IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. ZENARA PHARMA PRIVATE LTD. AND BIOPHORE INDIA PHARMACEUTICALS PRIVATE LTD., Defendants	Civ. Action No. 20-cv-1599-UNA

DEFENDANTS ZENARA PHARMA PRIVATE LTD. AND BIOPHORE INDIA PHARMACEUTICALS PRIVATE LTD'S ANSWER TO COMPLAINT

Defendants Zenara Pharma Private Ltd. ("Zenara") and Biophore India Pharmaceuticals Private Ltd. ("Biophore") (collectively, "Biophore"), by their counsel, hereby respond to the allegations set forth in Plaintiffs Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck")'s (collectively, "Plaintiffs") Complaint for patent infringement against Defendants under 35 U.S.C. § 271(e)(2). This response is based on Biophore's current knowledge as to its own activities, and on information and belief as to the activities of others. If not specifically admitted herein, the allegations of the Complaint are denied.

1. Biophore admits that this action purports to arise under the United States, Patent Laws, Title 35, United States Code. Biophore further admits that Plaintiffs purport to seek relief from alleged infringement of U.S. Reissue Patent No. RE48,059 ("the RE'059 patent"). Biophore admits that Zenara filed ANDA No. 213477 with the FDA for approval to sell its ANDA product, as a generic version of Otsuka's Rexulti® drug product prior to the expiration of the RE'059 patent. Biophore denies the remaining allegations of paragraph 1.

THE PARTIES

2. Biophore is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 of the Complaint, and therefore denies them.

3. Biophore is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 of the Complaint, and therefore denies them.

4. Biophore is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the Complaint, and therefore denies them.

5. Admitted.

6. Admitted.

7. Admitted.

JURISDICTION AND VENUE

8. Paragraph 8 of the Complaint states a legal conclusion to which no response is required. Biophore will not contest subject matter jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Biophore in this case and solely as they apply to the proposed products described in ANDA No. 213477. Biophore denies any remaining allegations in this paragraph.

9. Paragraph 9 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore will not contest personal jurisdiction for the limited purpose of this action only. Biophore denies any remaining allegations in this paragraph.

10. Paragraph 10 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore will not contest personal jurisdiction for the limited purpose of this action only. Biophore denies any remaining allegations in this paragraph.

11. Paragraph 11 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore will not contest personal jurisdiction for the limited purpose of this action only. Biophore denies any remaining allegations in this paragraph.

12. Paragraph 12 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore admits that it filed ANDA No. 213477. Biophore denies any remaining allegations in this paragraph.

13. Admitted.

14. Paragraph 14 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore admits that it filed ANDA No. 213477. Biophore will not contest personal jurisdiction for the limited purpose of this action only. Biophore denies any remaining allegations in this paragraph.

15. Paragraph 15 of the Complaint states a legal conclusion to which no response is required. Biophore admits that it filed ANDA No. 213477 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Biophore is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

16. Paragraph 16 of the Complaint states a legal conclusion to which no response is required. Biophore will not contest personal jurisdiction or venue for the limited purpose of this action only.

17. Paragraph 17 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore will not contest venue for the limited purpose of this action only. Biophore denies any remaining allegations in this paragraph.

FACTUAL BACKGROUND

The NDA

18. Admitted.

19. Biophore is without information sufficient to admit or deny the allegations in this paragraph and therefore denies the allegations.

20. Denied.

The Patent-In-Suit

21. Biophore admits that U.S. Patent No. 7,888,362 ("the '362 patent") is entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders" and on its face indicates that it issued on February 15, 2011.

22. Biophore admits that Plaintiffs purport that a true and correct copy of the RE'059 patent is attached to the Complaint as Exhibit A. Biophore further admits that the RE'059 patent on its face indicates that it was issued on June 23, 2020, as a reissue of the '362 patent.

23. Biophore is without knowledge or information sufficient to admit or deny whether Otsuka owns the rights to the RE'059 patent and/or whether Otsuka is an assignee of the RE'059 patent. Biophore admits that the RE'059 patent is assigned on its face to Otsuka.

24. Paragraph 24 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore is without knowledge or information sufficient to admit or deny whether the RE'059 patent is properly a subject to terminal disclaimer. Biophore admits that Plaintiffs purport that a true and correct copy of the terminal disclaimer is attached to the Complaint as Exhibit B.

25. Biophore is without knowledge or information sufficient to admit or deny whether Otsuka's calculation of the RE'059 patent expiration date is accurate.

26. Paragraph 26 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore admits that the RE'059 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations under Rexulti®.

