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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. SAMSUNG BIOEPIS CO., LTD., and SAMSUNG BIOLOGICS CO., LTD., 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 Samsung Bioepis Co., Ltd. ("Bioepis") and Samsung Biologics Co., Ltd., ("Biologics") (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the laws of the United States, Title 35 United States Code §§ 1, et seq., including 35 U.S.C. § 271(e)(2)(C), which was

enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("the BPCIA"), Pub. L. No. 111-148, §§ 7001–03, 124 Stat. 119, 804–21 (2010), including 42 U.S.C. § 262(*l*), and the Declaratory Judgment Act of 1934, 28 U.S.C. §§ 2201–02.

2. The BPCIA creates 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 to rely on the prior licensure and approval status of the innovative biologics the biosimilar seeks to replicate.

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

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

5. The asserted patents in this action cover denosumab (the active ingredient in Prolia and XGEVA), methods of manufacturing denosumab and denosumab products, and technologies necessary to produce, deliver and use these denosumab-containing medicines in patients. The asserted patents (collectively, "the Patents-In-Suit") are as follows: United States Patent Nos. 7,364,736 ("the '736 Patent"); 7,888,101 ("the '101 Patent"); 7,928,205 ("the '205 Patent"); 8,058,418 ("the '418 Patent"); 8,247,210 ("the '210 Patent"); 8,460,896 ("the '896 Patent"); 8,680,248 ("the '248 Patent"); 9,012,178 ("the '178 Patent"); 9,320,816 ("the '816 Patent"); 9,328,134 ("the '134 Patent"); 9,359,435 ("the '435 Patent"); 9,481,901 ("the '901 Patent"); 10,106,829 ("the '829 Patent"); 10,167,492 ("the '492 Patent"); 10,227,627 ("the '627 Patent"); 10,421,987 ("the '987 Patent"); 10,513,723 ("the '723 Patent"); 10,583,397 ("the '397 Patent"); 10,655,156 ("the '156 Patent"); 10,822,630 ("the '630 Patent"); 10,894,972 ("the '972 Patent"); 10,907,186 ("the '186 Patent"); 11,098,079 ("the '079 Patent"); 11,130,980 ("the '980 Patent"); 11,254,963 ("the '963 Patent"); 11,292,829 ("the '829 Patent"); 11,299,760 ("the '760 Patent"); 11,384,378 ("the '378 Patent"); 11,427,848 ("the '848 Patent"); 11,434,514 ("the '514 Patent"); 11,634,476 ("the '476 Patent"); 11,685,772 ("the '772 Patent"); 11,744,950 ("the '950 Patent"); and 11,946,085 ("the '085 Patent").

6. On [redacted], Defendants informed Amgen that, on [redacted] Defendants' BLA for "SB16" (Defendants' current designation for their denosumab biosimilar), submitted under section 262(k) and referencing Amgen's patented PROLIA and XGEVA products. On or around [redacted], Bioepis provided a secure file transfer link to a purported "copy of the application submitted to the FDA."

7. Contrary to Bioepis's representation, the purported BLA produced to Amgen contained numerous and substantial redactions (the "Incomplete BLA"). The redactions include,

but are not limited to [redacted] Additionally, the Incomplete BLA produced to Amgen consisted of more than 200,000 image files with no searchable text, no accompanying metadata, and no apparent organizational structure, impeding contextual navigation and review. On information and belief, the BLA Defendants submitted to the FDA did not contain the substantial redactions found in the Incomplete BLA and would have been provided to the FDA in an organized, searchable, eCTD format with internal hyperlinks.

8. Since receiving the Incomplete BLA, Amgen Inc has diligently evaluated the unredacted portions and repeatedly requested Bioepis correct and/or supplement their deficient production. Bioepis refused to provide an unredacted copy of the BLA as submitted to the FDA and has also refused to provide other information describing [redacted]

9. Amgen has participated in the pre-litigation exchange contemplated under the BPCIA to the best of its ability. Amgen's efforts, however, have been frustrated by Defendants' initial and ongoing failure to comply with subsection (*l*)(2)(A) of the BPCIA, which states that a biosimilar applicant "shall provide" to the reference product sponsor: "[1] a copy of the application submitted to the Secretary under subsection (k), and [2] such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A) (annotations added). Defendants failed to provide "a copy" of the BLA as it was "submitted to the Secretary" as required by the statute and have rebuffed Amgen's multiple letters identifying specific missing information and urging Bioepis to produce its BLA without redactions and in the organized manner in which it was presumably

submitted to the FDA. Defendants also failed to provide the second category of "other information that describes" the manufacturing process(es) for SB16.

10. Defendants' failure to produce the required information under § 262(*l*)(2)(A) has and will continue to prejudice Amgen's efforts to conduct a complete patent infringement analysis under the BPCIA. After conducting an analysis to the best of its ability based on the limited information available, Amgen provided to Bioepis a "list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor," as contemplated by § 262(*l*)(3)(A).

11. As alleged herein, the Defendants' failure to comply with § 262(*l*)(2)(A) authorizes Amgen to file a suit for a declaration of infringement. 42 U.S.C. § 262(*l*)(9)(C); *see also Sandoz Inc. v. Amgen Inc. et al*., 582 U.S. 1, 3 (2017) ("§ 262(*l*)(9)(C) provides a remedy for an applicant's failure to turn over its application and manufacturing information" by authorizing the sponsor "to bring an immediate declaratory-judgment action for artificial infringement"). On information and belief—based on the information available in unredacted portions of Defendants' BLA—the Defendants have infringed or will imminently infringe the Patents-In-Suit under 35 U.S.C. § 271(e)(2)(C), as evident by Defendants' submitting a BLA seeking the FDA's approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, sale, or offer for sale of their denosumab biosimilar product(s) before the expiration of the Patents-In-Suit, including, *inter alia*, the '736 Patent and the '248 Patent.

12. Further, as alleged herein, on information and belief, Defendants have infringed and will imminently infringe one or more claims of the Patents-In-Suit under at least 35 U.S.C. §§ 271(a), (b), and/or (g) by making, offering for sale, or selling within the United States, or

importing into the United States one or more of their denosumab biosimilar products before the expiration of the Patents-In-Suit.

