

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD.,)
)
Plaintiff,)
)
v.) C.A. No. _____
)
MSN LABORATORIES PRIVATE LIMITED)
and MSN PHARMACEUTICALS INC.)
)
Defendants.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants MSN Laboratories Private Limited (“MSN Laboratories”) and MSN Pharmaceuticals Inc. (“MSN Pharmaceuticals”) (collectively, “MSN”), hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent No. 8,501,730 (“the ’730 Patent”) and U.S. Patent No. 10,905,694 (“the ’694 Patent”) (collectively, the “Patents-in-Suit”) arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*
2. This action arises out of MSN’s submission of an Abbreviated New Drug Application (“ANDA”) No. 216949 (“MSN’s ANDA”) under § 505(j) of the Federal Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to commercially manufacture, use, offer for sell and sell in the United States, and/or import into the United States, generic versions of Otsuka’s SAMSCA® tolvaptan tablets (15 and 30 mg) (“MSN’s ANDA products”) prior to the expiration of the Patents-in-Suit.

PARTIES

3. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan. Otsuka is engaged in the research, development, manufacture and sale of innovative pharmaceutical products.

4. On information and belief, Defendant MSN Laboratories is an Indian corporation, having its principal place of business at MSN House, C-24, Industrial Estate, Sanathnagar, Hyderabad-18, Telangana, India.

5. On information and belief, Defendant MSN Pharmaceuticals is a corporation organized under the laws of the State of Delaware, having its principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

6. On information and belief, MSN Pharmaceuticals is a wholly-owned subsidiary of MSN Laboratories.

7. On information and belief, MSN Pharmaceuticals and MSN Laboratories develop, manufacture, and/or distribute generic drugs for sale and use throughout the United States, including in Delaware.

8. On information and belief, MSN Pharmaceuticals and MSN Laboratories are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic drug products. On information and belief, the acts of MSN Pharmaceuticals and MSN Laboratories complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

9. On information and belief, MSN Pharmaceuticals and MSN Laboratories have cooperated and assisted in the preparation and filing of MSN's ANDA for MSN's ANDA products,

and will be involved in the manufacture, importation, marketing, and sale of the drug that is the subject of MSN's ANDA if it is approved.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

11. This Court has personal jurisdiction over MSN Pharmaceuticals because, on information and belief, MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware.

12. This Court has personal jurisdiction over MSN Laboratories because, *inter alia*, MSN Laboratories, itself and/or through its wholly-owned subsidiaries, has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, MSN Laboratories directly or indirectly is in the business of developing, manufacturing, marketing, importing, offering to sell and selling pharmaceutical drug products, including generic drug products, throughout the United States, including in Delaware. Upon information and belief, MSN Laboratories derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware. Delaware would be a destination of MSN's ANDA products upon approval and marketing of the ANDA involved in this action. MSN Laboratories's filing of its ANDA constitutes a formal act that reliably indicates its plans to engage in marketing of the accused infringing ANDA products in Delaware.

13. Alternatively, assuming that the above facts do not establish personal jurisdiction over MSN Laboratories, this Court may exercise jurisdiction pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Otsuka's claims arise under federal law; (b) MSN Laboratories is a

foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) MSN Laboratories has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over MSN Laboratories satisfies due process.

14. This Court also has personal jurisdiction over MSN Laboratories because it has affirmatively availed itself of the jurisdiction of this Court through the assertion of counterclaims in suits brought in this District and/or by being sued in this District without challenging personal jurisdiction. *See, e.g., Vanda Pharmaceuticals, Inc. v. MSN Pharmaceuticals Inc. et al.*, Civil Action No. 19-926 (D. Del.); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. MSN Laboratories Private Ltd. et al.*, Civil Action No. 18-1785 (D. Del.); *Millennium Pharmaceuticals, Inc. v. MSN Laboratories Private Ltd. et al.*, Civil Action No. 16-1255 (D. Del.).

15. Venue is proper as to MSN in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

OTSUKA'S SAMSCA®

16. Otsuka is the holder of the New Drug Application (“NDA”) No. 22-275 for SAMSCA® tablets in 15 and 30 mg dosage forms (“SAMSCA® tablets”).

17. The FDA approved NDA No. 22-275 on May 19, 2009.

18. SAMSCA® is an oral medication used to treat hyponatremia (low blood sodium levels) in adults with conditions including congestive heart failure, cirrhosis and Syndrome of Inappropriate Antidiuretic Hormone.

THE PATENTS-IN-SUIT

19. The '730 Patent, entitled "Process for Preparing Benzazepine Compounds or Salts Thereof" was duly and legally issued on August 6, 2013. A true and correct copy of the '730 Patent is attached hereto as Exhibit A.

20. The '730 Patent claims compositions made by processes for preparing novel benzazepine compounds.

21. The '730 Patent is owned by Otsuka and is listed in *Approved Drug Products with Therapeutic Equivalents* (the "Orange Book") in connection with NDA No. 22-275 for SAMSCA® tablets.

22. According to the Orange Book, the '730 Patent expires on September 1, 2026.

23. The '694 Patent, entitled "Pharmaceutical Solid Preparation Comprising Benzazepines and Production Method Thereof," was duly and legally issued on February 2, 2021. A true and correct copy of the '694 Patent is attached hereto as Exhibit B.

24. The '694 Patent claims pharmaceutical solid preparations obtained by particular methods.

25. The '694 Patent is owned by Otsuka and is listed in the Orange Book in connection with NDA No. 22-275 for SAMSCA® tablets.

