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

AMGEN INC. and AMGEN MANUFACTURING LIMITED LLC Plaintiffs, v. CELLTRION, INC. and CELLTRION USA, INC. Defendants.	)	Civil Action No. **COMPLAINT & DEMAND FOR A JURY TRIAL** **Redacted Version**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Amgen Inc. and Amgen Manufacturing Limited LLC (together "Amgen" or "Plaintiffs"), by and through their undersigned attorneys, for their Complaint against Defendants Celltrion, Inc. and Celltrion USA, Inc. (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the laws of the United States, Title 35 United States Code §§ 1, *et seq*., including 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("the BPCIA"), Pub. L. No. 111-48, §§ 7001–03, 124 Stat. 119, 804–21 (2010), including 42 U.S.C. § 262(*l*), and the Declaratory Judgment Act of 1934, 28 U.S.C. §§ 2201–02. 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 Defendants, to rely on the prior licensure and approval status of the innovative biologic products that the proposed biosimilar seeks to replicate. This action arises out of Defendants' submission of a Biologic License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") pursuant to 42 U.S.C. § 262(k) seeking approval to manufacture and sell biosimilar versions of Amgen's Prolia® and XGEVA® products, as well as Defendants' imminent and actual commercial manufacture, import, offer for sale, and sale of that proposed biosimilar product.

2. Prolia is prescribed to treat patients with a high risk of bone fracture in certain settings, for example 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. Amgen's scientists 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.

3. The asserted patents in this action cover denosumab (the active ingredient in Prolia and XGEVA) and methods of manufacturing denosumab and denosumab products. The asserted patents (collectively, "the Patents-In-Suit") are as follows: United States Patent Nos. 7,364,736 ("the '736 Patent"); 7,427,659 ("the '659 Patent"); 7,928,205 ("the '205 Patent"); 8,053,236 ("the '236 Patent"); 8,460,896 ("the '896 Patent"); 8,680,248 ("the '248 Patent"); 9,012,178 ("the '178 Patent"); 9,228,168 ("the '168 Patent"); 9,320,816 ("the '816 Patent"); 9,328,134 ("the '134

Patent"); 9,359,435 ("the '435 Patent"); 10,106,829 ("the '829 Patent"); 10,167,492 ("the '492 Patent"); 10,227,627 ("the '627 Patent"); 10,513,723 ("the '723 Patent"); 10,583,397 ("the '397 Patent"); 10,822,630 ("the '630 Patent"); 10,894,972 ("the '972 Patent"); 11,077,404 ("the '404 Patent"); 11,098,079 ("the '079 Patent"); 11,130,980 ("the '980 Patent"); 11,254,963 ("the '963 Patent"); 11,299,760 ("the '760 Patent"); 11,319,568 ("the '568 Patent"); 11,434,514 ("the '514 Patent"); 11,459,595 ("the '595 Patent"); 11,486,883 ("the '883 Patent"); 11,946,085 ("the '085 Patent"); and 11,952,605 ("the '605 Patent").

4. Defendants informed Amgen Inc. that they had submitted to the FDA a BLA via the abbreviated 42 U.S.C. § 262(k) pathway, referencing Amgen's Prolia and XGEVA products, and provided a copy of that BLA to Amgen Inc. on [redacted] Following targeted requests by Amgen Inc. for [redacted] and for other information regarding its manufacturing processes, Defendants provided Amgen Inc. [redacted], which purports to show that the [redacted]. Defendants refused to provide any of the other requested information. Since receiving the BLA, Amgen Inc. has diligently evaluated the BLA, and has participated in the pre-litigation exchange contemplated under the BPCIA to the best of its ability. Amgen Inc.'s efforts, however, have been frustrated by Defendants' initial and continued failure to comply with subsection (*l*)(2)(A) of the BPCIA, which states that a biosimilar applicant "shall provide" to the reference product sponsor: "[1] a copy of the application submitted to the Secretary under subsection (k), *and* [2] such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A) (annotations and emphasis added). Defendants provided what appears to be the first required category of information—a copy of their BLA—but failed to provide to Amgen anything

from the second required category. Despite Amgen Inc.'s multiple correspondences identifying specific missing information in this second category, which Amgen Inc. needed to fully evaluate whether Defendants would infringe certain patents, Defendants refused—and continue to refuse—to produce such information.

5. On [redacted], pursuant to § 262(*l*)(3)(A), Amgen Inc. provided to Defendants a list of thirty (30) patents that it believed could be reasonably asserted against Defendants, despite Defendants' above-mentioned failure to comply with § 262(*l*)(2)(A).

6. As alleged herein, Defendants' failure to comply with § 262(*l*)(2)(A) authorizes Amgen Inc. to file a suit for a declaration of infringement. 42 U.S.C. § 262(*l*)(9)(C); *see also Sandoz v. Amgen*, 137 S. Ct. 1664, 1667-68 (2017) ("§ 262(*l*)(9)(C) provides a remedy for an applicant's failure to turn over its application and manufacturing information" by authorizing the sponsor "to bring an immediate declaratory judgment action for artificial infringement"). Defendants have infringed the Patents-In-Suit under 35 U.S.C. § 271(e)(2)(C) by 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 in the United States, or the importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-In-Suit, including the '736 Patent.

7. As further alleged herein, on information and belief, Defendants have infringed and will 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

8. 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.

9. 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.

10. 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.

11. 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 Defendants' actual and intended infringement of the Patents-In-Suit.

