IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

AMGEN INC., and AMGEN MANUFACTURING LIMITED LLC, Plaintiffs, vs. FRESENIUS KABI USA, LLC, FRESENIUS SWISSBIOSIM GmbH, FRESENIUS KABI DEUTSCHLAND GmbH, and FRESENIUS KABI AUSTRIA GmbH, Defendants.	Case No.: **JURY TRIAL DEMANDED** **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 Fresenius Kabi USA, LLC, Fresenius Kabi SwissBioSim GmbH, Fresenius Kabi Deutschland GmbH, and Fresenius Kabi Austria GmbH (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. 111-48, §§ 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 Fresenius Kabi USA, to rely on the prior licensure and approval status of the innovative biologic products that the proposed biosimilar seeks to replicate.

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

4. Prolia is prescribed to treat patients with a high risk of bone fracture in certain settings, such as patients suffering from osteoporosis. XGEVA is prescribed to prevent skeletal-related events (*e.g.*, fractures or spinal cord compression) in cancer patients whose cancer has spread to the bone, as well as to treat certain types of tumors. The active ingredient in both products 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 denosumab (the active ingredient in Prolia and XGEVA) and methods of manufacturing denosumab and denosumab products, and technologies necessary to produce, deliver, and use these denosumab-containing medicines in patients. The asserted patents (collectively, "the Patents-In-Suit") are as follows: United States Patent Nos. 7,364,736 ("the '736 Patent"); 7,888,101 ("the '101 Patent"); 7,928,205 ("the '205

Patent"); 8,053,236 ("the '236 Patent"); 8,058,418 ("the '418 Patent"); 8,460,896 ("the '896 Patent"); 8,680,248 ("the '248 Patent"); 9,012,178 ("the '178 Patent"); 9,228,168 ("the '168 Patent"); 9,320,816 ("the '816 Patent"); 9,328,134 ("the '134 Patent"); 9,359,435 ("the '435 Patent"); 10,106,829 ("the '829 Patent"); 10,167,492 ("the '492 Patent"); 10,227,627 ("the '627 Patent"); 10,513,723 ("the '723 Patent"); 10,583,397 ("the '397 Patent"); 10,655,156 ("the '156 Patent"); 10,822,630 ("the '630 Patent"); 10,894,972 ("the '972 Patent"); 11,077,404 ("the '404 Patent"); 11,098,079 ("the '079 Patent"); 11,130,980 ("the '980 Patent"); 11,254,963 ("the '963 Patent"); 11,299,760 ("the '760 Patent"); 11,319,568 ("the '568 Patent"); 11,434,514 ("the '514 Patent"); 11,459,595 ("the '595 Patent"); 11,744,950 ("the '950 Patent"); 11,786,866 ("the '866 Patent"); 11,946,085 ("the '085 Patent"); 11,952,605 ("the '605 Patent"); and 12,084,686 ("the '686 Patent").

6. On [redacted], Defendants informed Amgen Inc. that, on [redacted], the FDA had accepted for review Defendants' BLA for "FKS518" (Defendants' current designation for their denosumab biosimilar), submitted under 42 U.S.C. § 262(k) and referencing Amgen's Prolia and XGEVA products. On or around [redacted], Fresenius Kabi USA provided a secure file transfer link to a purported "copy of its BLA."

7. Contrary to Fresenius Kabi USA's representation, the purported BLA produced to Amgen contained numerous and substantial redactions (the "Incomplete BLA"). The redactions include, but are not limited to, redaction of manufacturer, supplier, and vendor identities, manufacturing locations, lot numbers, document titles, signatures on batch records, portions of testing printouts, and blanket redactions to entire portions of the BLA. On information and belief, the BLA Defendants submitted to the FDA did not contain the substantial redactions found in the

Incomplete BLA and would have been provided to the FDA in an organized, searchable, eCTD format with internal hyperlinks.

8. Since receiving the Incomplete BLA, Amgen Inc has diligently evaluated the unredacted portions and repeatedly requested Defendants correct and supplement their deficient production. Defendants refused to provide an unredacted copy of the BLA as submitted to the FDA and have also refused to provide other information describing the location of and processes used to manufacture the FKS518 biologic product.

9. Amgen has participated in the pre-litigation exchange contemplated under the BPCIA to the best of its ability. Amgen's efforts, however, have been frustrated by Defendants' initial and ongoing failure to comply with subsection (*l*)(2)(A) of the BPCIA, which states that a biosimilar 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)(A) (annotations added). Defendants failed to provide "a copy" of the BLA as it was "submitted to the Secretary" as required by the statute and have rebuffed Amgen's multiple letters identifying specific missing information and urging Defendants to produce the BLA without redactions and in the organized manner in which it was presumably submitted to the FDA.

10. Defendants' failure to produce the required information under § 262(*l*)(2)(A) has 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 Fresenius Kabi USA 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," as contemplated by § 262(*l*)(3)(A). Amgen supplemented its initial letter on [redacted] with a newly issued patent that could reasonably be asserted as the basis for patent infringement, as authorized by § 262(*l*)(7).

11. [redacted]

12. As alleged herein, Defendants' failure to comply with § 262(*l*)(2)(A) authorizes Amgen Inc. 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"). On information and belief—including based on the information available in the unredacted portions of the Defendants' BLA—Defendants have infringed or will imminently infringe the Patents-In-Suit under 35 U.S.C. § 271(e)(2)(C), as evidenced by Defendants' submitting a BLA seeking the FDA's approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, sale, or offer for sale of their denosumab biosimilar product(s) before the expiration of the Patents-In-Suit, including, *inter alia*, the '736 Patent and the '248 Patent.

13. Alternatively, Defendants' provision of a notice of commercial marketing under § 262(*l*)(8)(A) authorizes Amgen Inc. to bring an action for declaratory relief under § 262(*l*)(9)(A).

14. As further alleged herein, on information and belief, Defendants have infringed and 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 seeks to copy, Prolia and XGEVA, are the result of Amgen's innovations. Amgen brings this action to redress and halt Defendants' actual and intended infringement of the Patents-In-Suit.

B. Defendants

19. Fresenius Kabi USA, LLC is a corporation organized and existing under the laws of Delaware, with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. On information and belief, Fresenius Kabi USA is wholly owned by Fresenius Kabi Pharmaceuticals Holding, LLC; and Fresenius Kabi Pharmaceuticals Holding, LLC is wholly owned by Fresenius Kabi AG.[1]

20. Fresenius Kabi SwissBioSim GmbH is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Terre Bonne Business Park, Route de Crassier 23/Bâtiment A3, 1262 Eysins, Switzerland. On information and belief, Fresenius Kabi SwissBioSim is wholly owned by Fresenius Kabi Deutschland GmbH.[2]

21. Fresenius Kabi Deutschland GmbH is a corporation organized and existing under the laws of Germany, with its principal place of business at Else-Kröner-Straβe 1, 61352 Bad Homburg, Germany. On information and belief, Fresenius Kabi Deutschland is wholly owned by Fresenius Kabi AG.[3]

22. Fresenius Kabi Austria GmbH is a corporation organized and existing under the laws of Austria, with its principal place of business at Hafnerstraße 36 8055 Graz, Austria.