26. According to the Orange Book, the '694 Patent expires on April 7, 2030.

MSN'S ANDA

27. Upon information and belief, MSN submitted ANDA No. 216949 to the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use, offer for sale or sale in the United States, or importation into the United States, of MSN's ANDA products, which are generic versions of SAMSCA®.

28. Upon information and belief, ANDA No. 216949 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certifications”), alleging that no valid, enforceable claim of the ’730 Patent or the ’694 Patent will be infringed by MSN’s ANDA products.

29. Otsuka received a letter sent by MSN, dated January 24, 2022, purporting to be a “Notice of Paragraph IV Certification” for ANDA No. 216949 (“MSN’s Notice Letter”) pursuant to § 505(j)(2)(B) of the FDCA and 21 C.F.R. § 314.95. MSN’s Notice Letter notified Otsuka that MSN had filed ANDA No. 216949, seeking approval to engage in the commercial manufacture, use, offer for sale, sale or importation of MSN’s ANDA products before the expiration of the Patents-in-Suit.

30. Otsuka commenced this action within 45 days of receipt of MSN’s Notice Letter.

COUNT I

INFRINGEMENT OF '730 PATENT

31. Otsuka incorporates each of the preceding paragraphs as if fully set forth herein.

32. Upon information and belief, MSN submitted to the FDA ANDA No. 216949 seeking approval to commercially manufacture, use, offer to sell and/or sell MSN’s ANDA products in the United States, or import them into the United States, before the expiration of the ’730 Patent.

33. Upon information and belief, MSN submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the ’730 Patent are invalid, unenforceable and/or not infringed.

34. Upon information and belief, in its ANDA No. 216949, MSN has represented to the FDA that MSN's ANDA products are pharmaceutically and therapeutically equivalent to Otsuka's SAMSCA® tablets.

35. MSN has actual knowledge of Otsuka's '730 Patent.

36. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), MSN has infringed one or more claims of the '730 Patent, including at least claim 1, by submitting, or causing to be submitted, to the FDA ANDA No. 216949, seeking approval to commercially manufacture, use, offer to sell or sell MSN's ANDA products, or import them into the United States, before the expiration date of the '730 Patent.

37. Upon information and belief, if ANDA No. 216949 is approved, MSN intends to and will offer to sell, sell in the United States, or import into the United States, MSN's ANDA products.

38. Upon information and belief, if ANDA No. 216949 is approved, MSN will infringe one or more claims of the '730 Patent, including at least claim 1, under § 271(a), either literally or under the doctrine of equivalents, by commercially making, using, offering to sell, selling and/or importing MSN's ANDA products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216949 shall be no earlier than the expiration of the '730 Patent and any additional periods of exclusivity.

39. Otsuka will be irreparably harmed by MSN's infringing activities unless this Court enjoins those activities.

40. Otsuka does not have an adequate remedy at law.

COUNT II

INFRINGEMENT OF THE '694 PATENT

41. Otsuka incorporates each of the preceding paragraphs as if fully set forth herein.
42. Upon information and belief, MSN submitted to the FDA ANDA No. 216949 seeking approval to commercially manufacture, use, offer to sell and/or sell MSN's ANDA products in the United States, or import them into the United States, before the expiration of the '694 Patent.
43. Upon information and belief, MSN submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '694 Patent are invalid, unenforceable and/or not infringed.
44. Upon information and belief, in its ANDA No. 216949, MSN has represented to the FDA that MSN's ANDA products are pharmaceutically and therapeutically equivalent to Otsuka's SAMSCA® tablets.
45. MSN has actual knowledge of Otsuka's '694 Patent.
46. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), MSN has infringed one or more claims of the '694 Patent, including at least claim 1, by submitting, or causing to be submitted, to the FDA ANDA No. 216949, seeking approval to commercially manufacture, use, offer to sell or sell MSN's ANDA products, and/or import them into the United States, before the expiration date of the '694 Patent.
47. Upon information and belief, if ANDA No. 216949 is approved, MSN intends to and will offer to sell and sell in the United States, and/or import into the United States, MSN's ANDA products.
48. Upon information and belief, if ANDA No. 216949 is approved, MSN will infringe one or more claims of the '694 Patent, including at least claim 1, under § 271(a), either literally or

under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing MSN's ANDA products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216949 shall be no earlier than the expiration of the '694 Patent and any additional periods of exclusivity.

49. Otsuka will be irreparably harmed by MSN's infringing activities unless this Court enjoins those activities.

50. Otsuka does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Otsuka respectfully requests the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that MSN has infringed at least one claim of each of the Patents-in-Suit by MSN's submission of ANDA No. 216949 to the FDA seeking approval to manufacture, use, offer to sell and/or sell MSN's ANDA products in the United States, and/or import them into the United States, before the expiration of the Patents-in-Suit;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that MSN's making, using, offering to sell, selling or importation of MSN's ANDA products before the expiration of the Patents-in-Suit will infringe, actively induce infringement and/or contribute to the infringement of those patents under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of MSN's ANDA products shall be no earlier than the expiration date of the Patents-in-Suit and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and permanent injunction, enjoining MSN and all persons acting in concert with MSN from commercially manufacturing, using, offering for sale or selling MSN's ANDA products within the United States, or importing MSN's ANDA products into the United States, until the expiration of the Patents-in-Suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and permanent injunction, enjoining MSN and all persons acting in concert with MSN from seeking, obtaining or maintaining approval of the ANDA until the expiration of the Patents-in-Suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration that this is an exceptional case and an award to Otsuka of its costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. An award to Otsuka of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. An award to Otsuka of any further and additional relief that this Court deems just and proper.

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