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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. AMNEAL PHARMACEUTICALS, INC., AMNEAL PHARMACEUTICALS LLC, GH GENHELIX S.A., UNIVERSAL FARMA S.L., MABXIENCE RESEARCH S.L., 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 Amneal Pharmaceuticals, Inc. ("Amneal Inc."), Amneal Pharmaceuticals LLC ("Amneal LLC"), GH Genhelix S.A. ("Genhelix"), Universal Farma S.L. ("Universal Farma"), and mAbxience Research S.L. ("mAbxience") (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 Amneal LLC, 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' submissions of abbreviated Biologic License Application ("BLA") Nos. [redacted] and [redacted] to the U.S. Food and Drug Administration ("FDA"), which were initially made on, respectively, [redacted] and [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 those proposed biosimilar products.

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"); 8,058,418 (the "Boyle '418 Patent"); 8,460,896 (the "Crowell '896 Patent"); 8,680,248 (the "Crowell '248 Patent"); 9,012,178 (the "Kang '178 Patent"); 9,228,168 (the "Morris '168 Patent"); 9,320,816 (the "Zhou '816 Patent"); 9,328,134 (the "Allen '134 Patent"); 9,359,435 (the "Wu '435 Patent"); 10,106,829 (the "Gupta '829 Patent"); 10,167,492 (the "Leiske '492 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"); 10,822,630 (the "Leiske '630 Patent"); 10,894,972 (the "Huang '972 Patent"); 11,077,404 (the "Gefroh '404 Patent"); 11,098,079 (the "Hoang '079 Patent"); 11,130,980 (the "Pande '980 Patent"); 11,254,963 (the "Kang '963 Patent"); 11,299,760 (the "Pande '760 Patent"); 11,319,568 (the "Wu '568 Patent"); 11,434,514 (the "Huang '514 Patent"); 11,459,595 (the "Wu '595 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 produced to Amgen the abbreviated BLA Nos. [redacted] and [redacted] Defendants' applications indicate that Defendants are seeking approval to

manufacture and sell biosimilar versions of Amgen's Prolia and XGEVA denosumab drug products, designated "MB09." [redacted]

7. Upon reviewing Defendants' document production from [redacted], Amgen determined that Defendants had not fully complied with the requirements set out in section 262(*l*)(2)(A) of the BPCIA, which requires disclosure of not only a copy of the BLA, 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). Both categories of information are 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.

8. Since receiving the initial production of BLAs, Amgen has diligently evaluated the produced documents and repeatedly requested that Defendants correct or supplement their deficient production. On [redacted] Amgen informed Defendants that it had [redacted]

9. Amgen again informed Defendants of missing documents and information concerning the process used to manufacture MB09 on [redacted], and again on [redacted] Although Defendants subsequently supplemented their production on [redacted] those material only revealed further deficiencies and omitted documents, which Amgen brought to Amneal's attention on [redacted] Document deficiencies remain.

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 products that are the subject of the two BLAs Defendants provided on [redacted] are 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*)(3)(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. 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.").

13. On information and belief—including based on the information available in Defendants' two BLAs 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 BLAs 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.

14. 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

15. 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.

16. 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.

17. 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.

18. 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

19. Amneal Inc. is a domestic corporation organized and existing under the laws of Delaware, with, on information and belief, its principal place of business at 400 Crossing Blvd., Bridgewater, New Jersey 08807.

20. Amneal Inc. is the ultimate parent of Amneal LLC and, on information and belief, actively participated with Amneal LLC [redacted] and plans to participate in the actual marketing and sale of Defendants' denosumab biosimilar drug products. For example, [redacted] Additionally, Amneal Inc. has indicated in public filings that it "will be responsible for commercialization" of denosumab biosimilar products.

21. Amneal LLC is a limited liability company organized and existing under the laws of Delaware, with, on information and belief, its principal place of business at 400 Crossing Blvd., Bridgewater, New Jersey 08807. Amneal LLC is a wholly owned subsidiary of Amneal Inc.

22. Amneal LLC is [redacted] (which references Amgen's BLA No. 125320 for Prolia and XGEVA) to the FDA for review. On information and belief, Amneal LLC is the commercializing entity for Defendants' denosumab biosimilar drug products.

23. Genhelix is a corporation organized and existing under the laws of Spain, with its principal place of business at Parque Tecnológico de León Edifício GENHELIX C/Julia Morros, s/n Armunia, 24009 León, Spain. Genhelix is [redacted]

24. Universal Farma is a limited liability company organized and existing under the laws of Spain, with its principal place of business at Calle el Tejido 2, Azuqueca de Henares, Guadalajara, 19200, Spain. Universal Farma is [redacted]

25. mAbxience is a limited liability company organized and existing under the laws of Spain, with its principal place of business at Manuel Pombo Angulo 28, 3rd floor, Madrid, Spain. mAbxience wholly owns Genhelix.[1]

26. On information and belief, based on [redacted]

27. In October 2023, mAbxience published a press release announcing an exclusive licensing agreement with Amneal Inc. (the parent of Amneal LLC), under which mAbxience will "conduct the full development of the two biosimilars candidates and manufacture them in its state-of-the-art, Good Manufacturing Practice (GMP)-approved facilities," while "Amneal will guide the products through regulatory approval and have exclusive commercialization rights in the United States."[2] Amneal Inc. has publicly held out, in its Form 10-k for the December 2023 fiscal year, that it entered into a licensing and supply agreement with mAbxience to be the exclusive U.S. partner for separate denosumab biosimilars referencing Prolia and XGEVA.[3] On

[1] Fierce Pharma, *MABXIENCE ACQUIRES 100% OF BIOPHARMACEUTICAL COMPANY GENHELIX* (June. 12, 2014), https://www.fiercebiotech.com/biotech/mabxience-acquires-100-of-biopharmaceutical-company-genhelix (last visited Nov. 5, 2025).