23. Defendants are related corporate entities that act as agents of one another and/or act in concert. On information and belief, Defendants hold themselves out as coordinated entities. For example, Fresenius Kabi AG maintains on its public website that it is "a global company with strong local roots," touting its "combination of organizational cohesiveness and autonomy allows

[1] *See* Corporate Disclosure Statement, *Fresenius Kabi USA, LLC & Fresenius Kabi Deutschland GmbH v. Natco Pharma USA*, No. 1:24-cv-00472-GBW (D. Del. Apr. 12, 2024), ECF No. 4.

[2] *See* Corporate Disclosure Statement, *La Jolla Pharma. Co. et al. v. Gland Pharma Ltd. et al.*, No. 2:22-cv-01754-MEF-JBC (D.N.J. Apr. 14, 2023), ECF No. 109.

[3] *See id.*

for a high degree of flexibility to meet regional needs."[4] The Fresenius Kabi AG website publicly lists the names and locations of each of the named Defendants as part of its "organizational cohesiveness."

24. Fresenius Kabi USA describes itself as "a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition" whose "products and services are used to help care for critically and chronically ill patients."[5] Fresenius Kabi USA holds itself out as the manufacturer of biosimilars that are sold and marketed in the United States, including Stimufend® (pegfilgrastim-fpgk),[6] Idacio® (adalimumab-aacf),[7] and Tyenne® (tocilizumab-aazg).[8]

25. Fresenius Kabi USA is the named applicant for the BLA No. [redacted] submitted to the FDA on [redacted] pursuant to 42 U.S.C. § 262(k) and referencing Prolia and XGEVA (denosumab).

26. Fresenius Kabi SwissBioSim developed FKS518, including by sponsoring clinical trials necessary for FDA approval.[9]

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[4] *Care in Every Corner of the World*, https://www.fresenius-kabi.com/company/we-are-global#accordion-1c8a3190b5-item-e4a80df110 (last accessed October 4, 2024).

[5] *About Us*, Fresenius Kabi, USA, https://www.fresenius-kabi.com/us/company (last accessed October 4, 2024).

[6] Fresenius Kabi Launches Biosimilar Stimufend® (pegfilgrastim-fpgk) in the U.S. (February 16, 2023), https://www.fresenius-kabi.com/news/fresenius-kabi-launches-biosimilar-stimufend-in-the-us (last accessed October 4, 2024).

[7] *IDACIO® (adalimumab-aacf) Now Available in the United States*, Fresenius Kabi USA (July 3, 2023), https://www.fresenius-kabi.com/us/news/idacio-adalimumab-aacf-now-available-in-the-united-states (last accessed October 4, 2024).

[8] *Fresenius Accelerates Momentum in its (Bio)Pharma Business and Launches Tyenne®, its Third Approved Biosimilar in the U.S.*, Fresenius Kabi USA (April 15, 2024) https://www.fresenius-kabi.com/us/news/fresenius-accelerates-momentum-in-its-bio-pharma-business-2024 (last accessed October 4, 2024).

[9] *A Study to Evaluate the Efficacy, Pharmacodynamics, Safety, and Immunogenicity of FKS518 in Postmenopausal Women With Osteoporosis*, National Library of Medicine (last updated August 30, 2023),

27. On information and belief, Fresenius Kabi Deutschland was and is actively involved with planning Defendants' new products, including FKS518, as the parent company of Fresenius Kabi SwissBioSim. On information and belief, Fresenius Kabi Deutschland, in collaboration with other affiliates, develops, manufactures, imports, markets, distributes, offers to sell, and/or sells generic and biosimilar products in Illinois and throughout the United States.

28. On information and belief, Fresenius Kabi Austria will be involved in manufacturing FKS518 in Austria. Fresenius Kabi Austria publicly touts itself as a "state-of-the-art manufacturing unit for sterile pharmaceutical solutions and emulsions" "with an export rate of more than 90%."[10] On information and belief, Fresenius Kabi Austria has previously manufactured denosumab that has been imported to the United States.

29. On information and belief, Fresenius Kabi USA, acting in concert with Fresenius Kabi SwissBioSim, Fresenius Kabi Deutschland, and Fresenius Kabi Austria, 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 Illinois and throughout the United States, through its own actions and through the actions of its agents.

30. On information and belief, Fresenius Kabi USA, acting in concert with Fresenius Kabi SwissBioSim, Fresenius Kabi Deutschland, and Fresenius Kabi Austria, intends to develop, manufacture, import, market, distribute, offer for sale, and/or sell in Illinois and across the United

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https://clinicaltrials.gov/study/NCT04934072?intr=Denosumab&spons=fresenius%20kabi&rank=1 (last accessed October 4, 2024).

[10] *Pharmaceutical Sites, Graz, Austria*, https://cmo.fresenius-kabi.com/sterile-pharmaceuticals/pharmaceutical-sites/graz-austria (last accessed October 4, 2024).

States biosimilar versions of Amgen's Prolia and XGEVA upon FDA approval and, in doing so, will improperly exploit Amgen's intellectual property surrounding these important medicines.[11]

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, 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. Personal Jurisdiction and Venue

33. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b). On information and belief, Defendants collaborate to develop, manufacture, seek regulatory approval for, market, distribute, and sell pharmaceutical products, for use throughout the United States, including in this federal judicial District.

34. On information and belief, Defendants collaborated with each other to take substantial steps to prepare for and undertake the filing of a BLA for their proposed denosumab biosimilar products. Upon information and belief, such steps included preparing and submitting the BLA and sending and receiving correspondence with the FDA regarding Defendants' BLA.

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

[11] *See Fresenius Announces FDA Acceptance for Review of Denosumab Biosimilar Application*, Fresenius SE (May 27, 2024), https://www.fresenius.com/node/6848 (last accessed October 4, 2024) ("This BLA submission acceptance is the latest development in Fresenius Kabi's continuing commitment to improving patient access to high-quality biological products through expanding its biosimilars development capabilities and product portfolio.").

C. Fresenius Kabi USA, LLC

36. Fresenius Kabi USA is subject to personal jurisdiction in Illinois because, among other reasons, it has purposely availed itself of the benefits and protections of Illinois laws such that it should reasonably anticipate being sued in this Court.

37. On information and belief, Fresenius Kabi USA develops, manufactures, and imports generic and biosimilar drugs throughout the United States, including in the State of Illinois.

38. This Court has personal jurisdiction over Fresenius Kabi USA by virtue of the fact that Fresenius Kabi USA took the significant step to prepare and file Defendants' BLA seeking approval from the FDA to engage in the importation, use, offer for sale, or sale, of Defendants' proposed denosumab biosimilar products in Illinois and throughout the United States, which directly gives rise to Amgen's claims of patent infringement.

39. Venue is proper pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Fresenius Kabi USA has systematic and continuous contacts with Illinois; a regular and established place of business in Illinois; has its headquarters and principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047; and, in particular, Fresenius Kabi USA has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(C) by preparing and submitting Defendants' BLA for a proposed denosumab biosimilar in and from Illinois.

