IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

AMGEN INC. and AMGEN MANUFACTURING LIMITED LLC Plaintiffs, v. ACCORD BIOPHARMA, INC., ACCORD HEALTHCARE, INC., and INTAS PHARMACEUTICALS, LTD. Defendants.	)	**COMPLAINT & DEMAND FOR A JURY TRIAL**

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 Accord BioPharma, Inc. ("Accord BioPharma"), Accord Healthcare, Inc. ("Accord Healthcare"), and Intas Pharmaceuticals, Limited ("Intas") (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

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

2. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. 42 U.S.C. § 262(k). This abbreviated pathway allows a

biosimilar applicant, such as Accord BioPharma, Inc., to rely on the prior licensure and approval status of the innovative biologic products that the biosimilar seeks to replicate.

3. This action arises out of Defendants' submission of abbreviated Biologic License Application ("BLA") No. [redacted] to the U.S. Food and Drug Administration ("FDA") on [redacted], pursuant to 42 U.S.C. § 262(k), seeking approval to manufacture and sell biosimilar versions of Amgen's patented Prolia® and XGEVA® drug 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 these two drugs is an antibody called denosumab. Amgen's scientists and clinicians have spent decades elucidating the biology of bone remodeling, creating the denosumab antibody, and developing Prolia and XGEVA. Amgen's innovative work on Prolia and XGEVA has benefited a tremendous number of patients. To support its portfolio of complex biological products such as Prolia and XGEVA, Amgen scientists have also made significant advancements in manufacturing processes that enhance product yield, consistency, and quality.

5. The asserted patents in this action cover the denosumab antibody and pharmaceutical compositions comprising denosumab (the active ingredient in Prolia and XGEVA), innovative methods of manufacturing therapeutic proteins, like denosumab, and denosumab products. The asserted patents (collectively, "the Patents-In-Suit") are as follows: U.S. Patent Nos. 7,364,736 (the "Boyle '736 Patent");7,662,930 (the "Zhou '930 Patent");

7,888,101 (the "Crowell '101 Patent"); 7,928,205 (the "Dillon '205 Patent"); 8,053,236 (the "Morris '236 Patent"); 8,058,418 (the "Boyle '418 Patent"); 8,460,896 (the "Crowell '896 Patent"); 8,680,248 (the "Crowell '248 Patent"); 9,012,178 (the "Kang '178 Patent"); 9,133,493 (the "Jerums '493 Patent"); 9,228,168 (the "Morris '168 Patent"); 9,320,816 (the "Zhou '816 Patent"); 9,328,134 (the "Allen '134 Patent"); 9,359,435 (the "Wu '435 Patent"); 9,388,447 (the "Jerums '447 Patent"); 10,106,829 (the "Gupta '829 Patent"); 10,167,492 (the "Leiske '492 Patent"); 10,227,627 (the "Gupta '627 Patent"); 10,513,723 (the "Kang '723 Patent"); 10,583,397 (the "Gefroh '397 Patent"); 10,655,156 (the "Gupta '156 Patent"); 10,822,630 (the "Leiske '630 Patent"); 10,894,972 (the "Huang '972 Patent"); 11,077,404 (the "Gefroh '404 Patent"); 11,098,079 (the "Hoang '079 Patent"); 11,130,980 (the "Pande '980 Patent"); 11,254,963 (the "Kang '963 Patent"); 11,299,760 (the "Pande '760 Patent"); 11,319,568 (the "Wu '568 Patent"); 11,434,514 (the "Huang '514 Patent"); 11,459,595 (the "Wu '595 Patent"); 11,946,085 (the "Huang '085 Patent"); 11,952,605 (the "Wu '605 Patent"); 12,084,686 (the "Crowell '686 Patent").

6. On [redacted], Defendants informed Amgen that "[redacted]." Defendants' [redacted] letter stated that enclosed was "[redacted]." Defendants' BLA indicates Defendants intend to seek approval to manufacture and sell biosimilar versions of Amgen's patented Prolia and XGEVA denosumab drug products, designated "[redacted]."

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

also "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A). Such information is critical for Amgen arriving at a fuller understanding of Defendants' manufacturing process, which is necessary before Amgen could potentially reach a resolution with Defendants without litigation, as contemplated by the BPCIA.

8. Since receiving the initial BLA production, Amgen has diligently evaluated the produced documents and repeatedly requested Defendants supplement their deficient production. On [redacted], Amgen informed Defendants of "gaps in Accord's production regarding information that describes 'the process or processes used to manufacture the biological product that is the subject of [Accord's] application.'" Although Defendants subsequently supplemented their production on [redacted], the materials produced to Amgen remain deficient.

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 262(*l*)(2)(A) of the BPCIA, which states that a biosimilar applicant "shall provide" to the reference product sponsor both: "a copy of the application submitted to the Secretary under subsection (k)," and "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A). Defendants have declined to fully resolve the deficiencies identified in Amgen's multiple letters, insisting, for example, that Intas does not have various requested information regarding the manufacturing processes for [redacted].

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 Accord BioPharma a "list of patents for which it believes a claim of patent infringement could reasonably be asserted," as contemplated by § 262(*l*)(3)(A). Despite producing a list of patents as contemplated by the BPCIA, Amgen maintained that Defendants had not complied with section 262(*l*)(2)(A), and that, accordingly, Amgen had no obligation to provide a patent list under § 262(*l*)(3)(A).

11. Defendants' pattern of partial compliance with the BPCIA continued when, on [redacted], Defendants tendered to Amgen a purported "statement" in response to Amgen's list of patents. This four-page statement contained threadbare assertions of non-infringement for the patents listed in Amgen's list. Defendants' short statement does not satisfy the BPCIA requirement, which is:

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

42 U.S.C. § 262(*l*)(3)(B)(ii) (emphasis added). Defendants' purported statement did not have any meaningful detail at all, and it was solely directed to Defendants' apparent theories of non-infringement.

