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.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendants Zenara Pharma Private Ltd. ("Zenara") and Biophore India Pharmaceuticals Private Ltd. ("Biophore India") (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Reissue Patent No. RE48,059 ("the RE'059 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Defendants' filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to engage in the commercial manufacture, use or sale of generic pharmaceutical products before the expiration of the RE'059 patent.

THE PARTIES

2. 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.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the RE'059 patent.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

5. Upon information and belief, Zenara is a corporation organized under the laws of India and its principal place of business is located at Plot No. 83/B, 84 & 87-96, Phase III, IDA Cherlapally, Hyderabad 500051, India.

6. Upon information and belief, Zenara is a wholly owned subsidiary of Biophore India.

7. Upon information and belief, Biophore India is a corporation organized under the laws of India and its principal place of business is located at Plot No. 92, 1-98/2/92, Kavuri Hills, Phase II, Jubilee Hills, Hyderabad, 500033, India.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Zenara. Upon information and belief, Zenara is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Zenara directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Zenara purposefully has conducted and

continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

10. This Court has personal jurisdiction over Biophore India. Upon information and belief, Biophore India is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Biophore India directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Biophore India purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

11. Upon information and belief, Defendants hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States including in this judicial district.

12. Upon information and belief, Biophore India admits that it "is engaged in the development and manufacturing of niche pharmaceutical products for the generic industry. Within a decade since inception in 2007, Biophore has emerged as a trusted partner in the generic industry across US, Europe and ROW markets . . . We have filed 1st ANDA from Zenara Pharma Ltd and received acceptance from FDA & gearing up for US FDA in couple of months." https://iphex-india.com/exhibitor/view_details/474 (Biophore Company Profile, June 2019); *see also* http://www.biophore.com/ (accessed Nov. 21, 2020).

13. Upon information and belief, Biophore is the holder of FDA Drug Master File No. 33704 for brexpiprazole.

14. Defendants' ANDA filing regarding the RE'059 patent relates to this litigation and

is substantially connected with this judicial district because it reliably and non-speculatively predicts Defendants' intent to market and sell Defendants' generic products in this judicial district.

15. Defendants have taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of their generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Defendants intend to direct sales of their generic drugs in this judicial district, among other places, once Defendants receive the requested FDA approval to market their generic products. Upon information and belief, Defendants will engage in marketing of their proposed generic products in Delaware upon approval of their ANDA.

16. Upon information and belief, Defendants have thus been, and continue to be, the prime actors in the drafting, submission, approval and maintenance of ANDA No. 213477.

17. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Zenara and Biophore India are incorporated in India and may be sued in any judicial district.

FACTUAL BACKGROUND

The NDA

18. Otsuka is the holder of New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3 and 4 mg dosage forms ("REXULTI® Tablets").

19. The FDA approved NDA No. 205422 on July 10, 2015.

20. REXULTI® Tablets are prescription drugs approved for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia. Brexpiprazole is the active ingredient in REXULTI® Tablets.

The Patent In Suit

21. The United States Patent and Trademark Office ("the PTO") issued U.S. Patent No. 7,888,362 ("the '362 patent") on February 15, 2011, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders."

22. The PTO reissued the '362 patent as the RE'059 patent on June 23, 2020. A true and correct copy of the RE'059 patent is attached hereto as Exhibit A.

23. As the reissue of the '362 patent, Otsuka is the owner of the RE'059 patent through assignment as recorded by the PTO for the '362 patent at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

24. Pursuant to 35 U.S.C. § 251, the RE'059 patent issued for the unexpired term of the '362 patent, which would have expired on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed 317 days of patent term adjustment granted to the '362 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit B.

25. Otsuka filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156 and Response to Notice of Final Determination, requesting an extension under 35 U.S.C. § 156(c) of 986 days for the '362 patent. After the RE'059 patent issued, Otsuka filed a Petition Under 37 C.F.R. § 1.182 to Move Patent Term Extension Application from U.S. Patent No. 7,888,362 to RE 48,059, which was granted on October 6, 2020.