D. Fresenius Kabi SwissBioSim GmbH

40. Fresenius Kabi SwissBioSim is subject to personal jurisdiction in Illinois because, among other reasons, through its affiliate Fresenius Kabi USA, Fresenius Kabi SwissBioSim has purposely availed itself of the benefits and protections of Illinois laws such that it should reasonably anticipate being sued in this Court.

41. On information and belief, Fresenius Kabi SwissBioSim worked in concert with Fresnius Kabi USA to take the significant step to prepare and file Defendants' BLA seeking approval from the FDA to engage in the importation, use, offer for sale, or sale, of Defendants' proposed denosumab biosimilar products in Illinois and throughout the United States. Fresnius Kabi SwissBioSim specifically helped develop FKS518, Defendant's proposed biosimilar, by sponsoring the clinical trials necessary for FDA approval.

42. Additionally, and in the alternative, this Court has personal jurisdiction over Fresenius Kabi SwissBioSim under Federal Rule of Civil Procedure 4(k)(2) because Amgen's claims arise under federal law; Fresenius Kabi SwissBioSim is a foreign defendant that is not subject to general personal jurisdiction in any state; and, on information and belief, Fresenius Kabi Deutschland has sufficient contacts with the United States as a whole, including but not limited to, sponsoring the clinical trials for potential biosimilar pharmaceutical products intended to be sold through its U.S. affiliates and agents that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Fresenius Kabi SwissBioSim satisfies due process.

43. Venue is proper in this Court as to Fresenius Kabi SwissBioSim because it is a foreign entity that may be sued in any judicial district, including in the Northern District of Illinois. 28 U.S.C. § 1391(c)(3); see also 28 U.S.C. § 1400(b).

E. <u>Fresenius Kabi Deutschland GmbH</u>

44. Fresenius Kabi Deutschland is subject to personal jurisdiction in Illinois because, among other reasons, through its affiliate Fresenius Kabi USA, Fresenius Kabi Deutschland has purposely availed itself of the benefits and protections of Illinois laws such that it should reasonably anticipate being sued in this Court.

45. On information and belief, Fresenius Kabi Deutschland worked in concert with Fresenius Kabi USA to take the significant step to prepare and file Defendants' BLA seeking approval from the FDA to engage in the importation, use, offer for sale, or sale, of Defendants' proposed denosumab biosimilar products in Illinois and throughout the United States. On information and belief, Defendants [redacted]

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

47. Venue is proper in this Court as to Fresenius Kabi Deutschland because it is a foreign entity that may be sued in any judicial district, including in the Northern District of Illinois. 28 U.S.C. § 1391(c)(3); see also 28 U.S.C. § 1400(b).

F. Fresenius Kabi Austria GmbH

48. Fresenius Kabi Austria is subject to personal jurisdiction in Illinois because, among other reasons, through its affiliate Fresenius Kabi USA, Fresenius Kabi Austria has purposely availed itself of the benefits and protections of Illinois laws such that it should reasonably anticipate being sued in this Court.

49. On information and belief, Fresenius Kabi Austria worked in concert with Fresenius Kabi USA to take the significant step to prepare and file Defendants' BLA seeking approval from the FDA to engage in the importation, use, offer for sale, or sale, of Defendants' proposed denosumab biosimilar products in Illinois and throughout the United States. On information and belief, Fresenius Kabi Austria will manufacture Defendants biosimilar product for commercial sale in Illinois and throughout the United States.

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

51. Venue is proper in this Court as to Fresenius Kabi Austria because it is a foreign entity that may be sued in any judicial district, including in the Northern District of Illinois. 28 U.S.C. § 1391(c)(3); see also 28 U.S.C. § 1400(b).

THE PROLIA AND XGEVA DRUG PRODUCTS

A. Bone Metabolism and RANKL

52. 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.

53. 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").[12] 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.

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

B. Denosumab

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

56. 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.

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

C. Amgen's Invention of Prolia and XGEVA

57. 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.

58. 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.

59. In 2001, Dr. Boyle and his co-inventors filed U.S. Provisional Patent Application No. 60/301,172 (the "'172 Application"). The '736 Patent claims priority to the '172 Application. The '172 Application (and the '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 '736 Patent claims the denosumab antibody, as well as novel pharmaceutical compositions containing denosumab.

D. Amgen's Investment in Prolia and XGEVA

60. 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.

61. 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.

62. 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.

63. 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).

64. 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.

E. Amgen's Further Innovations in Antibody Manufacturing

65. 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, formulation, and devices, 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.

F. The Defendants' Knowledge of the Patents-In-Suit

66. As alleged herein, the '736 Patent issued on April 29, 2008. The '736 Patent was identified in Amgen's patent marking for Prolia and XGEVA before Defendants filed the BLA for their denosumab biosimilar products. Moreover, at least as early as May 24, 2023, several of the Patents-in-Suit were identified on the FDA's publication entitled *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluation* ("the Purple Book").[13] Thus, Defendants had notice and was aware of one or more of Amgen's patents before the filing of the BLA.

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

68. Further, as alleged herein, Amgen Inc. sent a letter to Defendants identifying thirty-two of the Patents-In-Suit on [redacted] Defendants were thus aware of these thirty-two Patents-In-Suit at least as of [redacted] Amgen Inc. sent a supplemental letter to Defendants on [redacted], identifying the '686 Patent as an additional patent issued on September 10, 2024. Defendants were thus aware of the new patent as of [redacted]

[13] *See* https://web.archive.org/web/20230524143320/https://purplebooksearch.fda.gov/patent-list (last accessed October 4, 2024).

DEFENDANTS' FAILURE TO COMPLY WITH THE BPCIA

A. The BPCIA's Framework for Confidential Information Exchange

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

70. 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) (emphasis added).

71. The initial disclosure contemplated by 262(*l*)(2) enables the reference product sponsor (here, Amgen) to prepare and provide "[n]ot later than 60 days after the receipt of the application and information under paragraph (2)," a "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor…." 42 U.S.C. § 262(*l*)(3). This is known colloquially as a "3A List," and helps facilitate an efficient resolution of patent claims by enabling the product sponsor to "identify relevant patents and to flesh out the legal arguments that they might raise in future litigation." *Sandoz v. Amgen*, 582 U.S. 1, 4 (2017).

72. However, if a subsection (k) applicant (here, Defendants) fails to comply with the initial disclosure requirements of (*l*)(2)(A) by failing "to provide the application and information

required," the reference product sponsor (here, Amgen) is permitted to file an action for declaratory judgment of patent infringement, validity, or enforceability. 42 U.S.C. § 262(*l*)(9)(C).

B. Defendants' Incomplete BLA Production

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

74. The FDA accepted for review Defendants' BLA No. [redacted] on [redacted]

75. On [redacted], Fresenius Kabi USA informed Amgen that it would produce what it described as "a copy of Fresenius's BLA No. [redacted] and such other information that describes the process or processes used to manufacture the biological product that is the subject of that application is provided herewith."