[2] mAbxience, *mAbxience and Amneal Strengthen Alliance with Two Denosumab Biosimilars in the U.S. for the Treatment of Oncology and Bone Diseases*, MABXIENCE (Oct. 12, 2023), https://mabxience.com/mabxience-and-amneal-strengthen-alliance-with-two-denosumab-biosimilars-in-the-u-s-for-the-treatment-of-oncology-and-bone-diseases/ (last visited Nov. 5, 2025).

[3] *Amneal Pharmaceuticals, Inc. Form 10-K* For The Fiscal Year Ended December 31, 2023, SEC, https://www.sec.gov/Archives/edgar/data/1723128/000172312824000014/amrx-20231231.htm#:~:text=This%20Annual%20Report%20on%20Form%2010%2DK%20and,(%E2%80%9CU.S.%E2%80%9D)%20Private%20Securities%20Litigation%20Reform%20Act%20of (last visited Nov. 5, 2025).

information and belief, mAbxience developed the denosumab biosimilars that are the subject of BLA Nos. [redacted] and [redacted]

28. [redacted]

29. On information and belief, Amneal LLC, acting in concert with Amneal Inc., Genhelix, Universal Farma, and mAbxience, 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.

30. On information and belief, Amneal LLC, in concert with Amneal Inc., Genhelix, Universal Farma, and mAbxience, intends to, upon FDA approval, 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 and, in doing so, will improperly exploit Amgen's intellectual property surrounding these important medicines.

[4] BPD, or Biosimilar Biological Product Development, 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." *See* 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 (last accessed Nov. 5, 2025).

JURISDICTION AND VENUE

A. Subject-Matter Jurisdiction

31. This action arises under the patent laws of the United States, Title 35 of the United States Code; the BPCIA, 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.

32. 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

33. Venue as to Amneal Inc. is proper in this District pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Amneal Inc. 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 Bridgewater, NJ 08807; and, in particular, on information and belief, Amneal Inc. has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(C) by actively participating with Amneal LLC in the preparation and submission of BLA Nos. [redacted] and [redacted] from its office in New Jersey.

34. Venue as to Amneal LLC is proper in this District pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Amneal 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 Bridgewater, NJ 08807; and, in particular, on information and belief, Amneal LLC has committed acts of patent infringement under 35 U.S.C. § 271(e)(2)(C) by preparing and submitting Defendants' BLAs for proposed denosumab biosimilars in and from New Jersey, receiving correspondence with the FDA regarding Defendants' BLAs at its office in New Jersey, 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.

35. Venue as to Genhelix 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.[5]

36. Venue as to Universal Farma 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.

37. Venue as to mAbxience 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. On information and belief, Amneal LLC, in concert with Amneal Inc., Genhelix, Universal Farma, and mAbxience, develops, manufactures, seeks regulatory approval for, markets, distributes, and sells pharmaceutical products, for use throughout the United States, including in this District.

39. On information and belief, Amneal Inc. collaborated with Amneal LLC, Genhelix, Universal Farma, and mAbxience to develop, manufacture, seek regulatory approval for, market, distribute, and sell pharmaceutical products, for use throughout the United States, including in this District.

40. On information and belief, Genhelix collaborated with Amneal LLC, Amneal Inc., Universal Farma, and mAbxience to develop, manufacture, seek regulatory approval for,

[5] *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).

market, distribute, and sell pharmaceutical products, for use throughout the United States, including in this District.

41. On information and belief, Universal Farma collaborated with Amneal LLC, Amneal Inc., Genhelix, and mAbxience 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, mAbxience collaborated with Amneal LLC, Amneal Inc., Universal Farma, and Genhelix 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, Amneal Inc., Genhelix, Universal Farma, and mAbxience collaborated with Amneal LLC to take substantial steps to prepare for and undertake the filing of BLAs for their proposed denosumab biosimilar products. On information and belief, such steps included preparing and submitting the BLAs and sending and receiving correspondence with the FDA regarding Defendants' BLAs.

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

C. Amneal Inc.

45. This Court has personal jurisdiction over Amneal Inc. because it maintains systematic and continuous business contacts within the State of New Jersey and has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court.

46. On information and belief, Amneal Inc., acting in concert with others, develops, manufactures, commercializes and imports generic and biosimilar drugs throughout the United States, including in the State of New Jersey.

47. This Court has personal jurisdiction over Amneal Inc. because, on information and belief, Amneal Inc. took significant steps from its principal place of business in New Jersey to prepare and submit Defendants' two BLAs 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. Amneal Inc. has thus purposely availed itself of the benefits and protections of New Jersey law such that it should reasonably anticipate being sued in this Court, and this Court's exercise of jurisdiction over Amneal Inc. satisfies due process.

