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

AMGEN INC. and AMGEN MANUFACTURING, LIMITED Plaintiffs, v. SANDOZ INC., SANDOZ GMBH, LEK PHARMACEUTICALS D.D., NOVARTIS PHARMACEUTICALS PRODUCTION D.O.O., and NOVARTIS AG Defendants.	Civil Action No. **COMPLAINT & DEMAND FOR A JURY TRIAL** **Redacted Version**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (together "Amgen" or "Plaintiffs"), by and through their undersigned attorneys, for their Complaint against Defendants Sandoz Inc., Sandoz GmbH, Lek Pharmaceuticals d.d., Novartis Pharmaceuticals Production d.o.o., and Novartis AG (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, §§ 7001–7003, 124 Stat. 119, 804–21 (2010), including 42 U.S.C. § 262(*l*), and the Declaratory Judgment Act of 1934, 28 U.S.C. §§ 2201–02. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. 42 U.S.C. § 262(k). This abbreviated pathway allows a biosimilar applicant, such as Defendants, to rely on the prior licensure and approval status of the innovative biologic products that the biosimilar seeks to replicate. This action arises out of Defendants' submission of a Biologic License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") pursuant to 42 U.S.C. § 262(k) seeking approval to manufacture and sell biosimilar versions of Amgen's Prolia® and XGEVA® products.

2. Prolia is prescribed to treat patients with a high risk of bone fracture in certain settings, for example patients suffering from osteoporosis. XGEVA is prescribed to prevent skeletal-related events (*e.g.*, fractures or spinal cord compression) in cancer patients whose cancer has spread to the bone, as well as to treat certain types of tumors. Amgen's scientists 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.

3. The asserted patents in this action cover denosumab (the active ingredient in Prolia and XGEVA) and methods of manufacturing denosumab and denosumab products. The asserted patents (collectively, "the Patents-In-Suit") are as follows: United States Patent Nos. 7,364,736 ("the '736 Patent"); 7,928,205 ("the '205 Patent"); 8,058,418 ("the '418 Patent");

9,012,178 ("the '178 Patent"); 9,133,493 ("the '493 Patent"); 9,228,168 ("the '168 Patent"); 9,320,816 ("the '816 Patent"); 9,328,134 ("the '134 Patent"); 9,359,435 ("the '435 Patent"); 9,481,901 ("the '901 Patent"); 10,167,492 ("the '492 Patent"); 10,513,723 ("the '723 Patent"); 10,583,397 ("the '397 Patent"); 10,822,630 ("the '630 Patent"); 10,894,972 ("the '972 Patent"); 11,077,404 ("the '404 Patent"); 11,098,079 ("the '079 Patent"); 11,130,980 ("the '980 Patent"); 11,254,963 ("the '963 Patent"); 11,299,760 ("the '760 Patent"); and 11,434,514 ("the '514 Patent").

4. On December 13, 2022, Sandoz Inc. ("Sandoz") informed Amgen Inc. that it had submitted to the FDA a BLA via the abbreviated 351(k) pathway, referencing Amgen's Prolia and XGEVA products. Sandoz provided a copy of that BLA to Amgen Inc. even though it had not been accepted by the FDA (and would not be accepted until February 2023). Since then, Amgen has diligently evaluated the BLA that was provided and 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 Sandoz's initial and continued failure to comply with subsection (*l*)(2)(A) of the BPCIA, which states that a biosimilar applicant "shall provide" to the reference product sponsor: "[1] a copy of the application submitted to the Secretary under subsection (k), *and* [2] such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A) (annotation and emphasis added). Sandoz provided the first required category of information—a copy of its BLA—prematurely but failed to provide to Amgen *anything* from the second required category. Despite Amgen's repeated requests for specific information in this category, which Amgen needed to fully evaluate whether Sandoz would infringe certain patents, Sandoz refused—and continues to refuse—to produce such information.

5. As alleged herein, Sandoz's 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*., 137 S. Ct. 1664, 1667-68 (2017) ("§ 262(*l*)(9)(C) provides a remedy for an applicant's failure to turn over its application and manufacturing information" by authorizing the sponsor "to bring an immediate declaratory-judgment action for artificial infringement"). Defendants have infringed the Patents-In-Suit under 35 U.S.C. § 271(e)(2)(C) by submitting a BLA seeking the FDA's approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, sale, or offer for sale of Defendants' denosumab biosimilar product(s) before the expiration of the Patents-In-Suit, including United States Patent No. 7,364,736.

6. As further alleged herein, on information and belief, Defendants have infringed and will infringe one or more claims of the Patents-In-Suit under at least 35 U.S.C. § 271(a), (b), and/or (g) by making, using, offering for sale, or selling within the United States, or importing into the United States Defendants' denosumab biosimilar product(s) before the expiration of the Patents-In-Suit.

THE PARTIES

A. Plaintiffs

7. 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.

8. 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.

9. Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of the Territory of Bermuda, 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.

10. Amgen is one of the world's leading biopharmaceutical companies and is dedicated to using discoveries in human biology to invent, develop, manufacture, and sell innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry for the benefit of patients suffering from serious illness. To that end, Amgen has invested billions of dollars into its research and development efforts. The two denosumab biological drug products that Defendants now seek to copy, Prolia and XGEVA, are the result of Amgen's innovations. Amgen brings this action to redress and halt Defendants' actual and intended infringement of the Patents-In-Suit.

A. Defendants

11. Sandoz is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 College Road West, Princeton, NJ 08540.

12. Sandoz GmbH is a corporation organized and existing under the laws of Austria, with its principal place of business at Biochemiestrasse 10, 6250 Kundl, Austria.

13. Lek Pharmaceuticals d.d. is a corporation organized and existing under the laws of Slovenia, with its principal place of business at Verovškova ulica 57, 1526 Ljubljana, Slovenia. On information and belief, Lek Pharmaceuticals d.d. holds itself out as a subsidiary of both Sandoz and Novartis AG. For example, Lek Pharmaceuticals d.d. maintains a public website where it identifies itself as "a Sandoz company" and as a part of Novartis. *See* https://lek.si/en/about-us/.