76. Upon receiving and reviewing the Incomplete BLA, Amgen's counsel observed the production contained numerous substantial redactions of information which ranged from redacted words and sentences to the redaction of entire pages. On information and belief, BLAs are submitted to the FDA without redactions, in a format that contains internal hyperlinks to provide internal relationships and enable contextual navigation and review.

77. On [redacted], Amgen's counsel wrote to Fresenius Kabi USA's counsel regarding the deficiencies in the alleged production of BLA materials. The letter noted the numerous unwarranted and unjustified redactions to Fresenius's BLA including, but not limited to, redaction of vendor information, manufacturing locations, lot numbers, document titles, signatures on batch records, portions of testing printouts, and even blanket redactions to entire portions of the BLA.

78. On [redacted], Fresenius Kabi USA wrote back to Amgen, asserting its intent to provide additional materials and information pursuant to Amgen's requests. On [redacted], Fresenius Kabi USA produced additional documents.

79. After Amgen reviewed these materials, Amgen responded promptly on [redacted], specifically listing information missing from Fresenius Kabi USA's productions that was essential for Amgen to determine the nature and extent of Defendants' patent infringement. Amgen requested, among other things, the amounts of each component in each base powder, cell culture media, feed media, or any other medium or solution used in the manufacturing process for FKS518; experimental data obtained during testing of FKS518; and the configuration and functionality of all processing units and equipment used in the manufacture of commercial batches of FKS518. Amgen's [redacted] letter further reiterated Fresenius Kabi USA's inappropriate use of redactions and underscored that the BPCIA requires a section (k) applicant to disclose "a copy" of the BLA submitted to the FDA, and the statute provides confidentiality provisions to allay applicant's concerns regarding the disclosure of sensitive information.

80. Counsel for Fresenius Kabi USA continued to provide "updates" to Amgen about the status of its "investigation" into Amgen's requests (via letters dated [redacted]). But despite Amgen's repeated insistence (via letters dated [redacted]) that Fresenius Kabi USA re-produce a complete and true "copy" of the BLA as submitted to the FDA, particularly with respect to manufacturing information, Fresenius Kabi USA has still not removed the improper redactions or produced "other information" required under 262(*l*)(2)(A).

81. 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' refusal to tender a complete BLA copy.

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

C. [redacted]

83. The BPCIA separately provides that "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). [redacted]

84. 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.[14] This 10-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' BLA

[14] *See Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027*, https://www.fda.gov/media/152279/download?attachment (last accessed October 4, 2024) ("Review performance goals: . . . Review and act on 90 percent of original 351(k) BLA submissions within 10 months of the 60 day filing date."). *See also*, *BsUFA III: Fiscal Years 2023-2027*, https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027 (last accessed October 4, 2024).

referencing Amgen's Prolia and XGEVA is [redacted], which is before the expiration of the one or more of the Patents-in-Suit.

85. 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, as soon as [redacted].

THE PATENTS-IN-SUIT

A. The Boyle '736 and '418 Patents

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

87. The '736 Patent is assigned to Amgen Inc. AML has a license to the '736 Patent that is exclusive with respect to denosumab and pharmaceutical compositions thereof.

88. The '736 Patent is and has been identified on the label for XGEVA and Prolia.[15]

89. The '736 Patent was identified in the letter Amgen 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 one or more of Defendants' proposed denosumab biosimilar products.

[15] *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).

90. The USPTO duly and legally issued the '418 Patent, titled "Polynucleotides Encoding Heavy and Light Chains of Antibodies to OPGL," on November 15, 2011. The '418 Patent discloses and claims polynucleotides encoding denosumab and methods of making it.

91. The '418 Patent is assigned to Amgen Inc. AML has an exclusive license to the '418 Patent.

92. The '418 Patent was identified in the letter Amgen Inc. sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar products.

B. <u>The Crowell '101, '896, and '248 Patents</u>

93. The USPTO duly and legally issued the '101 Patent, titled "Host Cells Comprising Alpha 1,2 Mannosidase and Culture Methods Thereof," on February 15, 2011. The '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 (an enzyme that can be natively expressed by the host cell), and a glycoprotein of interest.

94. The '101 Patent is assigned to Amgen Inc. AML has an exclusive license to the '101 Patent. The '101 Patent was identified in the letter Amgen 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 one or more of Defendants' proposed denosumab biosimilar products.

95. The USPTO duly and legally issued the '896 Patent, titled "Host Cells and Culture Methods," on June 11, 2013. The '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 (an enzyme that can be natively expressed by the host cell), and a glycoprotein of interest.

96. The ’896 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’896 Patent. The ’896 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.

97. The USPTO duly and legally issued the ’248 Patent, titled “Host Cells Comprising Alpha 1,2 Mannosidase and Culture Methods Thereof,” on March 25, 2014. The ’248 Patent as a general matter discloses and claims a glycoprotein product produced by a process of culturing an isolated host cell engineered to overexpress alpha 1,2 mannosidase (an enzyme that can be natively expressed by the host cell), and a glycoprotein of interest.

98. The ’248 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’248 Patent. The ’248 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.

C. The Crowell ’686 Patent

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

100. The ’686 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’686 Patent. The ’686 Patent was identified in the letter Amgen sent to Defendants on [redacted]

[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 one or more of Defendants' proposed denosumab biosimilar products.

D. The Dillon '205 Patent

101. The USPTO duly and legally issued the '205 Patent, titled "Methods for Refolding of Recombinant Antibodies," on April 19, 2011. The '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.

102. The '205 Patent is assigned to Amgen Inc. AML has an exclusive license to the '205 Patent. The '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 Morris '236 and '168 Patents

103. The USPTO duly and legally issued the '236 Patent, titled "Feed media," on November 8, 2011. The '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.

104. The '236 Patent is assigned to Amgen Inc. AML has an exclusive license to the '236 Patent. The '236 Patent was identified in the letter Amgen 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 one or more of Defendants' proposed denosumab biosimilar products.

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

106. The '168 Patent is assigned to Amgen Inc. AML has an exclusive license to the '168 Patent. The '168 Patent was identified in the letter Amgen 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 one or more of Defendants' proposed denosumab biosimilar products.

F. The Kang '178, '723, and '963 Patents

107. The USPTO duly and legally issued the '178 Patent, titled "Dipeptides to Enhance Yield and Viability from Cell Cultures," on April 21, 2015. The '178 Patent as a general matter discloses and claims methods of culturing mammalian cells that have been recombinantly engineered to express a protein in serum-free medium by adding particular dipeptides into the cell culture.

108. The '178 Patent is assigned to Amgen Inc. AML has an exclusive license to the '178 Patent. The '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.

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

110. The ’723 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’723 Patent. The ’723 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.

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

112. The ’963 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’963 Patent. The ’963 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.

G. The Zhou ’816 Patent

113. 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.

114. The ’816 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’816 Patent. The ’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

H. The Allen '134 Patent

115. The USPTO duly and legally issued the '134 Patent, titled "Carbohydrate Phosphonate Derivatives as Modulators of Glycosylation," on May 3, 2016. The '134 Patent as a general matter discloses and claims methods of making proteins with modified glycosylation by adding non-naturally occurring small sugar compounds to cell culture media to modulate glycosylation.