The ANDA

27. Biophore admits that it filed ANDA No. 213477 with the FDA for approval of the matters therein.

28. Biophore is without knowledge or information sufficient to admit or deny whether Otsuka has received a letter sent by Biophore. Biophore admits that on August 30, 2019, it sent a Notice Letter to Otsuka pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 and that it filed patent certifications with respect to the '362 patent and U.S. Patent Nos. 8,349,840 ("the '840 patent"), 8,618,109 ("the '109 patent"), 9,839,637 ("the '637 patent"), and 10,307,419 ("the '419 patent") pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its Abbreviated New Drug Application ("ANDA"). Biophore denies any remaining allegations in this paragraph.

29. Paragraph 29 of the Complaint states a legal conclusion to which no response is required.

30. Biophore admits that the RE'059 patent on its face indicates that it was issued on June 23, 2020, as a reissue of the '362 patent. Biophore is without knowledge or information sufficient to admit or deny whether Otsuka "timely notified the FDA." Biophore admits that the RE'059 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations under Rexulti®.

31. Biophore admits that it filed a patent certification with respect to the RE'059 patent pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its ANDA No. 213477. Biophore denies any remaining allegations in this paragraph.

32. Biophore is without knowledge or information sufficient to admit or deny whether Otsuka has received a letter sent by Biophore. Biophore admits that on October 13, 2020, it sent a Notice Letter to Otsuka pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 and that it filed a patent certification with respect to the RE '059 patent pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its ANDA No. 213477. Biophore denies any remaining allegations in this paragraph.

33. Paragraph 33 of the Complaint states a legal conclusion to which no response is required.

COUNT I

(INFRINGEMENT OF THE RE'059 PATENT)

34. Biophore incorporates by reference all of the answers in prior paragraphs.

35. Paragraph 35 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore admits that it filed ANDA No. 213477 with the FDA for approval of the matters therein.

36. Biophore admits that it filed a patent certification with respect to the RE'059 patent pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its ANDA No. 213477. Biophore denies any remaining allegations in this paragraph.

37. Paragraph 37 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Biophore admits that it filed ANDA No. 213477 with the FDA for approval of the matters therein.

38. Paragraph 38 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of willful infringement.

39. Paragraph 39 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of direct or indirect infringement.

40. Biophore admits that it filed ANDA No. 213477 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Biophore is without information sufficient to admit or deny the remaining allegations in this

paragraph and therefore denies the allegations.

41. Paragraph 41 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of direct or indirect infringement.

42. Biophore is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 42 of the Complaint, and therefore denies them.

43. Biophore is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 43 of the Complaint, and therefore denies them.

44. Denied.

REQUESTED RELIEF

Biophore denies that Otsuka is entitled to any of the relief sought in its Prayer for Relief, including the relief sought in Paragraphs (A) through (H) on pages 9-10 of the Complaint.

AFFIRMATIVE DEFENSES

An allegation of any defense below is not an admission that Biophore bears the burden of proof or persuasion on any claim or issue.

First Affirmative Defense – Non-Infringement of the Claims of the RE'059 Patent

Biophore has not infringed, is not infringing, will not infringe, will not induce to infringe, and will not contribute to infringement of, literally or under the doctrine of equivalents, any valid and enforceable claims of the RE'059 patent.

Second Affirmative Defense – Invalidity of the Claims of the RE'059 Patent

The claims of the RE'059 patent are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116, 251, and/or for double patenting.

Third Affirmative Defense – Collateral Estoppel

Otsuka's claims are barred, in whole or in part, by the doctrine of collateral estoppel.

Fourth Affirmative Defense – Failure to State a Claim

Otsuka's Complaint fails to state a claim upon which relief can be granted.

RESERVATION OF ADDITIONAL DEFENSES

Biophore reserves the right to assert such other defenses and damages, if such defenses or and damages are discovered during the course of this litigation.

PRAYER FOR RELIEF

WHEREFORE, Biophore respectfully prays that this Court enter judgment in Biophore's favor and grant the following relief:

A. Dismiss Otsuka's Complaint with prejudice and deny each and every prayer for relief contained therein;

B. A declaration that Biophore does not infringe the claims of the RE'059 patent;

C. A declaration that the claims of the RE'059 patent are invalid;

D. Assess the costs of this action against Otsuka;

E. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285, and that Biophore is entitled to recover its reasonable attorney fees and costs upon prevailing in this action;

F. That the effective date of any FDA approval of Biophore's ANDA product shall not be stayed thirty months from the date of the Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii);

G. An award to Biophore of such further and other relief as this Court deems necessary, just, and proper.

Dated: November 30, 2020

Respectfully submitted,

MORRIS JAMES LLP

/s/ Kenneth L. Dorsney

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