THE PARTIES

A. Plaintiffs

13. 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 is the exclusive licensee of the Patents-In-Suit in the United States and its territories for commercialization of Prolia and XGEVA.

14. 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.

15. 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.

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

B. Defendants

17. Samsung Biologics ("Biologics") is a biotechnology corporation organized and existing under the laws of South Korea, with its principal place of business at 300, Songdo bio-daero, Yeonsu-gu, Incheon, Republic of Korea.

18. Samsung Bioepis Co., Ltd., ("Bioepis") is a corporation organized and existing under the laws of South Korea, with its principal place of business at 76, Songdogyoyuk-ro, Yeonsu-gu, Incheon, Republic of Korea. Bioepis is a wholly owned subsidiary of Biologics.[1]

19. Biologics and Bioepis are related corporate entities that act as agents of one another and/or act in concert.

20. Biologics describes itself as "the world's leading" contract development and manufacturing organization "by production capacity, [which] can offer the large-scale commercial manufacturing of drug substance in multiple scales and capacity."[2] On information and belief, Biologics will be involved in commercializing SB16 in the United States, including in the District of New Jersey, as one manufacturer of SB16. Biologics already manufactures several of Bioepis's biosimilars marketed in the United States, including biosimilars for etanercept (Enbrel)[3], infliximab (Remicade),[4] and adalimumab (Humira).[5]

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[1] *Samsung Biologics completes full acquisition of Samsung Bioepis* (Biologics Company News, April 20, 2022), https://samsungbiologics.com/media/company-news-view?boardSeq=1681 (last accessed August 12, 2024).
[2] https://samsungbiologics.com/services/cmo/mammalian-cell-culture (last accessed August 12, 2024).
[3] https://www.ema.europa.eu/en/medicines/human/EPAR/benepali, at 64 (last accessed August 12, 2024).
[4] https://www.ema.europa.eu/en/medicines/human/EPAR/flixabi, at 38 (last accessed August 12, 2024).
[5] https://www.ema.europa.eu/en/medicines/human/EPAR/imraldi, at 158 (last accessed August 12, 2024).

21. Bioepis is the named applicant for the BLA [redacted] pursuant to 42 U.S.C. § 262(k) and referencing PROLIA and XGEVA (denosumab).

22. On information and belief, Bioepis, acting in concert with Biologics, 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, such as SB16) in New Jersey and throughout the United States.

23. On information and belief, Bioepis, acting in concert with Biologics, intends to develop, manufacture, import, market, distribute, offer for sale, and/or sell in New Jersey and across the United States biosimilar versions of Amgen's Prolia and XGEVA and, in doing so, will improperly exploit Amgen's intellectual property surrounding these medicines.[6]

JURISDICTION AND VENUE

A. Subject-Matter Jurisdiction

24. 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.

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

[6] *See Samsung Bioepis Presents Phase 1 and 3 Clinical Results for SB16, a Proposed Biosimilar to Prolia (denosumab)*, at ASBMR 2023, https://www.samsungbioepis.com/en/newsroom/newsroomView.do?idx=357 (Bioepis News Releases, October 16, 2023) (last accessed August 12, 2024).

B. Venue and Personal Jurisdiction

26. Venue is proper in this District pursuant to 28 U.S.C. § 1391(c)(3) and § 1400(b). Bioepis and Biologics are both foreign corporations and are therefore subject to suit in any judicial district.[7]

27. On information and belief, Defendants collaborate to develop, manufacture, seek regulatory approval for, market, distribute, and sell pharmaceutical products, for use throughout the United States, including in this federal judicial District.

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

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

C. Samsung Bioepis

30. This Court has personal jurisdiction over Bioepis by virtue of the fact that Bioepis took the significant step to prepare and file a BLA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of the Defendants' biosimilar products throughout the United States, including in this judicial district. For example, Bioepis, by itself or through others, conducted part of the SB16 Phase 1 study in Newark, New Jersey.[8]

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

[8] *Pharmacokinetics, Pharmacodynamics, Safety, Tolerability, and Immunogenicity Study of SB16 in Healthy Male Subjects*, ClinicalTrials.gov ID: NCT04621318, https://clinicaltrials.gov/study/NCT04621318? term=SB16%20DENOSUMAB&rank=2 ("Contacts and Locations:" New Jersey) (last accessed August 12, 2024).

31. On information and belief, Bioepis, by itself or through others including one of its manufacturers Biologics, intends to induce others to use, offer for sale, sell within the United States, and import into the United States, including in this judicial district, its FDA-approved denosumab biosimilar products.

32. On information and belief, the exercise of personal jurisdiction over Bioepis in this district would not unfairly burden Bioepis. Bioepis did not object to personal jurisdiction when sued by other patent holders in this district.[9]

33. Personal jurisdiction over Bioepis is also proper in any U.S. district court, including the District of New Jersey, under Fed. R. Civ. P. 4(k)(2): Amgen's claims arise under federal law; Bioepis is a foreign entity not subject to general personal jurisdiction in the courts of any state; and Bioepis has sufficient contacts in the United States as a whole, including but not limited to, participating in the preparation and submission of the BLA for SB16 and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Bioepis satisfies due process. *See* Fed. R. Civ. P. (4)(k)(2)(A), (B).

D. Samsung Biologics

34. On information and belief, Biologics 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. Biologics, in concert with or acting through its wholly owned subsidiary Bioepis and its other affiliates, develops, manufactures, imports, markets, distributes, offers to sell, and/or sells generic and biosimilar drugs throughout the United States, including in the State of New Jersey,

[9] *See, e.g.*, *Immunex Corp. v. Samsung Bioepis, Co. Ltd.*, Case No. 2:19-cv-11755 (CCC-MF); *Janssen Biotech, Inc. v. Samsung Bioepis, Co. Ltd.*, Case No. 2:17-cv-03524 (MCA).

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.