116. The '134 Patent is assigned to Amgen Inc. AML has an exclusive license to the '134 Patent. The '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.

I. The Wu '435, '568, '595, and '605 Patents

117. The USPTO duly and legally issued the '435 Patent, titled "Methods for Modulating Mannose Content of Recombinant Proteins," on June 7, 2016. The '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.

118. The '435 Patent is assigned to Amgen Inc. AML has an exclusive license to the '435 Patent. The '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.

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

120. The '568 Patent is assigned to Amgen Inc. AML has an exclusive license to the '568 Patent. The '568 Patent was identified in the letter Amgen 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 one or more of Defendants' proposed denosumab biosimilar products.

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

122. The '595 Patent is assigned to Amgen Inc. AML has an exclusive license to the '595 Patent. The '595 Patent was identified in the letter Amgen 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 one or more of Defendants' proposed denosumab biosimilar products.

123. The USPTO duly and legally issued the '605 Patent, titled "Methods for Increasing Mannose Content of Recombinant Proteins," on April 9, 2024. The '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.

124. The ’605 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’605 Patent. The ’605 Patent was identified in the letter Amgen 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 one or more of Defendants’ proposed denosumab biosimilar products.

J. The Gupta ’829, ’627, and ’156 Patents

125. The USPTO duly and legally issued the ’829 Patent, titled “Overexpression of N-Glycosylation Pathway Regulators to Modulate Glycosylation of Recombinant Proteins,” on October 23, 2018. The ’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.

126. The ’829 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’829 Patent. The ’829 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.

127. The USPTO duly and legally issued the ’627 Patent, titled “Overexpression of N-Glycosylation Pathway Regulators to Modulate Glycosylation of Recombinant Proteins,” on March 12, 2019. The ’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.

128. The ’627 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’627 Patent. The ’627 Patent was identified in the letter Amgen Inc. sent to Defendants on [redacted]

[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.

129. The USPTO duly and legally issued the '156 Patent, titled "Overexpression of N-Glycosylation Pathway Regulators to Modulate Glycosylation of Recombinant Proteins," on May 19, 2020. The '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.

130. The '156 Patent is assigned to Amgen Inc. AML has an exclusive license to the '156 Patent. The '156 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 Leiske '492 and '630 Patents

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

132. The '492 Patent is assigned to Amgen Inc. AML has an exclusive license to the '492 Patent. The '492 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.

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

134. The '630 Patent is assigned to Amgen Inc. AML has an exclusive license to the '630 Patent. The '630 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.

L. The Gefroh '397, '404, and '866 Patents

135. The USPTO duly and legally issued the '397 Patent, titled "Process Control Systems and Methods for Use with Filters and Filtration Processes," on March 10, 2020. The '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.

136. The '397 Patent is assigned to Amgen Inc. AML has an exclusive license to the '397 Patent. The '397 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.

137. The USPTO duly and legally issued the '404 Patent, titled "Process control systems and methods for use with filters and filtration processes," on August 3, 2021. The '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.

138. The ’404 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’404 Patent. The ’404 Patent was identified in the letter Amgen 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 one or more of Defendants’ proposed denosumab biosimilar products.

139. The USPTO duly and legally issued the ’866 Patent, titled “Process control systems and methods for use with filters and filtration processes,” on October 17, 2023. The ’866 Patent as a general matter discloses and claims systems and methods used to control tangential flow filtration.

140. The ’866 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’866 Patent. The ’866 Patent was identified in the letter Amgen 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 one or more of Defendants’ proposed denosumab biosimilar products.

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

141. The USPTO duly and legally issued the ’972 Patent, titled “Methods for Increasing Mannose Content of Recombinant Proteins” on January 19, 2021. The ’972 Patent 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.

142. The ’972 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’972 Patent. The ’972 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.

143. The USPTO duly and legally issued the '514 Patent, titled "Methods for Increasing Mannose Content of Recombinant Proteins" on September 6, 2022. The '514 Patent 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

144. The '514 Patent is assigned to Amgen Inc. AML has an exclusive license to the '514 Patent. The '514 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.

145. The USPTO duly and legally issued the '085 Patent, titled "Methods for Increasing Mannose Content of Recombinant Proteins," on April 2, 2024. The '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.

146. The '085 Patent is assigned to Amgen Inc. AML has an exclusive license to the '085 Patent. The '085 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.

N. The Hoang '079 Patent

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

148. The '079 Patent is assigned to Amgen Inc. AML has an exclusive license to the '079 Patent. The '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.

O. The Pande '980 and '760 Patents

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

150. The '980 Patent is assigned to Amgen Inc. AML has an exclusive license to the '980 Patent. The '980 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.

151. The USPTO duly and legally issued the '760 Patent, titled "Use of Monensin to Regulate Glycosylation of Recombinant Proteins," on April 12, 2022. The '760 Patent as a general matter discloses and claims methods of regulating the high mannose glycoform content of denosumab by adding monensin to the cell culture.

152. The ’760 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’760 Patent. The ’760 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.

P. The Perez-Pacheco ’950 Patent

153. The USPTO duly and legally issued the ’950 Patent, titled “Controlled Dispense Syringe,” on September 5, 2023. The ’950 Patent discloses and claims a syringe with a plunger assembly that is adapted to dispense product from the syringe using a plunger rod having a stop feature that stops a dispensing stroke of the plunger rod at a distance corresponding to a level of air or headspace within the syringe.

154. The ’950 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’950 Patent. The ’950 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

155. Paragraphs 1-154 are incorporated by reference as if fully set forth herein.

156. 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 refusal to provide missing information for Amgen to fully evaluate whether the ’736 Patent has been or will be infringed, on information and belief, Defendants have infringed the ’736 Patent under at least 35 U.S.C. §§ 271(a), (b), and (e).

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

158. 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 '736 Patent, including at least claim 3.

159. On information and belief, based on information presently available to Amgen, 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 '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 '736 Patent, constitutes willful infringement.

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

161. 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 '736 Patent.

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

162. Paragraphs 1-161 are incorporated by reference as if fully set forth herein.

163. 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 refusal to provide missing information for Amgen to fully evaluate whether the '736 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 '736 Patent, including at least claim 3, under at least 35 U.S.C. §§ 271(a) and (b). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '736 Patent.

164. 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 '736 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

165. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '736 Patent.

166. 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 '736 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 '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 refusal to provide missing information for Amgen to fully evaluate whether the '418 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '418 Patent under at least 35 U.S.C. §§ 271(a), (b), (e), and (g).

169. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '418 Patent, including at least claim 14.

170. 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 '418 Patent, including at least claim 14.

171. On information and belief, based on information presently available to Amgen, 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 '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 '418 Patent, constitutes willful infringement.

172. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the '418 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

173. 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 '418 Patent.