B. Defendants

12. Celltrion Inc. is a corporation organized and existing under the laws of the Republic of Korea, with its principal place of business at 23, Academy-ro, Yeonsu-gu, Incheon 22014, Republic of Korea.

13. Celltrion USA, Inc. ("Celltrion USA") is a corporation organized and existing under the laws of Delaware, with its principal place of business at One Evertrust Plaza Suite 1207, Jersey City, New Jersey 07302. On information and belief, Celltrion USA holds itself out as a subsidiary of Celltrion Inc. For example, Celltrion USA maintains a public website where it states that it is the U.S. subsidiary of Celltrion Healthcare.[1] On information and belief, Celltrion Healthcare Inc. merged with Celltrion Inc. on December 28, 2023.[2]

14. On information and belief, Celltrion Inc. and Celltrion USA are related corporate entities that act as agents of one another and/or act in concert.

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

16. On information and belief, Celltrion Inc., in concert with Celltrion USA, intends to develop, manufacture, import, market, distribute, offer for sale, and/or sell in New Jersey and

[1] *See* https://www.celltrionusa.com/#About (last accessed May 28, 2024).

[2] *See* https://www.koreatimes.co.kr/www/tech/2024/05/129_365966.html (last accessed May 28, 2024); https://www.celltrion.com/en-us/investment/ir/merger-info (last accessed May 28, 2024).

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

17. On information and belief, Celltrion USA will [redacted].

JURISDICTION AND VENUE

A. Subject-Matter Jurisdiction

18. 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.

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

B. Personal Jurisdiction and Venue

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

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

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

C. Celltrion Inc.

23. Celltrion Inc. is subject to personal jurisdiction in New Jersey because, among other reasons, Celltrion Inc. itself, and through its affiliate Celltrion USA, has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court.

24. On information and belief, Celltrion Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100984278.

25. On information and belief, Celltrion Inc. develops, manufactures, and imports generic and biosimilar drugs throughout the United States, including in the State of New Jersey; and [redacted] to develop, manufacture, seek approval for, import, and sell FDA approved biopharmaceutical drugs, which are being marketed, distributed, and sold in New Jersey and throughout the United States. On information and belief, Celltrion Inc. was and is actively involved with planning [redacted] new products, communicating with FDA regarding the Defendants' proposed denosumab biosimilar products, and preparing and submitting Defendants' BLA.

26. This Court has personal jurisdiction over Celltrion Inc. by virtue of the fact that Celltrion Inc. took the significant step to prepare and file a BLA seeking approval from the FDA to engage in [redacted], of Defendants' proposed denosumab biosimilar products in New Jersey and throughout the United States, which directly gives rise to Amgen's claims of patent infringement.

27. On information and belief, Celltrion Inc. intends to participate in the [redacted] of Defendants' proposed denosumab biosimilar products for sale in New Jersey and in the United States upon FDA approval. On information and belief, [redacted] On information and belief, Celltrion Inc. will accordingly benefit commercially and be financially compensated for [redacted] of Defendants' proposed denosumab biosimilar products in New Jersey and in the United States.

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

29. Celltrion Inc. consented to or did not contest jurisdiction and availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in this District, for example, in *Genentech, Inc. et al v. Celltrion, Inc. et al*, No. 18-00574 (D.N.J. Jan. 12, 2018).

30. Venue is proper in this Court as to Celltrion Inc. because it is a foreign entity that may be sued in any judicial district, including in the District of New Jersey. 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

D. Celltrion USA

31. On information and belief, Celltrion USA markets, distributes, offers for sale, and sells biopharmaceuticals for sale and use throughout the United States, including in New Jersey and this federal judicial District.

32. On information and belief, Celltrion USA [redacted] Defendants' proposed denosumab biosimilar products in the State of New Jersey and throughout the United States, which directly gives rise to Amgen's claims of patent infringement.

33. Celltrion USA is also subject to personal jurisdiction in New Jersey because, among other things, Celltrion USA has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Celltrion USA imports, markets, distributes, offers to sell, and/or sells generic and biosimilar drugs throughout the United States, including in the State of New Jersey, and therefore transacts or intends to transact business within the State of New Jersey related to Amgen's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

34. On information and belief, if Defendants' BLA is approved, Celltrion USA will import, market, distribute, offer for sale, and/or sell Defendants' proposed denosumab biosimilar products within the United States, including in New Jersey, consistent with Celltrion USA's practices for the marketing and distribution of other biopharmaceutical products. On information

and belief, Celltrion USA regularly conducts business in New Jersey, and its practices with other biopharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. On information and belief, Celltrion USA's pharmaceutical products are used and consumed within and throughout the United States, including in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the Patents-In-Suit in the event that one or more of Defendants' proposed denosumab biosimilar products are approved before the Patents-In-Suit expire.

35. On information and belief, Celltrion USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450347284.

36. Venue is proper with respect to Celltrion USA pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Celltrion USA has systematic and continuous contacts with New Jersey; a regular and established place of business in New Jersey; has its headquarters and principal place of business at One Evertrust Plaza, Suite 1207, Jersey City, New Jersey 07302; and, in particular, Celltrion USA has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(C) by preparing and submitting its BLA for a proposed denosumab biosimilar in and from New Jersey.

