IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

OSSIFI-MAB LLC, *Plaintiff*, *v.* AMGEN INC., *Defendant*.	Civil Action No. 23-10861 **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff OssiFi-Mab LLC ("OMAB" or "Plaintiff"), by and through its attorneys, for its Complaint for Patent Infringement against Defendant Amgen Inc. ("Amgen" or "Defendant"), hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 8,178,099 ("the '099 Patent"), 8,877,196 ("the '196 Patent"), and 11,608,373 ("the '373 Patent") (collectively, the "Patents-in-Suit"). This action arises out of Defendant's manufacture, use, sale, offer to sell within the United States, and/or importation to the United States, of Defendant's sclerostin inhibitor "romosozumab-aqqg," and sold under the brand name Evenity® for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture.

THE PARTIES

2. Plaintiff OMAB is a company organized under the laws of the state of Kansas, having its principal place of business at 11235 Mastin Street, Suite 102, Overland Park, Kansas 66210.

3. OMAB is a biotechnology company committed to developing first-in-class, novel therapeutic products promoting bone growth for the benefit of patients suffering from bone degeneration. OMAB is a pioneer in the field of therapeutics, specifically, sclerostin antagonist therapeutics harnessing the power of the Sclerostin/Wnt family to increase bone growth.

4. Upon information and belief, Defendant Amgen Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at One Amgen Center Drive, Thousand Oaks, CA 91320.

JURISDICTION AND VENUE

5. This civil action for patent infringement arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201, and 2202.

7. This Court has personal jurisdiction over Defendant because its contacts with Massachusetts are continuous and systematic. On information and belief, Defendant maintains large research and development facilities in Massachusetts; owns property in Massachusetts; maintains numerous employees in Massachusetts; solicits and conducts business in Massachusetts; is registered to do business in Massachusetts; and has appointed agents for the service of process in Massachusetts.

8. This Court also has personal jurisdiction over Defendant because, among other reasons, Defendant has engaged in substantial and not isolated activity within this state by conducting and transacting business operations throughout the United States, including in the Commonwealth of Massachusetts, and deriving substantial revenue from interstate commerce.

9. This Court also has personal jurisdiction over Defendant because, among other reasons, Defendant has established minimum contacts within the forum such that the exercise of jurisdiction over Defendant will not offend traditional notions of fair play and substantial justice. For instance, Defendant has placed at least one product that practices the claimed invention of the Patents-in-Suit into the stream of commerce with the reasonable expectation and/or knowledge that purchasers and users of such products were located within the District of Massachusetts. Defendant has sold, advertised, marketed and/or distributed products in this District. Further, physicians and patients practice the claimed inventions of the Patents-in-Suit within this District, and Defendant has induced and contributed to this practice with reasonable expectation and/or knowledge that it would actually occur within this District.

10. Additionally, this Court has personal jurisdiction over Defendant because Defendant has previously elected to avail itself of the benefits of litigating its disputes, including patent disputes, in the District of Massachusetts. *See e.g.*, *Amgen Inc. v. F. Hoffmann-LaRoche LTD et al.*, No. 1:05-cv-12237 (D. Mass.); *Amgen, Inc. v. Hoechst Marion, et al.*, No. 1:97-cv-10814 (D. Mass.); *Amgen Manufacturing, Limited*; *Immunex Rhode Island Corporation; and Amgen USA Inc. v. The Trustees of Columbia University in the City of New York*, No. 1:04-cv-12626 (D. Mass.); *Amgen, Inc. v. Genetics Institute, Inc.*, No. 1:94-cv-11818 (D. Mass.); *Amgen Inc. v. Integrated Genetics, Inc.*, No. 1:87-cv-02616 (D. Mass.); and *Amgen Inc., et al. v. Chugai Pharmaceutical Co., Ltd., et al.*, No. 1:87-cv-02617 (D. Mass.).

11. Amgen's public website lists the following address as one of its "U.S. Locations."

360 Binney Street
Cambridge, MA 02142

12. Defendant's Cambridge, Massachusetts location is a regular and established place of business. Defendant claims that when it opened its offices and major research facility in

Cambridge, Massachusetts in 2001, "Amgen bec[ame] one of the early pioneers in what would become a biotechnology hotbed in Kendall Square, opening a 285,000-square-foot facility." On information and belief, Defendant has operated its Cambridge offices and research facility continuously at least since they first opened in 2001.