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

174. Paragraphs 1-173 are incorporated by reference as if fully set forth herein.

175. 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 refusal to provide missing information for Amgen to fully evaluate whether the '418 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 '418 Patent, including at least claim 14, under at least 35 U.S.C. §§ 271(a) and (b). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '418 Patent.

176. 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 '418 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

177. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '418 Patent.

178. 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 '418 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 '418 Patent.

COUNT 5: INFRINGEMENT OF THE CROWELL '101 PATENT

179. Paragraphs 1-178 are incorporated by reference as if fully set forth herein.

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

181. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '101 Patent, including at least claim 15.

182. 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 '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.

183. On information and belief, based on information presently available to Amgen, 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 '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 '101 Patent, constitutes willful infringement.

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

185. 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 '101 Patent.

COUNT 6: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '101 PATENT

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

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

188. 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 '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.

189. 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 '101 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

190. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '101 Patent.

191. 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 '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 '101 Patent.

COUNT 7: INFRINGEMENT OF THE CROWELL '896 PATENT

192. Paragraphs 1-191 are incorporated by reference as if fully set forth herein.

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

194. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '896 Patent, including at least claim 1.

195. 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 '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.

196. On information and belief, based on information presently available to Amgen, 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 '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 '896 Patent, constitutes willful infringement.

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

198. 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 '896 Patent.

COUNT 8: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '896 PATENT

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

200. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '896 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 '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 '896 Patent, or will actively induce such activities.

201. 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 '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.

202. 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 '896 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

203. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '896 Patent.

204. 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 '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 '896 Patent.

COUNT 9: INFRINGEMENT OF THE CROWELL '248 PATENT

205. Paragraphs 1-204 are incorporated by reference as if fully set forth herein.

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

207. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '248 Patent, including at least claim 1.

208. 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 '248 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

209. On information and belief, based on information presently available to Amgen, 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 '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 '248 Patent, constitutes willful infringement.

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

211. 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 '248 Patent.

COUNT 10: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '248 PATENT

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

213. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '248 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 '248 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(a) and (b). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '248 Patent, or will actively induce such activities.

214. 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 '248 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

215. 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 '248 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

216. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '248 Patent.

217. 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 '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 '248 Patent.

COUNT 11: INFRINGEMENT OF THE CROWELL '686 PATENT

218. Paragraphs 1-217 are incorporated by reference as if fully set forth herein.

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

220. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '686 Patent, including at least claim 1.

221. 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 '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.

222. On information and belief, based on information presently available to Amgen, 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 '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 '686 Patent, constitutes willful infringement.

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

224. 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 '686 Patent.

COUNT 12: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '686 PATENT

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

226. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '686 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 '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 '686 Patent, or will actively induce such activities.

227. 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 '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.

228. 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 '686 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

229. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '686 Patent.

230. 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 '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 '686 Patent.

COUNT 13: INFRINGEMENT OF THE DILLON '205 PATENT

231. Paragraphs 1-230 are incorporated by reference as if fully set forth herein.

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

233. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '205 Patent, including at least claims 1 and 40.

234. 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 '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.

235. On information and belief, based on information presently available to Amgen, 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 '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 '205 Patent, constitutes willful infringement.

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

237. 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 '205 Patent.

COUNT 14: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE DILLON '205 PATENT

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

239. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '205 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 '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 '205 Patent, or will actively induce such activities.

240. 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 '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.

241. 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 '205 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

242. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '205 Patent.

243. 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 '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 '205 Patent.

COUNT 15: INFRINGEMENT OF THE MORRIS '236 PATENT

244. Paragraphs 1-243 are incorporated by reference as if fully set forth herein.

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

246. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '236 Patent, including at least claim 35.

247. 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 '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.

248. On information and belief, based on information presently available to Amgen, 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 '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 ’236 Patent, constitutes willful infringement.

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

250. 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 ’236 Patent.

COUNT 16: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE MORRIS ’236 PATENT

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

252. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the ’236 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 ’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 ’236 Patent, or will actively induce such activities.

253. 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 '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.

254. 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 '236 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

255. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '236 Patent.

256. 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 '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 '236 Patent.

COUNT 17: INFRINGEMENT OF THE MORRIS '168 PATENT

257. Paragraphs 1-256 are incorporated by reference as if fully set forth herein.

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

259. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '168 Patent, including at least claim 33.

260. 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 '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.

261. On information and belief, based on information presently available to Amgen, 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 '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 '168 Patent, constitutes willful infringement.

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

263. 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 '168 Patent.

COUNT 18: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE MORRIS '168 PATENT

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

265. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '168 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 '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 '168 Patent, or will actively induce such activities.

266. 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 '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.

267. 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 '168 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

268. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '168 Patent.

269. 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 '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 '168 Patent.

COUNT 19: INFRINGEMENT OF THE KANG '178 PATENT

270. Paragraphs 1-269 are incorporated by reference as if fully set forth herein.

271. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '178 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '178 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

272. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '178 Patent, including at least claim 1.

273. 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 '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.

274. On information and belief, based on information presently available to Amgen, 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 '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 '178 Patent, constitutes willful infringement.

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

276. 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 '178 Patent.

COUNT 20: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '178 PATENT

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

278. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '178 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 '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 '178 Patent, or will actively induce such activities.

279. 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 '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.

280. 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 '178 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

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

282. 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 '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 '178 Patent.

COUNT 21: INFRINGEMENT OF THE KANG '723 PATENT

283. Paragraphs 1-282 are incorporated by reference as if fully set forth herein.

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

285. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '723 Patent, including at least claim 1.

286. 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 '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.

287. On information and belief, based on information presently available to Amgen, 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 '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 '723 Patent, constitutes willful infringement.

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

289. 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 '723 Patent.

COUNT 22: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '723 PATENT

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

291. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '723 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 '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 '723 Patent, or will actively induce such activities.

292. 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 '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.

293. 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 '723 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

294. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '723 Patent.

295. 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 '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 '723 Patent.

COUNT 23: INFRINGEMENT OF THE KANG '963 PATENT

296. Paragraphs 1-295 are incorporated by reference as if fully set forth herein.

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

298. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '963 Patent, including at least claim 1.

299. 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 '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.

300. On information and belief, based on information presently available to Amgen, 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 '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 '963 Patent, constitutes willful infringement.

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

302. 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 '963 Patent.

COUNT 24: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '963 PATENT

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

304. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '963 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 '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 '963 Patent, or will actively induce such activities.

305. 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 '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.

306. 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 '963 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

307. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '963 Patent.

308. 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 '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 '963 Patent.

COUNT 25: INFRINGEMENT OF THE ZHOU '816 PATENT

309. Paragraphs 1-308 are incorporated by reference as if fully set forth herein.

310. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to 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).

311. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '816 Patent, including at least claim 1.

312. 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.

313. On information and belief, based on information presently available to Amgen, 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.

314. 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.

315. 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 26: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ZHOU '816 PATENT

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

317. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to 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.

318. 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 Defendants' proposed denosumab biosimilar products.

319. 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)(C); 28 U.S.C. §§ 2201, 2202.

320. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims 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.

321. 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.