THE PROLIA AND XGEVA DRUG PRODUCTS

A. Bone Metabolism and RANKL

37. Human bones are engaged in 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.

38. A variety of tissues throughout 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 is able to bind to another protein—its ligand—called RANK ligand ("RANKL").[3] When RANKL binds to RANK on the surface of osteoclast precursors, the interaction stimulates the precursor cell to form into a mature osteoclast cell. Mature osteoclasts carry out bone resorption, *i.e*. the breakdown of bone.

39. 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

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

41. 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.

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

C. Amgen's Invention of Prolia and XGEVA

42. Amgen Inc. 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 (or OPGL) and bone resorption. Amgen Inc. 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.

43. An Amgen Inc. 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.

44. 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

45. 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. Defendants intend to introduce proposed biosimilar versions of both products.[4]

46. 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. 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 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.

47. Based on the results of extensive clinical testing, Amgen Inc. filed Biologic BLA No. 125320 in December 2008. In June 2010, the FDA first approved Prolia (active ingredient denosumab), 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 and it remains the only RANKL-inhibiting biologic that is FDA approved today.

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[4] *See* https://www.jdsupra.com/legalnews/denosumab-biosimilar-updates-4353587/ (last accessed May 28, 2024).

48. Amgen Inc.'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) 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).

49. Amgen Inc.'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

50. Amgen Inc.'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 Inc.'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 Inc. obtained patent protection over many of these advancements, which are reflected in the Patents-in-Suit.

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

51. As alleged herein, the '736 Patent was issued on April 29, 2008. The '736 Patent was identified in Amgen Inc.'s patent marking for Prolia and XGEVA before the filing of Defendants' BLA for their proposed denosumab biosimilar products. At least as early as of May 2023, the '736, '659, '205, '178, '168, '816, '134, '435, '492, '723, '397, '630, '972, '404, '079, '980, '963,'760, and the '514 Patents were identified on FDA's publication entitled *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluation* ("the Purple Book").[5] Thus, Defendants had constructive notice of and were aware of at least the '736, '659, '205, '178, '168, '816, '134, '435, '492, '723, '397, '630, '972, '404, '079, '980, '963,'760, and the '514 Patents before the filing of their BLA. *See* 35 U.S.C. § 287.

52. On information and belief, Defendants, by the nature of their being involved in the business of developing biosimilars, monitor the Purple Book, 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 Defendants' proposed denosumab biosimilar products before the filing of Defendants' BLA.

[5] *See* https://web.archive.org/web/20230524143320/https://purplebooksearch.fda.gov/patent-list (last accessed May 28, 2024).

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

G. Defendants' Proposed Biosimilar Product

54. On information and belief, Celltrion Inc., [redacted], submitted its BLA with 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.

55. The BLA that Defendants provided to Amgen Inc. references and relies on the approval and licensure of Amgen's Prolia and XGEVA products in BLA No. 125320 in support of Defendants' request for FDA approval. Amgen Inc. is the holder of BLA No. 125320.

56. Based on the BLA that Defendants provided to Amgen Inc., the active ingredient in Defendants' proposed denosumab biosimilar products is [redacted]. Based on the BLA that Defendants provided to Amgen Inc., [redacted].

57. Based on the BLA that Defendants provided to Amgen Inc., [redacted].

58. On information and belief, Celltrion Inc., [redacted], Defendants' proposed denosumab biosimilar products, which were produced by the manufacturing processes partially described in the BLA that Defendants provided to Amgen Inc.

59. On information and belief, Celltrion Inc. has imported its denosumab biosimilar products into the United States. At least the FDA Imports Entry Data Search contains an entry directed to Shipment ID: BUP-1674659-9/11/1, which arrived in the United States on June 7, 2020. That shipment contains materials manufactured by Celltrion Inc that are "Drugs and Biologics" that bear the description "DENOSUMAB, MONOCLONAL ANTIBODIES."

60. On information and belief, in a race against other pharmaceutical companies to take a share of the market of Amgen's Prolia and XGEVA products, Defendants are moving swiftly to obtain FDA approval of their proposed denosumab biosimilar products for all approved indications for Prolia and XGEVA.[6] Defendants are seeking interchangeability status for their proposed denosumab biosimilar products,[7] which would allow the biosimilar to be automatically substituted by most pharmacies without prior physician approval.

H. Defendants' Failure to Comply with the BPCIA

61. 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 (k) pathway") permits a biosimilar applicant, here Celltrion Inc., to rely on the prior clinical

[6] *See* https://www.koreabiomed.com/news/articleView.html?idxno=22679 (last accessed May 28, 2024); https://www.koreatimes.co.kr/www/nation/2024/05/129_372692.html (last accessed May 28, 2024).

[7] *See* https://www.koreabiomed.com/news/articleView.html?idxno=22679 (last accessed May 28, 2024).

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.

62. 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—

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

42 U.S.C. § 262(*l*)(2) (emphasis added).

63. If a subsection (k) applicant (here, Celltrion Inc.) fails to comply with the requirements of (*l*)(2)(A), the reference product sponsor (here, Amgen Inc.) is permitted to file an action for declaratory judgment of patent infringement, validity, or enforceability:

> If a subsection (k) applicant fails to provide the application *and information required under paragraph (2)(A)*, 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 that claims the biological product or a use of the biological product.

42 U.S.C. § 262(*l*)(9)(C) (emphasis added). Defendants have failed to comply with § 262(*l*)(2)(A).

64. On [redacted], Defendants provided Amgen Inc. with what they described as a copy of the BLA that they had purportedly submitted to the FDA. Defendants did not accompany their production of their BLA with "other information that describes the process or processes used to manufacture the biological product," as required by § 262(*l*)(2)(A).

