 Patent, constitutes willful infringement.

191. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Crowell '101 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

192. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Crowell '101 Patent.

COUNT 8: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '101 PATENT

193. Paragraphs 1–192 are incorporated by reference as if fully set forth herein.

194. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) provide missing information for Amgen to fully evaluate whether the Crowell '101 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Crowell '101 Patent, including at least claim 15, under at least 35 U.S.C. §§ 271(a), (b), and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Crowell '101 Patent, or will actively induce such activities.

195. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Crowell '101 Patent, including at least claim 15, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

196. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Crowell '101 Patent, will infringe one or more claims of the Crowell '101 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. See 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

197. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Crowell '101 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Crowell '101 Patent.

198. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Crowell '101 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Crowell '101 Patent.

COUNT 9: INFRINGEMENT OF THE CROWELL '686 PATENT

199. Paragraphs 1–198 are incorporated by reference as if fully set forth herein.

200. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Crowell '686 Patent has been or will be infringed, the Defendants have infringed the Crowell '686 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

201. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Crowell '686 Patent, including at least claim 1.

202. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Crowell '686 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

203. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Crowell '686 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Crowell '686 Patent, constitutes willful infringement.

204. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Crowell '686 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

205. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Crowell '686 Patent.

COUNT 10: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '686 PATENT

206. Paragraphs 1–205 are incorporated by reference as if fully set forth herein.

207. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Crowell '686 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Crowell '686 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Crowell '686 Patent, or will actively induce such activities.

208. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Crowell '686 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

209. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Crowell '686 Patent, will infringe one or more claims of the Crowell '686 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

210. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Crowell '686 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Crowell '686 Patent.

211. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Crowell '686 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Crowell '686 Patent.

COUNT 11: INFRINGEMENT OF THE DILLON '205 PATENT

212. Paragraphs 1–211 are incorporated by reference as if fully set forth herein.

213. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Dillon '205 Patent has been or will be infringed, the Defendants have infringed the Dillon '205 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

214. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Dillon '205 Patent, including at least claims 1 and 40.

215. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Dillon '205 Patent, including at least claims 1 and 40, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

216. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Dillon '205 Patent, including at least claims 1 and 40. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Dillon '205 Patent, constitutes willful infringement.

217. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Dillon '205 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

218. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Dillon '205 Patent.

COUNT 12: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE DILLON '205 PATENT

219. Paragraphs 1–218 are incorporated by reference as if fully set forth herein.

220. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Dillon '205 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Dillon '205 Patent, including at least claims 1 and 40, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Dillon '205 Patent, or will actively induce such activities.

221. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Dillon '205 Patent, including at least claims 1 and 40, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

222. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Dillon ’205 Patent, will infringe one or more claims of the Dillon ’205 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

223. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Dillon ’205 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Dillon ’205 Patent.

224. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Dillon ’205 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants’ denosumab biosimilar products before the expiration of the Dillon ’205 Patent.

COUNT 13: INFRINGEMENT OF THE HUANG ’972 PATENT

225. Paragraphs 1–224 are incorporated by reference as if fully set forth herein.

226. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Huang ’972 Patent has been or will be infringed, the Defendants have infringed the Huang ’972 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

227. On information and belief, based on information presently available to Amgen, the submission of Defendants’ BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Huang '972 Patent, including at least claim 3.

228. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Huang '972 Patent, including at least claim 3, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

229. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Huang '972 Patent, including at least claim 3. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Huang '972 Patent, constitutes willful infringement.

230. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Huang '972 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

231. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Huang '972 Patent.

COUNT 14: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '972 PATENT

232. Paragraphs 1–231 are incorporated by reference as if fully set forth herein.

233. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Huang '972 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Huang '972 Patent, including at least claim 3, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Huang '972 Patent, or will actively induce such activities.

234. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Huang '972 Patent, including at least claim 3, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

235. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Huang ’972 Patent, will infringe one or more claims of the Huang ’972 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

236. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Huang ’972 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Huang ’972 Patent.

237. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Huang ’972 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants’ denosumab biosimilar products before the expiration of the Huang ’972 Patent.