COUNT 27: INFRINGEMENT OF THE ALLEN '134 PATENT

322. Paragraphs 1-321 are incorporated by reference as if fully set forth herein.

323. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '134 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '134 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

324. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '134 Patent, including at least claim 35.

325. 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 '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.

326. On information and belief, based on information presently available to Amgen, 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 '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 '134 Patent, constitutes willful infringement.

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

328. 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 '134 Patent.

COUNT 28: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ALLEN '134 PATENT

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

330. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '134 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 '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 '134 Patent, or will actively induce such activities.

331. 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 '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.

332. 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 '134 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

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

334. 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 '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 '134 Patent.

COUNT 29: INFRINGEMENT OF THE WU '435 PATENT

335. Paragraphs 1-334 are incorporated by reference as if fully set forth herein.

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

337. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '435 Patent, including at least claim 1.

338. 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 '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.

339. On information and belief, based on information presently available to Amgen, 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 '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 ’435 Patent, constitutes willful infringement.

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

341. 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 ’435 Patent.

COUNT 30: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU ’435 PATENT

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

343. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the ’435 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 ’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 ’435 Patent, or will actively induce such activities.

344. 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 '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.

345. 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 '435 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

346. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '435 Patent.

347. 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 '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 '435 Patent.

COUNT 31: INFRINGEMENT OF THE WU '568 PATENT

348. Paragraphs 1-347 are incorporated by reference as if fully set forth herein.

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

350. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '568 Patent, including at least claim 1.

351. 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 '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.

352. On information and belief, based on information presently available to Amgen, 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 '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 ’568 Patent, constitutes willful infringement.

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

354. 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 ’568 Patent.

COUNT 32: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU ’568 PATENT

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

356. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the ’568 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 ’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 ’568 Patent, or will actively induce such activities.

357. 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 '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.

358. 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 '568 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

359. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '568 Patent.

360. 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 '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 '568 Patent.

COUNT 33: INFRINGEMENT OF THE WU '595 PATENT

361. Paragraphs 1-360 are incorporated by reference as if fully set forth herein.

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

363. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '595 Patent, including at least claim 1.

364. 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 '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.

365. On information and belief, based on information presently available to Amgen, 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 '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 ’595 Patent, constitutes willful infringement.

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

367. 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 ’595 Patent.

COUNT 34: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU ’595 PATENT

368. Paragraphs 1-367 are incorporated by reference as if fully set forth herein.

369. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the ’595 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 ’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 ’595 Patent, or will actively induce such activities.

370. 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 '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.

371. 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 '595 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

372. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '595 Patent.

373. 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 '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 '595 Patent.

COUNT 35: INFRINGEMENT OF THE WU '605 PATENT

374. Paragraphs 1-373 are incorporated by reference as if fully set forth herein.

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

376. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '605 Patent, including at least claim 1.

377. 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 '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.

378. On information and belief, based on information presently available to Amgen, 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 '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 '605 Patent, constitutes willful infringement.

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

380. 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 '605 Patent.

COUNT 36: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU '605 PATENT

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

382. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '605 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 '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 '605 Patent, or will actively induce such activities.

383. 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 '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.

384. 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 '605 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

385. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '605 Patent.

386. 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 '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 '605 Patent.

COUNT 37: INFRINGEMENT OF THE GUPTA '829 PATENT

387. Paragraphs 1-386 are incorporated by reference as if fully set forth herein.

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

389. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '829 Patent, including at least claim 1.

390. 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 '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.

391. On information and belief, based on information presently available to Amgen, 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 '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 '829 Patent, constitutes willful infringement.

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

393. 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 '829 Patent.

COUNT 38: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '829 PATENT

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

395. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '829 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 '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 '829 Patent, or will actively induce such activities.

396. 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 '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.

397. 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 '829 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

398. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '829 Patent.

399. 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 '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 '829 Patent.

COUNT 39: INFRINGEMENT OF THE GUPTA '627 PATENT

400. Paragraphs 1-399 are incorporated by reference as if fully set forth herein.

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

402. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '627 Patent, including at least claim 1.

403. 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 '627 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

404. On information and belief, based on information presently available to Amgen, 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 '627 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 ’627 Patent, constitutes willful infringement.

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

406. 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 ’627 Patent.

COUNT 40: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA ’627 PATENT

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

408. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the ’627 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 ’627 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 ’627 Patent, or will actively induce such activities.

409. 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 '627 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

410. 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 '627 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

411. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '627 Patent.

412. 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 '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 '627 Patent.

COUNT 41: INFRINGEMENT OF THE GUPTA '156 PATENT

413. Paragraphs 1-412 are incorporated by reference as if fully set forth herein.

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

415. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '156 Patent, including at least claim 1.

416. 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 '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.

417. On information and belief, based on information presently available to Amgen, 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 '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 '156 Patent, constitutes willful infringement.

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

419. 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 '156 Patent.

COUNT 42: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '156 PATENT

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

421. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '156 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 '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 '156 Patent, or will actively induce such activities.

422. 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 '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.

423. 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 '156 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

424. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '156 Patent.

425. 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 '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 '156 Patent.

COUNT 43: INFRINGEMENT OF THE LEISKE '492 PATENT

426. Paragraphs 1-425 are incorporated by reference as if fully set forth herein.

427. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '492 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '492 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

428. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '492 Patent, including at least claim 1.

429. 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 '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.

430. On information and belief, based on information presently available to Amgen, 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 '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 '492 Patent, constitutes willful infringement.

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

432. 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 '492 Patent.

COUNT 44: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE LEISKE '492 PATENT

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

434. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '492 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 '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 '492 Patent, or will actively induce such activities.

435. 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 '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.

436. 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 '492 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

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

438. 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 '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 '492 Patent.

COUNT 45: INFRINGEMENT OF THE LEISKE '630 PATENT

439. Paragraphs 1-438 are incorporated by reference as if fully set forth herein.

440. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '630 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '630 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

441. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '630 Patent, including at least claim 1.

442. 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 '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.

443. On information and belief, based on information presently available to Amgen, 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 '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 '630 Patent, constitutes willful infringement.

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

445. 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 '630 Patent.

COUNT 46: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE LEISKE '630 PATENT

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

447. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '630 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 '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 '630 Patent, or will actively induce such activities.

448. 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 '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.

449. 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 '630 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

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

451. 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 '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 '630 Patent.

COUNT 47: INFRINGEMENT OF THE GEFROH '397 PATENT

452. Paragraphs 1-451 are incorporated by reference as if fully set forth herein.

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

454. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '397 Patent, including at least claim 13.

455. 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 '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.

456. On information and belief, based on information presently available to Amgen, 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 '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 '397 Patent, constitutes willful infringement.

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

458. 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 '397 Patent.

COUNT 48: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GEFROH '397 PATENT

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

460. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '397 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 '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 '397 Patent, or will actively induce such activities.

461. 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 '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.

462. 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 '397 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

463. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '397 Patent.

464. 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 '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 '397 Patent.

COUNT 49: INFRINGEMENT OF THE GEFROH '404 PATENT

465. Paragraphs 1-464 are incorporated by reference as if fully set forth herein.

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

467. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '404 Patent, including at least claim 14.