65. After carefully reviewing the BLA provided by Defendants, Amgen Inc. determined that information on certain manufacturing processes being used by Defendants to produce their

proposed biosimilar version of denosumab, but which was not found in Defendants' BLA, was required to fully evaluate whether Defendants would infringe certain of Amgen's patents. On [redacted], Amgen Inc. informed Defendants that this information was missing from Defendants' production. In a response on [redacted], Defendants refused to provide any of the missing information, stated vaguely that they "*may* be willing to provide more information," but indicated that this would preferably occur only following the receipt of Amgen's patent list under 42 U.S.C. § 262(*l*)(3)(A), despite Defendants' failure to comply with § 262(*l*)(2)(A).

66. On [redacted], Amgen Inc. wrote to Defendants again identifying other manufacturing and process information required by § 262(*l*)(2)(A). On [redacted], Defendants responded by continuing to refuse to provide the required information.

67. On [redacted], pursuant to § 262(*l*)(3)(A), Amgen Inc. provided Defendants a list of patents that could reasonably be asserted if Defendants' proposed denosumab biosimilar products that are the subject of the BLA Defendants provided on [redacted], were made, used, offered for sale, sold, or imported into the United States without a license from Amgen. In this letter, Amgen Inc. also objected to Defendants' failure to satisfy the requirements of § 262(*l*)(2)(A). All of the Patents-in-Suit were identified in the [redacted] letter. [redacted].

68. [redacted].

69. Despite Defendants' prior communications regarding a potential supplementation of its document production upon receipt of Amgen's patent list, Defendants have not provided any "other information that describes the process or processes used to manufacture the biological product" that is the subject of Defendants' BLA, as required by § 262(*l*)(2)(A).

70. The BPCIA requires a biosimilar applicant to provide to the reference product sponsor both "the application submitted to the Secretary under subsection (k)" (*i.e.*, the BLA), "*and* such other information that describes the process or processes used to manufacture the biological product" that is the subject of the BLA. 42 U.S.C. § 262(*l*)(2)(A) (emphasis added). Defendants' refusal to provide "such other information that describes the process or processes used to manufacture the biological product," even after multiple attempts by Amgen to obtain the information, constitutes a willful failure by Defendants to comply with § 262(*l*)(2)(A), as well as an attempt by Defendants to improperly hinder Amgen's ability to fully determine whether Defendants were or were not infringing its patents.

I. [redacted]

71. The FDA has stated publicly that the agency's goal is to act on the majority of subsection (k) applications within 10 months of an application's 60-day filing date.[8] This 10-month date is sometimes called a "BsUFA III date," which is an abbreviation for Biosimilar User Fee Act III date. [redacted]

[8] *See* https://www.fda.gov/media/152279/download?attachment (last accessed May 28, 2024) ("Review performance goals: . . . Review and act on 90 percent of original 351(k) BLA submissions within 10 months of the 60 day filing date."). *See also* https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027 (last accessed May 28, 2024).

[redacted].

72. [redacted].

73. On information and belief, in a race against other pharmaceutical companies to take a share of the market of Amgen's Prolia and XGEVA products, Defendants are moving swiftly to obtain FDA approval of their proposed denosumab biosimilar products for all approved indications for Prolia and XGEVA.[9]

74. Therefore, on information and belief, Defendants intend to and will immediately and imminently engage in the use, offer for sale, and sale in the United States, and importation into the United States, of one or more of their proposed denosumab biosimilar products before the expiration of the Patents-in Suit, including the '736 Patent, [redacted].

[9] *See* https://www.koreabiomed.com/news/articleView.html?idxno=22679 (last accessed May 28, 2024); https://www.koreatimes.co.kr/www/nation/2024/05/129_372692.html (last accessed May 28, 2024).

THE PATENTS-IN-SUIT

A. The Boyle '736 Patent

75. 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 and pharmaceutical compositions thereof.

76. The '736 Patent is assigned to Amgen Inc. AML has a license to the '736 Patent that is exclusive with respect to denosumab.

77. The '736 Patent is and has been identified on the label for XGEVA and Prolia.[10] Additionally, the '736 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants' proposed denosumab biosimilar products.

B. The Shukla '659 Patent

78. The USPTO duly and legally issued the '659 Patent, titled "Process for Purifying Proteins in a Hydrophobic Interaction Chromatography Flow-Through Fraction," on September 23, 2008. The '659 Patent as a general matter discloses and claims methods of purifying proteins by using a particular hydrophobic adsorbent that binds to non-target contaminants and allows the target proteins to flow-through and be collected.

79. The '659 Patent is assigned to Amgen Inc. AML has a license to the '659 Patent that is exclusive with respect to denosumab.

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

80. The ’659 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

C. The Dillon ’205 Patent

81. 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.

82. The ’205 Patent is assigned to Amgen Inc. AML has a license to the ’205 Patent that is exclusive with respect to denosumab.

83. The ’205 Patent was identified in the letter Amgen sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

D. The Morris ’236 and ’168 Patents

84. 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.

85. The ’236 Patent is assigned to Amgen Inc. AML has a license to the ’236 Patent that is exclusive with respect to denosumab.

86. The ’236 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

87. 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.

88. The ’168 Patent is assigned to Amgen Inc. AML has a license to the ’168 Patent that is exclusive with respect to denosumab.