COUNT 15: INFRINGEMENT OF THE HUANG ’514 PATENT

238. Paragraphs 1–237 are incorporated by reference as if fully set forth herein.

239. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Huang ’514 Patent has been or will be infringed, the Defendants have infringed the Huang ’514 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

240. On information and belief, based on information presently available to Amgen, the submission of Defendants’ BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Huang '514 Patent, including at least claim 1.

241. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Huang '514 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

242. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Huang '514 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Huang '514 Patent, constitutes willful infringement.

243. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Huang '514 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

244. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Huang '514 Patent.

COUNT 16: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '514 PATENT

245. Paragraphs 1–244 are incorporated by reference as if fully set forth herein.

246. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Huang '514 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Huang '514 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Huang '514 Patent, or will actively induce such activities.

247. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Huang '514 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

248. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Huang '514 Patent, will infringe one or more claims of the Huang '514 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

249. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Huang '514 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Huang '514 Patent.

250. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Huang '514 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Huang '514 Patent.

COUNT 17: INFRINGEMENT OF THE HUANG '085 PATENT

251. Paragraphs 1–250 are incorporated by reference as if fully set forth herein.

252. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Huang '085 Patent has been or will be infringed, the Defendants have infringed the Huang '085 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

253. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Huang '085 Patent, including at least claim 1.

254. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Huang '085 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

255. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Huang '085 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Huang '085 Patent, constitutes willful infringement.

256. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Huang '085 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

257. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Huang '085 Patent.

COUNT 18: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '085 PATENT

258. Paragraphs 1–257 are incorporated by reference as if fully set forth herein.

259. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Huang '085 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Huang '085 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Huang '085 Patent, or will actively induce such activities.

260. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Huang '085 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

261. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Huang ’085 Patent, will infringe one or more claims of the Huang ’085 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

262. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Huang ’085 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Huang ’085 Patent.

263. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Huang ’085 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants’ denosumab biosimilar products before the expiration of the Huang ’085 Patent.

COUNT 19: INFRINGEMENT OF THE GUPTA ’829 PATENT

264. Paragraphs 1–263 are incorporated by reference as if fully set forth herein.

265. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Gupta ’829 Patent has been or will be infringed, the Defendants have infringed the Gupta ’829 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

266. On information and belief, based on information presently available to Amgen, the submission of Defendants’ BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Gupta '829 Patent, including at least claim 1.

267. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Gupta '829 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

268. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Gupta '829 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Gupta '829 Patent, constitutes willful infringement.

269. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Gupta '829 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

270. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Gupta '829 Patent.

COUNT 20: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '829 PATENT

271. Paragraphs 1–272 are incorporated by reference as if fully set forth herein.

272. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Gupta '829 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Gupta '829 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Gupta '829 Patent, or will actively induce such activities.

273. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Gupta '829 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

274. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Gupta '829 Patent, will infringe one or more claims of the Gupta '829 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

275. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Gupta '829 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Gupta '829 Patent.

276. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Gupta '829 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Gupta '829 Patent.

COUNT 21: INFRINGEMENT OF THE GUPTA '627 PATENT

277. Paragraphs 1–276 are incorporated by reference as if fully set forth herein.

278. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Gupta '627 Patent has been or will be infringed, the Defendants have infringed the Gupta '627 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

279. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Gupta '627 Patent, including at least claim 6.

280. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Gupta '627 Patent, including at least claim 6, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

281. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Gupta '627 Patent, including at least claim 6. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Gupta '627 Patent, constitutes willful infringement.

282. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Gupta '627 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

283. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Gupta '627 Patent.

COUNT 22: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '627 PATENT

284. Paragraphs 1–283 are incorporated by reference as if fully set forth herein.

285. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Gupta '627 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Gupta '627 Patent, including at least claim 6, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Gupta '627 Patent, or will actively induce such activities.

286. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Gupta '627 Patent, including at least claim 6, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

287. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Gupta '627 Patent, will infringe one or more claims of the Gupta '627 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

288. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Gupta '627 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Gupta '627 Patent.

289. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Gupta '627 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Gupta '627 Patent.

COUNT 23: INFRINGEMENT OF THE GUPTA '156 PATENT

290. Paragraphs 1–289 are incorporated by reference as if fully set forth herein.

291. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Gupta '156 Patent has been or will be infringed, the Defendants have infringed the Gupta '156 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

292. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Gupta '156 Patent, including at least claim 1.

293. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Gupta '156 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

294. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Gupta '156 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Gupta '156 Patent, constitutes willful infringement.

295. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Gupta '156 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

296. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Gupta '156 Patent.

COUNT 24: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '156 PATENT

297. Paragraphs 1–296 are incorporated by reference as if fully set forth herein.

298. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Gupta '156 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Gupta '156 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Gupta '156 Patent, or will actively induce such activities.

299. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Gupta '156 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

300. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Gupta '156 Patent, will infringe one or more claims of the Gupta '156 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

301. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Gupta '156 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Gupta '156 Patent.

302. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Gupta '156 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Gupta '156 Patent.

COUNT 25: INFRINGEMENT OF THE KANG '723 PATENT

303. Paragraphs 1–302 are incorporated by reference as if fully set forth herein.

304. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Kang '723 Patent has been or will be infringed, the Defendants have infringed the Kang '723 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

305. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Kang '723 Patent, including at least claim 1.

306. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Kang '723 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

307. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Kang '723 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Kang '723 Patent, constitutes willful infringement.

308. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Kang '723 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

309. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Kang '723 Patent.

COUNT 26: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '723 PATENT

310. Paragraphs 1–309 are incorporated by reference as if fully set forth herein.

311. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Kang '723 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Kang '723 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Kang '723 Patent, or will actively induce such activities.

312. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Kang '723 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

313. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Kang '723 Patent, will infringe one or more claims of the Kang '723 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

314. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Kang '723 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Kang '723 Patent.

315. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Kang '723 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Kang '723 Patent.

COUNT 27: INFRINGEMENT OF THE KANG '963 PATENT

316. Paragraphs 1–315 are incorporated by reference as if fully set forth herein.

317. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Kang '963 Patent has been or will be infringed, the Defendants have infringed the Kang '963 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

318. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Kang '963 Patent, including at least claim 1.

319. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Kang '963 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

320. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Kang '963 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Kang '963 Patent, constitutes willful infringement.

321. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Kang '963 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

322. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Kang '963 Patent.

COUNT 28: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '963 PATENT

323. Paragraphs 1–322 are incorporated by reference as if fully set forth herein.

324. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Kang '963 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Kang '963 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Kang '963 Patent, or will actively induce such activities.

325. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Kang '963 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

326. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Kang '963 Patent, will infringe one or more claims of the Kang '963 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

327. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Kang '963 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Kang '963 Patent.

328. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Kang '963 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Kang '963 Patent.

COUNT 29: INFRINGEMENT OF THE GEFROH '397 PATENT

329. Paragraphs 1–328 are incorporated by reference as if fully set forth herein.

330. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Gefroh '397 Patent has been or will be infringed, the Defendants have infringed the Gefroh '397 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

331. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Gefroh '397 Patent, including at least claim 13.

332. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Gefroh '397 Patent, including at least claim 13, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

333. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Gefroh '397 Patent, including at least claim 13. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Gefroh '397 Patent, constitutes willful infringement.

334. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Gefroh '397 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

335. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Gefroh '397 Patent.

COUNT 30: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GEFROH '397 PATENT

336. Paragraphs 1–335 are incorporated by reference as if fully set forth herein.

337. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Gefroh '397 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Gefroh '397 Patent, including at least claim 13, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Gefroh '397 Patent, or will actively induce such activities.

338. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Gefroh '397 Patent, including at least claim 13, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

339. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Gefroh '397 Patent, will infringe one or more claims of the Gefroh '397 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

340. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Gefroh '397 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Gefroh '397 Patent.

341. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Gefroh '397 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Gefroh '397 Patent.

COUNT 31: INFRINGEMENT OF THE GEFROH '404 PATENT

342. Paragraphs 1–341 are incorporated by reference as if fully set forth herein.

343. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Gefroh '404 Patent has been or will be infringed, the Defendants have infringed the Gefroh '404 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

344. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Gefroh '404 Patent, including at least claim 14.

345. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Gefroh '404 Patent, including at least claim 14, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

346. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Gefroh '404 Patent, including at least claim 14. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Gefroh '404 Patent, constitutes willful infringement.

347. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Gefroh '404 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

348. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Gefroh '404 Patent.

COUNT 32: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GEFROH '404 PATENT

349. Paragraphs 1–348 are incorporated by reference as if fully set forth herein.

350. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Gefroh '404 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Gefroh '404 Patent, including at least claim 14, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Gefroh '404 Patent, or will actively induce such activities.

351. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Gefroh '404 Patent, including at least claim 14, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

352. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Gefroh '404 Patent, will infringe one or more claims of the Gefroh '404 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

353. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Gefroh '404 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Gefroh '404 Patent.

354. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Gefroh '404 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Gefroh '404 Patent.

COUNT 33: INFRINGEMENT OF THE HOANG '079 PATENT

355. Paragraphs 1–354 are incorporated by reference as if fully set forth herein.

356. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Hoang '079 Patent has been or will be infringed, the Defendants have infringed the Hoang '079 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

357. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Hoang '079 Patent, including at least claim 1.

358. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Hoang '079 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

359. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Hoang '079 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Hoang '079 Patent, constitutes willful infringement.

360. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Hoang '079 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

361. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Hoang '079 Patent.

COUNT 34: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HOANG '079 PATENT

362. Paragraphs 1–361 are incorporated by reference as if fully set forth herein.

363. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Hoang '079 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Hoang '079 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Hoang '079 Patent, or will actively induce such activities.

364. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Hoang '079 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

365. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Hoang ’079 Patent, will infringe one or more claims of the Hoang ’079 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

366. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Hoang ’079 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Hoang ’079 Patent.

367. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Hoang ’079 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants’ denosumab biosimilar products before the expiration of the Hoang ’079 Patent.

COUNT 35: INFRINGEMENT OF THE MORRIS ’236 PATENT

368. Paragraphs 1–368 are incorporated by reference as if fully set forth herein.

369. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Morris ’236 Patent has been or will be infringed, the Defendants have infringed the Morris ’236 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

370. On information and belief, based on information presently available to Amgen, the submission of Defendants’ BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Morris '236 Patent, including at least claim 35.

371. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Morris '236 Patent, including at least claim 35, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

372. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Morris '236 Patent, including at least claim 35. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Morris '236 Patent, constitutes willful infringement.

373. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Morris '236 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

374. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Morris '236 Patent.

COUNT 36: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE MORRIS '236 PATENT

375. Paragraphs 1–374 are incorporated by reference as if fully set forth herein.

376. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Morris '236 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Morris '236 Patent, including at least claim 35, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Morris '236 Patent, or will actively induce such activities.

377. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Morris '236 Patent, including at least claim 35, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

378. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Morris ’236 Patent, will infringe one or more claims of the Morris ’236 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

379. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Morris ’236 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Morris ’236 Patent.

380. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Morris ’236 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants’ denosumab biosimilar products before the expiration of the Morris ’236 Patent.

COUNT 37: INFRINGEMENT OF THE MORRIS ’168 PATENT

381. Paragraphs 1–380 are incorporated by reference as if fully set forth herein.

382. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Morris ’168 Patent has been or will be infringed, the Defendants have infringed the Morris ’168 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

383. On information and belief, based on information presently available to Amgen, the submission of Defendants’ BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Morris '168 Patent, including at least claim 33.

384. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Morris '168 Patent, including at least claim 33, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

385. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Morris '168 Patent, including at least claim 33. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Morris '168 Patent, constitutes willful infringement.

386. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Morris '168 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

387. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Morris '168 Patent.

COUNT 38: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE MORRIS '168 PATENT

388. Paragraphs 1–387 are incorporated by reference as if fully set forth herein.

389. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Morris '168 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Morris '168 Patent, including at least claim 33, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Morris '168 Patent, or will actively induce such activities.

390. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Morris '168 Patent, including at least claim 33, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

391. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Morris '168 Patent, will infringe one or more claims of the Morris '168 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

392. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Morris '168 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Morris '168 Patent.

393. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Morris '168 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Morris '168 Patent.

COUNT 39: INFRINGEMENT OF THE TREJO '919 PATENT

394. Paragraphs 1–393 are incorporated by reference as if fully set forth herein.

395. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Trejo '919 Patent has been or will be infringed, the Defendants have infringed the Trejo '919 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

396. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Trejo '919 Patent, including at least claim 1.

397. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Trejo '919 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

398. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Trejo '919 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Trejo '919 Patent, constitutes willful infringement.

399. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Trejo '919 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

400. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Trejo '919 Patent.