Accordingly, the RE'059 patent will expire on December 23, 2028, based on the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

26. The RE'059 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

The ANDA

27. Upon information and belief, Defendants filed ANDA No. 213477 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use or sale in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3 and 4 mg ("Defendants' generic products"), which are generic versions of Otsuka's REXULTI® (brexpiprazole) Tablets.

28. Otsuka received a letter sent by Defendants, dated August 30, 2019, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 213477 ("Defendants' August 30, 2019, First Notice Letter") pursuant to § 505(j)(2)(B)(ii) and § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Defendants' August 30, 2019, First Notice Letter notified Otsuka that Defendants had filed ANDA No. 213477, seeking approval to engage in the commercial manufacture, use or sale of Defendants' generic products before the expiration of 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").

29. In response to Defendants' August 30, 2019, First Notice Letter, Plaintiffs previously filed a separate action in this Court against Defendants for patent infringement, which included counts of infringement of the '362, '840, '109, '637 and '419 patents. *See Otsuka Pharmaceutical Co., Ltd., et al. v. Zenara Pharma Private Ltd., et al.*, C.A. No. 19-1938-LPS.

30. On June 23, 2020, the PTO issued the RE'059 patent as a reissue of the '362 patent. Plaintiffs timely notified the FDA and the RE'059 patent was listed in the Orange Book for REXULTI®.

31. Upon information and belief, ANDA No. 213477 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification"), alleging that the claims of the RE'059 patent are invalid, unenforceable and/or would not be infringed by the commercial manufacture, use, sale, offer for sale and/or importation of Defendants' generic products.

32. Otsuka received a second notice letter sent by Defendants, dated October 13, 2020, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 213477 ("Defendants' October 13, 2020, Second Notice Letter") pursuant to § 505(j)(2)(B)(ii) and § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Defendants' October 13, 2020, Second Notice Letter notified Otsuka that Defendants had filed ANDA No. 213477, seeking approval to engage in the commercial manufacture, use or sale of Defendants' generic products in the United States before the expiration of the RE'059 patent.

33. Plaintiffs commenced this action within 45 days of receiving Defendants' October 13, 2020, Second Notice Letter.

COUNT I

(INFRINGEMENT OF THE RE'059 PATENT)

34. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

35. Upon information and belief, Defendants filed ANDA No. 213477 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the RE'059 patent.

36. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the RE'059 patent are invalid, unenforceable and/or not infringed.

37. Upon information and belief, in ANDA No. 213477, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

38. Defendants have actual knowledge of Otsuka's RE'059 patent, as evidenced by Defendants' October 13, 2020, Second Notice Letter.

39. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the RE'059 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213477, seeking approval to commercially manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the RE'059 patent.

40. Upon information and belief, if ANDA No. 213477 is approved, Defendants intend to and will offer to sell, sell and/or import in the United States Defendants' generic products.

41. Upon information and belief, if ANDA No. 213477 is approved, Defendants will infringe one or more claims of the RE'059 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic 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. 213477 shall be no earlier than the expiration of the RE'059 patent and any additional periods of exclusivity.

42. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 213477 complained of herein were done by and for the benefit of Defendants.

43. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

44. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the RE'059 patent through Defendants' submission of ANDA No. 213477 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the RE'059 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the RE'059 patent will infringe, actively induce infringement and/or contribute to the infringement of the RE'059 patent 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 Defendants' generic products shall be no earlier than the expiration date of the RE'059 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the RE'059 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining or maintaining approval of

the ANDA until the expiration of the RE'059 patent, 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 Plaintiffs of their 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 Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

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

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Plaintiffs Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S

Of Counsel:

James B. Monroe
Denise Main
Erin M. Sommers
C. Collette Corser
Tyler B. Latcham
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4431
(202) 408-4000

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