13. According to a June 2, 2017 press release,[1] Amgen "expanded its presence in Cambridge and [] hosted members of the Massachusetts life sciences community and government officials at its newly renovated research and process development facility." The press release notes that Amgen "invested $100 million in the Cambridge facility since 2015" and had "more than 400 staff . . . based at the site." This expansive site accommodates "research scientists" as well as "process development scientists and engineers [that] support product commercialization and the advancement of manufacturing innovation."

14. On February 18, 2021 Amgen issued a press release titled "10 Things You Should Know About Amgen's Manufacturing Network."[2] Number 5 on this list highlighted that the company's "manufacturing roots began in California, and later expanded to Rhode Island and Massachusetts."

15. On information and belief, and as described in further detail below, Amgen has committed acts of infringement of the Patents-in-Suit within this District.

16. Venue is proper in this District and before this Court pursuant to 28 U.S.C. §§ 1391 and 1400.

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[1] Amgen, *Amgen Showcases A Legacy of Science, Innovation And Collaboration In Cambridge*, June 2, 2017, https://www.amgen.com/newsroom/press-releases/2017/06/amgen-showcases-a-legacy-of-science-innovation-and-collaboration-in-cambridge.

[2] Amgen, *10 Things You Should Know About Amgen's Manufacturing Network*, February 18, 2021, https://www.amgen.com/stories/2021/02/10-things-you-should-know-about-amgens-manufacturing-network.

BACKGROUND

Dr. Ellies' Groundbreaking Research, and Development of the Patented Inventions

17. Osteoporosis, often referred to as the "silent disease," develops when bone mineral density and bone mass decrease, or when the structure and strength of bone changes, and leads to a decrease in bone strength that increases the risk of fractures.

18. Osteoporosis is the most common bone disease in humans, with approximately 200 million people suffering from the disease worldwide. Osteoporosis affects 20% of women aged 50 and older.

19. Dr. Debra Ellies, Ph.D. is a pioneer in the treatment of Osteoporosis and is the inventor of the Patents-in-Suit. Below is a brief background of her distinguished career.

20. Dr. Ellies spent years developing novel WNT-LRP blocking antibodies to *SOST* and *SOSTDC1*.

21. Dr. Ellies successfully completed her MSc in 1996 in the Canadian lab of Dr. Marc Ekker at the LOEB Research Institute where she identified new genes involved in craniofacial development and patterning of the zebrafish. Dr. Ellies also studied the function of the newly identified genes in contrast with known genes such as WNT pathway genes.

22. Dr. Ellies then completed her PhD in 2000. Dr. Ellies' PhD research continued focusing on the WNT pathway.

23. In May of 2000, Dr. Ellies started her post-doctoral training in the lab of Dr. Robb Krumlauf of the National Academy of Science and was tasked with finding the function of the *SOSTDC1* gene that the lab had identified at the National Institute for Medical Research in Mill Hill, London.

24. In October of 2000, Dr. Ellies moved to the Stowers Institute for Medical Research in Kansas City, Missouri with her mentor, Dr. Krumlauf, to continue her research on the *SOSTDC1* gene.

25. While at the Stowers Institute, Dr. Ellies was the key scientist in the epochal discovery that *SOSTDC1* was a very closely related gene family member to *SOST* and that they both functioned as modulators of the WNT pathway.

26. Dr. Ellies later discovered, in February of 2002, that LRP5 and LRP6 proteins functioned to regulate WNT through the LRP receptors to regulate bone formation during embryogenesis or during pubescence/adulthood.

27. Dr. Ellies was the first to report that Sclerostin blocking antibodies function by blocking Sclerostin action on the WNT-LRP pathway and went on to develop the first WNT-LRP blocking antibodies to *SOST* and *SOSTDC1* in April of 2004. Dr. Ellies also produced wildtype and mutated peptide antibodies to help understand the Sclerostin (SOST)-LRP and the SOSTDC1-LRP binding sites.

28. In 2004, Dr. Ellies started to look for her next position as an assistant Professor. Dr. Krumlauf encouraged Dr. Ellies to continue her work on the SOSTDC1 and SOST in her next chapter.

29. In 2004, Dr. Ellies met with the Department of Medicinal Chemistry heads at the University of Kansas. Dr. Ellies was encouraged to submit an SBIR/NIH grant in partnership with the University of Kansas high-throughput screening lab as a fee-for-service to develop a high-throughput small molecule screen to identify small molecules that prevented sclerostin from binding to LRP, its target.

