IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| AMGEN INC. and<br>KAI PHARMACEUTICALS, INC.,<br><br>Plaintiffs,<br><br>v.<br><br>MSN LABORATORIES PRIVATE LIMITED,<br>MSN PHARMACEUTICALS INC., and<br>MSN LIFE SCIENCES PRIVATE LIMITED,<br><br>Defendants. | ) | C.A. No. _____ |

**COMPLAINT**

Plaintiffs Amgen Inc. ("Amgen") and KAI Pharmaceuticals, Inc. ("KAI") (collectively "Plaintiffs") by their attorneys, hereby allege as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendants MSN Laboratories Private Limited ("MSN Labs"), MSN Pharmaceuticals Inc. ("MSN Pharma"), and MSN Life Sciences Private Limited ("MSN Life") (collectively, "MSN") of Abbreviated New Drug Application ("ANDA") No. 215877 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, or sell a generic version of Parsabiv® (etelcalcetide) injection for intravenous use at strengths of 2.5 mg/0.5 mL, 5 mg/mL, and 10 mg/2 mL ("MSN's Proposed ANDA Product") prior to the expiration of U.S. Patent No. 11,162,500 ("the '500 Patent"). MSN notified Plaintiffs that it had submitted ANDA No. 215877 by letters received April 8, 2021 ("MSN's First Notice Letter") and November 30, 2022 ("MSN's Second Notice Letter"). Upon information and belief, MSN's Proposed ANDA Product will be marketed as a

competing product to Parsabiv® (etelcalcetide), a product developed by Plaintiffs for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis.

**PARTIES**

2. Plaintiff Amgen is a corporation organized and existing under the laws of Delaware, having its corporate offices and a place of business at One Amgen Center Drive, Thousand Oaks, CA 91320.

3. Plaintiff KAI is a corporation organized and existing under the laws of Delaware, having a place of business at One Amgen Center Drive, Thousand Oaks, CA 91320. KAI is a wholly owned subsidiary of Amgen.

4. Upon information and belief, Defendant MSN Labs is a private limited company organized and existing under the laws of the Republic of India, having a place of business at MSN House, Plot No. C-24, Sanathnagar Industrial Estate, Hyderabad, Telangana 500018, India. Upon information and belief, MSN Labs is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries throughout the United States, including in Delaware.

5. Upon information and belief, Defendant MSN Pharma is a corporation organized and existing under the laws of Delaware, having its corporate offices and a place of business at 20 Duke Road, Piscataway, NJ 08854. Upon information and belief, MSN Pharma is a wholly owned subsidiary of MSN Labs. Upon information and belief, MSN Pharma is the designated U.S. agent for MSN Labs in accordance with 21 C.F.R. §§ 314.50(a)(5) and 314.94(a)(1) for ANDA No. 215877. Upon information and belief, MSN Pharma is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products throughout the United States, including in Delaware.

6. Upon information and belief, Defendant MSN Life is a private limited company organized and existing under the laws of the Republic of India, having a place of business at Sy No. 21/A & 21AA, Mambapur, Gummadidala, Sangreddy, Telangana 502313, India. Upon information and belief, MSN Life is a wholly owned subsidiary of MSN Labs. Upon information and belief, MSN Life is the holder of FDA Drug Master File No. 35097 for MSN's Proposed ANDA Product. Upon information and belief, MSN Life is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products throughout the United States, including in Delaware.

7. Upon information and belief, MSN Labs, MSN Pharma, and MSN Life collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. Upon further information and belief, MSN Labs, MSN Pharma, and MSN Life are agents of each other and/or operate in concert as integrated parts of the same business group.

8. Upon information and belief, MSN Labs, MSN Pharma, and MSN Life acted in concert to develop MSN's Proposed ANDA Product that is the subject of ANDA No. 215877 and to seek regulatory approval from the FDA to market and sell MSN's Proposed ANDA Product throughout the United States, including in Delaware.

9. Upon information and belief, MSN Labs, MSN Pharma, and MSN Life intend to act collaboratively to obtain approval for MSN's ANDA No. 215877, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import MSN's Proposed ANDA Product in the United States, including in Delaware.

## JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a),

2201, and 2202.

11. This Court has personal jurisdiction over MSN Pharma because, on information and belief, MSN Pharma is a corporation organized and existing under the laws of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, MSN Pharma has consented to general jurisdiction in Delaware.

12. This Court has personal jurisdiction over MSN Labs and MSN Life because, *inter alia*, MSN Labs and MSN Life, themselves and through their affiliates and subsidiaries including MSN Pharma, have purposefully availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court here. On information and belief, MSN Labs and MSN Life, themselves and through their affiliates and subsidiaries including MSN Pharma, develop, manufacture, import, market, offer to sell, sell, and/or distribute a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transact business within Delaware relating to Plaintiffs' claims, and/or have engaged in systematic and continuous business contacts within Delaware.