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

bring an immediate declaratory judgment action for artificial infringement"). Further, as alleged herein, Defendants' failure to comply with § 262(*l*)(3)(B)(ii) also authorizes Amgen to file a suit for a declaration of infringement. 42 U.S.C. § 262(*l*)(9)(B).

13. On information and belief—including based on the information available in Defendants' BLA and documents produced thus far—Defendants have infringed or will imminently infringe the Patents-In-Suit under 35 U.S.C. § 271(e)(2)(C), as evidenced by Defendants' submitting a BLA seeking the FDA's approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, sale, or offer for sale of their denosumab biosimilar product(s) before the expiration of the Patents-In-Suit, including, *inter alia*, the '736 Patent and the '248 Patent.

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 seek to copy, Prolia and XGEVA, are the result of Amgen's innovations. Amgen brings this action to redress and halt the Defendants' actual and intended infringement of the Patents-In-Suit.

B. Defendants

19. Accord BioPharma, Inc. ("Accord BioPharma") is a biotechnology corporation organized and existing under the laws of Delaware, with, on information and belief, its principal place of business at 8041 Arco Corporate Dr. Suite 200 Raleigh, North Carolina 27617.

20. Accord Healthcare, Inc. ("Accord Healthcare") is a corporation organized and existing under the laws of North Carolina, with, on information and belief, its principal place of business at 8041 Arco Corporate Dr. Suite 200 Raleigh, North Carolina 27617.

21. Intas Pharmaceuticals, Limited ("Intas") is a corporation organized and existing under the laws of India, with, on information and belief, its principal place of business at Corporate House, Near Sola Bridge, S.G. Highway, Thaltej, Ahmedabad, 380054, Gujarat, India.

22. Accord BioPharma, Inc. describes itself as a "division" of Accord Healthcare.[1] Accord Healthcare, in turn, describes itself as a wholly owned "subsidiary" of Intas.[2]

23. Defendants Accord BioPharma, Accord Healthcare, and Intas are related corporate entities that act as agents of one another and/or act in concert, and hold themselves out as coordinated entities. For example, Accord BioPharma describes itself as a pharmaceutical company "[b]acked by the resources of [its] parent company, Intas Pharmaceuticals."[3] Further, Intas describes itself as "a leading, vertically integrated global pharmaceutical formulation development, manufacturing, and marketing company" that operates through "a network of subsidiaries, under the umbrella name of Accord Healthcare to operate in global markets."[4] Intas is "currently present in more than 85 countries worldwide with robust sales, marketing and distribution infrastructure in markets like North America, Europe, Central & Latin America, Asia-Pacific as well as CIS and MENA countries."[5]

24. Accord BioPharma is named as the applicant on the cover letter submitting BLA No. [redacted] (which reference Amgen's BLA No. 125320 for PROLIA and XGEVA) to the FDA for review. The FDA accepted that BLA on [redacted].

[1] Accord Healthcare, *About Accord BioPharma*, https://www.accordhealthcare.us/accord-biopharma/ (last accessed Nov. 13, 2024).

[2] Accord Healthcare, *Welcome to Accord Heathcar*e, https://www.accordhealthcare.us/#:~:text=Accord%20is%20a%20leading%2C%20vertically,parent%20name%20of%20Intas%20Pharmaceuticals (last accessed Nov. 13, 2024); Accord Healthcare, *Intas Completes Deal,* https://www.accord-healthcare.com/se/nyheter/intas-completes-deal-0. (accessed Nov. 13, 2024).

[3] Accord BioPharma, *Our commitment to biosimilars*, https://www.accordbiopharma.com/commitment-to-biosimilars/ (last accessed Nov. 13, 2024).

[4] Intas Pharmaceuticals, *About Us: Overview*, https://www.intaspharma.com/about-us/overview/ (last accessed Nov. 13, 2024).

[5] *Id*.

25. [redacted].

26. Intas publicly touts its "highly advanced global pharmaceutical manufacturing capabilities which include active pharmaceutical ingredients (API), oral solid dose (OSD), injectables, biosimilars, and plasma products."[6] Intas purports to have a biologics business unit which "caters to highly regulated markets of the EU, UK and US…."[7] On information and belief, Intas will be involved, or is involved, in manufacturing [redacted] for importation and sale into the United States, including in the Eastern District of North Carolina. [redacted] According to the FDA, the Pre-IND meeting "is designed to facilitate and foster early communications between the divisions of OID and potential sponsors of new therapeutics."[8]

27. On information and belief, Intas is in the process of completing Phase 3 clinical trials for [redacted] in India.[9] In addition to an ongoing clinical trial, Intas has also completed a Phase 3 clinical trial for [redacted] in 2017, which took place in India.[10]

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[6] Intas Pharmaceuticals, *Manufacturing: Overview*, https://www.intaspharma.com/manufacturing/overview/ (last accessed Nov. 13, 2024).

[7] Intas Pharmaceuticals, *Manufacturing: Biologics Business Unit*, https://www.intaspharma.com/manufacturing/biologics-business-unit/ (last accessed Nov. 13, 2024).

[8] US FDA, *Pre-IND Consultation Program* (Apr. 17, 2020), https://www.fda.gov/drugs/investigational-new-drug-ind-application/pre-ind-consultation-program (last accessed Nov. 13, 2024).

[9] *Denosumab Biosimilar Injection in Post Menopausal Women with Osteoporosis*, Clinical Trial ID NCT05419427, https://clinicaltrials.gov/study/NCT05419427 (last accessed Nov. 13, 2024) (listing Nov. 2024 as estimated completion date for Phase 3 Study of Intas' denosumab biosimilar).