14. Novartis Pharmaceuticals Production d.o.o. is a corporation organized and existing under the laws of Slovenia, with its principal place of business at Verovškova ulica 57,

1000 Ljubljana, Slovenia. On information and belief, Novartis Pharmaceuticals Production d.o.o is or will be a successor-in-interest to Lek Pharmaceuticals d.d.

15. Novartis AG is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Postfach CH-4056 Basel, Switzerland.

16. On information and belief, Sandoz, Sandoz GmbH, Lek Pharmaceuticals d.d., Novartis Pharmaceuticals Production d.o.o., and Novartis AG are related corporate entities that act as agents of one another and/or act in concert.

17. On information and belief, Sandoz, acting in concert with Sandoz GmbH, Lek Pharmaceuticals d.d., Novartis Pharmaceuticals Production d.o.o., and Novartis AG, is in the business of developing, manufacturing, and seeking regulatory approval for developing, manufacturing, importing, marketing, distributing, using, offering to sell, and/or selling biopharmaceutical products (including products intended to be sold as biosimilar versions of successful biopharmaceutical products developed by others) in New Jersey and throughout the United States, through its own actions and through the actions of its agents.

18. On information and belief, Sandoz, in concert with the other Defendants, intends to develop, manufacture, import, market, distribute, use, offer for sale, and/or sell in New Jersey and across the United States biosimilar versions of Amgen's Prolia and XGEVA upon FDA approval and, in doing so, will improperly exploit Amgen's intellectual property surrounding these important medicines.

JURISDICTION AND VENUE

B. Subject-Matter Jurisdiction

19. 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. §§ 2201-2202), Title 28 of the United States Code.

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

C. Personal Jurisdiction and Venue

21. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b). Upon information and belief, 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.

22. Upon information and belief, Defendants collaborated with each other to take substantial steps to prepare for and undertake the filing of a BLA for a denosumab biosimilar product(s). Such steps included preparing and submitting the BLA and sending and receiving correspondence with the FDA regarding Defendants' BLA from Sandoz's principal place of business in New Jersey.

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

D. Sandoz

24. On information and belief, Sandoz develops, manufactures, seeks regulatory approval for, markets, distributes, offers for sale and sells biopharmaceuticals for sale and use throughout the United States, including in New Jersey and this federal judicial District.

25. This Court has personal jurisdiction over Sandoz by virtue of the fact that Sandoz took the significant step to prepare and file a BLA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale or sale of Defendants' proposed denosumab biosimilar product(s) in New Jersey and throughout the United States, which directly gives rise to Amgen's claims of patent infringement.

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

27. On information and belief, if Defendants' BLA is approved, Sandoz will develop, manufacture, import, market, distribute, use, offer for sale, and/or sell Defendants' denosumab biosimilar product(s) within the United States, including in New Jersey, consistent with Sandoz's practices for the marketing and distribution of other biopharmaceutical products. On information and belief, Sandoz regularly conducts business in New Jersey, and its practices with other biopharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. On information and belief, Sandoz's generic pharmaceutical products are used and consumed within and throughout the United States, including in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the Patents-In-Suit in the event that Defendants' proposed denosumab biosimilar product(s) are approved before the Patents-In-Suit expire.

28. On information and belief, Sandoz is registered as "Manufacturer and Wholesaler" with the State of New Jersey's Department of Health under Registration No. 5003732.

29. On information and belief, Sandoz is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 010097265.

30. Sandoz consented to or did not contest jurisdiction and availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in this District, for example, in at least the following: *see, e.g., Vifor (Int'l) AG et al. v. Sandoz Inc.*, No. 19-16305 (D.N.J. Aug. 2, 2019); *Adamas Pharma, LLC v. Sandoz Inc.*, No. 18-09032 (D.N.J. May 10, 2018); *Par Pharm., Inc. et al. v. Sandoz Inc.*, No. 18-14895 (D.N.J. Oct. 11, 2018); *Sandoz Inc. v. Daiichi Sankyo, Inc.*, No. 16-00994 (D.N.J.).

31. Venue is proper with respect to Sandoz pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Sandoz has systematic and continuous contacts with New Jersey; a regular and established place of business in New Jersey; has its headquarters and principal place of business at 100 College Road, West Princeton, NJ 08540; and, in particular, Sandoz has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(C) by preparing and submitting its BLA for a denosumab biosimilar in and from New Jersey.

E. Sandoz GmbH (Austria)

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

33. On information and belief, Sandoz GmbH collaborates with Sandoz to develop, manufacture, seek approval for, and sell FDA approved biopharmaceutical drugs, which are being marketed, distributed, and sold in New Jersey and in the United States. On information and belief, Sandoz GmbH was and is actively involved with planning Sandoz's new products,

communicating with FDA regarding the Defendants' denosumab biosimilar product(s), and preparing and submitting Defendants' BLA. On information and belief, Sandoz GmbH collaborated and acted in concert with, directed, and/or authorized Sandoz to submit a BLA seeking approval from FDA to market and sell the Defendants' denosumab biosimilar product(s) in the State of New Jersey and throughout the United States, which directly gives rise to Amgen's claims of patent infringement.

34. On information and belief, Sandoz GmbH intends to participate in the commercial manufacturing and supply of Defendants' proposed denosumab biosimilar product(s) for sale in New Jersey and in the United States upon FDA approval. Sandoz GmbH facilities [redacted] On information and belief, Sandoz GmbH will accordingly benefit commercially and be financially compensated for its active involvement in the commercial manufacture, use, or sale of Defendants' proposed denosumab biosimilar product(s) in New Jersey and in the United States.