89. The ’168 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

E. <u>The Crowell ’896 and ’248 Patents</u>

90. 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.

91. The ’896 Patent is assigned to Amgen Inc. AML has a license to the ’896 Patent that is exclusive with respect to denosumab.

92. The ’896 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably

be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants' proposed denosumab biosimilar products.

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 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 '248 Patent is assigned to Amgen Inc. AML has a license to the '248 Patent that is exclusive with respect to denosumab.

95. The '248 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants' proposed denosumab biosimilar products.

F. <u>The Kang '178 Patent</u>

96. 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.

97. The '178 Patent is assigned to Amgen Inc. AML has a license to the '178 Patent that is exclusive with respect to denosumab.

98. The '178 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably

be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants' proposed denosumab biosimilar products.

G. The Zhou '816 Patent

99. 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.

100. The '816 Patent is assigned to Amgen Inc. AML has a license to the '816 Patent that is exclusive with respect to denosumab.

101. The '816 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants' proposed denosumab biosimilar products.

H. The Allen '134 Patent

102. 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.

103. The '134 Patent is assigned to Amgen Inc. AML has a license to the '134 Patent that is exclusive with respect to denosumab.

104. The '134 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably

be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants' proposed denosumab biosimilar products.

I. The Wu '435 Patent

105. 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.

106. The '435 Patent is assigned to Amgen Inc. AML has a license to the '435 Patent that is exclusive with respect to denosumab.

107. The '435 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' one or more of proposed denosumab biosimilar products.

J. The Gupta '829 and '627 Patents

108. 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.

109. The '829 Patent is assigned to Amgen Inc. AML has a license to the '829 Patent that is exclusive with respect to denosumab.

110. The '829 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably

be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants' proposed denosumab biosimilar products.

111. 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.

112. The '627 Patent is assigned to Amgen Inc. AML has a license to the '627 Patent that is exclusive with respect to denosumab.

113. The '627 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants' proposed denosumab biosimilar products.

K. <u>The Leiske '492 and '630 Patents</u>

114. 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.

115. The '492 Patent is assigned to Amgen Inc. AML has a license to the '492 Patent that is exclusive with respect to denosumab.

116. The '492 Patent was identified in the letter Amgen sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably

be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants' proposed denosumab biosimilar products.

117. 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.

118. The '630 Patent is assigned to Amgen Inc. AML has a license to the '630 Patent that is exclusive with respect to denosumab.

119. The '630 Patent was identified in the letter Amgen sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants' proposed denosumab biosimilar products.

L. <u>The Kang '723 and '963 Patents</u>

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 '723 Patent is assigned to Amgen Inc. AML has a license to the '723 Patent that is exclusive with respect to denosumab.

122. The '723 Patent was identified in the letter Amgen sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants' proposed denosumab biosimilar products.

123. The USPTO duly and legally issued the ’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.

124. The ’963 Patent is assigned to Amgen Inc. AML has a license to the ’963 Patent that is exclusive with respect to denosumab.

125. The ’963 Patent was identified in the letter Amgen sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

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

126. 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.

127. The ’397 Patent is assigned to Amgen Inc. AML has a license to the ’397 Patent that is exclusive with respect to denosumab.

128. The ’397 Patent was identified in the letter Amgen sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

129. 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.

130. The ’404 Patent is assigned to Amgen Inc. AML has a license to the ’404 Patent that is exclusive with respect to denosumab.

131. The ’404 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

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

132. 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 as a general matter discloses and claims methods of influencing the high mannose glycoform content of a recombinant protein during a mammalian cell culture by adding mannose sugars after establishing the cell culture and manipulating the mannose to total hexose ratio in the cell culture and feed media.

133. The ’972 Patent is assigned to Amgen Inc. AML has a license to the ’972 Patent that is exclusive with respect to denosumab.

134. The ’972 Patent was identified in the letter Amgen sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

135. 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 as a general

matter discloses and claims methods of influencing the high mannose glycoform content of denosumab during a mammalian cell culture by adding mannose sugars during a production phase and manipulating the mannose to total hexose ratio in the cell culture and feed media.

136. The ’514 Patent is assigned to Amgen Inc. AML has a license to the ’514 Patent that is exclusive with respect to denosumab.

137. The ’514 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

138. 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.

139. The ’085 Patent is assigned to Amgen Inc. AML has a license to the ’085 Patent that is exclusive with respect to denosumab.

140. The ’085 Patent was identified in the letter Amgen sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

O. The Hoang '079 Patent

141. 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.

142. The '079 Patent is assigned to Amgen Inc. AML has a license to the '079 Patent that is exclusive with respect to denosumab.

143. The '079 Patent was identified in the letter Amgen sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants' proposed denosumab biosimilar products.

P. The Pande '980 and '760 Patents

144. 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.

145. The '980 Patent is assigned to Amgen Inc. AML has a license to the '980 Patent that is exclusive with respect to denosumab.

146. The '980 Patent was identified in the letter Amgen sent to Defendants on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants' proposed denosumab biosimilar products.

147. 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.

148. The ’760 Patent is assigned to Amgen Inc. AML has a license to the ’760 Patent that is exclusive with respect to denosumab.

149. The ’760 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

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

150. 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.

151. The ’568 Patent is assigned to Amgen Inc. AML has a license to the ’568 Patent that is exclusive with respect to denosumab.

152. The ’568 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

153. 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.

