

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

OTSUKA PHARMACEUTICAL CO., LTD.
AND H. LUNDBECK A/S,

Plaintiffs,

v.

Civ. Action No. 20-cv-1531-LPS

HETERO LABS, LTD., HETERO LABS,
LTD. UNIT-V, HETERO USA, INC.,
HETERO DRUGS, LTD. and HONOUR
LAB LTD.,

Defendants

**DEFENDANTS HETERO USA, INC., HETERO DRUGS, LTD., HETERO LABS, LTD.,
UNIT-V, HETERO LABS, LTD. AND HONOUR LAB LTD.’S ANSWER TO
COMPLAINT**

Defendants Hetero USA, Inc., Hetero Drugs, Ltd., Hetero Labs, Ltd. Unit-V, and Hetero Labs, Ltd. (collectively, “Hetero”) and Defendant Honour Lab Ltd. (“Honour”) (collectively, “Defendants”), by their counsel, hereby respond to the allegations set forth in the Plaintiffs, Otsuka Pharmaceutical Co., Ltd. (“Otsuka”) and H. Lundbeck A/S’s (“Lundbeck”) (collectively, “Plaintiffs”) Complaint for patent infringement against Defendants under 35 U.S.C. § 271(e)(2). This response is based on Defendants’ current knowledge as to their 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. Hetero admits that this action purports to arise under the United States, Patent Laws, Title 35, United States Code. Hetero further admits that Plaintiffs purport to seek relief from alleged infringement of U.S. Reissue Patent No. RE48,059 (“the RE’059 patent”). Hetero

admits that it filed ANDA No. 213669 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.

Hetero denies the remaining allegations of paragraph 1.

THE PARTIES

2. Hetero 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. Hetero 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. Hetero 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.

8. Admitted.

9. Admitted.

10. Admitted.

11. Denied.

JURISDICTION AND VENUE

12. Paragraph 12 of the Complaint states a legal conclusion to which no response is required. Hetero will not contest subject matter jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Hetero in this case and solely as they apply to the proposed products described in ANDA No. 213669. Hetero denies any remaining allegations in this paragraph.

13. Paragraph 13 of the Complaint states a legal conclusion to which no response is

required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

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

15. Paragraph 15 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

16. Paragraph 16 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that it filed ANDA No. 213669. Hetero denies any remaining allegations in this paragraph.

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

18. Paragraph 18 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

19. Paragraph 19 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

20. Paragraph 20 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

21. Paragraph 21 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

22. Denied. The Court does not have personal jurisdiction over Honour, which has filed a motion to dismiss for lack of personal jurisdiction, lack of subject matter jurisdiction, and failure to state a claim upon which relief can be granted.

23. Paragraph 23 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Honour is one of many DMF holders for brexpiprazole. Honour denies any remaining allegations in this paragraph.

24. Paragraph 24 of the Complaint states a legal conclusion to which no response is required. Honour denies that this Court has personal jurisdiction over it. Contrary to Plaintiffs' allegation, Plaintiffs' first cited hyperlink at <https://www.indiamart.com/heterolabs-limited/aboutus.html> does not mention Honour and no association between Honour and Hetero can be ascertained from the link. Plaintiffs' second cited hyperlink at <http://pharma.industry-report.net/honour-lab-ltd/> refers to a source to which neither Honour, nor Hetero supplied their corporate information. Also, contrary to Plaintiffs' allegation, the recited hyperlinks <https://www.zaubacorp.com/company/HONOUR-LAB-LIMITED/U24233TG2011PLC077561> and <https://www.zaubacorp.com/company/HETERO-LABS LIMITED/U24110TG1989PLC009723> do not contain any overlapping names to support Plaintiffs' allegation that the named entities "share one or more corporate directors." Honour denies any remaining allegations in this paragraph.

25. Paragraph 25 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest personal jurisdiction for the

limited purpose of this action only. Hetero and Honour deny that they hold themselves out as a unitary entity. Hetero denies any remaining allegations in this paragraph. Honour denies any remaining allegations in this paragraph.

26. Paragraph 26 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that it filed ANDA No. 213669. Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

27. Paragraph 27 of the Complaint states a legal conclusion to which no response is required. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

28. Paragraph 28 of the Complaint states a legal conclusion to which no response is required. Hetero will not contest personal jurisdiction or venue for the limited purpose of this action only.

29. Paragraph 29 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest venue for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

30. Paragraph 30 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest venue for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

31. Paragraph 31 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest venue for the limited purpose

of this action only. Hetero denies any remaining allegations in this paragraph.

FACTUAL BACKGROUND

The NDA

32. Admitted.

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

34. Denied.

The Patent-In-Suit

35. Hetero 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.

36. Hetero admits that Plaintiffs purport that a true and correct copy of the RE’059 patent is attached to the Complaint as Exhibit A. Hetero 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.

37. Hetero 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. Hetero admits that the RE’059 patent is assigned on its face to Otsuka.

38. Paragraph 38 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to admit or deny whether the RE’059 patent is properly subject to terminal disclaimer. Hetero admits that Plaintiffs purport that a true and correct copy of the terminal disclaimer is attached to the Complaint as Exhibit B.

39. Hetero is without knowledge or information sufficient to admit or deny whether

Otsuka's calculation of the RE'059 patent expiration date is accurate.

40. Paragraph 40 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that the RE'059 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations under Rexulti®.

The ANDA

41. Hetero admits that it filed ANDA No. 213669 with the FDA for approval of the matters therein.

42. Hetero is without knowledge or information sufficient to admit or deny whether Otsuka has received a letter sent by Hetero. Hetero admits that on September 11, 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 ANDA No. 213669. Hetero denies any remaining allegations in this paragraph.

43. Paragraph 43 of the Complaint states a legal conclusion to which no response is required.

44. Hetero 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. Hetero is without knowledge or information sufficient to admit or deny whether Otsuka "timely notified the FDA." Hetero admits that the RE'059 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations under Rexulti®.

45. Hetero 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. 213669. Hetero denies any remaining allegations in this paragraph.

46. Hetero is without knowledge or information sufficient to admit or deny whether Otsuka has received a letter sent by Hetero. Hetero admits that on October 1, 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. 213669. Hetero denies any remaining allegations in this paragraph.

47. Paragraph 47 of the Complaint states a legal conclusion to which no response is required.

COUNT I

(INFRINGEMENT OF THE RE'059 PATENT)

48. Hetero incorporates by reference all of the answers in prior paragraphs.

49. Paragraph 49 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that it filed ANDA No. 213669 with the FDA for approval of the matters therein.

50. Hetero 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. 213669. Hetero denies any remaining allegations in this paragraph.

51. Paragraph 51 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that it filed ANDA No. 213669 with the FDA for approval of the matters therein.

52. Paragraph 52 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.

53. Paragraph 53 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.

54. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

55. Paragraph 55 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.

56. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 56 of the Complaint, and therefore denies them.

57. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 57 of the Complaint, and therefore denies them.

58. Denied.

REQUESTED RELIEF

Hetero 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 12-13 of the Complaint.

AFFIRMATIVE DEFENSES

An allegation of any defense below is not an admission that Hetero 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

Hetero 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

Hetero 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, Hetero respectfully prays that this Court enter judgment in Hetero’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 Hetero 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 Hetero 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 Hetero'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 Hetero of such further and other relief as this Court deems necessary, just, and proper.

Date: November 25, 2020

Respectfully submitted,

Of Counsel:

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