35. Personal jurisdiction over Biologics is also proper in any U.S. district court, including the District of New Jersey, under Fed. R. Civ. P. 4(k)(2): Amgen's claims arise under federal law; Biologics is a foreign entity not subject to general personal jurisdiction in the courts of any state; and Biologics has sufficient contacts in the United States as a whole, including but not limited to, participating in the preparation and submission of the BLA for SB16 and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Biologics satisfies due process. *See* Fed. R. Civ. P. (4)(k)(2)(A), (B).

THE PROLIA AND XGEVA DRUG PRODUCTS

A. Bone Metabolism and RANKL

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

37. All tissues in the body express, or produce, proteins. Among those proteins is receptor activator of nuclear factor kappa-β (also known as "RANK"), which is found on the surface of cells called osteoclast precursors. RANK selectively binds to another protein—its binding partner or "ligand"—called RANK ligand ("RANKL").[10] When RANKL binds to RANK on the surface of osteoclast precursors, the interaction stimulates the precursor cell to

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

transform into a mature osteoclast cell. Mature osteoclasts carry out bone resorption, *i.e.* the breakdown of bone. A different type of cell in the bone environment is called an "osteoblast." It performs the opposite function as the osteoclast—it forms new bone.

38. 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

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

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

C. Amgen's Invention of Prolia and XGEVA

41. Amgen developed Prolia and XGEVA after years of groundbreaking research into the bone remodeling pathway. This research dates back to the late 1990s, when studies by Amgen Inc. scientists identified the relationship between the protein RANKL (what they originally called "OPGL") and bone resorption. Amgen devoted significant resources to developing a treatment for diseases mediated by this mechanism, such as osteoporosis and

disease states characterized by weakened bones, and invented novel pharmaceutical compositions that could be used in the treatment of such diseases.

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

43. 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

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

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

46. Based on the results of extensive clinical testing, Amgen filed Biologic BLA No. 125320 in December 2008. In June 2010, the FDA first approved Prolia (active ingredient denosumab, formulated in combination with sorbitol and acetate), pursuant to BLA No. 125320, for treating postmenopausal women with osteoporosis at high risk for fracture. Prolia was the first biologic ever approved to treat osteoporosis.

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

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

E. Amgen's Further Innovations in Antibody Manufacturing and Delivery

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

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

50. As alleged herein, the '736 Patent issued on April 29, 2008. The '736 Patent was identified in Amgen's patent marking for Prolia and XGEVA before Defendants filed the BLA for their denosumab biosimilar products. At least as early as May 24, 2023, one of the Patents-in-

Suit, United States Patent No. 7,364,736 was identified on the FDA's publication entitled *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluation* ("the Purple Book"). *See* https://web.archive.org/web/20230524143320/https://purplebooksearch.fda.gov/patent-list (last accessed August 12, 2024). Thus, the Defendants had constructive notice of and were aware of at minimum one of Amgen's patents before the filing of the BLA. *See* 35 U.S.C. § 287.

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

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

DEFENDANTS FAIL TO COMPLY WITH THE BPCIA

A. The Defendants' Proposed Biosimilar Product and Application

53. Bioepis, acting in concert with Biologics, 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. Defendants' BLA references Amgen's Prolia and XGEVA products bearing BLA license No. 125320.

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

55. On information and belief, Defendants' proposed denosumab biosimilar products are manufactured by methods that utilize Amgen inventions related to various manufacturing processes, and on information and belief, Biologics, alone or in concert with others acting on

behalf of Bioepis or its affiliates, will manufacture these proposed denosumab biosimilar products.

56. On information and belief, Bioepis's proposed denosumab biosimilar product(s) are stored and delivered by devices that use Amgen inventions.

57. On information and belief, Bioepis, acting in concert with its affiliates, including at least Biologics, has imported into and/or used within the United States Bioepis's proposed denosumab biosimilar product(s).

B. The BPCIA's Framework for Confidential Information Exchange

58. 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 Defendants, to rely on the prior clinical tests, data, and results, and the prior licensure and approval status, of the innovative (or "reference") biological product, here, Prolia and XGEVA, to secure licensing of a biosimilar version of the reference biological product.

59. The BPCIA provides that "[n]ot later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant "shall provide to the reference product sponsor [1] **a copy of the application submitted to the Secretary** under subsection (k), and [2] such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2) (emphasis added).

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

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

61. Recognizing the sensitive nature of the information to be disclosed under 262(*l*)(2), the BPCIA also contains default confidentiality provisions that "apply to the exchange of information described" in subsection (*l*). 42 U.S.C. § 262(*l*)(1)(B)(i). Among other provisions, the statute limits *who* may have access to the exchanged information, 262(*l*)(1)(B)(ii), and prescribes that confidential information "shall be used for the sole and exclusive purpose of determining" whether "a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k)." 42 U.S.C. § 262(*l*)(1)(D). Violating the statute's confidentiality provisions may entitle the Section (k) applicant to seek immediate injunctive relief. 42 U.S.C. § 262(*l*)(1)(H).

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

C. <u>Bioepis's Deficient BLA Disclosure and Ongoing Evasion and Concealment</u>

63. On [redacted] Bioepis informed Amgen that Bioepis would produce what it described as "a copy of the application submitted to the FDA." On [redacted] Amgen proposed a confidentiality agreement consistent with the provisions of 42 U.S.C. § 262(*l*)(1).

64. Upon receiving and reviewing the Incomplete BLA, Amgen's counsel observed the production consisted of more than 200,000 image files with no searchable text, no accompanying metadata, no apparent organizational structure, and contained numerous and substantial redactions of information which ranged from redacted words and sentences to the redaction of entire pages (in once instance, sixteen consecutive redacted pages).

65. On information and belief, BLAs are submitted to the FDA without redactions, in a format that contains internal hyperlinks to provide internal relationships and enable contextual navigation and review.

66. On [redacted] Amgen's counsel wrote to Bioepis's counsel regarding the "unwarranted redactions" in Bioepis's BLA production. The letter noted that Bioepis had redacted [redacted] Amgen's counsel emphasized that such extensive redactions are not permitted under the terms of the statute, nor are such extensive redactions needed given the statute's confidentiality provisions and the added protections of Amgen's proposed confidentiality agreement. The letter closed by asking Bioepis to re-produce its BLA materials with redactions removed.