154. The ’595 Patent is assigned to Amgen Inc. AML has a license to the ’595 Patent that is exclusive with respect to denosumab.

155. The ’595 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

156. 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.

157. The ’605 Patent is assigned to Amgen Inc. AML has a license to the ’605 Patent that is exclusive with respect to denosumab.

158. The ’605 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

R. The Hewig ’883 Patent

159. The USPTO duly and legally issued the ’883 Patent, titled “Method for Using Light Scattering in Real Time to Directly Monitor and Control Impurity Removal in Purification Processes,” on November 1, 2022. The ’883 Patent as a general matter discloses and claims methods for determining a stop collection point for ion exchange chromatography by using light scattering and UV.

160. The ’883 Patent is assigned to Amgen Inc. AML has a license to the ’883 Patent that is exclusive with respect to denosumab.

161. The ’883 Patent was identified in the letter Amgen sent to Defendants on [redacted], as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Defendants engaged in the making, using, offering to sell, selling, or importing into the United States of one or more of Defendants’ proposed denosumab biosimilar products.

COUNT 1: INFRINGEMENT OF THE BOYLE ’736 PATENT

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

163. On information and belief, Defendants have infringed the ’736 Patent under at least 35 U.S.C. §§ 271(a), (b), and (e).

164. The submission of Defendants’ BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

165. 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 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.

166. 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.

167. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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

168. Paragraphs 1-167 are incorporated by reference as if fully set forth herein.

169. On information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '736 Patent, including at least claim 3, under at least 35 U.S.C. §§ 271(a) and (b). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '736 Patent, or will actively induce thereof, [redacted]

170. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '736 Patent, will infringe one or more claims of the '736 Patent. A judicial determination of infringement is necessary and appropriate to

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

171. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '736 Patent.

172. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the '736 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '736 Patent.

COUNT 3: INFRINGEMENT OF THE SHUKLA '659 PATENT

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

174. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '659 Patent has been or will be infringed, on information and belief, Defendants have infringed the '659 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

175. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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 '659 Patent, including at least claim 1.

176. On information and belief, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '659 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

177. 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 Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '659 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 '659 Patent, constitutes willful infringement.

178. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the '659 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

179. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 '659 Patent.

COUNT 4: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE SHUKLA '659 PATENT

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

181. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '659 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '659 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 make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '659 Patent, or will actively induce thereof, [redacted]

182. On information and belief, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '659 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

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

importing into the United States their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '659 Patent, will infringe one or more claims of the '659 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

184. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '659 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '659 Patent.

185. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the '659 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '659 Patent.

COUNT 5: INFRINGEMENT OF THE DILLON '205 PATENT

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

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

188. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

189. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

190. 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 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.

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

192. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 6: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE DILLON '205 PATENT

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

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

195. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no

subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

196. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '205 Patent, will infringe one or more claims of the '205 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

197. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '205 Patent.

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

COUNT 7: INFRINGEMENT OF THE MORRIS '236 PATENT

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

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

201. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

202. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

203. 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 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.

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

205. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 8: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE MORRIS '236 PATENT

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

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

208. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

209. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '236 Patent, will infringe one or more claims of the '236 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

210. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '236 Patent.

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

States, Defendants' proposed denosumab biosimilar products before the expiration of the '236 Patent.

COUNT 9: INFRINGEMENT OF THE CROWELL '896 PATENT

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

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

214. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

215. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

216. 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 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.

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

218. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 10: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '896 PATENT

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

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

proposed denosumab biosimilar products before expiration of the '896 Patent, or will actively induce thereof, [redacted]

221. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

222. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '896 Patent, will infringe one or more claims of the '896 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

223. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '896 Patent.

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

COUNT 11: INFRINGEMENT OF THE CROWELL '248 PATENT

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

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

227. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

228. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '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.

229. 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 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.

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

231. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 12: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '248 PATENT

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

233. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '248 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '248 Patent, including at least claim 1, under 35 U.S.C. §§ 271(a) or (b). On

information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '248 Patent, or will actively induce thereof, [redacted]

234. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '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.

235. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '248 Patent, will infringe one or more claims of the '248 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

236. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '248 Patent.

237. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the '248 Patent. Amgen does

not have an adequate remedy at law and seeks injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '248 Patent.

COUNT 13: INFRINGEMENT OF THE KANG '178 PATENT

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

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

240. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

241. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

242. 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 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.

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

244. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 14: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '178 PATENT

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

246. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '178 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '178 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b)

and (g). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '178 Patent, or will actively induce thereof, [redacted]

247. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

248. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '178 Patent, will infringe one or more claims of the '178 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

249. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '178 Patent.

250. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the '178 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '178 Patent.

COUNT 15: INFRINGEMENT OF THE MORRIS '168 PATENT

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

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

253. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

254. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

255. 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 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.

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

257. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 16: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE MORRIS '168 PATENT

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

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

260. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

261. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '168 Patent, will infringe one or more claims of the '168 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA

and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

262. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '168 Patent.

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

COUNT 17: INFRINGEMENT OF THE ZHOU '816 PATENT

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

265. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '816 Patent has been or will be infringed, on information and belief, Defendants have infringed the '816 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

266. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

267. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

268. 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 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.

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

270. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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

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

272. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '816 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '816 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '816 Patent, or will actively induce thereof, [redacted]

273. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

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

importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '816 Patent, will infringe one or more claims of the '816 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

275. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '816 Patent.

276. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the '816 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '816 Patent.