[10] Singh I, Jose V, Patel R, Arora S., *Denosumab biosimilar in postmenopausal osteoporotic women: A randomized, assessor-blind, active-controlled clinical trial,* Indian J Pharmacology. 2021 Jan-Feb;53(1):6-12, https://pmc.ncbi.nlm.nih.gov/articles/PMC8216120/ (last accessed Nov. 12, 2024).

28. On information and belief, Accord BioPharma, acting in concert with Accord Healthcare and Intas, 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 North Carolina and throughout the United States, through its own actions and through the actions of its agents.

29. On information and belief, Accord BioPharma, acting in concert with Accord Healthcare and Intas, intends to develop, manufacture, import, market, distribute, offer for sale, and/or sell in North Carolina and across the United States biosimilar versions of Amgen's Prolia and XGEVA and, in doing so, will improperly exploit Amgen's intellectual property surrounding these medicines.[11]

JURISDICTION AND VENUE

A. Subject-Matter Jurisdiction

30. 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.

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

[11] *Denosumab Biosimilar Injection in Post Menopausal Women with Osteoporosis*, Clinical Trial ID NCT05419427, https://pubmed.ncbi.nlm.nih.gov/33975993/ (last accessed Nov. 13, 2024) (listing Nov. 2024 as estimated completion date for Phase 3 Study of Intas' denosumab biosimilar).

B. Venue and Personal Jurisdiction

32. Venue as to Accord BioPharma is proper in this District pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Accord BioPharma has systematic and continuous contacts with North Carolina; a regular and established place of business in North Carolina; has its headquarters and principal place of business at 8041 Arco Corporate Dr., Suite 200, Raleigh, North Carolina 27617; and, in particular, Accord BioPharma 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 North Carolina, and receiving correspondence with the FDA regarding Defendants' BLA at its office in North Carolina.

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

34. Venue as to Accord Healthcare is proper in this District pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Accord Healthcare resides in this District. Accord Healthcare is corporation organized and existing under the laws of North Carolina, with its principal place of business located in this District at 8041 Arco Corporate Dr., Suite 200, Raleigh, North Carolina 27617.

35. Venue as to Intas is proper in this District pursuant to 28 U.S.C. § 1391(c)(3) because it is a foreign corporation and is therefore subject to suit in any judicial district.[12]

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

36. On information and belief, Intas collaborated with Accord Healthcare and Accord BioPharma to develop, manufacture, seek regulatory approval for, market, distribute, and sell pharmaceutical products, for use throughout the United States, including in this District.

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

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

C. Accord BioPharma

39. This Court has personal jurisdiction over Accord BioPharma by virtue of the fact that Accord BioPharma maintains its principal place of business in North Carolina, and has thus purposely availed itself of the benefits and protections of North Carolina laws such that it should reasonably anticipate being sued in this Court.

40. On information and belief, Accord BioPharma develops, manufactures, and imports generic and biosimilar drugs throughout the United States, including in the State of North Carolina.

41. This Court has personal jurisdiction over Accord BioPharma by virtue of the fact that Accord BioPharma took the significant step to prepare and file Defendants' BLA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of the Defendants' biosimilar products in North Carolina and throughout the United States, which directly gives rise to Amgen's claims of patent infringement.

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

D. Accord Healthcare

43. Accord Healthcare is subject to personal jurisdiction in North Carolina because it is incorporated in and maintains its principal place of business in North Carolina. Accord Healthcare has thus purposely availed itself of the benefits and protections of North Carolina laws such that it should reasonably anticipate being sued in this Court, and this Court's exercise of jurisdiction over Accord Healthcare satisfies due process.

44. On information and belief, Accord Healthcare worked in concert with Accord BioPharma and Intas 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 North Carolina and throughout the United States.

E. Intas Pharmaceuticals

45. Intas Pharmaceuticals is subject to personal jurisdiction in North Carolina because, among other reasons, through its subsidiary Accord Healthcare, Intas has purposely availed itself of the benefits and protections of North Carolina laws such that it should reasonably anticipate being sued in this Court.

46. On information and belief, Intas worked in concert with Accord Healthcare and Accord BioPharma 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 North Carolina and throughout the United States. Intas specifically helped develop [redacted], Defendant's proposed biosimilar, by sponsoring the clinical trials necessary for FDA approval.

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

THE PROLIA AND XGEVA DRUG PRODUCTS

A. Bone Metabolism and RANKL

48. 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.

49. 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").[13] 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.

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

50. 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

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

52. 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.

C. Amgen's Invention of Prolia and XGEVA

53. 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.

54. 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.

55. 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

56. 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.

57. 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.

58. 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.

59. 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).

60. 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

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

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

62. 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. At least as early as May 24, 2023, one of the Patents-in-Suit, United States Patent No. 7,364,736 was identified on the FDA's publication entitled *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluation* ("the Purple Book").[14] Thus, the Defendants had constructive

[14] US FDA, *Purple Book Database of Licensed Biological Products*, https://web.archive.org/web/20230524143320/https://purplebooksearch.fda.gov/patent-list (last accessed Nov. 13, 2024).

notice of and were aware of at minimum one of Amgen's patents before the filing of the BLA. *See* 35 U.S.C. § 287.

63. On information and belief, the 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.

64. Further, as alleged herein, Amgen Inc sent a letter to Accord BioPharma identifying 33 of the 34 Patents-In-Suit on [redacted]. Defendants were thus aware of 33 of the 34 the Patents-In-Suit at least as of [redacted]. Amgen Inc. subsequently sent a letter to Accord BioPharma on [redacted], pursuant to 42 U.S.C. § 262(*l*)(7)(B), identifying the Crowell '868 Patent. Defendants were thus aware of all Patents-In-Suit at least as of [redacted].

DEFENDANTS' FAILURE TO COMPLY WITH THE BPCIA

A. The BPCIA's Framework for Confidential Information Exchange

65. 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.