13. In addition, this Court has personal jurisdiction over MSN Labs and MSN Life because, among other things, on information and belief: (1) MSN Labs, MSN Life, and their affiliate MSN Pharma submitted MSN's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of MSN's Proposed ANDA Product in the United States, including in Delaware; and (2) upon approval of MSN's ANDA, MSN Labs, MSN Life, and their affiliate MSN Pharma, themselves and through their affiliates and subsidiaries, will market, distribute, offer for sale, sell, and/or import MSN's Proposed ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of MSN's Proposed ANDA Product in Delaware. On information and belief, upon approval of

MSN's ANDA, MSN's Proposed ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware.

14. In addition, this Court has personal jurisdiction over MSN Labs and MSN Life because they have committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Amgen and KAI, both Delaware corporations.

15. In addition, this Court has personal jurisdiction over MSN Labs and MSN Life because they regularly engage in patent litigation concerning MSN's ANDA products in this District, do not contest personal jurisdiction in this District, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Otsuka Pharmaceutical Co., Ltd. et al. v. MSN Laboratories Private Ltd.*, *MSN Pharmaceuticals Inc. and MSN Life Sciences Pvt. Ltd.*, C.A. No. 20-01428 (D. Del.); *Intercept Pharmaceuticals, Inc. et al. v. MSN Laboratories Private Ltd.*, *MSN Pharmaceuticals, Inc. and MSN Life Sciences Private Ltd.*, C.A. No. 20-01214 (D. Del.).

16. In addition, to the extent personal jurisdiction does not exist over MSN Labs and MSN Life in Delaware, this Court has personal jurisdiction over them under Federal Rule of Civil Procedure 4(k)(2) because MSN Labs and MSN Life are not subject to jurisdiction in any state's courts of general jurisdiction and exercising jurisdiction over them is consistent with the United States Constitution and laws.

17. For at least the above reasons, it would not be unfair or unreasonable for MSN Labs, MSN Life, and MSN Pharma to litigate this action in this District, and MSN Labs, MSN Life, and MSN Pharma are subject to personal jurisdiction in this District.

18. Venue is proper in this Court under 28 U.S.C. § 1391(c) with respect to MSN Labs at least because, on information and belief, MSN Labs is a foreign corporation that may be sued in any judicial district.

19. Venue is proper in this Court under 28 U.S.C. § 1391(c) with respect to MSN Life at least because, on information and belief, MSN Life is a foreign corporation that may be sued in any judicial district.

20. Venue is proper in this Court under 28 U.S.C. § 1400(b) with respect to MSN Pharma at least because, on information and belief, MSN Pharma is a corporation organized and existing under the laws of Delaware and therefore resides in Delaware for purposes of venue.

## BACKGROUND

### *PARSABIV® (ETELCALCETIDE)*

21. On February 7, 2017, the FDA granted approval to market Parsabiv® (etelcalcetide) for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis.

22. The active pharmaceutical ingredient in Parsabiv® is etelcalcetide, which was invented by scientists at KAI and developed by KAI and Amgen. Etelcalcetide is a synthetic peptide calcium-sensing receptor agonist. It is a calcimimetic agent that allosterically modulates the calcium-sensing receptor ("CaSR"). Etelcalcetide binds to the CaSR and enhances activation of the receptor by extracellular calcium. Activation of the CaSR on parathyroid chief cells decreases parathyroid hormone ("PTH") secretion.

23. Parsabiv® (etelcalcetide) is FDA approved for intravenous injection. It is FDA approved as a sterile, preservative-free, ready-to-use clear and colorless solution in a single-dose vial containing 5 mg/mL of etelcalcetide. Each vial contains 2.5, 5, or 10 mg etelcalcetide. Each vial is formulated with 0.85% weight/volume sodium chloride, 10 mM succinic acid, and adjusted to pH 3.3 with sodium hydroxide and/or hydrochloric acid.

24. Amgen, itself or through a subsidiary, markets Parsabiv® (etelcalcetide) in the United States pursuant to approved New Drug Application ("NDA") No. 208325.

25. KAI, a wholly owned subsidiary of Amgen, is the holder of approved NDA No. 208325 for Parsabiv® (etelcalcetide).

26. The '500 Patent is listed for NDA No. 208325 for Parsabiv® (etelcalcetide) in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

27. The '500 Patent, titled "Stable Liquid Formulation of AMG 416 (Etelcalcetide)," was duly and legally issued on November 2, 2021. A copy of the '500 Patent is attached as Exhibit A.

28. Plaintiffs own and have rights to the '500 Patent.

29. There is an actual case or controversy between the parties regarding MSN's liability for their infringement of the '500 Patent.

***MSN'S ANDA***

30. On April 8, 2021, Plaintiffs received MSN's First Notice Letter, which informed Plaintiffs that MSN seeks through ANDA No. 215877 approval to engage in the commercial manufacture, use, or sale of MSN's Proposed ANDA Product prior to the expiration of U.S. Patent Nos. 8,377,880, 8,999,932, 9,278,995, 9,701,712, 9,820,938, and 10,344,765. Amgen received

MSN's Second Notice Letter on November 30, 2022, which informed Plaintiffs that MSN seeks through ANDA No. 215877 approval to engage in the commercial manufacture, use, or sale of MSN's Proposed ANDA Product prior to the expiration of the '500 Patent. According to MSN's Second Notice Letter, included within ANDA No. 215877 is a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '500 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of MSN's Proposed ANDA Product.