67. On [redacted] Bioepis wrote back to Amgen, asserting Bioepis had "fully complied with its statutory obligations and that the redactions made in the BLA production are appropriate."

68. Amgen responded promptly on [redacted] reiterating the impropriety of numerous and substantial redactions. This letter also detailed the disparate, unconnected, and disorganized manner in which the BLA was produced. Amgen's [redacted] letter underscored that the BPCIA requires a section (k) applicant to disclose "a copy" of the BLA submitted to the FDA, and the statute provides confidentiality provisions to allay applicant's concerns regarding the disclosure of sensitive information.

69. On [redacted] Bioepis responded and maintained that the redactions are permitted. Bioepis also erroneously claimed "the documents were provided with their original order intact, ensuring a coherent and organized production," and asserted that no statutory language or legal authority requires the documents be provided with load files containing file paths or metadata.

70. Amgen responded the following day further specifying why the redactions impaired Amgen's ability to fully assess whether claims of patent infringement could reasonably be asserted by Amgen, [redacted]. Critically, Bioepis's inconsistent redactions revealed an attempt to [redacted] Presumably, Defendants did not submit an application to the Secretary under section (k) that contained the redactions appearing in the version of the BLA that Samsung Bioepis produced to Amgen. Defendants thus failed to "provide a 'copy' (i.e., reproduction) of the BLA as provided to FDA."

71. Amgen's [redacted] letter also countered Bioepis's assertion that the Incomplete BLA was produced in an organized and orderly fashion. The very first page of the BLA "copy," at Bates number SB16-00000001, [redacted]

[redacted]. The fifteenth page, at Bates number SB16-00000015, was [redacted]. On information and belief, it is implausible that these sorts of documents would be among the first pages of an application submitted to the FDA seeking a biological license. Amgen's counsel also informed Bioepis that it could not verify whether the documents were produced with the "original order intact" because Bioepis declined to provide any load files with file paths to confirm that assertion. Further, on information and belief, Bioepis's BLA production was processed in a commercial discovery database making all the missing load file information readily available.

72. Two weeks passed before Bioepis's counsel responded. Despite continued correspondence (dated [redacted]), Bioepis has still not removed the improper redactions or produced any "other information" required under 262(*l*)(2)(A). On [redacted] Bioepis produced an [redacted]. That letter referenced [redacted] none of which has been produced.

THE PATENTS-IN-SUIT

A. The Boyle '736 and '418 Patents

73. 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.

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

75. The ’736 Patent is and has been identified on the label for XGEVA and Prolia.[11]

76. The ’736 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

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

78. The ’418 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’418 Patent.

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

B. <u>The Crowell ’248, ’896, ’210, and ’101 Patents</u>

80. 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.

[11] *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).

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

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

83. 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.

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

85. The ’896 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

86. The USPTO duly and legally issued the ’210 Patent, titled “Host Cells Comprising Alpha 1,2 Mannosidase and Culture Methods Thereof,” on August 21, 2012. The ’210 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.

87. The ’210 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’210 Patent.

88. The ’210 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

89. The USPTO duly and legally issued the ’101 Patent, titled “Host Cells Comprising Alpha 1,2 Mannosidase and Culture Methods Thereof,” on February 15, 2011. The ’101 Patent as a general matter discloses and claims methods of producing glycoproteins of interest by culturing an isolated host cell engineered to overexpress alpha 1,2 mannosidase native to the host cell, and a glycoprotein of interest.

90. The ’101 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’101 Patent.

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

C. <u>The Dillon ’205 Patent</u>

92. 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.

93. The ’205 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’205 Patent.

94. The ’205 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably

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

D. The Kang '178 Patent

95. 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.

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

97. The '178 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar products.

E. The Zhou '816 Patent

98. 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.

99. The '816 Patent is assigned to Amgen Inc. AML has an exclusive license to the '816 Patent.

100. The '816 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably

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

F. The Allen '134 Patent

101. 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.

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

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

G. The Wu '435 Patent

104. 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.

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

106. The '435 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably

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

H. The Huang '901, '972, '514, '987, and '085 Patents

107. The USPTO duly and legally issued the '901 Patent, titled "Methods for Increasing Mannose Content of Recombinant Proteins" on November 1, 2016. The '901 Patent discloses and claims methods of influencing the high mannose glycoform content of a recombinant protein during a mammalian cell culture by adding mannose sugars during a production phase and manipulating the mannose to total hexose ratio in the cell culture and feed media.

108. The '901 Patent is assigned to Amgen Inc. AML has an exclusive license to the '901 Patent.

109. The '901 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar products.

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

111. The '972 Patent is assigned to Amgen Inc. AML has an exclusive license to the '972 Patent.

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

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

114. The ’514 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’514 Patent.

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

116. The USPTO duly and legally issued the ’987 Patent, titled “Methods for Increasing Mannose Content of Recombinant Proteins” on September 24, 2019. The ’987 Patent discloses and claims methods of influencing the high mannose glycoform content of a recombinant protein during a mammalian cell culture by adding mannose sugars during a production phase and manipulating the mannose to total hexose ratio in the cell culture and feed media.

117. The ’987 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’987 Patent.

118. The ’987 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

119. The USPTO duly and legally issued the ’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.

120. The ’085 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’085 Patent.

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

I. The Gupta ’829, ’627, ’156, and ’186 Patents

122. 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.

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

124. The ’829 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

125. 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.

126. The ’627 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’627 Patent.

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

128. The USPTO duly and legally issued the ’156 Patent, titled “Overexpression of N-Glycosylation Pathway Regulators to Modulate Glycosylation of Recombinant Proteins,” on May 19, 2020. The ’156 Patent as a general matter discloses and claims methods of regulating the high mannose glycoform content of recombinant proteins during a mammalian cell culture process.

129. The ’156 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’156 Patent.

130. The ’156 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

131. The USPTO duly and legally issued the ’186 Patent, titled “Overexpression of N-Glycosylation Pathway Regulators to Modulate Glycosylation of Recombinant Proteins,” on February 2, 2021. The ’186 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.