48. Amneal Inc. is subject to personal jurisdiction in New Jersey because it maintains its principal place of business in New Jersey. On information and belief, Amneal Inc. 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. Amneal Inc. 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 Amneal Inc. satisfies due process.

49. On information and belief, the exercise of personal jurisdiction over Amneal Inc. in this federal judicial district would not unfairly burden Amneal Inc.

D. Amneal LLC

50. This Court has personal jurisdiction over Amneal LLC because, among other reasons, Amneal LLC, has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court.

51. On information and belief, Amneal LLC, in concert with others, develops, manufactures, commercializes and imports generic and biosimilar drugs throughout the United States, including in the State of New Jersey.

52. This Court has personal jurisdiction over Amneal LLC because it took the significant step in its principal place of business in New Jersey to prepare and file Defendants' BLAs 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.

53. On information and belief, Amneal LLC will commercialize Defendants' proposed denosumab biosimilar products, for sale in New Jersey and in the United States, upon FDA approval. On information and belief, Amneal LLC is responsible for conducting sales, marketing, and distribution activities for Defendants' proposed denosumab biosimilar drug products, and will 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.

54. On information and belief, the exercise of personal jurisdiction over Amneal LLC in this federal judicial district would not unfairly burden Amneal LLC.

55. Amneal LLC is subject to personal jurisdiction in New Jersey because it maintains its principal place of business in New Jersey. On information and belief, Amneal 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. Amneal 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 Amneal LLC satisfies due process.

E. Genhelix

56. Genhelix is subject to personal jurisdiction in New Jersey because, among other reasons, by collaborating with Amneal LLC and [redacted] for sale in New Jersey and in the United States, Genhelix has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court.

57. On information and belief, Genhelix 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, Genhelix is [redacted] and will 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.

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

59. Additionally, and in the alternative, this Court has personal jurisdiction over Genhelix under Federal Rule of Civil Procedure 4(k)(2) because Amgen's claims arise under federal law; Genhelix is a foreign defendant that is not subject to general personal jurisdiction in any state; and, on information and belief, Genhelix has sufficient contacts with the United States

as a whole, including but not limited to coordinating with Amneal LLC to file BLAs seeking FDA approval to proposed denosumab biosimilar products in the United States and acting in concert with others to manufacture and sell biosimilar drug products through U.S. affiliates and agents that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Genhelix satisfies due process.

F. Universal Farma

60. Universal Farma is subject to personal jurisdiction in New Jersey because, among other reasons, by collaborating with Amneal LLC and [redacted] for sale in New Jersey and in the United States, Universal Farma has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court.

61. On information and belief, Universal Farma 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, Universal Farma is [redacted] and will 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.

62. On information and belief, the exercise of personal jurisdiction over Universal Farma in this federal judicial district would not unfairly burden Universal Farma.

63. Additionally, and in the alternative, this Court has personal jurisdiction over Universal Farma under Federal Rule of Civil Procedure 4(k)(2) because Amgen's claims arise under federal law; Universal Farma is a foreign defendant that is not subject to general personal jurisdiction in any state; and, on information and belief, Universal Farma has sufficient contacts

with the United States as a whole, including but not limited to, coordinating with Amneal LLC to file BLAs seeking FDA approval to proposed denosumab biosimilar products in the United States and manufacturing Defendants' denosumab biosimilar drug products for sale in the United States, such that this Court's exercise of jurisdiction over Universal Farma satisfies due process.

G. mAbxience

64. mAbxience is subject to personal jurisdiction in New Jersey because, among other reasons, through its collaboration with Amneal Inc. and/or Amneal LLC and its agreement to develop denosumab biosimilar drug products for sale in New Jersey and in the United States, mAbxience has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court.

65. On information and belief, mAbxience 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, mAbxience is responsible for the development of the denosumab products and the manufacture and supply of the commercial products for Amneal Inc. and Amneal LLC, and will 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.

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

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

for sale in the United States, such that this Court's exercise of jurisdiction over mAbxience satisfies due process.

THE PROLIA AND XGEVA DRUG PRODUCTS

A. Bone Metabolism and RANKL

68. 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.

69. 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").[6] 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.

70. 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

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

consequence of this imbalance is excess bone loss, putting patients at higher risk for bone fractures.

B. Amgen's Invention of Prolia and XGEVA

71. 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.

72. 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.

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

74. 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.

75. 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

76. 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.

77. 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.

78. 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.

79. 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).

80. 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

81. 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

82. 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 BLAs for their denosumab biosimilar products. 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").[7] Thus, the Defendants had constructive notice of and were aware of at minimum one of Amgen's patents before the filing of the BLAs. *See* 35 U.S.C. § 287.

83. On information and belief, the Defendants, by nature of being involved in the business of developing and distributing biosimilars, monitor the patent filings and patent

[7] US FDA, *Purple Book Database of Licensed Biological Products*, https://web.archive.org/web/20230524143320/https://purplebooksearch.fda.gov/patent-list (last accessed Nov. 5, 2025).

ownership of reference product sponsors, including Amgen, and were thus aware of the Patents-in-Suit and their applicability to Defendants' denosumab biosimilar products before the filing of the BLAs.

84. 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

85. 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 biosimilar applicants (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.

86. 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).