30. In November of 2005, Dr. Ellies was contacted by the NIH/CRO chair who was in charge of the SBIR grant review who shared with Dr. Ellies that the grant was moving to funding review and that she should start to process NIH paperwork in order to receive the grant.

31. In March 2006, Dr. Ellies founded OsteoGeneX.

32. In 2006, Dr. Ellies was notified of an SBIR Phase I grant award from NIH/NIAMS (in partnership with KU as subcontractor) to fund her own work focused on developing a first-in-class, novel sclerostin-inhibitor therapeutic.

33. Dr. Ellies' employment at the Stowers Institute ceased in early June 2006.

34. Subsequently, in mid-June 2006, OsteoGeneX received the SBIR grant award, and operations of OsteoGeneX began.

35. In 2006, Dr. Ellies became a Fellow of the KTEC PIPELINE, an eMBA program ("the Pipeline program"). The Pipeline program encouraged Dr. Ellies to research and study the various bone disease markets to identify potential market opportunities. Dr. Ellies also applied to the NIH/SBIR to obtain coaching in developing her new business.

36. At the time of Dr Ellies' invention of the Patents-in-Suit, a serious and unmet need existed for new bone-building therapeutics due to the lack of orally available bone-building drugs. In or around September 2006, Dr. Ellies conceived the ideas which led to one or more of the inventions at issue here, including Dr. Ellies' groundbreaking discovery and patented methods of treatment using the serial or co-administration of an anti-sclerostin antibody with an anti-resorptive.

THE PATENTS-IN-SUIT

The '099 Patent

37. On May 15, 2012, United States Patent No. 8,178,099, titled "Methods of Altering Bone Growth by Administration of SOST or WISE Antagonist or Agonist," was duly and legally issued by the United States Patent and Trademark Office ("USPTO").

38. A true and correct copy of the '099 Patent is attached hereto as Exhibit A.

39. Debra L. Ellies is the named inventor of the '099 Patent.

40. OMAB is the sole owner by assignment of all rights, title, and interest in the '099 Patent. OMAB has the right to sue and recover for any past, present, or future infringement of the '099 Patent. The '099 Patent is valid and enforceable.

41. The '099 Patent is directed to, among other things, "a method of promoting local bone growth by administering a therapeutic amount of a Sost antagonist to a mammalian patient in need thereof." '099 Patent (Exhibit A) at Abstract.

42. The '099 Patent relates to Dr. Ellies' groundbreaking discovery of methods of increasing bone density via administration of a sclerostin (also known as Sost) antagonist together with an antiresorptive. Claim 12 of the '099 Patent is exemplary. It recites: "[a] method of systemically increasing bone density, comprising the steps of administering, to a mammalian patient in need thereof, a therapeutic comprising an effective amount of a Sclerostin antagonist together with an antiresorptive drug, wherein said Sclerostin antagonist comprises an antibody or FAB fragment specifically binding a peptide comprising 10 contiguous amino acids of a sequence selected from the group consisting of SEQ ID NOs: 2-13, 22 and 23, and wherein the antibody interferes with Sclerostin's ability to bind to LRP, thereby systemically increasing bone density." '099 Patent (Exhibit A) at claim 12.

The '196 Patent

43. On November 4, 2014, United States Patent No. 8,877,196, titled "Methods of Altering Bone Growth by Administration of SOST or WISE Antagonist or Agonist," was duly and legally issued by the USPTO.

44. A true and correct copy of the '196 Patent is attached hereto as Exhibit B.

45. Debra L. Ellies is the named inventor of the '196 Patent.

46. OMAB is the sole owner by assignment of all rights, title, and interest in the '196 Patent. OMAB has the right to sue and recover for any past, present, or future infringement of the '196 Patent. The '196 Patent is valid and enforceable.

47. The '196 Patent is directed to, among other things, "a method of promoting local bone growth by administering a therapeutic amount of a Sost antagonist to a mammalian patient in need thereof." '196 Patent at Abstract.