66. The BPCIA provides that "[n]ot later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant "shall provide to the reference product sponsor [1] a copy of the application submitted to the Secretary under subsection (k), and [2] such other information that describes the process or

processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2) (numeration added).

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

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

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

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

> (II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires….

42 U.S.C. § 262(*l*)(3)(B)(ii).

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

71. However, "[i]f a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii)" (i.e., by tendering a 3B Statement), then "the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7)."

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

72. 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.

73. The FDA [redacted] Defendants' BLA No. [redacted] on [redacted].

74. On [redacted], Accord BioPharma informed Amgen that it was sending a hard drive containing Defendants' BLA No. [redacted], which Amgen received the following day. Accord BioPharma's [redacted] production did not purport to include "such other information that describes the process or processes used to manufacture the biological product that is the subject of that application," as contemplated by the second prong of section 262(*l*)(2)(A).

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

76. On [redacted], Amgen sent Defendants a deficiency letter identifying "[redacted]." The missing information included, but was not limited to: [redacted]. Amgen informed Defendants that [redacted]."

77. Defendants disclosed additional documents on [redacted], but remained deficient with respect to manufacturing information. Defendants informed Amgen that, [redacted]. Amgen sent a second deficiency letter on [redacted] again requesting "[redacted]" as requested in Amgen's [redacted] letter. Defendants' response to Amgen's second deficiency letter reiterated that Accord [redacted].

[redacted]

78. After conducting an analysis to the best of its ability based on the limited information available, Amgen provided to Defendants on [redacted] a 3A List "of patents for which it believes a claim of patent infringement could reasonably be asserted if the denosumab biosimilar product that is the subject of Accord's BLA is made, used, offered for sale, or sold in, or imported into, the United States without a license from Amgen." Amgen's cover letter to its 3A List maintained Defendants had not complied with section 262(*l*)(2)(A), and that compliance with section 262(*l*)(2)(A) was a condition precedent to Amgen's obligation to provide a 3A List.

79. On [redacted], Defendants tendered to Amgen a purported "statement" in response to Amgen's 3A List. This document contained only a few pages of conclusory noninfringement statements rife with factual errors. The statement failed to provide, as required by 42 U.S.C. § 262(*l*)(3)(B)(ii), the factual and legal basis for Defendants' opinion that the patents in Amgen's 3A List are invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of Defendants' BLA. This failure has and deprived Amgen of the opportunity to meaningfully evaluate Defendants' position on the patents asserted in Amgen's 3A List.

80. Nevertheless, on [redacted], Amgen provided a response to address Defendants' non-infringement conclusions and to provide additional information to Defendants' regarding the factual and legal basis of Amgen's opinion that each patent identified in Defendants' [redacted] letter will be infringed by Defendants' proposed denosumab biosimilar products. Amgen maintained its position that Defendants had not complied with 262(*l*)(3)(B)(ii) by withholding information, which necessarily limited Amgen's opinion on

patent infringement. Amgen also noted that Accord had failed to respond to Amgen's [redacted] correspondence regarding the '686 Crowell Patent by [redacted], as required by 42 U.S.C. § 262(*l*)(7)(B).

81. On [redacted], Defendants belatedly responded to Amgen's [redacted] correspondence in which Amgen identified the '686 Crowell Patent as an additional patent for which a claim of patent infringement could reasonably be asserted. Purporting to provide its statement pursuant to 42 U.S.C. § 262(*l*)(7)(B)—which incorporates section 262(*l*)(3)(B), *i.e.*, the "detailed statement" requirement—Defendants asserted, with no further analysis, that "[redacted]."

82. Amgen has participated in the pre-litigation exchange contemplated under the BPCIA to the best of its ability. Amgen's efforts, however, have been frustrated by Defendants' initial and ongoing failure to comply with subsection 262(*l*)(2)(A) of the BPCIA, as well as Defendant's subsequent failure to comply with subsection 262(*l*)(3)(B)(ii). Defendants' failure to produce the required manufacturing information under subsection 262(*l*)(2)(A), and a detailed statement subsection 262(*l*)(3)(B)(ii), has and will continue to prejudice Amgen's efforts to conduct a complete patent infringement analysis.

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

84. Defendants' failure to comply with 262(*l*)(3)(B)(ii) authorizes Amgen to file an action for declaratory judgment of patent infringement, validity, or enforceability "of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7)." 42 U.S.C. § 262(*l*)(9)(B).

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

C. Defendants' Importation of Infringing Material

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

87. According to the publicly available FDA Dashboard, between August 2019 and July 2023, Intas imported twelve shipments of denosumab from India into the United States.[15]

88. According to publicly available records in the FDA Dashboard, some of Intas's twelve product shipments were labeled as "denosumab pharma for lab testing."[16] Other shipments were simply labeled "denosumab" and additionally included "water for injection filled PFS."[17] Still other shipments were labeled "denosumab drug product" and additionally included "water for injection filled vial."[18]

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[15] *See* US FDA, *FDA Data Dashboard*, https://datadashboard.fda.gov/ora/cd/impentry-table.htm (using search with "denosumab" as a Product Code Description and "Intas" as the Manufacturer Legal Name) (last accessed Nov. 13, 2024).

[16] *See, e.g.*, US FDA, *FDA Data Dashboard*, Entry Number: 147-0220393-7, https://www.access.fda.gov/itacs/#/ (last accessed Nov, 13, 2024).

[17] *See, e.g.*, US FDA, *FDA Data Dashboard*, Entry Number 231-9955612-2, https://www.access.fda.gov/itacs/#/ (last accessed Nov, 13, 2024).

[18] *See, e.g.*, US FDA, *FDA Data Dashboard*, Entry Number 231-9955849-0, FDA, https://www.access.fda.gov/itacs/#/ (last accessed Nov, 13, 2024).