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

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

F. Lek Pharmaceuticals d.d. (Slovenia)

37. Lek Pharmaceuticals d.d. is subject to personal jurisdiction in New Jersey because, among other reasons, Lek Pharmaceuticals d.d. itself, and through its affiliate Sandoz, purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court. On information and belief, Lek Pharmaceuticals d.d. collaborates with Sandoz to develop, manufacture, seek approval for, and sell FDA approved biopharmaceutical drugs, which are being marketed, distributed, and sold in New Jersey and in the United States.

38. On information and belief, Lek Pharmaceuticals d.d. was and is actively involved with planning Sandoz's new products, communicating with FDA regarding Defendants' denosumab biosimilar product(s), and submitting Defendants' denosumab biosimilar BLA. On information and belief, Lek Pharmaceuticals d.d. collaborated and acted in concert with, directed, and/or authorized Sandoz to submit a BLA seeking approval from FDA to market and sell the Defendants' denosumab biosimilar product(s) in the State of New Jersey and throughout the United States, which directly gives rise to Amgen's claims of patent infringement.

39. On information and belief, Lek Pharmaceuticals d.d. intends to participate in the manufacturing and supply of Defendants' proposed denosumab biosimilar product(s) for sale in New Jersey and in the United States upon FDA approval. Specifically, Lek Pharmaceuticals d.d.

[redacted]

[redacted] On information and belief, Lek Pharmaceuticals d.d. will accordingly benefit commercially and be financially compensated for its active involvement in the commercial manufacture, use, or sale of Defendants' proposed denosumab biosimilar product(s) in New Jersey and in the United States.

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

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

G. <u>Novartis Pharmaceuticals Production d.o.o. (Slovenia)</u>

42. On information and belief, Novartis Pharmaceuticals Production d.o.o is or will be a successor-in-interest to Lek Pharmaceuticals d.d. On information and belief, Novartis Pharmaceuticals Production d.o.o. intends to assume the responsibilities of Lek Pharmaceuticals d.d. with regards to Defendants' proposed denosumab biosimilar product(s). Accordingly, it is

subject to personal jurisdiction in New Jersey for the same reasons as alleged above for Lek Pharmaceuticals d.d.

43. Additionally, and in the alternative, to the extent Novartis Pharmaceuticals Production d.o.o. is not subject to the jurisdiction of the courts of general jurisdiction of the State of New Jersey, Novartis Pharmaceuticals Production d.o.o. likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

44. Venue is proper in this Court as to Novartis Pharmaceuticals Production d.o.o. because it is a foreign entity who may be sued in any judicial district, including in the District of New Jersey. 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

H. Novartis AG (Switzerland)

45. Novartis AG is subject to personal jurisdiction in New Jersey because, among other reasons, Novartis AG itself, and through its affiliate Sandoz, purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court. On information and belief, Novartis AG collaborates with Sandoz to develop, manufacture, seek approval for, and sell FDA approved biopharmaceutical drugs, which are being marketed, distributed, and sold in New Jersey and in the United States. On information and belief, Sandoz is a subsidiary of Novartis AG and was one when Defendants filed their BLA for a denosumab biosimilar product.

46. On information and belief, Novartis AG was and is actively involved with planning Sandoz's new products, communicating with FDA regarding the Defendants' denosumab biosimilar product(s), and preparing and submitting Defendants' BLA. On

information and belief, Novartis AG collaborated and acted in concert with, directed, and/or authorized Sandoz to submit a BLA seeking approval from FDA to market and sell the Defendants' denosumab biosimilar product(s) in the State of New Jersey and throughout the United States, which directly gives rise to Amgen's claims of patent infringement. Specifically, on information and belief, Novartis AG [redacted] For example, Novartis AG announced the FDA's acceptance of Defendants' denosumab biosimilar BLA on its own website. *See* https://www.novartis.com/news/media-releases/sandoz-biologics-license-application-proposed-biosimilar-denosumab-accepted-us-fda.

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

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

THE DENOSUMAB DRUG PRODUCTS

I. Bone Metabolism and RANKL

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

50. A variety of tissues throughout the body express, or produce, proteins. Among those proteins is receptor activator of nuclear factor kappa- β (also known as "RANK"), which is found on the surface of cells called osteoclast precursors. RANK is able to bind to another protein—its ligand—called RANK ligand ("RANKL").[1] When RANKL binds to RANK on the surface of osteoclast precursors, the interaction stimulate the precursor cell to form into a mature osteoclast cell. Mature osteoclasts carry out bone resorption, *i.e.* the breakdown of bone.

51. 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.

J. Denosumab

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

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

53. 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.

K. Amgen's Invention of Denosumab

54. Amgen Inc. developed denosumab after years of groundbreaking research into the bone remodeling pathway. This research dates back to the late 1990s, when studies by Amgen Inc. scientists identified the relationship between the protein RANKL (or OPGL) and bone resorption. Amgen Inc. devoted significant resources to developing a treatment for diseases mediated by this mechanism, such as osteoporosis and disease states characterized by weakened bones.

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

56. In 2001, Dr. Boyle and his co-inventors filed U.S. Provisional Patent Application No. 60/301,172 (the "'172 Application"). The '736 Patent and the '418 Patent both claim priority to the '172 Application. The '172 Application (and the '736 and '418 Patents) disclose and describe 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 by reference to the disclosed denosumab amino acid sequences, as well as pharmaceutical compositions of denosumab. The '418 Patent claims methods and compositions for making denosumab and the product of such methods.

L. Amgen's Investment in Prolia and XGEVA (denosumab)

57. Today, denosumab is the active ingredient in two drugs that Amgen sells under two different brand names: Prolia and XGEVA. Prolia is indicated for the treatment of osteoporosis and other conditions associated with bone loss. XGEVA is indicated to treat bone cancers and to prevent fractures in cancer patients with bone metastases. Defendants intend to introduce biosimilar versions of both products. *See* https://www.us.sandoz.com/news/media-releases/sandoz-biologics-license-application-proposed-biosimilar-denosumab-accepted-us.

