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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED and SALIX PHARMACEUTICALS, INC., Plaintiffs, v. MSN LABORATORIES PRIVATE LTD. and MSN PHARMACEUTICALS INC., Defendants.	Civil Action No. 24-11179 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. (collectively, "Plaintiffs") by way of Complaint against Defendants MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. (collectively, "MSN" or "Defendants") allege as follows:

THE PARTIES

1. Plaintiff Bausch Health Ireland Limited ("Bausch") is a company organized and existing under the laws of Ireland, having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

2. Plaintiff Salix Pharmaceuticals, Inc. ("Salix") is a corporation organized and existing under the laws of California, having its principal place of business at 400 Somerset Blvd., Bridgewater, New Jersey 08807. Salix is the registered holder of approved New Drug Application ("NDA") No. 208745, which covers Trulance®.

3. Upon information and belief, MSN Laboratories Private Ltd. ("MSN Labs") is a corporation organized and existing under the laws of India, having a place of business at MSN House, Plot No. C-24, Industrial Estate, Sanath Nagar, Hyderabad, Telangana, 500018 India.

4. Upon information and belief, MSN Pharmaceuticals Inc. ("MSN Pharms") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 20 Duke Rd., Piscataway, New Jersey 08854.

5. Upon information and belief, MSN Pharms is a wholly-owned subsidiary of MSN Labs.

NATURE OF THE ACTION

6. This is an action for infringement of United States Patent No. 12,146,003 ("the '003 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to MSN's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic plecanatide oral tablets, 3 mg ("MSN's generic plecanatide oral tablets").

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Upon information and belief, this court has jurisdiction over MSN Labs. Upon information and belief, MSN Labs is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, MSN Labs directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for MSN's generic plecanatide oral tablets. Upon information and belief, MSN Labs purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, MSN Labs has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

9. Upon information and belief, this court has jurisdiction over MSN Pharms. Upon information and belief, MSN Pharms is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, MSN Pharms directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for MSN's generic plecanatide oral tablets. Upon information and belief, MSN Pharms purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, MSN Pharms has its principal place of business at 20 Duke Rd., Piscataway, New Jersey 08854. Upon information and belief, MSN Pharms has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. MSN Labs has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be

purposefully directed at, upon information and belief, the State of New Jersey and elsewhere. MSN Labs' ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, MSN Labs intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, MSN Labs will engage in marketing of its generic Plecanatide oral tablets in New Jersey upon approval of its ANDA.

11. Upon information and belief, MSN Labs and MSN Pharms operate as a single integrated business. Upon information and belief, MSN Labs and MSN Pharms each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

12. MSN Labs and MSN Pharms know or should know that Trulance® is manufactured for Salix Pharmaceuticals, Inc., a division of Bausch Health US, LLC, in Bridgewater, NJ 08807 USA at least because that information is included in the label and prescribing information for Trulance®.

13. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

14. Venue is proper against MSN Labs, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

15. Venue is proper against MSN Pharms because it operates a principal place of business in this judicial district.

THE PATENT IN SUIT

16. The U.S. Patent and Trademark Office ("PTO") issued the '003 patent on November 19, 2024. The '003 patent claims, *inter alia*, oral formulations of a purified peptide. Plaintiffs hold all substantial rights in the '003 patent and have the right to sue for infringement thereof. A copy of the '003 patent is attached hereto as Exhibit A.

17. Salix is the holder of NDA No. 208745 for Trulance®, which the FDA approved on January 19, 2017. In conjunction with NDA No. 208745, the '003 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

18. Plecanatide oral tablets, 3mg, are sold in the United States under the trademark Trulance®.

MSN'S INFRINGING ANDA SUBMISSION

19. Upon information and belief, MSN Labs filed or caused to be filed with the FDA ANDA No. 215780, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

20. Upon information and belief, MSN's ANDA No. 215780 seeks FDA approval to engage in commercial manufacture, use, and sale in the United States of MSN's generic plecanatide oral tablets, intended to be generic versions of Trulance®.

21. Plaintiffs received a letter from MSN Labs dated March 15, 2021, purporting to be a Notice of ANDA No. 215780 with Paragraph IV Certifications ("MSN's First Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. MSN's First Notice Letter was addressed to Salix and Bausch.

22. MSN's First Notice Letter alleges that MSN Labs has submitted to the FDA ANDA No. 215780 seeking approval to engage in the commercial manufacture, use and/or sale of MSN's generic plecanatide oral tablets, intended to be generic versions of Trulance®.

23. MSN's First Notice Letter states that MSN's ANDA No. 215780 "contains the required bioavailability and/or bioequivalence data from studies on the plecanatide oral tablet drug product," for MSN's generic plecanatide oral tablets.

24. Plaintiffs received a second letter from MSN Labs dated May 2, 2023, purporting to be a Notice of ANDA No. 215780 with Paragraph IV Certifications ("MSN's Second Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. MSN's Second Notice Letter was addressed to Salix and Bausch.

