

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

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 manufacture and 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 Nos. 8,377,880 (“the ’880 patent”), 8,999,932 (“the ’932 patent”), 9,278,995 (“the ’995 patent”), 9,701,712 (“the ’712 patent”), 9,820,938 (“the ’938 patent”), and 10,344,765 (“the ’765 patent”) (collectively, “the Asserted Patents”). MSN notified Plaintiffs that it had submitted this ANDA by a letter received April 8, 2021 (“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.

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