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

59. Based on the results of extensive clinical testing, Amgen Inc. filed Biologic BLA No. 125320 in December 2008. In June 2010, the FDA first approved Prolia (active ingredient denosumab), pursuant to BLA No. 125320, for treating postmenopausal women with

osteoporosis at high risk for fracture. Prolia was the first biologic ever approved to treat osteoporosis and it remains the only RANKL-inhibiting biologic that is FDA approved today.

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

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

M. Amgen's Further Innovations in Antibody Manufacturing

62. Amgen Inc.'s further investments in research led to the development of novel manufacturing processes related to denosumab and the larger field of commercial manufacturing

of antibody therapeutics for humans. Amgen Inc.'s efforts in this field yielded advancements in several key areas of manufacturing, such as cell culture and purification methods, to improve and maintain product quality, consistency, safety, and effectiveness. Amgen Inc. obtained patent protection over many of these advancements, which are reflected in the Patents-in-Suit.

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

63. As alleged herein, the '736 Patent issued on April 29, 2008 and the '418 Patent issued on November 15, 2011. Both the '736 and '418 Patents were identified in Amgen Inc.'s patent marking for Prolia and XGEVA before Sandoz filed its BLA for its denosumab biosimilar product(s). Thus, Defendants had constructive notice of and were aware of at least the '736 and '418 Patents before the filing of their BLA. *See* 35 U.S.C. § 287.

64. On information and belief Defendants, by the nature of their 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 Defendants' denosumab biosimilar product(s) before the filing of Defendants' BLA.

65. Further, as alleged herein, Amgen Inc. sent a letter to Sandoz identifying each of the Patents-In-Suit on February 10, 2023. Defendants were thus aware of the Patents-In-Suit at least as of February 10, 2023.

O. Defendants' Biosimilar Product

66. On information and belief, Sandoz, acting in concert with the other Defendants, submitted its BLA with the FDA pursuant to Section 351(k) of the Public Health Service Act in order to obtain approval to commercially manufacture, use, offer to sell, sell, and import into the United States Defendants' proposed denosumab biosimilar product(s).

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

68. Based on the BLA that Sandoz provided to Amgen Inc., the active ingredient in Defendants' proposed denosumab biosimilar product(s) [redacted] Based on the BLA that Sandoz provided to Amgen Inc., Defendants' proposed denosumab biosimilar product(s) are [redacted]

69. Based on the BLA that Sandoz provided to Amgen Inc., Defendants' proposed denosumab biosimilar product(s) are [redacted] In particular, during development of their proposed biosimilar product(s), [redacted]

[redacted]

70. Further, based on the BLA that Sandoz provided to Amgen Inc., and on information and belief Defendants' proposed denosumab biosimilar product(s) are manufactured by [redacted] For example, based on the BLA that Sandoz provided to Amgen Inc., Defendants' proposed denosumab biosimilar product(s) are manufactured by [redacted]

71. On information and belief, Sandoz, acting in concert with the other Defendants, has imported into and/or used within the United States Defendants' proposed denosumab biosimilar product(s), which were produced by the manufacturing processes described in the BLA that Sandoz provided to Amgen Inc.

P. Defendants' Failure to Comply with the BPCIA

72. 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 Sandoz, 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.

73. 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 a copy of the application submitted to the Secretary under subsection (k), *and such other information that describes the process or processes*

> *used to manufacture the biological product* that is the subject of such application; and
>
> may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor."

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

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

> If a subsection (k) applicant fails to provide the application *and information required under paragraph* (*2*)(*A*), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

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

75. Sandoz notified Amgen Inc. by letter dated December 13, 2022, that it had recently submitted to the FDA a BLA pursuant to the BPCIA, seeking authorization from the FDA to engage in the commercial manufacture, use, sale, or offer for sale of biosimilar versions of Amgen's Prolia and XGEVA products containing the active ingredient denosumab. Sandoz provided a hard drive containing a copy of the BLA it had purportedly submitted to the FDA with its December 13, 2022 letter.

76. At the time of Sandoz's December 13, 2022 letter, Defendants' BLA had not yet been accepted by the FDA for review. Although the FDA would not accept Defendants' BLA until nearly two months later on February 6, 2023, Sandoz took the position in its December 2022 letter that its early BLA production, which it unilaterally sent to Amgen Inc.'s chairman and CEO, without any prior discussions with counsel regarding confidentiality, triggered the start of the BPCIA information exchange, and in particular, the 60-day window for Amgen Inc. to

provide a list of patents to Sandoz pursuant to 42 U.S.C. § 262(*l*)(3)(A). Sandoz requested that Amgen Inc. provide its disclosure under § 262(*l*)(3)(A) "as soon as possible and in any event no later than 60 days from the date" of the letter.

77. Because the BLA Sandoz provided had not been accepted by the FDA, Amgen Inc. could not determine whether it contained the same information that the FDA would review after acceptance. Amgen Inc. accordingly wrote to Sandoz on December 29, 2022, noting that Sandoz's premature production did not satisfy the requirements of § 262(*l*)(2)(A) and requested that Sandoz notify Amgen Inc. if and when Defendants' BLA was accepted by the FDA and that Sandoz agree to provide any changes to the Defendants' BLA, any supplemental submissions, or any other information provided to the FDA that was not contained in the Defendants' BLA provided to Amgen Inc. on December 13, 2022. Amgen Inc. followed up on this request on January 31, 2023. Sandoz did not respond at that time.

78. After carefully reviewing the BLA provided by Sandoz, Amgen Inc. determined that additional information on certain manufacturing processes being used by Sandoz to produce its biosimilar version of denosumab, but which was not found in Defendants' BLA, was required to fully evaluate whether Defendants would infringe certain of Amgen's patents. Amgen Inc. requested that additional information from Sandoz by letter on January 19, 2023. In particular, Amgen Inc. requested specific information such as [redacted] In a response on January 26, 2023, Sandoz refused to provide any of the requested information.