31. This action is being filed within 45 days of Plaintiffs' receipt on November 30, 2022, of MSN's Second Notice Letter.

32. MSN was aware of the '500 Patent when it submitted ANDA No. 215877 with a Paragraph IV Certification.

33. On information and belief, etelcalcetide is the active ingredient in MSN's Proposed ANDA Product. On information and belief, MSN's Proposed ANDA Product is a pharmaceutical formulation comprising etelcalcetide in an aqueous solution having a pH of 2.0 to 5.0 and an etelcalcetide concentration of between 0.5 mg/mL to 15 mg/mL.

34. On information and belief, ANDA No. 215877 refers to and relies upon the NDA for Parsabiv® (etelcalcetide) and contains data that, according to MSN, demonstrate bioequivalence of MSN's Proposed ANDA Product and Parsabiv® (etelcalcetide), *see* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7), or MSN has sought a waiver of the requirement to demonstrate bioequivalence of MSN's Proposed ANDA Product and Parsabiv® (etelcalcetide).

35. On information and belief, MSN intends to have healthcare providers use MSN's Proposed ANDA Product, if approved, as set forth in MSN's Proposed ANDA Product label. On information and belief, MSN's Proposed ANDA Product label will instruct healthcare providers

to prescribe MSN's Proposed ANDA Product in the manner set forth in the label.

**COUNT I**
**(Infringement by MSN of the '500 Patent)**

36. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

37. On information and belief, MSN's purpose for filing MSN's ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of a generic version of Parsabiv® (etelcalcetide) for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis.

38. Amgen received MSN's Second Notice Letter on November 30, 2022, which states that MSN had submitted ANDA No. 215877 seeking approval to manufacture, use, offer to sell, and sell a generic version of Parsabiv® (etelcalcetide) before the expiration of the '500 Patent.

39. Claim 1 of the '500 Patent covers "[a] pharmaceutical formulation, comprising: etelcalcetide in aqueous solution, wherein the formulation has a pH of 2.0 to 5.0 and wherein etelcalcetide is present at a concentration of between 0.5 mg/mL to 15 mg/mL."

40. Upon information and belief, MSN's Proposed ANDA Product is covered by one or more claims of the '500 Patent, including at least claim 1, because it is a pharmaceutical formulation comprising etelcalcetide in an aqueous solution having a pH of 2.0 to 5.0 and an etelcalcetide concentration of between 0.5 mg/mL to 15 mg/mL.

41. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, will infringe one or more claims of the '500 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

42. Upon information and belief, MSN filed an amendment to ANDA No. 215877 containing a Paragraph IV Certification which asserts that the claims of the '500 Patent are invalid, unenforceable, and/or not infringed by the manufacture, use, sale, or offer for sale of MSN's Proposed ANDA Product.

43. MSN has no reasonable basis to believe that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe one or more valid claims of the '500 Patent.

44. The purpose of filing ANDA No. 215877 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product prior to the expiration of the '500 Patent.

45. MSN's submission of ANDA No. 215877 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA Product prior to the expiration of the '500 Patent is an act of infringement of the '500 Patent under 35 U.S.C. § 271(e)(2)(A).

46. Upon information and belief, MSN intends to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto, *i.e.*, prior to the expiration of the '500 Patent.

47. Upon information and belief, MSN has knowledge of the '500 Patent at least because the '500 Patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Amgen's Parsabiv® (etelcalcetide) drug product. Notwithstanding this knowledge, MSN continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product and the proposed labeling

therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto.

48. Upon information and belief, MSN plans and intends to, and will, actively induce infringement of the '500 Patent when ANDA No. 215877 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '500 Patent. Further upon information and belief, MSN plans and intends to, and will, do so immediately and imminently upon approval.

49. The foregoing actions by MSN constitute and/or will constitute infringement of the '500 Patent and active inducement of infringement of the '500 Patent, either literally or under the doctrine of equivalents.

50. Unless MSN is enjoined from infringing the '500 Patent and actively inducing infringement of the '500 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

## REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that MSN's submission of ANDA No. 215877 to the FDA was an act of infringement of one or more claims of U.S. Patent No. 11,162,500;

(b) A judgment that MSN's making, using, offering to sell, selling, marketing, distributing, or importing into the United States MSN's Proposed ANDA Product prior to the expiration of the '500 Patent will infringe and/or will actively induce infringement of one or more claims of the '500 Patent;

(c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for MSN to make, use, offer for sale, sell, market, distribute, or import MSN's

Proposed ANDA Product, or any product the use of which infringes the '500 Patent, be not earlier than the expiration date of the '500 Patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) enjoining MSN, MSN's affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with MSN, from making, using, selling, offering to sell, marketing, distributing, or importing MSN's Proposed ANDA Product, or any product the use of which infringes the '500 Patent, or the inducement of any of the foregoing, prior to the expiration date of the '500 Patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Karen Jacobs*

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