

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALKERMES PHARMA IRELAND LIMITED)
and JAZZ PHARMACEUTICALS, INC.,)

Plaintiffs,)

v.)

C.A. No. _____

TORRENT PHARMACEUTICALS)
LIMITED and TORRENT PHARMA INC.,)

Defendants.)

COMPLAINT

Plaintiffs, Alkermes Pharma Ireland Limited (“Alkermes”) and Jazz Pharmaceuticals, Inc. (“Jazz Pharmaceuticals”) (collectively, “Plaintiffs”), for their Complaint against Defendants Torrent Pharmaceuticals Limited (“Torrent Ltd.”) and Torrent Pharma Inc. (“Torrent Inc.”) (collectively “the Torrent Defendants”), hereby state as follows:

THE PARTIES

1. Alkermes is an Irish company having its principal place of business at Monksland, Athlone, County Westmeath, Ireland.
2. Jazz Pharmaceuticals is a Delaware corporation having its principal place of business at 3180 Porter Drive, Palo Alto, CA 94304.
3. On information and belief, Torrent Ltd. is a company organized and existing under the laws of India, having its principal place of business at Torrent House, Off Ashram Road, Ahmedabad - 380 009, Gujarat, India.
4. On information and belief, Torrent Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 5380 Holiday Terrace, Suite 40, Kalamazoo, Michigan 49009.

5. On information and belief, Torrent Inc. sells numerous generic drugs, manufactured and supplied by Torrent Ltd., throughout the United States, including this judicial district.

6. On information and belief, Torrent Inc. is a wholly-owned subsidiary of Torrent Ltd.

7. On information and belief, the acts of Torrent Ltd. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Torrent Inc.

8. On information and belief, the acts of Torrent Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Torrent Ltd.

NATURE OF THE ACTION

9. This is an action for infringement of United States Patent No. 7,465,462 (“the ‘462 patent”). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. On information and belief, Torrent Ltd. is in the business of formulating, manufacturing, and commercializing pharmaceutical products. Torrent Ltd. maintains a website at the uniform resource locator (URL) <http://www.torrentpharma.com>. According to that website, www.torrentpharma.com/corporate%20profile.php, “The flagship company of Torrent group, Torrent Pharmaceuticals Limited, is a dominant player in the therapeutic areas of

cardiovascular (CV) and central nervous system (CNS) and has achieved significant presence in gastro-intestinal, diabetology, anti-infective and pain management segments.” On information and belief, Torrent Ltd., either directly or through one or more of its wholly-owned subsidiaries, agents, or distributors, markets, sells, and/or distributes pharmaceutical products in this judicial district.

12. On information and belief, Torrent Inc., a wholly-owned subsidiary of Torrent Ltd., is in the business of marketing and selling Torrent generic drugs throughout the United States. On information and belief, Torrent Inc. markets and/or sells Torrent Ltd. drug products in this judicial district.

13. On information and belief, Torrent Ltd. and Torrent Inc. operate as an integrated, unitary business. For example, Torrent Ltd. states in its 2010-2011 Annual Report that Torrent Inc. is a wholly owned subsidiary of Torrent Ltd. and that those entities, together with other subsidiaries of Torrent Ltd., are collectively referred to as “the Group.” Torrent Ltd.’s 2010-2011 Annual Report also reports annual revenues earned by Torrent Inc. of \$24.47 million.

14. On information and belief, Torrent Ltd.’s website, www.torrentpharma.com, serves as the website for all of Torrent Ltd.’s subsidiaries, including Torrent Inc. On Torrent Ltd.’s website, the activities of Torrent Inc. are attributed to Torrent Ltd. For example, Torrent Ltd.’s website, www.torrentpharma.com/int_operational.php, states: “After ascertaining its credentials in the pharmaceutical industry of the country, Torrent Pharmaceuticals Limited began spreading its wings beyond India with thrust on becoming a global player in the international market.” That same webpage states that, “[t]o enable strategic differentiation, Torrent Pharma’s international business is segregated into five different zones,” including the United States of America, for which Torrent Inc. is identified as a contact for

“general inquiries” and “business development.” Torrent Ltd.’s website also states, at www.torrentpharma.com/int_usa.php:

The world largest market for pharmaceuticals, USA, has always been on Torrent Pharma’s strategic radar. That intent has been converted in early 2004 into a concrete undertaking, a fully owned subsidiary called Torrent Pharma Inc. This was floated to serve a large and growing need for high quality yet affordable medicines in the USA.

15. On information and belief, Torrent Ltd. and Torrent Inc. acted in concert to develop the Torrent Defendants’ generic copies of Plaintiffs’ LUVOX CR[®] Capsules, and to seek approval from the FDA to sell the Torrent Defendants’ generic copies of Plaintiffs’ LUVOX CR[®] Capsules throughout the United States and in this judicial district.