87. 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 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)(A). 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).

88. However, if subsection (k) applicants (here, Defendants) fail 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).

89. 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).

90. 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

91. Defendants submitted two BLAs to the FDA pursuant to 42 U.S.C. § 262(k) in order to obtain approval to commercially manufacture, offer to sell, sell, and import in or into the United States Defendants' proposed denosumab biosimilar products. Defendants' BLA Nos. [redacted] and [redacted] reference Amgen's Prolia and XGEVA products.

92. On information and belief, the FDA accepted for review Defendants' BLA Nos. [redacted] and [redacted] on or before [redacted]

93. On [redacted] Defendants produced the abbreviated BLA application Nos. [redacted] and [redacted] as part of their initial production. 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 specified by section 262(*l*)(2)(A).

94. 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 and the missing information from the BLAs.

95. On [redacted] Amgen informed Defendants of missing documents and information concerning the process used to manufacture MB09. In that deficiency letter, Amgen catalogued several gaps in Defendants' production that hindered Amgen's ability to conduct the patent analysis contemplated by the BPCIA. [redacted]

[redacted]

96. Amgen sent a second deficiency letter on [redacted] again requesting [redacted]

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 products that are the subject of the two BLAs Defendants provided on [redacted] were 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 section 262(*l*)(3)(A) had Defendants complied with section 262(*l*)(2)(A).

98. On [redacted] Defendants provided a supplemental production. Upon diligently evaluating Defendants' [redacted] supplemental BLA production, Amgen determined that what was initially produced by Defendants on [redacted]—which Amgen relied upon to develop its patent list included in its [redacted] letter—did not include the operative BLAs accepted for review by the FDA. Instead, Defendants' initial production consisted of only their incomplete BLAs [redacted] one month before Amgen provided its list of patents on [redacted]

99. Amgen would later come to learn, on [redacted] that on [redacted], Defendants submitted [redacted] Despite Amgen's request months prior for prompt production of [redacted] Defendants failed to give Amgen prompt notice of the [redacted] of BLA Nos. [redacted] and [redacted] Instead, Defendants unreasonably withheld from Amgen [redacted] for over two months and waited one month after filing to produce their BLAs as submitted in [redacted] Defendants' delays in providing these highly relevant materials undermined the information exchange contemplated by the BPCIA and prejudiced Amgen.

100. On [redacted] Defendants responded to Amgen's [redacted] and [redacted] deficiency letters. Defendants' [redacted] letter asserted that [redacted]

101. On [redacted] Amgen responded to Defendants, [redacted]

[redacted] Instead, Amgen explained, [redacted] These deficiencies remain.

102. 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. Defendants' failure to produce the manufacturing information required by section 262(*l*)(2)(A) has and will continue to prejudice Amgen's efforts to conduct a complete patent infringement analysis.

103. 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).

104. 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. Defendants' Intent to Commercialize Before the Patents-in-Suit Expire

105. 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.[8] This 10-

[8] *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 Nov. 5, 2025) ("Review performance goals . . . Review and act on 90

month date is sometimes called a "BsUFA III date," which is an abbreviation for Biosimilar User Fee Act III date. On information and belief, the anticipated BsUFA III date for Defendants' BLAs referencing Amgen's Prolia and XGEVA is on or before [redacted] which is before the expiration of one or more of the Patents-In-Suit.

106. Therefore, on information and belief, Defendants intend to and will immediately and imminently engage in the use, offer for sale, and sale in the United States, and importation into the United States, of one or more of their proposed denosumab biosimilar products before the expiration of the Patents-In-Suit.

D. Defendants' Importation of Infringing Material

107. 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 products. The full extent of Defendants' importation of denosumab products cannot yet be ascertained due to Defendants' failure to provide complete information.

108. According to the publicly available FDA Dashboard, Defendants have imported at least five shipments containing denosumab into the United States between November 2021 and June 2025.[9]

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 Nov. 5, 2025).

[9] *See* FDA, FDA Imports Entry Data Search, https://datadashboard.fda.gov/ora/cd/impentry-table.htm (last accessed Nov. 5, 2025) (using search with "mAbxience" as the Manufacturer Legal Name and "denosumab" as the Product Code Description; and using search with "Genhelix" as the Manufacturer Legal Name and "denosumab" as the Product Code Description)

THE PATENTS-IN-SUIT

A. The Boyle '736 Patent and '418 Patents

109. 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 Patent discloses and claims denosumab. The Boyle '736 Patent is and has been identified on the label for XGEVA and Prolia.[10]

110. The USPTO duly and legally issued the Boyle '418 Patent, titled "Polynucleotides Encoding Heavy and Light Chains of Antibodies to OPGL" on November 15, 2011. The Boyle '418 Patent as a general matter discloses compositions comprising polynucleotides encoding heavy and light chains of antibodies that interact with osteoproteogerin ligand and methods of making such antibodies.

111. The Boyle '736 and '418 Patents are assigned to Amgen Inc. AML has a license to the Boyle '736 and '418 Patents that is exclusive with respect to Prolia and XGEVA. The Boyle '736 and '418 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.

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

[10] *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 Nov. 5, 2025).

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 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. The Huang ’972, ’514, and ’085 Patents

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] 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.