132. The ’186 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’186 Patent.

133. The ’186 Patent was identified in the letter Amgen Inc. sent to Bioepis [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

J. <u>The Leiske ’492 and ’630 Patents</u>

134. 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.

135. The ’492 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’492 Patent.

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

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

137. The USPTO duly and legally issued the '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.

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

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

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

140. 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.

141. The '723 Patent is assigned to Amgen Inc. AML has an exclusive license to the '723 Patent.

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

143. The USPTO duly and legally issued the ’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.

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

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

L. <u>The Gefroh ’397 Patent</u>

146. 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.

147. The ’397 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’397 Patent.

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

M. The Hoang ’079 Patent

149. 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.

150. The ’079 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’079 Patent.

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

N. The Pande ’980 and ’760 Patents

152. 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.

153. The ’980 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’980 Patent.

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

155. 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.

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

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

O. <u>The Follstad ’829, ’476, and ’772 Patents</u>

158. The USPTO duly and legally issued the ’829 Patent, titled “Mammalian Cell Culture,” on April 5, 2022. The ’829 Patent discloses and claims a method for culturing mammalian cells that provides greater control over cell growth to achieve high product titer cell cultures.

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

160. The ’829 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

161. The USPTO duly and legally issued the ’476 Patent, titled “Mammalian Cell Culture,” on April 25, 2023. The ’476 Patent discloses and claims a method for culturing mammalian cells that provides greater control over cell growth to achieve high product titer cell cultures.

162. The ’476 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’476 Patent.

163. The ’476 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

164. The USPTO duly and legally issued the ’772 Patent, titled “Mammalian Cell Culture,” on June 27, 2023. The ’772 Patent discloses and claims a method for culturing mammalian cells that provides greater control over cell growth to achieve high product titer cell cultures.

165. The ’772 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’772 Patent.

166. The ’772 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar products.

P. <u>The Goudar ’378 and ’848 Patents</u>

167. The USPTO duly and legally issued the ’378 Patent, titled “Methods for Harvesting Mammalian Cell Cultures,” on July 12, 2022. The ’378 Patent discloses and claims methods and materials for culturing mammalian cells and harvesting recombinant protein.

168. The ’378 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’378 Patent.

169. The ’378 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably

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

170. The USPTO duly and legally issued the '848 Patent, titled "Methods for Harvesting Mammalian Cell Cultures," on August 30, 2022. The '848 Patent discloses and claims methods and materials for culturing mammalian cells and harvesting recombinant protein.

171. The '848 Patent is assigned to Amgen Inc. AML has an exclusive license to the '848 Patent.

172. The '848 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar products.

Q. <u>The Perez-Pacheco '950 Patent</u>

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

174. The '950 Patent is assigned to Amgen Inc. AML has an exclusive license to the '950 Patent.

175. The '950 Patent was identified in the letter Amgen Inc. sent to Bioepis on [redacted] as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Bioepis engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar products.

COUNT 1: INFRINGEMENT OF THE BOYLE '736 PATENT

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

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

178. 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.

179. 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.

180. 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.

181. 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

182. Paragraphs 1-181 are incorporated by reference as if fully set forth herein.

183. 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]

184. 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.

185. 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.

186. 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 CROWELL '248 PATENT

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

188. 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, the Defendants have infringed the '248 Patent under at least 35 U.S.C. §§ 271(a), (b), and (e).

189. 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.

190. 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.

191. 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.

192. 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.

193. 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 4: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '248 PATENT

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

195. 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, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the ’248 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(a) and (b). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants’ proposed denosumab biosimilar products before expiration of the ’248 Patent or will actively induce thereof [redacted]

196. 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.

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

198. Amgen is entitled to a declaratory judgment that the Defendants will infringe one or more claims of the ’248 Patent by making, using, offering to sell, or selling within the United

States, or importing into the United States, their denosumab biosimilar product(s) before the expiration of the ’248 Patent.

199. 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’ denosumab biosimilar product(s) before the expiration of the ’248 Patent.

COUNT 5: INFRINGEMENT OF THE BOYLE ’418 PATENT

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

201. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and refusal to provide missing information for Amgen to fully evaluate whether the ’418 Patent has been or will be infringed, on information and belief, the Defendants have infringed the ’418 Patent under at least 35 U.S.C. §§ 271(a), (b), (e), and (g).

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

203. On information and belief, Defendants’ proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the ’418 Patent, including at least claim 14.

204. On information and belief, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '418 Patent, including at least claim 14. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '418 Patent, constitutes willful infringement.

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

206. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '418 Patent.

COUNT 6: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE BOYLE '418 PATENT

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

208. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and refusal to provide missing information for Amgen to fully evaluate whether the '418 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one

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

209. An actual controversy has arisen and now exists between the parties concerning whether the Defendants’ making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the ’418 Patent, will infringe one or more claims of the ’418 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

210. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the ’418 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Samsung’s denosumab biosimilar products before the expiration of the ’418 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 ’418 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants’ denosumab biosimilar products before the expiration of the ’418 Patent.

COUNT 7: 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), the redaction of information regarding the

location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the ’896 Patent has been or will be infringed, on information and belief, the Defendants have infringed the ’896 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

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

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

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

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, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '896 Patent.

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

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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '896 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '896 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '896 Patent or will actively induce thereof [redacted]

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

222. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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, Samsung's 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 preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '896 Patent.

COUNT 9: INFRINGEMENT OF THE CROWELL '210 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 refusal to provide missing information for Amgen to fully evaluate whether the '210 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '210 Patent under at least 35 U.S.C. §§ 271(a), (b) and (e).

227. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '210 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 '210 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, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '210 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 ’210 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 ’210 Patent. Amgen has been injured by Defendants’ infringement and is entitled to damages.

231. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants’ proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the ’210 Patent.