COUNT 19: INFRINGEMENT OF THE ALLEN '134 PATENT

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

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

279. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

280. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

281. 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 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.

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

283. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 20: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ALLEN '134 PATENT

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

285. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '134 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '134 Patent, including at least claim 35, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '134 Patent, or will actively induce thereof, [redacted]

286. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no

subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

287. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '134 Patent, will infringe one or more claims of the '134 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

288. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '134 Patent.

289. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the '134 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '134 Patent.

COUNT 21: INFRINGEMENT OF THE WU '435 PATENT

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

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

292. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

293. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

294. 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 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.

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

296. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 22: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU '435 PATENT

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

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

299. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

300. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '435 Patent, will infringe one or more claims of the '435 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

301. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '435 Patent.

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

States, Defendants' proposed denosumab biosimilar products before the expiration of the '435 Patent.

COUNT 23: INFRINGEMENT OF THE GUPTA '829 PATENT

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

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

305. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

306. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

307. 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 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.

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

309. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 24: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '829 PATENT

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

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

proposed denosumab biosimilar products before expiration of the '829 Patent, or will actively induce thereof, [redacted]

312. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

313. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '829 Patent, will infringe one or more claims of the '829 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

314. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '829 Patent.

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

COUNT 25: INFRINGEMENT OF THE GUPTA '627 PATENT

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

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

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

319. On information and belief, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '627 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products. On information and belief, there is no

subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

320. 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 Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '627 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '627 Patent, constitutes willful infringement.

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

322. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 26: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '627 PATENT

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

324. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '627 Patent has been or will be infringed, on information

and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '627 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '627 Patent, or will actively induce thereof, [redacted]

325. On information and belief, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '627 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

326. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '627 Patent, will infringe one or more claims of the '627 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

327. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '627 Patent.

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

COUNT 27: INFRINGEMENT OF THE LEISKE '492 PATENT

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

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

331. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

332. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

333. 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 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.

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

335. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 28: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE LEISKE '492 PATENT

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

337. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '492 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '492 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '492 Patent, or will actively induce thereof, [redacted]

338. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

339. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '492 Patent, will infringe one or more

claims of the ’492 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

340. 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, Defendants’ proposed denosumab biosimilar products before the expiration of the ’492 Patent.

341. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the ’492 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants’ proposed denosumab biosimilar products before the expiration of the ’492 Patent.

COUNT 29: INFRINGEMENT OF THE LEISKE ’630 PATENT

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

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

344. On information and belief, the submission of Defendants’ BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United

States, and/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.

345. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

346. 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 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.

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

348. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 30: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE LEISKE '630 PATENT

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

350. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '630 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '630 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '630 Patent, or will actively induce thereof, [redacted]

351. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

352. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '630 Patent, will infringe one or more claims of the '630 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

353. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '630 Patent.

354. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the '630 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '630 Patent.

COUNT 31: INFRINGEMENT OF THE KANG '723 PATENT

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

356. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '723 Patent has been or will be infringed, on information

and belief, Defendants have infringed the '723 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

357. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

358. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

359. 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 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.

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

361. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 32: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '723 PATENT

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

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

364. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

365. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '723 Patent, will infringe one or more claims of the '723 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

366. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '723 Patent.

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

COUNT 33: INFRINGEMENT OF THE KANG '963 PATENT

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

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

370. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

371. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

372. 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 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.

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

374. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 34: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '963 PATENT

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

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

[redacted]

377. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

378. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '963 Patent, will infringe one or more claims of the '963 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

379. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '963 Patent.

380. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the '963 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief prohibiting Defendants from

making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '963 Patent.

COUNT 35: INFRINGEMENT OF THE GEFROH '397 PATENT

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

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

383. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

384. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

385. 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 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.

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

387. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 36: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GEFROH '397 PATENT

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

389. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '397 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '397 Patent, including at least claim 13, under at least 35 U.S.C. §§ 271(b)

and (g). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '397 Patent, or will actively induce thereof, [redacted]

390. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

391. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '397 Patent, will infringe one or more claims of the '397 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

392. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '397 Patent.

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

COUNT 37: INFRINGEMENT OF THE GEFROH '404 PATENT

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

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

396. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

397. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

398. 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 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.

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

400. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 38: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GEFROH '404 PATENT

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

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

403. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

404. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '404 Patent, will infringe one or more claims of the '404 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA

and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

405. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '404 Patent.

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

COUNT 39: INFRINGEMENT OF THE HUANG '972 PATENT

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

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

409. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

410. On information and belief, Defendants’ manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

411. 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 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.

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

413. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 40: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '972 PATENT

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

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

416. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

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

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

418. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '972 Patent.

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

COUNT 41: INFRINGEMENT OF THE HUANG '514 PATENT

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

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

422. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

423. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

424. 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 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.

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

426. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 42: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '514 PATENT

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

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

429. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no

subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

430. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '514 Patent, will infringe one or more claims of the '514 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

431. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '514 Patent.

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

COUNT 43: INFRINGEMENT OF THE HUANG '085 PATENT

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

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

435. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

436. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

437. 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 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.

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

439. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 44: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '085 PATENT

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

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

442. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

443. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '085 Patent, will infringe one or more claims of the '085 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

444. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '085 Patent.

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

States, Defendants' proposed denosumab biosimilar products before the expiration of the '085 Patent.

COUNT 45: INFRINGEMENT OF THE HOANG '079 PATENT

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

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

448. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

449. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

450. 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 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.