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

THE PATENTS-IN-SUIT

A. The Boyle '736 and '418 Patents

90. 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. The '736 Patent is and has been identified on the label for XGEVA and Prolia.[19]

91. 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.

92. The '736 and '418 Patents are assigned to Amgen Inc. AML has a license to the '736 and '418 Patents that are exclusive with respect to denosumab and pharmaceutical compositions thereof. The '736 and '418 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] as patents for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar products.

B. The Crowell '248, '896, '101 and '686 Patents

93. 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

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

process of culturing an isolated host cell engineered to overexpress alpha 1,2 mannosidase native to the host cell, and a glycoprotein of interest.

94. 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 native to the host cell, and a glycoprotein of interest.

95. 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 native to the host cell, and a glycoprotein of interest.

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

C. The Crowell ’686 Patent

97. 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.

98. The ’686 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’686 Patent. The ’686 Patent was identified in a supplementary 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.

D. The Dillon '205 Patent

99. 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.

100. 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 Kang '178 Patent

101. 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.

102. 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.

F. The Zhou ’816 Patent

103. 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.

104. 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.

G. The Zhou ’930 Patent

105. The USPTO duly and legally issued the ’930 Patent, titled “Polishing Steps Used in Multi-step Protein Purification Processes,” on February 16, 2010. The ’930 Patent discloses and claims methods of using a cation-exchange (CEX) chromatography column and Q membrane filter to purify a target protein molecule.

106. The ’930 Patents is assigned to Amgen Inc. AML has an exclusive license to the ’930 Patent. The ’930 Patent was identified in the letter Amgen Inc. sent to Defendants on [redacted] as a patents for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

H. The Allen ’134 Patent

107. 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.

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

109. 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.

110. 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

111. 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.

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

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

113. 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.

114. 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.

115. 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.

116. The ’829, ’627, and ’156 Patents are assigned to Amgen Inc. AML has an exclusive license to the ’829, ’627, and ’156 Patents. The ’829, ’627, and ’156 Patents were

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

K. The Leiske '492 and '630 Patents

117. 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.

118. 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.

119. The '492 and '630 Patents are assigned to Amgen Inc. AML has an exclusive license to the '492 and '630 Patents. The '492 and '630 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] as patents for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar products.

L. The Kang '723 and '963 Patents

120. 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.

121. 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.

122. The ’723 and ’963 Patents are assigned to Amgen Inc. AML has an exclusive license to the ’723 and ’963 Patents. The ’723 and ’963 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

M. <u>The Gefroh ’397 and ’404 Patent</u>

123. 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.

124. 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.

125. The ’397 and ’404 Patents are assigned to Amgen Inc. AML has an exclusive license to the ’397 and ’404 Patents. The ’397 and ’404 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] as patents for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making,

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

N. The Hoang '079 Patent

126. 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.

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

128. 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

129. 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.

130. 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.

131. The '980 and '760 Patents are assigned to Amgen Inc. AML has an exclusive license to the '980 and '760 Patents. The '980 and '760 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] as patents for which Amgen Inc. believes a

claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar products.

P. The Morris '236 and '168 Patents

132. 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.

133. 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.

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

Q. The Jerums '493 and '447 Patents

135. The USPTO duly and legally issued the '493 Patent, titled "Method for Culturing Mammalian Cells to Improve Recombinant Protein Production," on September 15, 2015. The '493 Patent discloses and claims methods of culturing mammalian cells expressing a recombinant protein comprising the use of independent tyrosine and cystine feed media for mammalian cell cultures.

136. The USPTO duly and legally issued the ’447 Patent, titled “Method for Culturing Mammalian Cells to Improve Recombinant Protein Production,” on July 12, 2016. The ’447 Patent discloses and claims methods of culturing mammalian cells expressing a recombinant protein comprising the use independent tyrosine feed media for mammalian cell cultures.

137. The ’493 and ’447 Patents are assigned to Amgen Inc. AML has an exclusive license to the ’168 and ’447 Patents. The ’493 and ’447 Patents were identified in the letter Amgen Inc. sent to Defendants on [redacted] as patents for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

R. <u>The Wu ’435 Patent</u>

138. 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.

139. 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.

S. <u>The Wu ’568, ’595, and ’605 Patents</u>

140. 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.

141. 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.

142. 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.

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

COUNT 1: INFRINGEMENT OF THE BOYLE ’736 PATENT

144. Paragraphs 1–143 are incorporated by reference as if fully set forth herein.

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

146. 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.

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

148. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

149. 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.

150. 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

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

152. Based on information presently available to Amgen, on information and belief, the Defendants have infringed and 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.

153. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

154. 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.

155. 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

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

157. Based on information presently available to Amgen, on information and belief, the Defendants have infringed the ’418 Patent under at least 35 U.S.C. §§ 271(a), (b), and (g).

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 ’418 Patent, including at least claim 14.

159. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants’ past imports of denosumab from India into the United States, Defendants’ importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants’ proposed denosumab biosimilar products, or Defendants’ active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the ’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.

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

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

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

162. Based on information presently available to Amgen, on information and belief, the Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the ’418 Patent, including at least claim 14, under at least 35 U.S.C. §§ 271(a), (b), and (g).

163. 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, infringed 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

164. Amgen is entitled to a declaratory judgment that Defendants infringed 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.

COUNT 5: INFRINGEMENT OF THE CROWELL ’248 PATENT

165. Paragraphs 1–164 are incorporated by reference as if fully set forth herein.

166. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '248 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '248 Patent under at least 35 U.S.C. §§ 271(a), (b) and (e).

167. 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.

168. 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.

169. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims

of the ’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.

170. 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.

171. 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 6: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL ’248 PATENT

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

173. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’248 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed and 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.

174. 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.

175. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

176. 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.

177. 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 7: INFRINGEMENT OF THE CROWELL '896 PATENT

178. Paragraphs 1–177 are incorporated by reference as if fully set forth herein.

179. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '896 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '896 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

180. 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.