79. On February 6, 2023, Sandoz publicly announced that the FDA had accepted a BLA for a proposed denosumab biosimilar product(s). (*See*

https://www.us.sandoz.com/news/media-releases/sandoz-biologics-license-application-proposed-biosimilar-denosumab-accepted-us.) Amgen Inc. immediately requested, again, that Sandoz provide it with any changes, supplements, or other information that Sandoz had submitted to the FDA not contained in the Defendants' BLA provided to Amgen Inc. on December 13, 2022. Sandoz did not respond at that time. The following day, February 7, 2023, Amgen Inc. wrote to Sandoz again requesting other manufacturing and process information required by § 262(*l*)(2)(A). Sandoz did not respond at that time.

80. On February 10, 2023, Amgen Inc. provided Sandoz a list of patents that could reasonably be asserted if the denosumab biosimilar product(s) that is the subject of the BLA Sandoz provided on December 13, 2022 is made, used, offered for sale, sold, or imported into the United States without a license from Amgen. In this letter, Amgen Inc. also objected to Sandoz's failure to satisfy the requirements of § 262(*l*)(2)(A). All of the Patents-in-Suit were identified in the February 10, 2023 letter and could have been identified in Amgen's list pursuant to 42 U.S.C. § 262(*l*)(3)(A) had Defendants complied with § 262(*l*)(2)(A).

81. On February 25, 2023, more than two weeks after Amgen Inc. provided its patent list, Sandoz provided to Amgen Inc. some correspondence and supplemental submissions to the FDA, most of which were in Sandoz's possession before February 10, 2023. Sandoz did not provide any "other information that describes the process or processes used to manufacture the biological product" that is the subject of Defendants' BLA, as required by § 262(*l*)(2)(A).

82. On March 10, 2023, Sandoz provided Amgen Inc. with a letter titled "Detailed Statement Pursuant to 42 U.S.C. § 262(*l*)(3)(B)." On information and belief, to prepare this letter Sandoz reviewed or relied upon documents and information that Sandoz was required to produce to Amgen under § 262(*l*)(2)(A). On information and belief, Sandoz reviewed or relied

upon the same information that Amgen had requested in January and again in February, and that Sandoz had refused and continues to refuse to provide to Amgen.

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

Q. Defendants' Intent to Commercialize Before the Patents-In-Suit Expire

84. The FDA has stated publicly that the agency's goal is to act on the majority of subsection (k) applications within 10 months of an application's 60 day filing date. *See* https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-ii-assessment-program-enhanced-review-transparency-and-communication-biosimilar-user-fee-act. This 10-month date is sometimes called a "BsUFA II date," which is an abbreviation for Biosimilar User Fee Act II date. On information and belief, the anticipated BsUFA II date for Defendants' BLA referencing Amgen's Prolia and XGEVA is in December 2023, which is before the expiration of the '736 Patent, and other Patents-in-Suit.

85. The BPCIA separately provides that "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). Defendants have not provided notice to Amgen pursuant to (*l*)(8)(A); by its terms,

that subsection precludes Sandoz from commercial marketing until, at a minimum, 180 days following such notice.

86. Additionally, under 42 U.S.C. § 262(*l*)(3)(B)(ii), a biosimilar applicant may provide to the reference product sponsor, on a patent-by-patent basis, a certification that the applicant does not intend to begin commercial marketing of its proposed biosimilar product before the expiration of such patent. Sandoz did not provide a statement pursuant to § 262(*l*)(3)(B)(ii) for any of the Patents-In-Suit.

87. Therefore, on information and belief, Defendants intend to and will immediately and imminently after notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of their denosumab biosimilar product(s) before the expiration of the Patents-in Suit, including the '736 Patent.

THE PATENTS-IN-SUIT

R. The '736 and '418 Patents

88. 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 by its unique amino acid sequence.

89. The '736 Patent is assigned to Amgen Inc. AML has an exclusive license to the '736 Patent.

90. The '736 Patent was identified in the letter Amgen Inc. sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar product(s).

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

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

93. The ’418 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

S. The ’205 Patent

94. The USPTO duly and legally issued the ’205 Patent, titled “Methods for Refolding of Recombinant Antibodies,” on April 19, 2011. The ’205 Patent discloses and claims methods of producing IgG2 antibodies by using a reduction/oxidation coupling reagent and optionally a chaotropic agent.

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

96. The ’205 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

T. The ’178 Patent

97. 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 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.

98. The ’178 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’178 Patent.

99. The ’178 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

U. The ’493 Patent

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

101. The ’493 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’493 Patent.

102. The ’493 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

V. The ’168 Patent

103. The USPTO duly and legally issued the ’168 Patent, titled “Feed Media,” on January 5, 2016. The ’168 Patent discloses and claims methods for stabilizing feed media for culturing mammalian cells by adding pyruvate.

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

105. The ’168 was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

W. The ’816 Patent

106. 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 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.

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

108. The ’816 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

X. The ’134 Patent

109. The USPTO duly and legally issued the ’134 Patent, titled “Carbohydrate Phosphonate Derivatives as Modulators of Glycosylation” on May 3, 2016. The ’134 Patent 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.

110. The ’134 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’134 Patent.

111. The ’134 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

Y. The ’435 Patent

112. 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 methods of modulating the high-mannose glycoform content of a recombinant protein during a mammalian cell culture.

113. The ’435 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’435 Patent.

114. The ’435 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

Z. The ’901, ’972, and ’514 Patents

115. 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.

116. The ’901 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’901 Patent.

117. The ’901 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

118. 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.

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

120. The ’972 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

121. 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.

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

123. The ’514 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

AA. The ’492 and ’630 Patent

124. 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 discloses and claims methods for influencing the fucosylated glycan content of a recombinant protein.

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

126. The ’492 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

127. 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 discloses and claims methods for influencing the fucosylated glycan content of a recombinant protein.

