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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA) INC.,
CADILA HEALTHCARE LTD. and
ZYDUS HEALTHCARE (USA) LLC,

Defendants.

Civil Action No. 20-20269

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. (“Otsuka”) and H. Lundbeck A/S (“Lundbeck”) (collectively, “Plaintiffs”), by way of Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. (“Zydus Inc.”), Cadila Healthcare Ltd. d/b/a Zydus Cadila (“Zydus Cadila”) and Zydus Healthcare (USA) LLC (“Zydus LLC”) (collectively, “Zydus”), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. 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 Zydus' 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, sale, offer to sell within, or importation into, the United States 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, Zydus Cadila is a corporation organized under the laws of India and its principal place of business is located at 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382 481, India.

6. Upon information and belief, Zydus Inc. is a corporation organized under the laws of New Jersey and its principal place of business is located at 73 Route 31 N., Pennington, NJ 08534. Upon information and belief, Zydus Inc. is a wholly owned subsidiary of Zydus Cadila.

7. Upon information and belief, Zydus LLC is a limited liability company organized under the laws of Delaware and its principal place of business is located at 73 Route 31 N.,

Pennington, NJ 08534. Upon information and belief, Zydus LLC is a wholly owned subsidiary of Zydus Cadila.

JURISDICTION AND VENUE

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

9. Plaintiffs believe this case belongs in Delaware but are concurrently filing a case in this district out of an abundance of caution.

10. This Court has personal jurisdiction over Zydus Cadila because, upon information and belief, Zydus Cadila directly or indirectly develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district.

11. This Court has personal jurisdiction over Zydus Inc. because, upon information and belief, Zydus Inc. directly or indirectly develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district.

12. This Court has personal jurisdiction over Zydus LLC because, upon information and belief, Zydus LLC directly or indirectly develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district.

13. Upon information and belief, Zydus Inc., Zydus Cadila and Zydus LLC 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.

14. Upon information and belief, Zydus has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 213660.

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

16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Zydus Inc. is incorporated in New Jersey.

17. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because, upon information and belief, Zydus LLC's principal place of business is located in New Jersey.

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 owns 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 RE48,059, 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, Zydus filed ANDA No. 213660 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use, sale, offer to sell within, or importation into, the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3 and 4 mg ("Zydus' generic products"), which are generic versions of Otsuka's REXULTI® (brexpiprazole) Tablets.

28. Otsuka received a letter sent by Zydus, dated September 12, 2019, purporting to be a "Notice of Certification" for ANDA No. 213660 ("Zydus' September 12, 2019, First Notice

Letter”) pursuant to 21 U.S.C. § 355(j)(2)(B) and § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act. Zydus’ September 12, 2019, First Notice Letter notified Otsuka that Zydus had filed ANDA No. 213660, seeking approval to engage in the commercial manufacture, use or sale of Zydus’ 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 Zydus’ September 12, 2019, First Notice Letter, Plaintiffs previously filed separate actions in this Court and the District of Delaware against Zydus 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. Zydus Pharmaceuticals (USA) Inc., et al.*, 19-1934-FLW (D.N.J.); *Otsuka Pharmaceutical Co., Ltd., et al. v. Zydus Pharmaceuticals (USA) Inc., et al.*, C.A. No. 19-2024-LPS (D. Del.)

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. 213660 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 Zydus’ generic products.

32. Otsuka received a second notice letter sent by Zydus, dated November 12, 2020 purporting to be a Notice of Certification for ANDA No. 213660 (“Zydus’ November 12, 2020, Second Notice Letter”) pursuant to 21 U.S.C. § 355(j)(2)(B) and § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act. Zydus’ November 12, 2020, Second Notice Letter notified Otsuka

that Zydus had filed ANDA No. 213660, seeking approval to engage in the commercial manufacture, use, sale, offer to sell within, or importation into, the United States of Zydus' generic products before the expiration of the RE'059 patent.

33. Plaintiffs commenced this action within 45 days of receiving Zydus' November 12, 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, Zydus filed ANDA No. 213660 seeking approval to manufacture, use, import, offer to sell and/or sell Zydus' generic products in the United States before the expiration of the RE'059 patent.

36. Upon information and belief, Zydus 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 its ANDA No. 213660, Zydus has represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

38. Zydus has actual knowledge of Otsuka's RE'059 patent, as evidenced by Zydus' November 12, 2020, Second Notice Letter.

39. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed one or more claims of the RE'059 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213660, seeking approval to commercially manufacture, use, import, offer to sell or sell Zydus' generic products before the expiration date of the RE'059 patent.

40. Upon information and belief, if ANDA No. 213660 is approved, Zydus intends to and will offer to sell, sell and/or import in the United States Zydus' generic products.

41. Upon information and belief, if ANDA No. 213660 is approved, Zydus 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 Zydus' 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. 213660 shall be no earlier than the expiration of the RE'059 patent and any additional periods of exclusivity.

42. Upon information and belief, Zydus' actions relating to Zydus' ANDA No. 213660 complained of herein were done by and for the benefit of Zydus.

43. Plaintiffs will be irreparably harmed by Zydus' 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 Zydus has infringed at least one claim of the RE'059 patent through Zydus' submission of ANDA No. 213660 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Zydus' 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 Zydus' making, using, offering to sell, selling or importing of Zydus' 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 Zydus' 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 Zydus and all persons acting in concert with Zydus from commercially manufacturing, using, offering for sale or selling Zydus' generic products within the United States, or importing Zydus' 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 Zydus and all persons acting in concert with Zydus 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.

Dated: December 23, 2020
Newark, New Jersey

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