48. The '196 Patent relates to Dr. Ellies' groundbreaking discovery of methods of increasing bone density via administration of a sclerostin antagonist together with an antiresorptive. Claim 1 of the '196 Patent is exemplary. It recites: "[a] method of increasing bone density in a mammalian patient in need thereof, comprising the steps of: systemically administering to a said mammalian patient a therapeutic comprising an effective amount of a Sclerostin antagonist sequentially with an antiresorptive drug, said Sclerostin antagonist comprising an antibody or FAB fragment specifically binding a peptide selected from the group consisting of SEQ ID NOS:2-13, 22 and 23, wherein the antibody interferes with Sclerostin's ability to bind to LRP, thereby systemically increasing bone density." '196 Patent (Exhibit B) at claim 1.

The '373 Patent

49. On March 21, 2023, United States Patent No. 11,608,373, titled "Methods of Altering Bone Growth by Administration of SOST or WISE Antagonist or Agonist," was duly and legally issued by the USPTO.

50. A true and correct copy of the '373 Patent is attached hereto as Exhibit C.

51. Debra L. Ellies is the named inventor of the '373 Patent.

52. OMAB is the sole owner by assignment of all rights, title, and interest in the '373 Patent. OMAB has the right to sue and recover for any past, present, or future infringement of the '373 Patent. The '373 Patent is valid and enforceable.

53. The '373 Patent is directed to, among other things, "[a] method of increasing bone density by administering to a mammalian patient a therapeutic amount of a Sost antagonist together with an antiresorptive drug." '373 Patent (Exhibit C) at Abstract.

54. The '373 Patent relates to Dr. Ellies' groundbreaking discovery of methods of increasing bone density in osteoporosis patients undergoing therapy with a sclerostin antagonist together with an antiresorptive. Claims 1 and 15 of the '373 Patent are exemplary. Claim 1 recites: "[a] method of promoting bone growth in a human subject being treated with a humanized sclerostin-recognizing antibody, comprising administering an antiresorptive drug to the subject." '373 Patent (Exhibit C) at claim 1. Claim 15 recites: "[a] method for increasing bone density in a human subject with low bone mass being treated with a sclerostin-recognizing antibody, comprising serially administering an antiresorptive drug to the subject." *Id.* at claim 15.

Amgen's Evenity®

55. Amgen is in the business of developing, formulating, manufacturing, marketing, and selling pharmaceutical drug products, including antibody products.

56. Amgen's Evenity®, which is indicated for the "treatment of osteoporosis in postmenopausal women at high risk of fracture … or patients who have failed or are intolerant to other available osteoporosis therapy,"[3] was approved by the FDA in the United States on April 9, 2019. Global sales of Evenity® exceeded $780 million in 2022 alone. *See* https://www.amgen.com/newsroom/press-releases/2023/01/amgen-reports-fourth-quarter-and-full-year-2022-financial-results.

57. On information and belief, Amgen has developed and is selling its Evenity® product for the treatment of osteoporosis in postmenopausal women at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

58. On information and belief, Amgen publishes a "package insert" or "label" (the "Evenity® Label"; Exhibit D) that provides a description of Evenity®, other information about Evenity, and instructions for use of Evenity®. Amgen provides the Evenity® Label to physicians and patients along with the Evenity® product whenever Amgen sells the product throughout the United States, including within the District of Massachusetts. Amgen also publishes the Evenity® Label on its public website, which is accessible throughout the United States, including in the District of Massachusetts. *See* https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Evenity/evenity_pi_hcp_english.pdf.

59. Evenity® works by inhibiting the action of sclerostin, a regulatory factor in bone metabolism. *See* Evenity® Label at 11. Evenity® increases bone formation and, to a lesser extent, decreases bone resorption. *Id*.

60. The Evenity® Label states that "EVENITY is a sclerostin inhibitor indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history

[3] The current FDA-approved label for Evenity® is attached as Exhibit D.

of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy." Evenity® Label (Exhibit D) at 1 (Indications and Usage).

61. The active ingredient in Evenity® is romosozumab-aqqg. The Evenity® Label states that "[r]omosozumab-aqqg is a humanized monoclonal antibody (IgG2) produced in a mammalian cell line (Chinese Hamster Ovary) by recombinant DNA technology that binds to and inhibits sclerostin." *Id.* at Section 11 (Description). The Evenity® Label further states that "EVENITY inhibits the action of sclerostin, a regulatory factor in bone metabolism. EVENITY increases bone formation and, to a lesser extent, decreases bone resorption." *Id.* at Section 12.1 (Mechanism of Action).