COUNT 10: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL ’210 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 refusal to provide missing information for Amgen to fully evaluate whether the ’210 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the ’210 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(a) and (b). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants’ proposed denosumab biosimilar products before expiration of the ’210 Patent or will actively induce thereof [redacted]

234. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '210 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

235. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '210 Patent, will infringe one or more claims of the '210 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 '210 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Samsung's denosumab biosimilar products before the expiration of the '210 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 '210 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '210 Patent.

COUNT 11: INFRINGEMENT OF THE CROWELL '101 PATENT

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

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

240. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '101 Patent, including at least claim 1.

241. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '101 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

242. On information and belief, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '101 Patent, including at least claim 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 '101 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 '101 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

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

COUNT 12: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE CROWELL '101 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '101 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '101 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(a) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '101 Patent or will actively induce thereof [redacted]

[redacted]

247. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '101 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

248. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '101 Patent, will infringe one or more claims of the '101 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

249. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '101 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Samsung's denosumab biosimilar products before the expiration of the '101 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 '101 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '101 Patent.

COUNT 13: INFRINGEMENT OF THE DILLON '205 PATENT

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

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

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

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

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

offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '205 Patent, constitutes willful infringement.

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

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

COUNT 14: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE DILLON '205 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '205 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '205 Patent, including at least claims 1 and 40, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '205 Patent or will actively induce thereof [redacted]

[redacted]

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

261. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

262. 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, Samsung's denosumab biosimilar products before the expiration of the '205 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 '205 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '205 Patent.

COUNT 15: INFRINGEMENT OF THE KANG '178 PATENT

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

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

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

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

268. On information and belief, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '178 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '178 Patent, constitutes willful infringement.

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

270. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '178 Patent.

COUNT 16: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '178 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '178 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '178 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '178 Patent or will actively induce thereof [redacted]

[redacted]

273. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '178 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

274. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

275. 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, Samsung's denosumab biosimilar products before the expiration of the '178 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 '178 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '178 Patent.

COUNT 17: INFRINGEMENT OF THE ZHOU '816 PATENT

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

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

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

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

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

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '816 Patent, constitutes willful infringement.

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

283. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '816 Patent.

COUNT 18: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ZHOU '816 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '816 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '816 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '816 Patent or will actively induce thereof [redacted]

[redacted]

286. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '816 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

287. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

288. 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, Samsung's denosumab biosimilar products before the expiration of the '816 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 '816 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '816 Patent.

COUNT 19: INFRINGEMENT OF THE ALLEN ’134 PATENT

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

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

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

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

294. On information and belief, based on information presently available to Amgen, Defendants’ importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants’ proposed denosumab biosimilar products, or Defendants’ active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the ’134 Patent, including at least claim 35. On information and belief, Defendants’ importation into, commercial manufacture, sale, offer for

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '134 Patent, constitutes willful infringement.

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

296. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '134 Patent.

COUNT 20: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ALLEN '134 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '134 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '134 Patent, including at least claim 35, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '134 Patent or will actively induce thereof [redacted]

[redacted]

299. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '134 Patent, including at least claim 35, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

300. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

301. 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, Samsung's denosumab biosimilar products before the expiration of the '134 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 '134 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '134 Patent.

COUNT 21: INFRINGEMENT OF THE WU '435 PATENT

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

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

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

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

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

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '435 Patent, constitutes willful infringement.

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

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

COUNT 22: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE WU '435 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '435 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '435 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '435 Patent or will actively induce thereof [redacted]

[redacted]

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

313. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

314. 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, Samsung's denosumab biosimilar products before the expiration of the '435 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 '435 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '435 Patent.

COUNT 23: INFRINGEMENT OF THE HUANG '901 PATENT

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

317. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '901 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '901 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

318. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '901 Patent, including at least claim 1.

319. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '901 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

320. On information and belief, based on information presently available to Amgen, Defendants' importation 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 '901 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 '901 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 '901 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

322. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '901 Patent.

COUNT 24: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '901 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '901 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '901 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '901 Patent or will actively induce thereof [redacted]

[redacted]

325. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '901 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

326. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '901 Patent, will infringe one or more claims of the '901 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 '901 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Samsung's denosumab biosimilar products before the expiration of the '901 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 '901 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '901 Patent.

COUNT 25: INFRINGEMENT OF THE HUANG '972 PATENT

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

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

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

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

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

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '972 Patent, constitutes willful infringement.

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

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

COUNT 26: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '972 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '972 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '972 Patent, including at least claim 3, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '972 Patent or will actively induce thereof [redacted]

[redacted]

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

339. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

340. 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, Samsung's denosumab biosimilar products before the expiration of the '972 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 '972 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '972 Patent.

COUNT 27: INFRINGEMENT OF THE HUANG '514 PATENT

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

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

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

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

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

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '514 Patent, constitutes willful infringement.

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

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

COUNT 28: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '514 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '514 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '514 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '514 Patent or will actively induce thereof [redacted]

[redacted]

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

352. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

353. 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, Samsung's denosumab biosimilar products before the expiration of the '514 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 '514 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '514 Patent.

COUNT 29: INFRINGEMENT OF THE HUANG '987 PATENT

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

356. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '987 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '987 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

357. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '987 Patent, including at least claim 1.

358. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '987 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

359. On information and belief, based on information presently available to Amgen, Defendants' importation 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 '987 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 '987 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 '987 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

361. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '987 Patent.

COUNT 30: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '987 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '987 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '987 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '987 Patent or will actively induce thereof [redacted]

[redacted]

364. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '987 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

365. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '987 Patent, will infringe one or more claims of the '987 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 '987 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Samsung's denosumab biosimilar products before the expiration of the '987 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 '987 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '987 Patent.

COUNT 31: INFRINGEMENT OF THE HUANG '085 PATENT

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

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

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

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

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

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '085 Patent, constitutes willful infringement.

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

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

COUNT 32: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HUANG '085 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '085 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '085 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '085 Patent or will actively induce thereof [redacted]

[redacted]

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

378. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

379. 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, Samsung's denosumab biosimilar products before the expiration of the '085 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 '085 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '085 Patent.

COUNT 33: INFRINGEMENT OF THE GUPTA '829 PATENT

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

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

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

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

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

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '829 Patent, constitutes willful infringement.