G. The Kang '178 Patent

128. The USPTO duly and legally issued the Kang '178 Patent, titled "Dipeptides to Enhance Yield and Viability from Cell Cultures," on April 21, 2015. The Kang '178 Patent as a general matter discloses and claims particular dipeptides that can improve recombinant protein production and cell viability in cell cultures.

129. The Kang '178 Patent is assigned to Amgen Inc. AML has a license to the Kang '178 Patent that is exclusive with respect to Prolia and XGEVA. The Kang '178 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.

H. The Kang '723 and '963 Patents

130. 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.

131. 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.

132. 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.

I. The Gefroh '397 and '404 Patent

133. 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.

134. 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.

135. 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.

J. The Hoang '079 Patent

136. 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.

137. 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.

K. The Morris '236 and '168 Patents

138. 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.

139. 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.

140. 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

141. 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.

142. 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

143. 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.

144. 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.

145. 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.

146. 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 Allen '134 Patent

147. The USPTO duly and legally issued the Allen '134 Patent, titled "Carbohydrate Phosphonate Derivatives and Modulators of Glycosylation" on May 3, 2016. The Allen '134 Patent as a general matter discloses and claims compounds useful for modulating glycosylation.

148. The Allen '134 Patent is assigned to Amgen Inc. AML has a license to the Allen '134 Patent that is exclusive with respect to Prolia and XGEVA. The Allen '134 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.

O. The Leiske '492 and '630 Patents

149. The USPTO duly and legally issued the Leiske '492 Patent, titled "Process for Manipulating the Level of Glycan Content of a Glycoprotein" on January 1, 2019. The Leiske '492 Patent as a general matter discloses and claims a method for manipulating the fucosylated glycan content on a recombinant protein.

150. The USPTO duly and legally issued the Leiske '630 Patent, titled "Process for Manipulating the Level of Glycan Content of a Glycoprotein" on November 3, 2020. The Leiske '630 Patent as a general matter discloses and claims a method for manipulating the fucosylated glycan content on a recombinant protein.

151. The Leiske '492 and '630 Patents are assigned to Amgen Inc. AML has a license to the Leiske '492 and '630 Patents that is exclusive with respect to Prolia and XGEVA. The Leiske '492 and '630 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.

P. The Pande '980 and '760 Patents

152. The USPTO duly and legally issued the Pande '980 Patent, titled "Use of Monensin to Regulate Glycosylation of Recombinant Proteins" on September 28, 2021. The Pande '980 Patent as a general matter discloses and claims methods of modulating high mannose glycoform content of a protein in a cell culture by contacting the cells expressing the protein with monensin.

153. The USPTO duly and legally issued the Pande '760 Patent, titled "Use of Monensin to Regulate Glycosylation of Recombinant Proteins" on April 12, 2022. The Pande '760 Patent as a general matter discloses and claims methods of modulating the properties of a cell culture expressing a protein of interest with various embodiments relating to the addition of cell-cycle inhibitors to growing cell cultures.

154. The Pande '980 and '760 Patents are assigned to Amgen Inc. AML has a license to the Pande '980 and '760 Patents that is exclusive with respect to Prolia and XGEVA. The Pande '980 and '760 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.

Q. The Zhou '816 Patent

155. The USPTO duly and legally issued the '816 Patent, titled "Methods of Treating Cell Culture Media for Use in a Bioreactor," on April 26, 2016. The '816 Patent as a general matter discloses and claims methods of treating cell culture media for use in a bioreactor, such as to support mammalian cell growth, using ultraviolet C light and filtration.

156. The Zhou '816 Patent is assigned to Amgen Inc. AML has a license to the Zhou '816 Patent that is exclusive with respect to Prolia and XGEVA. The Zhou '816 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

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

158. 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).

159. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

160. 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.

161. 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 Spain 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.

162. 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

163. Paragraphs 1–162 are incorporated by reference as if fully set forth herein.

164. 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.

165. 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.

166. 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 BOYLE '418 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 Boyle '418 Patent has been or will be infringed, the Defendants have infringed the Boyle '418 Patent under at least 35 U.S.C. §§ 271(a), (b), and (g).

169. 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 Boyle '418 Patent, including at least claim 14.

170. 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 Spain 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 '418 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 Boyle '418 Patent, constitutes willful infringement.

171. 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 '418 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

COUNT 4: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE BOYLE '418 PATENT

172. Paragraphs 1–171 are incorporated by reference as if fully set forth herein.

173. 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 '418 Patent, including at least claim 14, under at least 35 U.S.C. §§ 271(a), (b), and (g).

174. 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 '418 Patent, infringed one or more claims of the Boyle '418 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.

175. Amgen is entitled to a declaratory judgment that Defendants infringed one or more claims of the Boyle '418 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 '418 Patent.

COUNT 5: INFRINGEMENT OF THE CROWELL '248 PATENT

176. Paragraphs 1–175 are incorporated by reference as if fully set forth herein.

177. 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), (g) and (e).

178. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

179. 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.

180. 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 Spain 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.

181. 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.

182. 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 6: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '248 PATENT

183. Paragraphs 1–182 are incorporated by reference as if fully set forth herein.

184. 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), (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 '248 Patent, or will actively induce such activities.

185. 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.

186. 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.

187. 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.