62. Evenity® interferes with sclerostin's ability to bind to LRP.

63. Evenity® is "administered subcutaneously." *Id.* at Section 2.2 (Recommended Dosage). The Evenity® Label instructs that "[p]atients should be adequately supplemented with calcium and vitamin D during treatment with EVENITY." *Id.* Vitamin D is an antiresorptive drug. The Evenity® Label further instructs that "[t]he anabolic effect of EVENITY wanes after 12 monthly doses of therapy. Therefore, the duration of EVENITY use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered." *Id.* at Section 1.2 (Limitations of Use).

64. The Evenity® Label further states that, for the clinical trial NCT01575834, "[a]fter the 12-month treatment period, women in both arms transitioned to open-label anti-resorptive therapy (denosumab) for 12 months while remaining blinded to their initial treatment. Women received 500 to 1000 mg calcium and 600 to 800 international units vitamin D supplementation daily." *Id.* at Section 14.1 (Treatment of Osteoporosis in Postmenopausal Women). This study

found that "EVENITY significantly reduced the incidence of new vertebral fractures through month 12 compared to placebo. In addition, the significant reduction in fracture risk persisted through the second year in women who received EVENITY during the first year and transitioned to denosumab compared to those who transitioned from placebo to denosumab." *Id.* This study additionally found that, "[f]ollowing the transition from EVENITY to denosumab at month 12, BMD [bone mineral density] continued to increase through month 24." *Id.* This study further found that, "[a]fter EVENITY discontinuation, BMD returns to approximately baseline levels within 12 months in the absence of follow-on antiresorptive therapy." *Id.*

65. The Evenity® Label further states that for a second clinical trial, NCT01631214, "[w]omen were randomized (1:1) to receive either monthly subcutaneous injections of EVENITY (N = 2046) or oral alendronate 70 mg weekly (N = 2047) for 12 months, with 500 to 1000 mg calcium and 600 to 800 international units vitamin D supplementation daily. After the 12-month treatment period, women in both arms transitioned to open-label alendronate 70 mg weekly while remaining blinded to their initial treatment." *Id.* This study found that "EVENITY followed by alendronate also significantly reduced the risk of nonvertebral fracture through the primary analysis period (with a median follow-up of 33 months), with a hazard ratio of 0.81 (95% CI: 0.66, 0.99; p = 0.04) compared to alendronate alone." *Id.* This study further found that "[t]welve months of treatment with EVENITY followed by 12 months of treatment with alendronate significantly increased BMD compared with alendronate alone." *Id.*

66. On information and belief, physicians and patients purchase and use Evenity® in accordance with the instructions in the Evenity® Label in this District and throughout the United States. In marketing and selling Evenity® and in publishing and distributing the Evenity® Label

and other sources of information about Evenity®, Amgen encourages and intends for Evenity® to be used in accordance with the instructions in the Evenity® Label.

67. On information and belief, Amgen has long had knowledge of the Patents-in-Suit and that use of Evenity® infringes them. For example, Amgen cited the '099 patent during prosecution of Amgen's U.S. Patent Number 9,352,043, which issued on May 31, 2016.

68. Moreover, in 2012 and 2013, OsteoGeneX—then the owner of the Patents-in-Suit and related patent applications—engaged in both written and verbal communications with Amgen and UCB, Amgen's partner in development of Evenity®, about OsteoGeneX, OsteoGeneX's development program, OsteoGeneX's patents and patent applications, and a potential collaboration between the companies. During these discussions, OsteoGeneX presented to Amgen information about the '099 patent, its claims, and then-pending patent applications. OsteoGeneX offered to negotiate a license for Amgen to patents and patent applications that OsteoGeneX owned, including the '099 patent and related pending applications. In August 2012, Amgen made an offer for a exclusive, fully-paid license OsteoGeneX's patents and pending applications, but no agreement was reached. OsteoGeneX later assigned the Patents-in-Suit to OMAB.

69. On information and belief, Defendants later began marketing and selling Evenity® and publishing and distributing the Evenity® Label and other sources of information about the use of Evenity® despite knowledge of OMAB's patents and knowledge that their conduct infringes the patents.

COUNT I
INFRINGEMENT OF THE '099 PATENT

70. OMAB incorporates by reference the preceding paragraphs 1-69 of this Complaint as if fully set forth herein.

71. OMAB is the owner of the ’099 Patent with all substantial rights to the ’099 Patent, including the exclusive right to enforce, sue, and recover damages for any past, present, or future infringement.