181. 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.

182. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial

manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

183. 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.

184. 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

185. Paragraphs 1–184 are incorporated by reference as if fully set forth herein.

186. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '896 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

187. 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.

188. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

189. 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.

190. 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 '101 PATENT

191. Paragraphs 1–190 are incorporated by reference as if fully set forth herein.

192. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '101 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '101 Patent under at least 35 U.S.C. §§ 271(a), (b), (e), and (g).

193. 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.

194. 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.

195. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

196. 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.

197. 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 10: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '101 PATENT

198. Paragraphs 1–197 are incorporated by reference as if fully set forth herein.

199. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) provide missing information for Amgen to fully evaluate whether the '101 Patent has been or will be infringed, and in view of Defendants'

subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

200. 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.

201. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

202. 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.

203. 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 11: INFRINGEMENT OF THE CROWELL ’686 PATENT

204. Paragraphs 1–203 are incorporated by reference as if fully set forth herein.

205. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’686 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed the ’686 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

206. 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.

207. 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.

208. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

209. 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.

210. 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

211. Paragraphs 1–210 are incorporated by reference as if fully set forth herein.

212. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '686 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

213. 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.

214. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

215. 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.

216. 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

217. Paragraphs 1–216 are incorporated by reference as if fully set forth herein.

218. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '205 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '205 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

219. 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.

220. 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.

221. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants’ past imports of denosumab from India into the United States, Defendants’ importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants’ proposed denosumab biosimilar products, or Defendants’ active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the ’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.

222. 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.

223. 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

224. Paragraphs 1–223 are incorporated by reference as if fully set forth herein.

225. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’205 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed and 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.

226. 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.

227. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

228. 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.

229. 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 KANG ’178 PATENT

230. Paragraphs 1–229 are incorporated by reference as if fully set forth herein.

231. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(l)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’178 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed the ’178 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

232. 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.

233. 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.

234. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

235. 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.

236. 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 16: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '178 PATENT

237. Paragraphs 1–236 are incorporated by reference as if fully set forth herein.

238. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '178 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

239. 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.

240. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

241. 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.

242. 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 17: INFRINGEMENT OF THE ZHOU '816 PATENT

243. Paragraphs 1–242 are incorporated by reference as if fully set forth herein.

244. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '816 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient

and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '816 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

245. 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.

246. 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.

247. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '816 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '816 Patent, constitutes willful infringement.

248. 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.

249. 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 18: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ZHOU ’816 PATENT

250. Paragraphs 1–249 are incorporated by reference as if fully set forth herein.

251. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’816 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed and 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.

252. 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.

253. An actual controversy has arisen and now exists between the parties concerning whether the Defendants’ making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the ’816 Patent, will infringe one or more claims of the ’816 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

254. 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.

255. 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 19: INFRINGEMENT OF THE ZHOU ’930 PATENT

256. Paragraphs 1–255 are incorporated by reference as if fully set forth herein.

257. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to

fully evaluate whether the ’930 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, Defendants have infringed the ’930 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

258. 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 ’930 Patent, including at least claim 1.

259. 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 ’930 Patent, including at least claim 1.

260. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants’ past imports of denosumab from India into the United States, Defendants’ importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants’ proposed denosumab biosimilar products, or Defendants’ active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the ’930 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 ’930 Patent, constitutes willful infringement.

261. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the ’930 Patent. Amgen has been injured by Defendants’ infringement and is entitled to damages.

262. 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 ’930 Patent.

COUNT 20: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ZHOU ’930 PATENT

263. Paragraphs 1–262 are incorporated by reference as if fully set forth herein.

264. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’930 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the ’930 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 ’930 Patent.

265. 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.

266. 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 '930 Patent, will infringe one or more claims of the '930 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

267. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '930 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 '930 Patent.

268. 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 '930 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 '930 Patent.

COUNT 21: INFRINGEMENT OF THE ALLEN '134 PATENT

269. Paragraphs 1–268 are incorporated by reference as if fully set forth herein.

270. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '134 Patent has been or will be infringed, and in view of Defendants'

subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '134 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

271. 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.

272. 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.

273. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

274. 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.

275. 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 22: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ALLEN '134 PATENT

276. Paragraphs 1–275 are incorporated by reference as if fully set forth herein.

277. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '134 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

278. 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.

279. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

280. 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.

281. 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 23: INFRINGEMENT OF THE HUANG '972 PATENT

282. Paragraphs 1–281 are incorporated by reference as if fully set forth herein.

283. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '972 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '972 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

284. 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.

285. 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.

286. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims

of the ’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.

287. 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.

288. 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 24: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG ’972 PATENT

289. Paragraphs 1–288 are incorporated by reference as if fully set forth herein.

290. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’972 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed and 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.

291. 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.

292. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

293. 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.

294. 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 25: INFRINGEMENT OF THE HUANG '514 PATENT

295. Paragraphs 1–294 are incorporated by reference as if fully set forth herein.

296. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '514 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '514 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

297. 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.

298. 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.

299. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial

manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

300. 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.

301. 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 26: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '514 PATENT

302. Paragraphs 1–301 are incorporated by reference as if fully set forth herein.

303. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '514 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

304. 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.

305. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

306. 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.

307. 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 27: INFRINGEMENT OF THE HUANG ’085 PATENT

308. Paragraphs 1–307 are incorporated by reference as if fully set forth herein.

309. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’085 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed the ’085 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

310. 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.

311. 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.

312. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

313. 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.

314. 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 28: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '085 PATENT

315. Paragraphs 1–314 are incorporated by reference as if fully set forth herein.

316. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '085 Patent has been or will be infringed, and in view of Defendants'

subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

317. 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.

318. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

319. 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.