128. The ’630 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’630 Patent.

129. The ’630 was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be

asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar product(s).

BB. The '723 and '963 Patents

130. 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 discloses and claims methods of influencing the high-mannose glycoform content of a recombinant protein.

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

132. The '723 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar product(s).

133. 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 discloses and claims methods of influencing the high-mannose glycoform content of a recombinant protein.

134. The '963 Patent is assigned to Amgen Inc. AML has an exclusive license to the '963 Patent.

135. The '963 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants' proposed denosumab biosimilar product(s).

CC. The ’397 and ’404 Patents

136. 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 discloses and claims systems and methods used to control flow filtration in the production and/or purification of recombinant proteins.

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

138. The ’397 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

139. The USPTO duly and legally issued the ’404 Patent, titled “Process Control Systems and Methods for Use with Filters and Filtration Processes,” on August 3, 2021. The ’404 Patent discloses and claims systems and methods used to control flow filtration in the production and/or purification of recombinant proteins.

140. The ’404 Patent is assigned to Amgen Inc. AML has an exclusive license to the ’404 Patent.

141. The ’404 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

DD. The ’079 Patent

142. The USPTO duly and legally issued the ’079 Patent, titled “Charging Depth Filtration of Antigen-Binding Proteins,” on August 24, 2021. The ’079 Patent discloses and claims methods of using a charged depth filter to purify an antigen-binding protein.

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

144. The ’079 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

EE. The ’760 and ’980 Patents

145. 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 discloses and claims methods of regulating the high mannose glycoform content of denosumab by adding monensin to the cell culture.

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

147. The ’760 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

148. 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

discloses and claims methods of modulating the high mannose glycoform content of a recombinant protein by adding monensin to the cell culture.

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

150. The ’980 Patent was identified in the letter Amgen sent to Sandoz on February 10, 2023 as a patent for which Amgen Inc. believes a claim of patent infringement could reasonably be asserted if Sandoz engaged in the making, using, offering to sell, selling, or importing into the United States of Defendants’ proposed denosumab biosimilar product(s).

COUNT 1: INFRINGEMENT OF THE ’736 PATENT

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

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

153. The submission of Defendants’ BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of Defendants’ proposed denosumab biosimilar product(s) 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.

154. On information and belief, Defendants’ importation into and/or use within the United States of Defendants’ denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants’ denosumab biosimilar product(s) despite knowledge of the ’736 Patent constitutes willful infringement.

155. 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.

156. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 '736 PATENT

157. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

158. 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/or (b). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.,* December 2023), begin to make, use, offer for sale, sell within the United States, or import into the United States, Defendants' denosumab biosimilar product(s) before expiration of the '736 Patent.

159. 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 denosumab biosimilar product(s) 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.

160. 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' denosumab biosimilar product(s) before the expiration of the '736 Patent.

161. 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' denosumab biosimilar product(s) before the expiration of the '736 Patent.

COUNT 3: INFRINGEMENT OF THE '418 PATENT

162. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

163. On information and belief, Defendants have infringed the '418 Patent under at least 35 U.S.C. §§ 271(a), (b), (e), and (g).

164. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of Defendants' proposed denosumab biosimilar product(s) before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, one or more claims of the '418 Patent, including at least claim 14.

165. On information and belief, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '418 Patent constitutes willful infringement.

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

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

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

168. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

169. On information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '418 Patent, including at least claim 14, under at least 35 U.S.C. §§ 271(a), (b), and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to make, use, offer for sale, or sell within the United States, or import into the United States, Defendants' denosumab biosimilar product(s) before expiration of the '418 Patent.

170. On information and belief, Defendants' denosumab antibody made by the process of the '418 Patent is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially

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

171. 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 denosumab biosimilar product(s) 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.

172. 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, Defendants' denosumab biosimilar product(s) before the expiration of the '418 Patent and that such infringement is willful.

173. 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 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 '418 Patent.

COUNT 5: INFRINGEMENT OF THE '205 PATENT

174. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

175. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide information requested by Amgen to fully evaluate whether the '205 Patent has been or will be infringed, on

information and belief, Defendants have infringed the '205 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

176. 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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

177. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '205 Patent constitutes willful infringement.

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

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

COUNT 6: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '205 PATENT

180. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

181. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide information requested by Amgen to fully evaluate whether the '205 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '205 Patent, including at least claims 1 and 40, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '205 Patent.

182. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '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 product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

183. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

184. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the ’205 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants’ denosumab biosimilar product(s) before the expiration of the ’205 Patent.

185. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the ’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 product(s) before the expiration of the ’205 Patent.

COUNT 7: INFRINGEMENT OF THE ’178 PATENT

186. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

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

188. 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 import into the United States, of Defendants’ proposed denosumab biosimilar product(s) 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.

189. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '178 Patent constitutes willful infringement.

190. 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.

191. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 8: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '178 PATENT

192. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

193. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide information requested by Amgen to fully evaluate whether the '178 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of

equivalents, one or more claims of the '178 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '178 Patent.

194. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '178 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

195. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

196. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '178 Patent by making, using, offering to sell, or selling within the United

States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '178 Patent.

197. 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 product(s) before the expiration of the '178 Patent.

COUNT 9: INFRINGEMENT OF THE '493 PATENT

198. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

199. On information and belief, Defendants have infringed the '493 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

200. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of Defendants' proposed denosumab biosimilar product(s) before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '493 Patent, including at least claim 1.

201. On information and belief, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '493 Patent, including at least claim 1. On information and belief, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '493 Patent constitutes willful infringement.

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

203. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '493 Patent.

COUNT 10: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '493 PATENT

204. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

205. On information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '493 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '493 Patent.

206. On information and belief, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '493 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

207. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), before the expiration of the '493 Patent, will infringe one or more claims of the '493 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

208. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '493 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '493 Patent.

209. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the '493 Patent. Amgen does not have an adequate remedy at law and seeks injunctive relief preventing Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '493 Patent.

COUNT 11: INFRINGEMENT OF THE '168 PATENT

210. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

211. 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 information requested by Amgen to fully evaluate whether the '168 Patent has been or will be infringed, on information and belief, Defendants have infringed the '168 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

212. 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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '168 Patent, including at least claim 33.

213. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '168 Patent, including at least claim 33. On information and belief, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '168 Patent constitutes willful infringement.

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

215. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '168 Patent.

COUNT 12: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '168 PATENT

216. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

217. 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 information requested by Amgen to fully evaluate whether the '168 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '168 Patent, including at least claim 33, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '168 Patent.

218. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '168 Patent, including at least claim 33, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

219. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), before the expiration of the '168 Patent, will infringe one or more claims of the '168 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the

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

220. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '168 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '168 Patent.

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

COUNT 13: INFRINGEMENT OF THE '816 PATENT

222. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

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

224. 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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

225. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '816 Patent constitutes willful infringement.

226. 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.

227. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 14: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '816 PATENT

228. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

229. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide information requested by Amgen to fully evaluate whether the '816 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '816 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will,

immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '816 Patent.

230. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '816 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

231. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

232. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '816 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '816 Patent.

233. 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 product(s) before the expiration of the '816 Patent.

COUNT 15: INFRINGEMENT OF THE '134 PATENT

234. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

235. 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 information requested by Amgen to fully evaluate whether the '134 Patent has been or will be infringed, on information and belief, Defendants have infringed the '134 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

236. 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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

237. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the

United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '134 Patent constitutes willful infringement.

238. 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.

239. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 16: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '134 PATENT

240. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

241. 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 information requested by Amgen to fully evaluate whether the '134 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '134 Patent, including at least claim 35, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '134 Patent.

242. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '134 Patent, including at least claim 35, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

243. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

244. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '134 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '134 Patent.

245. 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 product(s) before the expiration of the '134 Patent.

COUNT 17: INFRINGEMENT OF THE '435 PATENT

246. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

247. 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 information requested by Amgen to fully evaluate whether the '435 Patent has been or will be infringed, on information and belief, Defendants have infringed the '435 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

248. 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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

249. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '435 Patent constitutes willful infringement.

250. 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.

251. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 18: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '435 PATENT

252. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

253. 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 information requested by Amgen to fully evaluate whether the '435 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '435 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '435 Patent.

254. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '435 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

255. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

256. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '435 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '435 Patent.

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

COUNT 19: INFRINGEMENT OF THE '901 PATENT

258. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

259. On information and belief, Defendants have infringed the '901 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

260. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

261. On information and belief, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '901 Patent constitutes willful infringement.

262. Amgen is entitled to a judgment that Defendants have infringed, either literally or under the doctrine of equivalents, one or more claims of the '901 Patent. Amgen has been injured by Defendants' infringement and is entitled to damages.

263. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 20: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '901 PATENT

264. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

265. On information and belief, 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/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023),

begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '901 Patent.

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

267. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

268. 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, Defendants' denosumab biosimilar product(s) before the expiration of the '901 Patent.

269. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the '901 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 '901 Patent.

COUNT 21: INFRINGEMENT OF THE '972 PATENT

270. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

271. On information and belief, Defendants have infringed the '972 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

272. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

273. On information and belief, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '972 Patent constitutes willful infringement.

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

275. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 22: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '972 PATENT

276. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

277. On information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '972 Patent, including at least claim 3, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '972 Patent.

278. On information and belief, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '972 Patent, including at least claim 3, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

279. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

280. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '972 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '972 Patent.

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

COUNT 23: INFRINGEMENT OF THE '514 PATENT

282. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

283. On information and belief, Defendants have infringed the '514 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

284. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

285. On information and belief, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '514 Patent constitutes willful infringement.

286. 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.

287. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 24: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '514 PATENT

288. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

289. On information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '514 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '514 Patent.

290. On information and belief, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '514 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no

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

291. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

292. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '514 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '514 Patent.

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

COUNT 25: INFRINGEMENT OF THE '492 PATENT

294. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

295. 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 information requested by Amgen to fully evaluate whether the '492 Patent has been or will be infringed, on

information and belief, Defendants have infringed the '492 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

296. 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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

297. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '492 Patent constitutes willful infringement.

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

299. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 26: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '492 PATENT

300. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

301. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide information requested by Amgen to fully evaluate whether the '492 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '492 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '492 Patent.

302. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '492 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

303. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

304. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '492 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '492 Patent.

305. Amgen will suffer irreparable injury for which damages are an inadequate remedy if Defendants are not enjoined from infringing one or more claims of the '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 product(s) before the expiration of the '492 Patent.

COUNT 27: INFRINGEMENT OF THE '630 PATENT

306. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

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

308. 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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

309. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '630 Patent constitutes willful infringement.

310. 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.

311. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 28: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '630 PATENT

312. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

313. 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 information requested by Amgen to fully evaluate whether the '630 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of

equivalents, one or more claims of the '630 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '630 Patent.

314. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '630 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

315. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

316. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '630 Patent by making, using, offering to sell, or selling within the United

States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '630 Patent.

317. 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 product(s) before the expiration of the '630 Patent.

COUNT 29: INFRINGEMENT OF THE '723 PATENT

318. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

319. 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 information requested by Amgen to fully evaluate whether the '723 Patent has been or will be infringed, on information and belief, Defendants have infringed the '723 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

320. 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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

321. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '723 Patent constitutes willful infringement.

322. 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.

323. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 30: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '723 PATENT

324. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

325. 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 information requested by Amgen to fully evaluate whether the '723 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '723 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '723 Patent.

326. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '723 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

327. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

328. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '723 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '723 Patent.

329. 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 product(s) before the expiration of the '723 Patent.