188. 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 7: INFRINGEMENT OF THE CROWELL '896 PATENT

189. Paragraphs 1–188 are incorporated by reference as if fully set forth herein.

190. 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).

191. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

192. 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.

193. 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 Spain 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.

194. 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.

195. 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 8: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '896 PATENT

196. Paragraphs 1–195 are incorporated by reference as if fully set forth herein.

197. 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.

198. 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.

199. 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.

200. 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.

201. 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 9: INFRINGEMENT OF THE CROWELL '101 PATENT

202. Paragraphs 1–201 are incorporated by reference as if fully set forth herein.

203. 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(b), (e), and (g).

204. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

205. 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.

206. 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 Spain 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 '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 active inducement thereof, despite knowledge of the Crowell '101 Patent, constitutes willful infringement.

207. 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.

208. 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 10: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '101 PATENT

209. Paragraphs 1–208 are incorporated by reference as if fully set forth herein.

210. 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 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 (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.

211. 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.

212. 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.

213. 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.

214. 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 11: INFRINGEMENT OF THE CROWELL '686 PATENT

215. Paragraphs 1–214 are incorporated by reference as if fully set forth herein.

216. 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).

217. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

218. 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.

219. 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 Spain 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.

220. 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.

221. 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 12: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '686 PATENT

222. Paragraphs 1–221 are incorporated by reference as if fully set forth herein.

223. 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.

224. 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.

225. 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.

226. 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.

227. 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 13: INFRINGEMENT OF THE DILLON '205 PATENT

228. Paragraphs 1–227 are incorporated by reference as if fully set forth herein.

229. 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).

230. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

231. 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.

232. 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 Spain 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.

233. 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.

234. 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 14: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE DILLON '205 PATENT

235. Paragraphs 1–234 are incorporated by reference as if fully set forth herein.

236. 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.

237. 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.

238. 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.

239. 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.

240. 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 15: INFRINGEMENT OF THE HUANG '972 PATENT

241. Paragraphs 1–240 are incorporated by reference as if fully set forth herein.

242. 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).

243. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

244. 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.

245. 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 Spain 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.

246. 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.

247. 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 16: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '972 PATENT

248. Paragraphs 1–247 are incorporated by reference as if fully set forth herein.

249. 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.

250. 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.

251. 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.

252. 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.

253. 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 17: INFRINGEMENT OF THE HUANG '514 PATENT

254. Paragraphs 1–253 are incorporated by reference as if fully set forth herein.

255. 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).

256. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

257. 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.

258. 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 Spain 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.

259. 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.

260. 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 18: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '514 PATENT

261. Paragraphs 1–260 are incorporated by reference as if fully set forth herein.

262. 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.

263. 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.

264. 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.

265. 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.

266. 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 19: INFRINGEMENT OF THE HUANG '085 PATENT

267. Paragraphs 1–266 are incorporated by reference as if fully set forth herein.

268. 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).

269. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

270. 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.

271. 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 Spain 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.

272. 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.

273. 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 20: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '085 PATENT

274. Paragraphs 1–273 are incorporated by reference as if fully set forth herein.

275. 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.

276. 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.

277. 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.

278. 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.

279. 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 21: INFRINGEMENT OF THE GUPTA '829 PATENT

280. Paragraphs 1–279 are incorporated by reference as if fully set forth herein.

281. 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).

282. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

283. 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.

284. 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 Spain 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.

285. 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.

286. 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 22: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '829 PATENT

287. Paragraphs 1–286 are incorporated by reference as if fully set forth herein.

288. 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.

289. 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.

290. 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.

291. 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.

292. 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 23: INFRINGEMENT OF THE GUPTA '627 PATENT

293. Paragraphs 1–292 are incorporated by reference as if fully set forth herein.

294. 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).

295. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

296. 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.

297. 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 Spain 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.

298. 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.

299. 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 24: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '627 PATENT

300. Paragraphs 1–299 are incorporated by reference as if fully set forth herein.

301. 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.

302. 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.

303. 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.

304. 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.

305. 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 25: INFRINGEMENT OF THE GUPTA '156 PATENT

306. Paragraphs 1–305 are incorporated by reference as if fully set forth herein.

307. 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).

308. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

309. 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.

310. 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 Spain 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.

311. 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.

312. 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 26: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '156 PATENT

313. Paragraphs 1–312 are incorporated by reference as if fully set forth herein.

314. 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.

315. 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.

316. 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.

317. 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.

318. 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 27: INFRINGEMENT OF THE KANG '723 PATENT

319. Paragraphs 1–318 are incorporated by reference as if fully set forth herein.

320. 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).

321. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

322. 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.

323. 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 Spain 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.

324. 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.

325. 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 28: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '723 PATENT

326. Paragraphs 1–325 are incorporated by reference as if fully set forth herein.

327. 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.

328. 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.

329. 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.

330. 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.

331. 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 29: INFRINGEMENT OF THE KANG '963 PATENT

332. Paragraphs 1–331 are incorporated by reference as if fully set forth herein.

333. 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).

334. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

335. 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.

336. 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 Spain 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.

337. 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.

338. 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 30: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '963 PATENT

339. Paragraphs 1–338 are incorporated by reference as if fully set forth herein.

340. 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.

341. 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.

342. 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.

343. 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.