320. 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 29: INFRINGEMENT OF THE GUPTA ’829 PATENT

321. Paragraphs 1–320 are incorporated by reference as if fully set forth herein.

322. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’829 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed the ’829 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

323. 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.

324. 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.

325. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

326. 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.

327. 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 30: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '829 PATENT

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

329. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '829 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

330. 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.

331. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

332. 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.

333. 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 31: INFRINGEMENT OF THE GUPTA '627 PATENT

334. Paragraphs 1–333 are incorporated by reference as if fully set forth herein.

335. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '627 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '627 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

336. 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 6.

337. 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 6, and the denosumab made by that process is the essential active ingredient of Defendants’ proposed denosumab biosimilar products.

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

339. 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.

340. 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 32: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '627 PATENT

341. Paragraphs 1–340 are incorporated by reference as if fully set forth herein.

342. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '627 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the '627 Patent, including at least claim 6, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '627 Patent, or will actively induce such activities.

343. 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 6, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

344. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

345. 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.

346. 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 33: INFRINGEMENT OF THE GUPTA ’156 PATENT

347. Paragraphs 1–346 are incorporated by reference as if fully set forth herein.

348. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’156 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed the ’156 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

349. 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.

350. 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.

351. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

352. 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.

353. 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 34: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '156 PATENT

354. Paragraphs 1–353 are incorporated by reference as if fully set forth herein.

355. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '156 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

356. 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.

357. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

358. 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.

359. 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 35: INFRINGEMENT OF THE LEISKE '492 PATENT

360. Paragraphs 1–359 are incorporated by reference as if fully set forth herein.

361. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '492 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient

and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '492 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

362. 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.

363. 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.

364. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

365. 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.

366. 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 36: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE LEISKE ’492 PATENT

367. Paragraphs 1–366 are incorporated by reference as if fully set forth herein.

368. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’492 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed and 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.

369. 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.

370. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

371. 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.

372. 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 37: INFRINGEMENT OF THE LEISKE ’630 PATENT

373. Paragraphs 1–372 are incorporated by reference as if fully set forth herein.

374. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to

fully evaluate whether the ’630 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed the ’630 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

375. 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.

376. 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.

377. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants’ past imports of denosumab from India into the United States, Defendants’ importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants’ proposed denosumab biosimilar products, or Defendants’ active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the ’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.

378. 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.

379. 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 38: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE LEISKE '630 PATENT

380. Paragraphs 1–379 are incorporated by reference as if fully set forth herein.

381. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '630 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

382. 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.

383. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

384. 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.

385. 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 39: INFRINGEMENT OF THE KANG '723 PATENT

386. Paragraphs 1–385 are incorporated by reference as if fully set forth herein.

387. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '723 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '723 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

388. 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.

389. 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.

390. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims

of the ’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.

391. 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.

392. 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 40: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG ’723 PATENT

393. Paragraphs 1–392 are incorporated by reference as if fully set forth herein.

394. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’723 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed and 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.

395. 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.

396. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

397. 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.

398. 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 41: INFRINGEMENT OF THE KANG '963 PATENT

399. Paragraphs 1–398 are incorporated by reference as if fully set forth herein.

400. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '963 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '963 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

401. 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.

402. 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.

403. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial

manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

404. 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.

405. 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 42: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '963 PATENT

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

407. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '963 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

408. 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.

409. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

410. 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.

411. 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 43: INFRINGEMENT OF THE GEFROH ’397 PATENT

412. Paragraphs 1–411 are incorporated by reference as if fully set forth herein.

413. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’397 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed the ’397 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

414. 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.

415. 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.

416. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

417. 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.

418. 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 44: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GEFROH '397 PATENT

419. Paragraphs 1–418 are incorporated by reference as if fully set forth herein.

420. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '397 Patent has been or will be infringed, and in view of Defendants'

subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

421. 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.

422. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

423. 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.

424. 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 45: INFRINGEMENT OF THE GEFROH ’404 PATENT

425. Paragraphs 1–424 are incorporated by reference as if fully set forth herein.

426. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’404 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed the ’404 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

427. 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.

428. 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.

429. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

430. 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.

431. 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 46: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GEFROH '404 PATENT

432. Paragraphs 1–431 are incorporated by reference as if fully set forth herein.

433. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '404 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

434. 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.

435. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

436. 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.

437. 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 47: INFRINGEMENT OF THE HOANG '079 PATENT

438. Paragraphs 1–437 are incorporated by reference as if fully set forth herein.

439. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '079 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '079 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

440. 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.

441. 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.

442. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants’ past imports of denosumab from India into the United States, Defendants’ importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants’ proposed denosumab biosimilar products, or Defendants’ active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the ’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.

443. 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.

444. 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 48: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HOANG ’079 PATENT

445. Paragraphs 1–444 are incorporated by reference as if fully set forth herein.

446. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’079 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed and 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.

447. 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.

448. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

449. 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.

450. 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 49: INFRINGEMENT OF THE PANDE ’980 PATENT

451. Paragraphs 1–450 are incorporated by reference as if fully set forth herein.

452. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’980 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed the ’980 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

453. 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.

454. 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.

455. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

456. 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.

457. 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 50: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE PANDE '980 PATENT

458. Paragraphs 1–457 are incorporated by reference as if fully set forth herein.

459. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '980 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

460. 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.

461. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

462. 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.

463. 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 51: INFRINGEMENT OF THE PANDE '760 PATENT

464. Paragraphs 1–463 are incorporated by reference as if fully set forth herein.

465. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '760 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient

and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '760 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

466. 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.

467. 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.

468. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

469. 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.

470. 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 52: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE PANDE ’760 PATENT

471. Paragraphs 1–470 are incorporated by reference as if fully set forth herein.

472. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’760 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed and 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.

473. 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.

474. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

475. 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.