25. MSN's Second Notice Letter alleges that MSN Labs has submitted to the FDA ANDA No. 215780 seeking approval to engage in the commercial manufacture, use and/or sale of MSN's generic plecanatide oral tablets, intended to be generic versions of Trulance®.

26. MSN's Second Notice Letter states that MSN's ANDA No. 215780 "contains the required bioavailability and/or bioequivalence data from studies on the plecanatide oral tablet drug product," for MSN's generic plecanatide oral tablets.

27. Plaintiffs received a third letter from MSN Labs dated May 7, 2024, purporting to be a Notice of ANDA No. 215780 with Paragraph IV Certification ("MSN's Third Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. MSN's Third Notice Letter was addressed to Salix and Bausch.

28. MSN's Third Notice Letter alleges that MSN Labs has submitted to the FDA ANDA No. 215780 seeking approval to engage in the commercial manufacture, use and/or sale of MSN's generic plecanatide oral tablets, intended to be generic versions of Trulance®.

29. MSN's Third Notice Letter states that MSN's ANDA No. 215780 "contain[s] any required bioavailability or bioequivalence data or information," for MSN's generic plecanatide oral tablets.

30. Upon information and belief, ANDA No. 215780 seeks approval of MSN's generic plecanatide oral tablets that are the same, or substantially the same, as Trulance®.

31. Upon information and belief, MSN Labs' actions related to ANDA No. 215780 complained of herein were done at the direction of, with the authorization of, or with the cooperation, the participation, the assistance of, or at least in part for the benefit of MSN Pharms.

32. As a result of MSN's Notice Letters, Plaintiffs filed related Complaints against MSN in this District. *See Bausch Health Ireland Limited, et al. v. MSN Laboratories Pvt. Ltd., et al.*, Civil Action No. 21-10057 (SRC)(JSA) (CONSOLIDATED); *Bausch Health Ireland Limited, et al. v. MSN Laboratories Pvt. Ltd., et al.*, Civil Action No. 23-3333 (SRC)(JSA), consolidated into *Bausch Health Ireland Limited, et al. v. MSN Laboratories Pvt. Ltd., et al.*, Civil Action No. 21-10057 (SRC)(JSA) (CONSOLIDATED); and *Bausch Health Ireland Limited, et al. v. MSN Laboratories Pvt. Ltd., et al.*, Civil Action No. 24-7182 (SRC)(JSA).

33. Plaintiffs have not yet received a Notice of Paragraph IV Certification regarding ANDA No. 215780 for the '003 patent ("'003 Patent Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 C.F.R. § 314.95.

34. Despite that Defendants have not yet sent a '003 Patent Notice Letter, Defendants' prior Notice Letters and the information contained therein, coupled with regulatory requirements, demonstrate Defendants' infringement of the '003 patent.

COUNT I FOR PATENT INFRINGEMENT

Infringement of the '003 Patent Under § 271(e)(2)

35. Paragraphs 1-34 are incorporated herein as set forth above.

36. Under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '003 patent by submitting, or causing to be submitted to the FDA, ANDA No. 215780 seeking approval

for the commercial marketing of MSN's generic plecanatide oral tablets before the expiration date of the '003 patent.

37. Upon information and belief, MSN's generic plecanatide oral tablets will, if approved and marketed, infringe at least one claim of the '003 patent.

38. Upon information and belief, MSN will, through the manufacture, use, import, offer for sale, and/or sale of MSN's generic plecanatide oral tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '003 patent.

39. If MSN's marketing and sale of MSN's generic plecanatide oral tablets prior to the expiration of the '003 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '003 Patent

40. Paragraphs 1-39 are incorporated herein as set forth above.

41. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

42. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

43. MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import MSN's generic plecanatide oral tablets before the expiration date of the '003 patent, including MSN's filing of ANDA No. 215780.

44. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of MSN's generic plecanatide oral tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '003 patent.

45. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of MSN's generic plecanatide oral tablets will constitute infringement of at least one claim of the '003 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against MSN on the patent infringement claims set forth above and respectfully request that this Court:

1. Enter judgment that, under 35 U.S.C. § 271(e)(2), MSN has infringed at least one claim of the '003 patent by submitting or causing to be submitted ANDA No. 215780 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of MSN's generic plecanatide oral tablets before the expiration of the '003 patent;

2. Order that the effective date of any approval by the FDA of MSN's generic plecanatide oral tablets be a date that is not earlier than the expiration of the '003 patent, or such later date as the Court may determine;

3. Enjoin MSN from the commercial manufacture, use, import, offer for sale, and/or sale of MSN's generic plecanatide oral tablets until expiration of the '003 patent, or such later date as the Court may determine;

4. Enjoin MSN and all persons acting in concert with MSN from seeking, obtaining, or maintaining approval of MSN's ANDA No. 215780 until expiration of the '003 patent;

5. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees; and

6. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: December 16, 2024
Newark, New Jersey

s/ William P. Deni, Jr.
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