72. The ’099 Patent is valid and enforceable for OMAB to collect damages for any and all infringement.

73. The ’099 patent claims methods of treating osteoporosis patients with an antisclerostin antibody and an antiresorptive drug. For example, claim 12 recites “[a] method of systemically increasing bone density, comprising the steps of administering, to a mammalian patient in need thereof, a therapeutic comprising an effective amount of a Sclerostin antagonist together with an antiresorptive drug, wherein said Sclerostin antagonist comprises an antibody or FAB fragment specifically binding a peptide comprising 10 contiguous amino acids of a sequence selected from the group consisting of SEQ ID NOs: 2-13, 22 and 23, and wherein the antibody interferes with Sclerostin’s ability to bind to LRP, thereby systemically increasing bone density.” ’099 Patent (Exhibit A) at claim 12.

74. The Evenity® Label instructs and encourages physicians to systemically increase bone density in a mammalian patient in need thereof by administering an effective amount of a sclerostin antagonist together with an antiresorptive as recited in the ’099 Patent in accordance with the claimed methods of the ’099 Patent.

75. On information and belief, the use of Amgen’s Evenity® in accordance with the Evenity® Label satisfies each element and directly infringes at least one claim of the ’099 Patent.

76. Amgen actively induces infringement of the ’099 Patent under U.S.C. § 271(b) in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Evenity® Product in the United States and by instructing

and encouraging others to practice the claimed invention and directly infringe the '099 Patent, including through the Evenity® Label.

77. On information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that the use of Amgen's Evenity® in accordance with the Evenity® Label infringes one or more claims of '099 Patent, either literally or under the doctrine of equivalents, and that Evenity is especially made or adapted for use in a manner that infringes one or more claims of the '099 patent.

78. Upon information and belief, Amgen has been and is contributing to the infringement of the '099 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing Evenity® in violation of 35 U.S.C. § 271(c). Evenity® is a component for use in the claimed methods of the '099 Patent, is a material part of the invention, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

79. OMAB has suffered damages and currently is, and will continue to be substantially and irreparably, harmed if Amgen is not enjoined from inducing infringement of the '099 Patent.

80. Upon information and belief, Defendants' infringement of the '099 Patent is knowing and willful.

81. This case is exceptional, and OMAB is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II
INFRINGEMENT OF THE '196 PATENT

82. OMAB incorporates by reference the preceding paragraphs 1-81 of this Complaint as if fully set forth herein.

83. OMAB is the owner of the '196 Patent with all substantial rights to the '196 Patent, including the exclusive right to enforce, sue, and recover damages for any past, present, or future infringement.

84. The '196 Patent is valid and enforceable for OMAB to collect damages for any and all infringement.

85. The '196 patent claims methods of treating osteoporosis patients with an antisclerostin antibody and an antiresorptive drug. For example, claim 1 recites "[a] method of increasing bone density in a mammalian patient in need thereof, comprising the steps of: systemically administering to a said mammalian patient a therapeutic comprising an effective amount of a Sclerostin antagonist sequentially with an antiresorptive drug, said Sclerostin antagonist comprising an antibody or FAB fragment specifically binding a peptide selected from the group consisting of SEQ ID NOS:2-13, 22 and 23, wherein the antibody interferes with Sclerostin's ability to bind to LRP, thereby systemically increasing bone density." '196 Patent (Exhibit B) at claim 1.

86. The Evenity® Label instructs and encourages physicians to increase bone density in a mammalian patient in need thereof by systemically administering an effective amount of a sclerostin antagonist sequentially with an antiresorptive as recited in the '196 Patent in accordance with the claimed methods of the '196 Patent.

87. On information and belief, the use of Amgen's Evenity® in accordance with the Evenity® Label satisfies each element and directly infringes at least one claim of the '196 Patent.

88. Amgen actively induces infringement of the '196 Patent under U.S.C. § 271(b) in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Evenity® Product in the United States and by instructing

and encouraging others to practice the claimed invention and directly infringe the '196 Patent, including through the Evenity® Label.

89. On information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that the use of Amgen's Evenity® in accordance with the Evenity® Label infringes one or more claims of '196 Patent, either literally or under the doctrine of equivalents, and that Evenity® is especially made or adapted for use in a manner that infringes one or more claims of the '196 patent.