344. 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 31: INFRINGEMENT OF THE KANG '178 PATENT

345. Paragraphs 1–344 are incorporated by reference as if fully set forth herein.

346. 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 '178 Patent has been or will be infringed, the Defendants have infringed the Kang '178 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

347. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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 '178 Patent, including at least claim 1.

348. 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 '178 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

349. 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 Spain 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 '178 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 '178 Patent, constitutes willful infringement.

350. 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 '178 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

351. 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 '178 Patent.

COUNT 32: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '178 PATENT

352. Paragraphs 1–351 are incorporated by reference as if fully set forth herein.

353. 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 '178 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 '178 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 '178 Patent, or will actively induce such activities.

354. 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 '178 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

355. 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 '178 Patent, will infringe one or more claims of the Kang '178 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.

356. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Kang '178 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 '178 Patent.

357. 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 '178 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 '178 Patent.

COUNT 33: INFRINGEMENT OF THE GEFROH '397 PATENT

358. Paragraphs 1–357 are incorporated by reference as if fully set forth herein.

359. 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).

360. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

361. 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.

362. 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 Spain 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.

363. 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.

364. 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 34: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GEFROH '397 PATENT

365. Paragraphs 1–364 are incorporated by reference as if fully set forth herein.

366. 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.

367. 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.

368. 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.

369. 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.

370. 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 35: INFRINGEMENT OF THE GEFROH '404 PATENT

371. Paragraphs 1–370 are incorporated by reference as if fully set forth herein.

372. 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).

373. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

374. 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.

375. 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 Spain 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.

376. 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.

377. 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 36: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GEFROH '404 PATENT

378. Paragraphs 1–377 are incorporated by reference as if fully set forth herein.

379. 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.

380. 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.

381. 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.

382. 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.

383. 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 37: INFRINGEMENT OF THE HOANG '079 PATENT

384. Paragraphs 1–383 are incorporated by reference as if fully set forth herein.

385. 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).

386. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

387. 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.

388. 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 Spain 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.

389. 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.

390. 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 38: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HOANG '079 PATENT

391. Paragraphs 1–390 are incorporated by reference as if fully set forth herein.

392. 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.

393. 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.

394. 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.

395. 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.

396. 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 39: INFRINGEMENT OF THE MORRIS '236 PATENT

397. Paragraphs 1–396 are incorporated by reference as if fully set forth herein.

398. 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).

399. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

400. 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.

401. 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 Spain 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.

402. 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.

403. 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 40: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE MORRIS '236 PATENT

404. Paragraphs 1–403 are incorporated by reference as if fully set forth herein.

405. 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.

406. 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.

407. 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.

408. 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.

409. 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 41: INFRINGEMENT OF THE MORRIS '168 PATENT

410. Paragraphs 1–409 are incorporated by reference as if fully set forth herein.

411. 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).

412. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

413. 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.

414. 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 Spain 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.

415. 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.

416. 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 42: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE MORRIS '168 PATENT

417. Paragraphs 1–416 are incorporated by reference as if fully set forth herein.

418. 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.

419. 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.

420. 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.

421. 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.

422. 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 43: INFRINGEMENT OF THE WU '435 PATENT

423. Paragraphs 1–422 are incorporated by reference as if fully set forth herein.

424. 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).

425. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

426. 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.

427. 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 Spain 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.

428. 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.

429. 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

430. Paragraphs 1–429 are incorporated by reference as if fully set forth herein.

431. 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.

432. 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.

433. 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.

434. 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.

435. 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

436. Paragraphs 1–435 are incorporated by reference as if fully set forth herein.

437. 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).

438. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

439. 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.

440. 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 Spain 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.

441. 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.

442. 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

443. Paragraphs 1–442 are incorporated by reference as if fully set forth herein.

444. 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.

445. 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.

446. 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.

447. 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.

448. 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

449. Paragraphs 1–448 are incorporated by reference as if fully set forth herein.

450. 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).

451. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

452. 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.

453. 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 Spain 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.

454. 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.

455. 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

456. Paragraphs 1–455 are incorporated by reference as if fully set forth herein.

457. 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.

458. 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.

459. 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.

460. 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.

461. 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

462. Paragraphs 1–461 are incorporated by reference as if fully set forth herein.

463. 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).

464. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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.

465. 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.

466. 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 Spain 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.

467. 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.

468. 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

469. Paragraphs 1–468 are incorporated by reference as if fully set forth herein.

470. 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.

471. 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.

472. 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.

473. 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.

474. 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 ALLEN '134 PATENT

475. Paragraphs 1–474 are incorporated by reference as if fully set forth herein.

476. 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 Allen '134 Patent has been or will be infringed, the Defendants have infringed the Allen '134 Patent under at least 35 U.S.C. §§ 271 (b), (e), and (g).

477. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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 Allen '134 Patent, including at least claim 35.

478. 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 Allen '134 Patent, including at least claim 35, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

479. 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 Spain 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 Allen '134 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 Allen '134 Patent, constitutes willful infringement.

480. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Allen '134 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

481. 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 Allen '134 Patent.

COUNT 52: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ALLEN '134 PATENT

482. Paragraphs 1–481 are incorporated by reference as if fully set forth herein.

483. 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 Allen '134 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 Allen '134 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 Allen '134 Patent, or will actively induce such activities.