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

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

COUNT 34: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '829 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '829 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '829 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '829 Patent or will actively induce thereof [redacted]

[redacted]

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

391. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

392. 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, Samsung's denosumab biosimilar products before the expiration of the '829 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 '829 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '829 Patent.

COUNT 35: INFRINGEMENT OF THE GUPTA '627 PATENT

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

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

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

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

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

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '627 Patent, constitutes willful infringement.

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

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

COUNT 36: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '627 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '627 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '627 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '627 Patent or will actively induce thereof [redacted]

[redacted]

403. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '627 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

404. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

405. 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, Samsung's denosumab biosimilar products before the expiration of the '627 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 '627 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '627 Patent.

COUNT 37: INFRINGEMENT OF THE GUPTA '156 PATENT

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

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

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

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

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

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '156 Patent, constitutes willful infringement.

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

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

COUNT 38: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '156 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '156 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '156 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '156 Patent or will actively induce thereof [redacted]

[redacted]

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

417. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '156 Patent, will infringe one or more claims of the '156 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

418. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '156 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Samsung's denosumab biosimilar products before the expiration of the '156 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 '156 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '156 Patent.

COUNT 39: INFRINGEMENT OF THE GUPTA '186 PATENT

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

421. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '186 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '186 Patent under at least 35 U.S.C. §§ 271(a), (b), and (e).

422. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '186 Patent, including at least claim 1.

423. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '186 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

424. On information and belief, based on information presently available to Amgen, Defendants' importation 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 '186 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 '186 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 '186 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

426. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '186 Patent.

COUNT 40: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GUPTA '186 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '186 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '186 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(a) and (b). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '186 Patent or will actively induce thereof [redacted]

[redacted]

429. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '186 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

430. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '186 Patent, will infringe one or more claims of the '186 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 '186 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Samsung's denosumab biosimilar products before the expiration of the '186 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 '186 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '186 Patent.

COUNT 41: INFRINGEMENT OF THE LEISKE '492 PATENT

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

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

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

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

437. On information and belief, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '492 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '492 Patent, constitutes willful infringement.

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

439. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '492 Patent.

COUNT 42: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE LEISKE '492 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '492 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '492 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '492 Patent or will actively induce thereof [redacted]

[redacted]

442. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '492 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

443. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

444. 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, Samsung's denosumab biosimilar products before the expiration of the '492 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 '492 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '492 Patent.

COUNT 43: INFRINGEMENT OF THE LEISKE '630 PATENT

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

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

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

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

450. On information and belief, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '630 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '630 Patent, constitutes willful infringement.

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

452. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '630 Patent.

COUNT 44: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE LEISKE '630 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '630 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '630 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '630 Patent or will actively induce thereof [redacted]

[redacted]

455. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '630 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

456. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

457. 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, Samsung's denosumab biosimilar products before the expiration of the '630 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 '630 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '630 Patent.

COUNT 45: INFRINGEMENT OF THE KANG '723 PATENT

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

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

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

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

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

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '723 Patent, constitutes willful infringement.

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

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

COUNT 46: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '723 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '723 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '723 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '723 Patent or will actively induce thereof [redacted]

[redacted]

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

469. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

470. 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, Samsung's denosumab biosimilar products before the expiration of the '723 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 '723 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '723 Patent.

COUNT 47: INFRINGEMENT OF THE KANG '963 PATENT

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

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

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

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

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

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '963 Patent, constitutes willful infringement.

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

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

COUNT 48: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE KANG '963 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '963 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '963 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '963 Patent or will actively induce thereof [redacted]

[redacted]

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

482. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '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.

483. 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, Samsung's denosumab biosimilar products before the expiration of the '963 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 '963 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '963 Patent.

COUNT 49: INFRINGEMENT OF THE GEFROH '397 PATENT

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

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

487. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '397 Patent, including at least claim 7.

488. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '397 Patent, including at least claim 7, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

489. On information and belief, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '397 Patent, including at least claim 7. 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.

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 '397 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, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '397 Patent.

COUNT 50: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GEFROH '397 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '397 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '397 Patent, including at least claim 7, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '397 Patent or will actively induce thereof [redacted]

[redacted]

494. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '397 Patent, including at least claim 7, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

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

496. 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, Samsung's denosumab biosimilar products before the expiration of the '397 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 '397 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '397 Patent.

COUNT 51: INFRINGEMENT OF THE HOANG '079 PATENT

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

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

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

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

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

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '079 Patent, constitutes willful infringement.

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 '079 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, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '079 Patent.

COUNT 52: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE HOANG '079 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '079 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '079 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '079 Patent or will actively induce thereof [redacted]

[redacted]

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

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

509. 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, Samsung's denosumab biosimilar products before the expiration of the '079 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 '079 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '079 Patent.

COUNT 53: INFRINGEMENT OF THE PANDE '980 PATENT

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

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

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

514. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '980 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

515. On information and belief, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '980 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '980 Patent, constitutes willful infringement.

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 '980 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, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '980 Patent.

COUNT 54: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE PANDE '980 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '980 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '980 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '980 Patent or will actively induce thereof [redacted]

[redacted]

520. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '980 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

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

522. 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, Samsung's denosumab biosimilar products before the expiration of the '980 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 '980 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '980 Patent.

COUNT 55: INFRINGEMENT OF THE PANDE '760 PATENT

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

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

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

527. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '760 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

528. On information and belief, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '760 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '760 Patent, constitutes willful infringement.

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 '760 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, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '760 Patent.

COUNT 56: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE PANDE '760 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), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '760 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '760 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '760 Patent or will actively induce thereof [redacted]

[redacted]

533. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '760 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

534. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '760 Patent, will infringe one or more claims of the '760 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

535. 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, Samsung's denosumab biosimilar products before the expiration of the '760 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 '760 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '760 Patent.

COUNT 57: INFRINGEMENT OF THE FOLLSTAD '829 PATENT

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

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

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

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

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

sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or active inducement thereof, despite knowledge of the '829 Patent, constitutes willful infringement.

542. 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.