90. Upon information and belief, Amgen has been and is contributing to the infringement of the '196 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing Evenity® in violation of 35 U.S.C. § 271(c). Upon information and belief, Evenity® is a component for use in the claimed methods of the '196 Patent, is a material part of the invention, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

91. OMAB currently is, and will continue to be substantially and irreparably, harmed if Amgen is not enjoined from inducing infringement of the '196 Patent.

92. Upon information and belief, Defendants' infringement of the '196 Patent is knowing and willful.

93. This case is exceptional, and OMAB is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III
INFRINGEMENT OF THE '373 PATENT

94. OMAB incorporates by reference the preceding paragraphs 1-93 of this Complaint as if fully set forth herein.

95. OMAB is the owner of the ’373 Patent with all substantial rights to the ’373 Patent, including the exclusive right to enforce, sue, and recover damages for past, present, or future infringement.

96. The ’373 Patent is valid and enforceable for OMAB to collect damages for any and all infringement.

97. The ’373 patent claims methods of treating osteoporosis patients with an antisclerostin antibody and an antiresorptive drug. For example, claim 1 recites “[a] method of promoting bone growth in a human subject being treated with a humanized sclerostin-recognizing antibody, comprising administering an antiresorptive drug to the subject.” ’373 Patent (Exhibit C) at claim 1. Further, claim 15 recites “[a] method for increasing bone density in a human subject with low bone mass being treated with a sclerostin-recognizing antibody, comprising serially administering an antiresorptive drug to the subject.” *Id.* at claim 15.

98. The Evenity® Label instructs and encourages physicians to administer an antiresorptive drug to patients being treated with a sclerostin-recognizing antibody as recited in the ’373 Patent in accordance with the claimed methods of the ’373 Patent.

99. On information and belief, treatment of osteoporosis in accordance with the Evenity® Label satisfies each element and directly infringes at least one claim of the ’373 Patent. The Evenity® Label therefore instructs and encourages physicians to administer treatment in accordance with the claimed methods of the ’373 Patent.

100. Amgen actively induces infringement of the ’373 Patent under U.S.C. § 271(b) in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Evenity® Product in the United States and by instructing and encouraging others to directly infringe the ’373 Patent, including through the Evenity® Label.

101. On information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that the use of Amgen's Evenity® in accordance with the Evenity® Label infringes one or more claims of '373 Patent, either literally or under the doctrine of equivalents, and that Evenity® is especially made or adapted for use in a manner that infringes one or more claims of the '373 patent.

102. Upon information and belief, Amgen has been and is contributing to the infringement of the '373 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing Evenity® in violation of 35 U.S.C. § 271(c). Upon information and belief, Evenity® is a component for use in the claimed methods of the '373 Patent, is a material part of the invention, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

103. OMAB currently is, and will continue to be substantially and irreparably, harmed if Amgen is not enjoined from inducing infringement of the '373 Patent.

104. Upon information and belief, Defendants' infringement of the '373 Patent is knowing and willful.

105. This case is exceptional, and OMAB is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, OMAB respectfully demands judgment in its favor and respectfully prays for the following relief:

a) Judgment that Amgen has infringed each of the Asserted Patents under 35 U.S.C. §§ 271(b)–(c) by actively inducing others to infringe and/or by contributing to the infringement of others during the term of each of the Asserted Patents;

b) Awarding damages sufficient to compensate OMAB for Amgen's infringement under 35 U.S.C. § 284, in no event less than a reasonable royalty on all past, current or future infringing sales or other dispositions of Evenity®;

c) Any equitable relief that the Court deems just and proper as a result of Amgen's infringement;

d) A judgment that this is an exceptional case and that OMAB be awarded its attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

e) An order awarding OMAB pre- and post-judgment interest on its damages;

f) Costs and expenses in this action; and

g) Awarding such other relief as the Court deems just and proper.

JURY DEMAND

OMAB, by and through its undersigned counsel, hereby demands, pursuant to Fed. R. Civ. P. 38, a trial by jury on all claims so triable.

Dated April 21, 2022

Respectfully submitted,

/s/ *Srikanth K. Reddy*

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CERTIFICATE OF SERVICE

Counsel for OssiFi-Mab LLC further certifies that the foregoing document will be served upon the Defendant pursuant to FRCP 4.

/s/ *Srikanth K. Reddy*