484. 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 Allen '134 Patent, including at least claim 35, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

485. 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 Allen '134 Patent, will infringe one or more claims of the Allen '134 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.

486. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Allen '134 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 Allen '134 Patent.

487. 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 Allen '134 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 Allen '134 Patent.

COUNT 53: INFRINGEMENT OF THE LEISKE '492 PATENT

488. Paragraphs 1–487 are incorporated by reference as if fully set forth herein.

489. 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 Leiske '492 Patent has been or will be infringed, the Defendants have infringed the Leiske '492 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

490. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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 Leiske '492 Patent, including at least claim 1.

491. 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 Leiske '492 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

492. 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 Spain 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 Leiske '492 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 Leiske '492 Patent, constitutes willful infringement.

493. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Leiske '492 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

494. 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 Leiske '492 Patent.

COUNT 54: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE LEISKE '492 PATENT

495. Paragraphs 1–494 are incorporated by reference as if fully set forth herein.

496. 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 Leiske '492 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 Leiske '492 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 Leiske '492 Patent, or will actively induce such activities.

497. 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 Leiske '492 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

498. 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 Leiske '492 Patent, will infringe one or more claims of the Leiske '492 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.

499. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Leiske '492 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 Leiske '492 Patent.

500. 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 Leiske '492 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 Leiske '492 Patent.

COUNT 55: INFRINGEMENT OF THE LEISKE '630 PATENT

501. Paragraphs 1–500 are incorporated by reference as if fully set forth herein.

502. 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 Leiske '630 Patent has been or will be infringed, the Defendants have infringed the Leiske '630 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

503. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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 Leiske '630 Patent, including at least claim 1.

504. 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 Leiske '630 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

505. 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 Spain 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 Leiske '630 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 Leiske '630 Patent, constitutes willful infringement.

506. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Leiske '630 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

507. 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 Leiske '630 Patent.

COUNT 56: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE LEISKE '630 PATENT

508. Paragraphs 1–507 are incorporated by reference as if fully set forth herein.

509. 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 Leiske '630 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 Leiske '630 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 Leiske '630 Patent, or will actively induce such activities.

510. 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 Leiske '630 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

511. 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 Leiske '630 Patent, will infringe one or more claims of the Leiske '630 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.

512. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Leiske '630 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 Leiske '630 Patent.

513. 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 Leiske '630 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 Leiske '630 Patent.

COUNT 57: INFRINGEMENT OF THE PANDE '980 PATENT

514. Paragraphs 1–513 are incorporated by reference as if fully set forth herein.

515. 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 Pande '980 Patent has been or will be infringed, the Defendants have infringed the Pande '980 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

516. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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 Pande '980 Patent, including at least claim 1.

517. 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 Pande '980 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

518. 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 Spain 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 Pande '980 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 Pande '980 Patent, constitutes willful infringement.

519. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Pande '980 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

520. 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 Pande '980 Patent.

COUNT 58: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE PANDE '980 PATENT

521. Paragraphs 1–520 are incorporated by reference as if fully set forth herein.

522. 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 Pande '980 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 Pande '980 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 Pande '980 Patent, or will actively induce such activities.

523. 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 Pande '980 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

524. 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 Pande '980 Patent, will infringe one or more claims of the Pande '980 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.

525. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Pande '980 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 Pande '980 Patent.

526. 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 Pande '980 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 Pande '980 Patent.

COUNT 59: INFRINGEMENT OF THE PANDE '760 PATENT

527. Paragraphs 1–526 are incorporated by reference as if fully set forth herein.

528. 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 Pande '760 Patent has been or will be infringed, the Defendants have infringed the Pande '760 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

529. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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 Pande '760 Patent, including at least claim 1.

530. 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 Pande '760 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

531. 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 Spain 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 Pande '760 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 Pande '760 Patent, constitutes willful infringement.

532. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the Pande '760 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

533. 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 Pande '760 Patent.

COUNT 60: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE PANDE '760 PATENT

534. Paragraphs 1–533 are incorporated by reference as if fully set forth herein.

535. 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 Pande '760 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 Pande '760 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 Pande '760 Patent, or will actively induce such activities.

536. 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 Pande '760 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

537. 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 Pande '760 Patent, will infringe one or more claims of the Pande '760 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.

538. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the Pande '760 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 Pande '760 Patent.

539. 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 Pande '760 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 Pande '760 Patent.

COUNT 61: INFRINGEMENT OF THE ZHOU '816 PATENT

540. Paragraphs 1–539 are incorporated by reference as if fully set forth herein.

541. 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 '816 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '816 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

542. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLAs 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 '816 Patent, including at least claim 1.

543. 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 '816 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

544. 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 Spain 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 '816 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 '816 Patent, constitutes willful infringement.

545. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the '816 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

546. 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 '816 Patent.

COUNT 62: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ZHOU '816 PATENT

547. Paragraphs 1–546 are incorporated by reference as if fully set forth herein.

548. 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 '816 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '816 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 '816 Patent or will actively induce such activities.

549. 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 '816 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendant's proposed denosumab biosimilar products.

550. 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 '816 Patent, will infringe one or more claims of the '816 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..

551. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more of the '816 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 '816 Patent.

552. 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 '816 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 '816 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: November 6, 2025

/s/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: November 6, 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.

Dated: November 6, 2025

/s/ Liza M. Walsh

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