

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVERIO PHARMA GMBH, BAYER AG,)
and BAYER HEALTHCARE)
PHARMACEUTICALS INC.,)
)
Plaintiffs,)
)
v.) C.A. No. _____
)
MSN LABORATORIES PRIVATE LIMITED)
and MSN PHARMACEUTICALS INC.,)
)
Defendants.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Adverio Pharma GmbH, Bayer AG, and Bayer HealthCare Pharmaceuticals Inc. (collectively, “Bayer” or “Plaintiffs”) bring this Complaint for patent infringement against Defendants MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. (collectively, “MSN” or “Defendants”) and allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement by MSN of U.S. Patent No. 10,662,188 (“the ’188 Patent”), arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and, more particularly 35 U.S.C. § 271. This action relates to an amendment to Abbreviated New Drug Application (“ANDA”) No. 211135, filed by MSN with the United States Food and Drug Administration (“FDA”) for approval to market generic versions of Bayer’s Adempas® (riociguat tablets) drug product (0.5 mg, 1 mg, 1.5 mg, 2 mg, and 2.5 mg) prior to the expiration of the ’188 Patent.

PARTIES

2. Plaintiff Adverio Pharma GmbH (“Adverio”) is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Kaiser-Wilhelm-Allee 1, 51373 Leverkusen, Germany.

3. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

4. Plaintiff Bayer HealthCare Pharmaceuticals Inc. (“Bayer HealthCare”) is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 100 Bayer Boulevard, Whippany, New Jersey, 07981.

5. On information and belief, Defendant MSN Laboratories Private Limited (“MSN Labs”) is a corporation organized and existing under the laws of India, having a principal place of business at MSN House Plot No. C-24, Industrial Estate, Sanath Nagar, Hyderabad 500018, India. On information and belief, MSN Labs is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the United States market.

6. On information and belief, Defendant MSN Pharmaceuticals Inc. (“MSN Pharma”) is a corporation organized and existing under the laws of Delaware, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. On information and belief, MSN Pharma is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the United States market.

7. On information and belief, MSN Pharma is a wholly owned subsidiary of MSN Labs and is controlled and dominated by MSN Labs. On information and belief, MSN Pharma is the U.S. FDA Agent for MSN Labs.

8. On information and belief, Defendants acted in concert to prepare and submit the amendment to ANDA No. 211135 to the FDA.

9. On information and belief, and consistent with their practice with respect to other generic products, Defendants will act to distribute and sell the generic riociguat tablet drug product (0.5 mg, 1 mg, 1.5 mg, 2 mg, and 2.5 mg) that is the subject of ANDA No. 211135 (“Defendants’ ANDA Product”) throughout the United States, including within Delaware. On information and belief, MSN knows and intends that Defendants’ ANDA Product will be distributed and sold in the United States, including within Delaware.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

11. On information and belief, this Court has personal jurisdiction over Defendants because Defendants have purposefully availed themselves of the benefits and protections of Delaware’s laws such that they should reasonably anticipate being haled into court in Delaware.

12. On information and belief, Defendants have had persistent and continuous contacts within this judicial district, including developing, manufacturing, and/or selling pharmaceutical products that are sold in this judicial district.

13. On information and belief, MSN Pharma is organized under the laws of the State of Delaware and is therefore “at home” in Delaware and subject to suit in this judicial district.

14. On information and belief, MSN Pharma is registered to do business in Delaware (File Number 5454849), and has thereby consented to suit in Delaware.

15. On information and belief, MSN Pharma has appointed United States Corporation Agents, Inc., 221 N Broad St, Suite 3A, Middletown, Delaware 19709, as its registered agent for receipt and service of process.

16. On information and belief, Defendants are in the business of, among other things, formulating, developing, manufacturing, packaging, marketing, and selling generic copies of branded pharmaceutical products for the United States market, including in Delaware. On information and belief, Defendants, directly or through their affiliates and agents, formulate, manufacture, package, market, and/or sell pharmaceutical products throughout the United States and in Delaware.

17. On information and belief, Defendants derive substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

18. On information and belief, Defendants either sell their generic pharmaceuticals directly into Delaware or have a network of independent wholesalers and distributors with which they contract to market generic pharmaceuticals products in Delaware.

19. Defendants also engaged in Delaware-related activities in connection with their efforts to obtain FDA approval to market Defendants' ANDA Product. On information and belief, Defendants sent a letter dated October 16, 2020 to Plaintiff Bayer HealthCare, a corporation organized under the laws of the State of Delaware, stating that MSN had submitted an amendment to ANDA No. 211135 seeking approval to commercially manufacture, use, import, offer for sale, and sell Defendants' ANDA Product prior to the expiration of the '188 Patent.

20. On information and belief, Defendants have previously invoked this Court's jurisdiction, or have stipulated and/or consented to personal jurisdiction in this district, including in related patent case, *Adverio Pharma GmbH v. MSN Laboratories Private Limited*, C.A. No. 18-73-LPS (consolidated).

21. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

BACKGROUND

. 22. On May 26, 2020, the United States Patent and Trademark Office issued the '188 Patent, entitled "Forms of Methyl {4,6-Diamino-2-[1(2-Fluorobenzyl)-1H-Pyrazolo[3-4-b]Pyridino-3-yl]Pyrimidino-5-yl} Methyl Carbamate." A true and correct copy of the '188 Patent is attached hereto as Exhibit A.

23. The '188 Patent claims forms of methyl {4,6-diamino-2-[1-(2-fluorobenzyl)-1H-pyrazolo[3,4-b]pyridino-3-yl]pyrimidino-5-yl}methylcarbamate comprising its Modification I, Modification II, mono-DMSO solvate, sesqui-DMSO solvate and ¼-ethyl acetate solvate; pharmaceutical compositions thereof; and methods for treatment and/or prophylaxis of cardiovascular, pulmonary, thromboembolic, or fibrotic disorders using these forms and pharmaceutical compositions thereof. Riociguat is covered by one or more of the claims in the '188 Patent.

24. Adverio is the assignee of the '188 Patent and holds title to the '188 Patent.

25. Bayer AG is the exclusive licensee of the '188 Patent in the United States.

26. Plaintiff Bayer HealthCare is the holder of approved New Drug Application ("NDA") No. 204819 for 0.5 mg, 1 mg, 1.5 mg, 2 mg and 2.5 mg tablets of riociguat, which are sold under the trade name Adempas®. Adempas® is a soluble guanylate cyclase (sGC) stimulator indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension or pulmonary arterial hypertension. Bayer HealthCare markets Adempas® in the United States under Bayer AG's exclusive license.

27. Adempas® is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." The '188 Patent is listed in the Orange Book in association with Adempas®. Claims of the '188 Patent cover Adempas®.

28. On information and belief, MSN submitted ANDA No. 211135 (and its amendment) to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product—a generic version of Adempas®.

29. On information and belief, MSN continues to seek approval of ANDA No. 211135 from the FDA and intends to engage in the marketing, commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product if the FDA approves ANDA No. 211135.

30. On or about October 16, 2020, Plaintiffs received a letter from MSN dated October 16, 2020 (MSN's "Paragraph IV Letter") purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto, and stating that MSN had submitted an amendment to ANDA No. 211135 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import Defendants' ANDA Product prior to the expiration of the '188 Patent.

31. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), MSN's Paragraph IV Letter shall contain "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."

32. MSN's Paragraph IV Letter contends, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), that the '188 Patent is invalid or unenforceable and/or will not be infringed (MSN's "Paragraph IV Certification").

33. Plaintiffs are commencing this action within forty-five days of the date on which they received MSN's Paragraph IV Letter.

CLAIM FOR INFRINGEMENT
(Infringement of the '188 Patent under 35 U.S.C. § 271(e))

34. Plaintiffs incorporate all preceding paragraphs of this Complaint as if fully set forth herein.

35. On information and belief, MSN submitted its amendment to ANDA No. 211135 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product before the expiration of the '188 Patent.

36. Under 35 U.S.C. § 271(e)(2), MSN has infringed the '188 Patent by submitting its amendment to ANDA No. 211135 with its Paragraph IV Certification and seeking FDA approval to market Defendants' ANDA Product prior to the expiration of the '188 Patent.

37. Upon information and belief, the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product prior to the expiration of the '188 Patent would infringe, contribute to the infringement of, and/or induce the infringement of claims 15-18, 21-22, and 26-30 of the '188 Patent.

38. MSN's Paragraph IV Letter does not contend that Defendants' ANDA Product, or its use, will not infringe claims 15-18, 21-22, and 26-30 of the '188 Patent, if valid and enforceable.

39. MSN had actual and constructive notice of the '188 Patent prior to filing its amendment to ANDA No. 211135.

40. Plaintiffs have no adequate remedy at law to redress the infringement by MSN.

41. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing, actively inducing, or contributing to the infringement of the '188 Patent.

42. Plaintiffs respectfully request the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to MSN's ANDA No. 211135 shall be a date that is not earlier than the current expiration date of the '188 Patent and any additional periods of exclusivity.

43. MSN has proceeded with knowledge of the '188 Patent and has no reasonable basis to conclude that it has not infringed the '188 Patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

- A. a judgment that MSN has infringed one or more claims of the '188 Patent under 35 U.S.C. § 271(e)(2)(A);
- B. a judgment pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of MSN's ANDA No. 211135 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration date of the '188 Patent, including any additional exclusivity period applicable to that patent;
- C. a judgment declaring that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product described in ANDA No. 211135 would constitute infringement by MSN of the '188 Patent, or actively induce and/or contribute to infringement by others, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c), either literally or under the doctrine of equivalents;
- D. a judgment permanently enjoining MSN and each of its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendants' ANDA Product until the day after the expiration of the '188 Patent, including any additional exclusivity period applicable to that patent, and from otherwise infringing one or more claims of the '188 Patent, either literally or under the doctrine of equivalents;
- E. damages from MSN if it engages in any commercial activity constituting infringement of the '188 Patent, or inducing or contributing to such infringement, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c);

- F. a declaration that this case is exceptional;
- G. an award of Plaintiffs' costs, expenses, reasonable attorneys' fees, and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and
- H. such other and further relief as the Court may deem just and proper.

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