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

COUNT 58: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE FOLLSTAD '829 PATENT

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

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

[redacted]

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

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

548. 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, Samsung's denosumab biosimilar products before the expiration of the '829 Patent.

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

COUNT 59: INFRINGEMENT OF THE FOLLSTAD '476 PATENT

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

551. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '476 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '476 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

552. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '476 Patent, including at least claim 1.

553. 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 '476 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

554. On information and belief, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '476 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 '476 Patent, constitutes willful infringement.

555. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the '476 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

556. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '476 Patent.

COUNT 60: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE FOLLSTAD '476 PATENT

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

558. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '476 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '476 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '476 Patent or will actively induce thereof [redacted]

[redacted]

559. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '476 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

560. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '476 Patent, will infringe one or more claims of the '476 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.

561. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '476 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Samsung's denosumab biosimilar products before the expiration of the '476 Patent.

562. 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 '476 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '476 Patent.

COUNT 61: INFRINGEMENT OF THE FOLLSTAD '772 PATENT

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

564. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '772 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '772 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

565. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '772 Patent, including at least claim 1.

566. 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 '772 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

567. On information and belief, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '772 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 '772 Patent, constitutes willful infringement.

568. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the '772 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

569. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '772 Patent.

COUNT 62: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE FOLLSTAD '772 PATENT

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

571. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '772 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '772 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '772 Patent or will actively induce thereof [redacted]

[redacted]

572. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '772 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

573. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '772 Patent, will infringe one or more claims of the '772 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.

574. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '772 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Samsung's denosumab biosimilar products before the expiration of the '772 Patent.

575. 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 '772 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '772 Patent.

COUNT 63: INFRINGEMENT OF THE GOUDAR '378 PATENT

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

577. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '378 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '378 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

578. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '378 Patent, including at least claim 1.

579. 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 '378 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

580. On information and belief, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '378 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 '378 Patent, constitutes willful infringement.

581. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the '378 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

582. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '378 Patent.

COUNT 64: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GOUDAR '378 PATENT

583. Paragraphs 1-582 are incorporated by reference as if fully set forth herein.

584. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '378 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '378 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '378 Patent or will actively induce thereof [redacted]

[redacted]

585. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '378 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

586. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '378 Patent, will infringe one or more claims of the '378 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.

587. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '378 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Samsung's denosumab biosimilar products before the expiration of the '378 Patent.

588. 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 '378 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '378 Patent.

COUNT 65: INFRINGEMENT OF THE GOUDAR '848 PATENT

589. Paragraphs 1-588 are incorporated by reference as if fully set forth herein.

590. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '848 Patent has been or will be infringed, on information and belief, the Defendants have infringed the '848 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

591. On information and belief, based on information presently available to Amgen, the submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or importation into the United States, of Defendants' proposed denosumab biosimilar products before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '848 Patent, including at least claim 1.

592. 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 '848 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar products.

593. On information and belief, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '848 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 '848 Patent, constitutes willful infringement.

594. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the '848 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

595. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants' proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '848 Patent.

COUNT 66: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE GOUDAR '848 PATENT

596. Paragraphs 1-595 are incorporated by reference as if fully set forth herein.

597. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the '848 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '848 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants' proposed denosumab biosimilar products before expiration of the '848 Patent or will actively induce thereof [redacted]

[redacted]

598. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '848 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Samsung's proposed denosumab biosimilar products.

599. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '848 Patent, will infringe one or more claims of the '848 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.

600. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '848 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Samsung's denosumab biosimilar products before the expiration of the '848 Patent.

601. 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 '848 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '848 Patent.

COUNT 67: INFRINGEMENT OF THE PEREZ-PACHECO '950 PATENT

602. Paragraphs 1-601 are incorporated by reference as if fully set forth herein.

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

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

605. On information and belief, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '950 Patent, including at least claim 1.

606. On information and belief, based on information presently available to Amgen, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab biosimilar products, or Defendants' active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '950 Patent, including at least claim 1. On information and belief, Defendants' importation into, commercial manufacture, sale, offer for sale, or use within the United States of one or more of Defendants' proposed denosumab

biosimilar products, or active inducement thereof, despite knowledge of the ’950 Patent, constitutes willful infringement.

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

608. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, and importation into the United States of Defendants’ proposed denosumab biosimilar products. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the ’950 Patent.

COUNT 68: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE PEREZ-PACHECO ’950 PATENT

609. Paragraphs 1-608 are incorporated by reference as if fully set forth herein.

610. Based on information presently available to Amgen, and in view of Defendants’ failure to comply with 42 U.S.C. § 262(*l*)(2)(A), the redaction of information regarding the location of manufacturing activities, and refusal to provide missing information for Amgen to fully evaluate whether the ’950 Patent has been or will be infringed, on information and belief, the Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the ’950 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(a), (b) and (g). On information and belief, Defendants intend to and will begin to use, offer for sale, and sell within the United States, and import into the United States, one or more of Defendants’ proposed denosumab biosimilar products before expiration of the ’950 Patent or will actively induce thereof [redacted]

[redacted]

611. On information and belief, based on information presently available to Amgen, Defendants' proposed denosumab biosimilar products and manufacturing process infringe, either literally or under the doctrine of equivalents, one or more claims of the '950 Patent.

612. An actual controversy has arisen and now exists between the parties concerning whether the Defendants' making, using, offering to sell, and selling within the United States, and importing into the United States, their proposed denosumab biosimilar products, before the expiration of the '950 Patent, will infringe one or more claims of the '950 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, inter alia, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

613. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '950 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Samsung's denosumab biosimilar products before the expiration of the '950 Patent.

614. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the '950 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar products before the expiration of the '950 Patent.

PRAYER FOR RELIEF

WHEREFORE, Amgen with respect to the Patents-In-Suit respectfully requests that this Court enter judgment in their favor against Bioepis and Biologics 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' 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' denosumab biosimilar products during the term of the Patents-In-Suit;

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

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

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

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

DEMAND FOR A JURY TRIAL

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

Dated: August 12, 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: August 12, 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.

/s/ Liza M. Walsh

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