COUNT 31: INFRINGEMENT OF THE '963 PATENT

330. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

331. 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 information requested by Amgen to fully evaluate whether the '963 Patent has been or will be infringed, on information and belief, Defendants have infringed the '963 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

332. 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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

333. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '963 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 '963 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, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 32: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '963 PATENT

336. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

337. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide information requested by Amgen to fully evaluate whether the '963 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '963 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '963 Patent.

338. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '963 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

339. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

340. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '963 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '963 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 '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 product(s) before the expiration of the '963 Patent.

COUNT 33: INFRINGEMENT OF THE '397 PATENT

342. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

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

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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '397 Patent, including at least claim 13.

345. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '397 Patent, including at least claim 13. On information and belief, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '397 Patent constitutes willful infringement.

346. 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.

347. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 34: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '397 PATENT

348. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

349. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(l)(2)(A) and their refusal to provide information requested by Amgen to fully evaluate whether the '397 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '397 Patent, including at least claim 13, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '397 Patent.

350. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '397 Patent, including at least claim 13, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

351. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

352. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '397 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '397 Patent.

353. 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 product(s) before the expiration of the '397 Patent.

COUNT 35: INFRINGEMENT OF THE '404 PATENT

354. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

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

356. 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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) before the expiration of the Patents-in-Suit is an act of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '404 Patent, including at least claim 14.

357. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their active inducement thereof, constitutes acts of infringement, either literally or under the doctrine of equivalents, of one or more claims of the '404 Patent, including at least claim 14. On information and belief, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '404 Patent constitutes willful infringement.

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

359. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such infringement of one or more claims of the '404 Patent.

COUNT 36: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '404 PATENT

360. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

361. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide information requested by Amgen to fully evaluate whether the '404 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '404 Patent, including at least claim 14, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will,

immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '404 Patent.

362. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '404 Patent, including at least claim 14, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

363. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), before the expiration of the '404 Patent, will infringe one or more claims of the '404 Patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy. This declaratory judgment action is authorized by, *inter alia*, the BPCIA and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(2)(A), 262(*l*)(9)(C); 28 U.S.C. §§ 2201, 2202.

364. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '404 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '404 Patent.

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

COUNT 37: INFRINGEMENT OF THE '079 PATENT

366. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

367. 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 information requested by Amgen to fully evaluate whether the '079 Patent has been or will be infringed, on information and belief, Defendants have infringed the '079 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

368. 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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

369. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the

United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '079 Patent constitutes willful infringement.

370. 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.

371. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 38: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '079 PATENT

372. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

373. 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 information requested by Amgen to fully evaluate whether the '079 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '079 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '079 Patent.

374. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '079 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

375. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

376. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '079 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '079 Patent.

377. 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 product(s) before the expiration of the '079 Patent.

COUNT 39: INFRINGEMENT OF THE '760 PATENT

378. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

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

380. 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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

381. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '760 Patent constitutes willful infringement.

382. 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.

383. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 40: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '760 PATENT

384. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

385. Based on information presently available to Amgen, and in view of Defendants' failure to comply with 42 U.S.C. § 262(*l*)(2)(A) and their refusal to provide information requested by Amgen to fully evaluate whether the '760 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '760 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '760 Patent.

386. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '760 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

387. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

388. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '760 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '760 Patent.

389. 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 product(s) before the expiration of the '760 Patent.

COUNT 41: INFRINGEMENT OF THE '980 PATENT

390. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

391. 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 information requested by Amgen to fully evaluate whether the '980 Patent has been or will be infringed, on information and belief, Defendants have infringed the '980 Patent under at least 35 U.S.C. §§ 271(b), (e) and (g).

392. 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 import into the United States, of Defendants' proposed denosumab biosimilar product(s) 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.

393. On information and belief, based on information presently available to Amgen, Defendants' importation into and/or use within the United States of Defendants' denosumab biosimilar product(s), or their 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 and/or use within the United States of Defendants' denosumab biosimilar product(s) despite knowledge of the '980 Patent constitutes willful infringement.

394. 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.

395. Amgen will be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' denosumab biosimilar product(s) upon FDA approval. 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 42: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '980 PATENT

396. Paragraphs 1-150 are incorporated by reference as if fully set forth herein.

397. 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 information requested by Amgen to fully evaluate whether the '980 Patent has been or will be infringed, on information and belief, Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '980 Patent, including at least claim 1, under at least 35 U.S.C. §§ 271(b) and/or (g). On information and belief, Defendants intend to and will, immediately after 180 days from notice pursuant to 42 U.S.C. § 262(*l*)(8)(A), and in any event no later than 10 months after FDA acceptance of Defendants BLA (*i.e.*, December 2023), begin to import into the United States, and offer to sell, sell, and use within the United States, Defendants' denosumab biosimilar product(s) before expiration of the '980 Patent.

398. On information and belief, based on information presently available to Amgen, Defendants' manufacturing process infringes, either literally or under the doctrine of equivalents, one or more claims of the '980 Patent, including at least claim 1, and the denosumab made by that process is the essential active ingredient of Defendants' proposed denosumab biosimilar product(s). On information and belief, there is no subsequent process that materially changes that active ingredient, prior to its importation, offer for sale, sale or use in the United States.

399. An actual controversy has arisen and now exists between the parties concerning whether Defendants, by importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), their denosumab biosimilar product(s), 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.

400. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the '980 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Defendants' denosumab biosimilar product(s) before the expiration of the '980 Patent.

401. 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 product(s) before the expiration of the '980 Patent.

PRAYER FOR RELIEF

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

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

B. Based on that judgment, a permanent injunction against the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Defendants' denosumab biosimilar product(s) 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, Defendants' denosumab biosimilar product(s) during the term of the Patents-In-Suit;

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

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

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

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

DEMAND FOR A JURY TRIAL

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

Dated: May 1, 2023

/s/ Liza M. Walsh

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RULE 11.2 CERTIFICATION

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

Dated: May 1, 2023

/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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