476. 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 53: INFRINGEMENT OF THE MORRIS ’236 PATENT

477. Paragraphs 1–476 are incorporated by reference as if fully set forth herein.

478. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to

fully evaluate whether the ’236 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed the ’236 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

479. 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.

480. 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.

481. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants’ past imports of denosumab from India into the United States, Defendants’ importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants’ proposed denosumab biosimilar products, or Defendants’ active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the ’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.

482. 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.

483. 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 54: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE MORRIS '236 PATENT

484. Paragraphs 1–483 are incorporated by reference as if fully set forth herein.

485. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '236 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

486. 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.

487. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

488. 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.

489. 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 55: INFRINGEMENT OF THE MORRIS '168 PATENT

490. Paragraphs 1–489 are incorporated by reference as if fully set forth herein.

491. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '168 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '168 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

492. 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.

493. 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.

494. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims

of the ’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.

495. 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.

496. 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 56: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE MORRIS ’168 PATENT

497. Paragraphs 1–496 are incorporated by reference as if fully set forth herein.

498. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’168 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed and 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.

499. 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.

500. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

501. 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.

502. 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 57: INFRINGEMENT OF THE JERUMS '493 PATENT

503. Paragraphs 1–502 are incorporated by reference as if fully set forth herein.

504. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '493 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '493 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

505. 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 '493 Patent, including at least claim 1.

506. 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 '493 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

507. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial

manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '493 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 '493 Patent, constitutes willful infringement.

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

509. 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 '493 Patent.

COUNT 58: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE JERUMS '493 PATENT

510. Paragraphs 1–509 are incorporated by reference as if fully set forth herein.

511. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '178 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more

claims of the ’493 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 ’493 Patent, or will actively induce such activities.

512. 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 ’493 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants’ proposed denosumab biosimilar products.

513. 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 ’493 Patent, will infringe one or more claims of the ’493 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

514. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the ’493 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 ’493 Patent.

515. 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 '493 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 '493 Patent.

COUNT 59: INFRINGEMENT OF THE JERUMS '447 PATENT

516. Paragraphs 1–515 are incorporated by reference as if fully set forth herein.

517. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '447 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '447 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

518. 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 '447 Patent, including at least claim 1.

519. 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 '447 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

520. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '447 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 '447 Patent, constitutes willful infringement.

521. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the '447 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

522. 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 '447 Patent.

COUNT 60: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE JERUMS '447 PATENT

523. Paragraphs 1–522 are incorporated by reference as if fully set forth herein.

524. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '447 Patent has been or will be infringed, and in view of Defendants'

subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and will infringe, either literally or under the doctrine of equivalents, one or more claims of the '447 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 '447 Patent, or will actively induce such activities.

525. 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 '447 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

526. 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 '447 Patent, will infringe one or more claims of the '447 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

527. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '447 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 ’447 Patent.

528. 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 ’447 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 ’447 Patent.

COUNT 61: INFRINGEMENT OF THE WU ’435 PATENT

529. Paragraphs 1–528 are incorporated by reference as if fully set forth herein.

530. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’435 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed the ’435 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

531. 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.

532. 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.

533. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

534. 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.

535. 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 62: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU '435 PATENT

536. Paragraphs 1–535 are incorporated by reference as if fully set forth herein.

537. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '435 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

538. 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.

539. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

540. 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.

541. 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 63: INFRINGEMENT OF THE WU '568 PATENT

542. Paragraphs 1–541 are incorporated by reference as if fully set forth herein.

543. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '568 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '568 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

544. 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.

545. 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.

546. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants’ past imports of denosumab from India into the United States, Defendants’ importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants’ proposed denosumab biosimilar products, or Defendants’ active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the ’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.

547. 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.

548. 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 64: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU ’568 PATENT

549. Paragraphs 1–548 are incorporated by reference as if fully set forth herein.

550. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’568 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed and 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.

551. 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.

552. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

553. 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.

554. 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 65: INFRINGEMENT OF THE WU ’595 PATENT

555. Paragraphs 1–554 are incorporated by reference as if fully set forth herein.

556. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’595 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed the ’595 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

557. 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.

558. 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.

559. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

560. 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.

561. 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 66: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU '595 PATENT

562. Paragraphs 1–561 are incorporated by reference as if fully set forth herein.

563. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '595 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed and 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.

564. 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.

565. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

566. 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.

567. 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 67: INFRINGEMENT OF THE WU '605 PATENT

568. Paragraphs 1–567 are incorporated by reference as if fully set forth herein.

569. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the '605 Patent has been or will be infringed, and in view of Defendants' subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient

and cursory response to Amgen's 3A List, on information and belief, the Defendants have infringed the '605 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

570. 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.

571. 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.

572. On information and belief, based on information presently available to Amgen, including information from the FDA Dashboard pertaining to Defendants' past imports of denosumab from India into the United States, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '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.

573. 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.

574. 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 68: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU ’605 PATENT

575. Paragraphs 1–574 are incorporated by reference as if fully set forth herein.

576. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and provide missing information for Amgen to fully evaluate whether the ’605 Patent has been or will be infringed, and in view of Defendants’ subsequent failure to comply with 42 U.S.C. § 262(*l*)(3)(B)(ii) and instead providing a deficient and cursory response to Amgen’s 3A List, on information and belief, the Defendants have infringed and 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.

577. 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.

578. 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)(B), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

579. 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.

580. 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.

PRAYER FOR RELIEF

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

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

B. Based on that judgment, a permanent injunction against the commercial manufacture, use, offer to sell, and sale within the United States, and importation into the United States, of Defendants' denosumab biosimilar products before the expiration of each of the Patents-In-Suit that are found infringed;

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

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

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

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

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

DEMAND FOR A JURY TRIAL

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

Dated: November 13, 2024

/s/ James L Lester

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