COUNT 40: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE TREJO '919 PATENT

401. Paragraphs 1–400 are incorporated by reference as if fully set forth herein.

402. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Trejo '919 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Trejo '919 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Trejo '919 Patent, or will actively induce such activities.

403. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Trejo '919 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

404. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Trejo '919 Patent, will infringe one or more claims of the Trejo '919 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

405. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Trejo '919 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Trejo '919 Patent.

406. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Trejo '919 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Trejo '919 Patent.

COUNT 41: INFRINGEMENT OF THE TREJO '372 PATENT

407. Paragraphs 1–406 are incorporated by reference as if fully set forth herein.

408. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Trejo '372 Patent has been or will be infringed, the Defendants have infringed the Trejo '372 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

409. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Trejo '372 Patent, including at least claim 1.

410. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Trejo '372 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

411. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Trejo '372 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Trejo '372 Patent, constitutes willful infringement.

412. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Trejo '372 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

413. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Trejo '372 Patent.

COUNT 42: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE TREJO '372 PATENT

414. Paragraphs 1–413 are incorporated by reference as if fully set forth herein.

415. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Trejo '372 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Trejo '372 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Trejo '372 Patent, or will actively induce such activities.

416. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Trejo '372 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

417. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Trejo '372 Patent, will infringe one or more claims of the Trejo '372 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

418. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Trejo '372 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Trejo '372 Patent.

419. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Trejo '372 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Trejo '372 Patent.

COUNT 43: INFRINGEMENT OF THE WU '435 PATENT

420. Paragraphs 1–419 are incorporated by reference as if fully set forth herein.

421. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Wu '435 Patent has been or will be infringed, the Defendants have infringed the Wu '435 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

422. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Wu '435 Patent, including at least claim 1.

423. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Wu '435 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

424. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Wu '435 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Wu '435 Patent, constitutes willful infringement.

425. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Wu '435 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

426. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Wu '435 Patent.

COUNT 44: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU '435 PATENT

427. Paragraphs 1–426 are incorporated by reference as if fully set forth herein.

428. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Wu '435 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Wu '435 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Wu '435 Patent, or will actively induce such activities.

429. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Wu '435 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

430. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Wu ’435 Patent, will infringe one or more claims of the Wu ’435 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

431. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Wu ’435 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Wu ’435 Patent.

432. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Wu ’435 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants’ denosumab biosimilar products before the expiration of the Wu ’435 Patent.

COUNT 45: INFRINGEMENT OF THE WU ’568 PATENT

433. Paragraphs 1–432 are incorporated by reference as if fully set forth herein.

434. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Wu ’568 Patent has been or will be infringed, the Defendants have infringed the Wu ’568 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

435. On information and belief, based on information presently available to Amgen, the submission of Defendants’ BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Wu '568 Patent, including at least claim 1.

436. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Wu '568 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

437. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Wu '568 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Wu '568 Patent, constitutes willful infringement.

438. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Wu '568 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

439. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Wu '568 Patent.

COUNT 46: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU '568 PATENT

440. Paragraphs 1–439 are incorporated by reference as if fully set forth herein.

441. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Wu '568 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Wu '568 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Wu '568 Patent, or will actively induce such activities.

442. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Wu '568 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

443. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Wu ’568 Patent, will infringe one or more claims of the Wu ’568 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

444. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Wu ’568 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Wu ’568 Patent.

445. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Wu ’568 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants’ denosumab biosimilar products before the expiration of the Wu ’568 Patent.

COUNT 47: INFRINGEMENT OF THE WU ’595 PATENT

446. Paragraphs 1–445 are incorporated by reference as if fully set forth herein.

447. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Wu ’595 Patent has been or will be infringed, the Defendants have infringed the Wu ’595 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

448. On information and belief, based on information presently available to Amgen, the submission of Defendants’ BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Wu '595 Patent, including at least claim 1.

449. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Wu '595 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

450. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Wu '595 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Wu '595 Patent, constitutes willful infringement.

451. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Wu '595 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

452. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Wu '595 Patent.

COUNT 48: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU '595 PATENT

453. Paragraphs 1–452 are incorporated by reference as if fully set forth herein.

454. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Wu '595 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Wu '595 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Wu '595 Patent, or will actively induce such activities.

455. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Wu '595 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

456. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Wu '595 Patent, will infringe one or more claims of the Wu '595 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

457. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Wu '595 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Wu '595 Patent.

458. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Wu '595 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Wu '595 Patent.

COUNT 49: INFRINGEMENT OF THE WU '605 PATENT

459. Paragraphs 1–458 are incorporated by reference as if fully set forth herein.

460. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Wu '605 Patent has been or will be infringed, the Defendants have infringed the Wu '605 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

461. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Wu '605 Patent, including at least claim 1.

462. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Wu '605 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

463. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Wu '605 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Wu '605 Patent, constitutes willful infringement.

464. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Wu '605 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

465. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Wu '605 Patent.

COUNT 50: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU '605 PATENT

466. Paragraphs 1–465 are incorporated by reference as if fully set forth herein.

467. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Wu '605 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Wu '605 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Wu '605 Patent, or will actively induce such activities.

468. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Wu '605 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

469. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Wu ’605 Patent, will infringe one or more claims of the Wu ’605 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

470. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Wu ’605 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Wu ’605 Patent.

471. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Wu ’605 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants’ denosumab biosimilar products before the expiration of the Wu ’605 Patent.

COUNT 51: INFRINGEMENT OF THE ZHOU ’153 PATENT

472. Paragraphs 1–471 are incorporated by reference as if fully set forth herein.

473. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Zhou ’153 Patent has been or will be infringed, the Defendants have infringed the Zhou ’153 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

474. On information and belief, based on information presently available to Amgen, the submission of Defendants’ BLA to obtain FDA approval to engage in the commercial

manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Zhou '153 Patent, including at least claim 1.

475. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Zhou '153 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

476. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from China into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the Zhou '153 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the Zhou '153 Patent, constitutes willful infringement.

477. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Zhou '153 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

478. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the Zhou '153 Patent.

COUNT 52: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ZHOU '153 PATENT

479. Paragraphs 1–478 are incorporated by reference as if fully set forth herein.

480. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the Zhou '153 Patent has been or will be infringed, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the Zhou '153 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the Zhou '153 Patent, or will actively induce such activities.

481. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the Zhou '153 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

482. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and

importing into the United States, their proposed denosumab biosimilar products, before the expiration of the Zhou '153 Patent, will infringe one or more claims of the Zhou '153 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

483. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Zhou '153 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, their denosumab biosimilar products before the expiration of the Zhou '153 Patent.

484. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the Zhou '153 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the Zhou '153 Patent.

PRAYER FOR RELIEF

WHEREFORE, Amgen with respect to the Patents-in-Suit respectfully requests that this Court enter judgment in their favor against Defendants and grant the following relief:

A. A judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(C);

B. Based on that judgment, a permanent injunction against the commercial manufacture, use, offer to sell, and sale within the United States, and importation into the United

States, of Defendants' denosumab biosimilar products before the expiration of each of the Patents-in-Suit that are found infringed;

C. A judgment that Defendants have infringed and/or will infringe one or more claims of each of the Patents-in-Suit by making, using, offering for sale, or selling within the United States, or importing into the United States, one or more of Defendants' denosumab biosimilar products during the term of the Patents-in-Suit;

D. Based on that judgment, a permanent injunction against future infringement by Defendants, as well as by its officers, employees, agents, representatives, affiliates, assignees, successors, and all persons acting on behalf of, at the direction of, or in active concert with Defendants, until each of the Patents-in-Suit that are found infringed has expired;

E. A judgment and order requiring Defendants to pay Amgen damages in an amount adequate to compensate Amgen for Defendants' infringement, but in no event less than a reasonable royalty under 35 U.S.C. § 284, including supplemental damages for any continuing post-verdict infringement up until entry of judgment and beyond, with accounting, as needed;

F. A declaration that this is an exceptional case and awarding attorneys' fees and costs pursuant to 35 U.S.C. § 285;

G. On all counts, such other relief in law and equity as this Court may deem just, necessary, or proper.

DEMAND FOR A JURY TRIAL

Amgen hereby demands a jury trial on all issues so triable.

Dated: June 25, 2025

/s/ Liza M. Walsh

Liza M. Walsh

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RULE 11.2 CERTIFICATION

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, nor are there any non-parties known to Plaintiffs 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: June 25, 2025

/s/ Liza M. Walsh

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

/s/ Liza M. Walsh

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