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

452. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 46: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HOANG '079 PATENT

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

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

proposed denosumab biosimilar products before expiration of the '079 Patent, or will actively induce thereof, [redacted]

455. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

456. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '079 Patent, will infringe one or more claims of the '079 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

457. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '079 Patent.

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

COUNT 47: INFRINGEMENT OF THE PANDE '980 PATENT

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

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

461. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

462. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no

subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

463. 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 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.

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

465. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 48: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE PANDE '980 PATENT

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

467. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '980 Patent has been or will be infringed, on information

and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '980 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '980 Patent, or will actively induce thereof, [redacted]

468. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

469. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '980 Patent, will infringe one or more claims of the '980 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

470. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '980 Patent.

471. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the '980 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '980 Patent.

COUNT 49: INFRINGEMENT OF THE PANDE '760 PATENT

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

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

474. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

475. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

476. 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 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.

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

478. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 50: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE PANDE '760 PATENT

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

480. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '760 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '760 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '760 Patent, or will actively induce thereof, [redacted]

481. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

482. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '760 Patent, will infringe one or more

claims of the ’760 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

483. 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, Defendants’ proposed denosumab biosimilar products before the expiration of the ’760 Patent.

484. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the ’760 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants’ proposed denosumab biosimilar products before the expiration of the ’760 Patent.

COUNT 51: INFRINGEMENT OF THE WU ’568 PATENT

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

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

487. On information and belief, the submission of Defendants’ BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United

States, and/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.

488. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

489. 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 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.

490. 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.

491. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 52: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU '568 PATENT

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

493. 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 their refusal to provide missing information for Amgen to fully evaluate whether the '568 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '568 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '568 Patent, or will actively induce thereof, [redacted]

494. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

495. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '568 Patent, will infringe one or more claims of the '568 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

496. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '568 Patent.

497. 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 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '568 Patent.

COUNT 53: INFRINGEMENT OF THE WU '595 PATENT

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

499. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '595 Patent has been or will be infringed, on information

and belief, Defendants have infringed the '595 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

500. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

501. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

502. 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 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.

503. 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.

504. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 54: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU '595 PATENT

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

506. 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 their refusal to provide missing information for Amgen to fully evaluate whether the '595 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '595 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '595 Patent, or will actively induce thereof, [redacted]

507. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

508. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '595 Patent, will infringe one or more claims of the '595 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

509. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '595 Patent.

510. 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 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '595 Patent.

COUNT 55: INFRINGEMENT OF THE WU '605 PATENT

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

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

513. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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.

514. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

515. 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 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.

516. 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.

517. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 56: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU '605 PATENT

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

519. 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 their refusal to provide missing information for Amgen to fully evaluate whether the '605 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '605 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '605 Patent, or will actively induce thereof, [redacted]

[redacted]

520. On information and belief, Defendants' manufacturing process infringes, 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. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

521. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '605 Patent, will infringe one or more claims of the '605 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

522. 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, Defendants' proposed denosumab biosimilar products before the expiration of the '605 Patent.

523. 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 prohibiting Defendants from

making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '605 Patent.

COUNT 57: INFRINGEMENT OF THE HEWIG '883 PATENT

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

525. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide missing information for Amgen to fully evaluate whether the '883 Patent has been or will be infringed, on information and belief, Defendants have infringed the '883 Patent under at least 35 U.S.C. §§ 271(b), (e), and (g).

526. On information and belief, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/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 '883 Patent, including at least claim 8.

527. On information and belief, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '883 Patent, including at least claim 8, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

528. 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 Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '883 Patent, including at least claim 8. 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 '883 Patent, constitutes willful infringement.

529. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the '883 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

530. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, and 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 '883 Patent.

COUNT 58: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HEWIG '883 PATENT

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

532. 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 their refusal to provide missing information for Amgen to fully evaluate whether the '883 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '883 Patent, including at least claim 8, under at least 35 U.S.C. §§ 271(b)

and (g). On information and belief, Defendants intend to and will begin to make, use, offer for sale, or sell within the United States, or import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '883 Patent, or will actively induce thereof, [redacted]

533. On information and belief, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '883 Patent, including at least claim 8, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products. On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

534. An actual controversy has arisen and now exists between the parties concerning whether Defendants' making, using, offering to sell, or selling within the United States, or importing into the United States, their proposed denosumab biosimilar products, or Defendants' active inducement thereof, before the expiration of the '883 Patent, will infringe one or more claims of the '883 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

535. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '883 Patent by making, using, offering to sell, or selling within the United

States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '883 Patent.

536. 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 '883 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' proposed denosumab biosimilar products before the expiration of the '883 Patent.

PRAYER FOR RELIEF

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

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

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

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

D. Based on that judgment, a permanent injunction against future infringement by Defendants, as well as by their officers, employees, agents, representatives, affiliates, assignees,

successors, and all persons acting on behalf of, at the direction of, or in active concert with Defendants, until each of the Patents-In-Suit that are found infringed has expired;

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

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

G. On all counts, such other relief as this Court may deem just, necessary, or proper pursuant to 28 U.S.C. § 2202.

DEMAND FOR A JURY TRIAL

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

Dated: May 28, 2024

/s/ Liza M. Walsh

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RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: May 28, 2024

/s/ *Liza M. Walsh*

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LOCAL RULE 201.1 CERTIFICATION

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

Dated: May 28, 2024

/s/ Liza M. Walsh

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