468. 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 '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.

469. On information and belief, based on information presently available to Amgen, 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 '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 '404 Patent, constitutes willful infringement.

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

471. 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 '404 Patent.

COUNT 50: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GEFROH '404 PATENT

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

473. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '404 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 '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 '404 Patent, or will actively induce such activities.

474. 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 '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.

475. 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 '404 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

476. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '404 Patent.

477. 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 '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 '404 Patent.

COUNT 51: INFRINGEMENT OF THE GEFROH '866 PATENT

478. Paragraphs 1-477 are incorporated by reference as if fully set forth herein.

479. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '866 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '866 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

480. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '866 Patent, including at least claim 10.

481. 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 '866 Patent, including at least claim 10, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

482. On information and belief, based on information presently available to Amgen, 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 '866 Patent, including at least claim 10. 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 '866 Patent, constitutes willful infringement.

483. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the '866 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

484. 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 '866 Patent.

COUNT 52: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GEFROH '866 PATENT

485. Paragraphs 1-484 are incorporated by reference as if fully set forth herein.

486. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '866 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 '866 Patent, including at least claim 10, 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 '866 Patent, or will actively induce such activities.

487. 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 '866 Patent, including at least claim 10, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

488. 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 '866 Patent, will infringe one or more claims of the '866 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)(C); 28 U.S.C. §§ 2201, 2202.

489. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '866 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 '866 Patent.

490. 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 '866 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 '866 Patent.

COUNT 53: INFRINGEMENT OF THE HUANG '972 PATENT

491. Paragraphs 1-490 are incorporated by reference as if fully set forth herein.

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

493. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '972 Patent, including at least claim 3.

494. 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 '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.

495. On information and belief, based on information presently available to Amgen, 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 '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 '972 Patent, constitutes willful infringement.

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

497. 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 '972 Patent.

COUNT 54: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '972 PATENT

498. Paragraphs 1-497 are incorporated by reference as if fully set forth herein.

499. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '972 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 '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 '972 Patent, or will actively induce such activities.

500. 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 '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.

501. 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 '972 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

502. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '972 Patent.

503. 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 '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 '972 Patent.

COUNT 55: INFRINGEMENT OF THE HUANG '514 PATENT

504. Paragraphs 1-503 are incorporated by reference as if fully set forth herein.

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

506. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '514 Patent, including at least claim 1.

507. 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 '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.

508. On information and belief, based on information presently available to Amgen, 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 '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 '514 Patent, constitutes willful infringement.

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

510. 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 '514 Patent.

COUNT 56: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '514 PATENT

511. Paragraphs 1-510 are incorporated by reference as if fully set forth herein.

512. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '514 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 '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 '514 Patent, or will actively induce such activities.

513. 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 '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.

514. 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 '514 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

515. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '514 Patent.

516. 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 '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 '514 Patent.

COUNT 57: INFRINGEMENT OF THE HUANG '085 PATENT

517. Paragraphs 1-516 are incorporated by reference as if fully set forth herein.

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

519. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '085 Patent, including at least claim 1.

520. 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 '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.

521. On information and belief, based on information presently available to Amgen, 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 '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 ’085 Patent, constitutes willful infringement.

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

523. 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 ’085 Patent.

COUNT 58: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG ’085 PATENT

524. Paragraphs 1-523 are incorporated by reference as if fully set forth herein.

525. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the ’085 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 ’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 ’085 Patent, or will actively induce such activities.

526. 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 '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.

527. 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 '085 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

528. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '085 Patent.

529. 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 '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 '085 Patent.

COUNT 59: INFRINGEMENT OF THE HOANG '079 PATENT

530. Paragraphs 1-529 are incorporated by reference as if fully set forth herein.

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

532. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '079 Patent, including at least claim 1.

533. 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 '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.

534. On information and belief, based on information presently available to Amgen, 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 '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 '079 Patent, constitutes willful infringement.

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

536. 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 '079 Patent.

COUNT 60: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HOANG '079 PATENT

537. Paragraphs 1-536 are incorporated by reference as if fully set forth herein.

538. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '079 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 '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 '079 Patent, or will actively induce such activities.

539. 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 '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.

540. 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 '079 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

541. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '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 '079 Patent.

542. 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 '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 '079 Patent.

COUNT 61: INFRINGEMENT OF THE PANDE '980 PATENT

543. Paragraphs 1-542 are incorporated by reference as if fully set forth herein.

544. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '980 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '980 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

545. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '980 Patent, including at least claim 1.

546. 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 '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.

547. On information and belief, based on information presently available to Amgen, 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 '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 '980 Patent, constitutes willful infringement.

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

549. 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 '980 Patent.

COUNT 62: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE PANDE '980 PATENT

550. Paragraphs 1-549 are incorporated by reference as if fully set forth herein.

551. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '980 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 '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 '980 Patent, or will actively induce such activities.

552. 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 '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.

553. 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 '980 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

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

555. 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 '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 '980 Patent.

COUNT 63: INFRINGEMENT OF THE PANDE '760 PATENT

556. Paragraphs 1-555 are incorporated by reference as if fully set forth herein.

557. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '760 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '760 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

558. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '760 Patent, including at least claim 1.

559. 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 '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.

560. On information and belief, based on information presently available to Amgen, 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 '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 '760 Patent, constitutes willful infringement.

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

562. 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 '760 Patent.

COUNT 64: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE PANDE '760 PATENT

563. Paragraphs 1-562 are incorporated by reference as if fully set forth herein.

564. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '760 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 '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 '760 Patent, or will actively induce such activities.

565. 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 '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.

566. 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 '760 Patent, will infringe one or more claims of the '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)(C); 28 U.S.C. §§ 2201, 2202.

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

568. 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 '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 '760 Patent.

COUNT 65: INFRINGEMENT OF THE PEREZ-PACHECO '950 PATENT

569. Paragraphs 1-568 are incorporated by reference as if fully set forth herein.

570. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '950 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '950 Patent under at least 35 U.S.C. §§ 271(a), (b), (e) and (g).

571. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '950 Patent, including at least claim 1.

572. 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 '950 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

573. On information and belief, based on information presently available to Amgen, 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 '950 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 '950 Patent, constitutes willful infringement.

574. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the '950 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

575. 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 '950 Patent.

COUNT 66: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE PEREZ-PECHECO '950 PATENT

576. Paragraphs 1-575 are incorporated by reference as if fully set forth herein.

577. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '950 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 '950 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 '950 Patent, or will actively induce such activities.

578. 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 '950 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

579. 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 '950 Patent, will infringe one or more claims of the '950 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)(C); 28 U.S.C. §§ 2201, 2202.

580. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '950 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 '950 Patent.

581. 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 '950 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 '950 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 each 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' proposed denosumab biosimilar products before the expiration of each of the Patents-In-Suit that are found infringed;

C. A judgment that Defendants have infringed 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' proposed 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 their 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.

Date: October 4, 2024

Respectfully submitted,

/s/ Steven J. Horowitz

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