16. On information and belief, Torrent Ltd., through its authorized agent Torrent Inc., filed ANDA No. 203240 with the FDA.

17. On information and belief, Torrent Ltd. stated in its Paragraph IV Notice letter to Plaintiffs that it (Torrent Ltd.) had submitted ANDA No. 203240. On information and belief, Torrent Ltd. thus attributed the acts of Torrent Inc. to itself. On information and belief, Torrent Ltd. and Torrent Inc. thus acted jointly as a single entity in connection with preparing and filing ANDA No. 203240. On further information and belief, Torrent Inc. acted as an agent of Torrent Ltd. On further information and belief, in its Paragraph IV Notice letter to Plaintiffs, Torrent Ltd. specifically identified Torrent Inc. as its “U.S. Agent.”

18. On information and belief, and as previously noted, Torrent Inc. is a corporation organized and existing under the laws of Delaware. By virtue of its incorporation in Delaware, this Court has personal jurisdiction over Torrent Inc.

19. On information and belief, by virtue of, *inter alia*, Torrent Ltd.’s relationship with Torrent Inc. in connection with the preparation and/or filing of ANDA No.

203240, Torrent Ltd.'s designation of Torrent Inc. as its agent for service of process, and their sales-related activities in Delaware, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of Delaware, this Court has personal jurisdiction over Torrent Ltd.

20. On information and belief, separate and apart from its relationship with Torrent Inc., Torrent Ltd. has availed itself of the laws of the State of Delaware and engaged in a course of conduct in the State of Delaware, at least by incorporating its U.S. subsidiary, Torrent Inc., under Delaware law, and identifying the Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808, as the registered agent of its subsidiary, Torrent Inc.

21. On information and belief, Torrent Ltd. and Torrent Inc. have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g., Wyeth v. Torrent Pharmaceuticals Limited et al* (D. Del. No. 1:09-cv-00019-JJF); *Sanofi-Aventis v. Actavis South Atlantic LLC* (D. Del. No. 1:07-cv-00572-GMS); *Teva Pharma. Indus. Ltd. v. Torrent Pharma. Ltd.* (D. Del. No. 1:07-cv-00332-GMS).

22. On information and belief, by virtue of, *inter alia*, the revenue derived from the sales of the Torrent Defendants' drug products throughout the United States, including Delaware, the Torrent Defendants' continuous and systematic contacts with Delaware, including but not limited to the above-described contacts, and the actions on behalf of Torrent Ltd. in connection with ANDA No. 203240 undertaken by its agent Torrent Inc., a Delaware corporation, this Court has general and specific personal jurisdiction over Torrent Ltd. and Torrent Inc. These activities satisfy due process and confer personal jurisdiction over Torrent Ltd. and Torrent Inc. consistent with the Delaware Long Arm Statute.

23. On information and belief, Torrent Ltd., directly and/or through its Delaware agent, Torrent Inc., caused tortious injury in Delaware to Jazz, a Delaware corporation by filing ANDA No. 203240, further supporting specific and/or general jurisdiction over Torrent Ltd.

24. On information and belief, if Torrent Ltd. were not subject to the jurisdiction of the courts of general jurisdiction of the State of Delaware, it likewise would not be subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to personal jurisdiction and service of process based on its aggregate contacts with the United States, including but not limited to the above-described contacts, as authorized by Federal Rule of Civil Procedure 4(k)(2).

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

BACKGROUND

26. On December 16, 2008, the '462 patent, entitled "Multiparticulate Controlled Release Selective Serotonin Reuptake Inhibitor Formulations," was duly and legally issued to Elan Pharma International Limited ("EPIL") as assignee. Alkermes subsequently acquired the '462 patent from EPIL, and Alkermes now is the owner by assignment of the '462 Patent and has the right to sue for infringement thereof. Jazz Pharmaceuticals is the exclusive licensee under the '462 patent. A true and correct copy of the '462 patent is attached as Exhibit A.

27. On February 28, 2008, the United States Food And Drug Administration ("FDA") approved an new drug application ("NDA"), No. 22-033, for LUVOX CR® extended release capsules, which contain fluvoxamine maleate, under § 505(a) of the Federal Food, Drug

and Cosmetic Act, 21 U.S.C. § 355(a), for the treatment of social anxiety disorder and obsessive compulsive disorder. The '462 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for LUVOX CR® capsules. Jazz Pharmaceuticals is the holder of NDA No. 22-033.

28. On information and belief, the Torrent Defendants submitted to the FDA an abbreviated new drug application ("ANDA"), No. 203240, under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of Fluvoxamine Maleate Extended-Release Capsules in 100 and 150 mg strengths, as generic versions of the LUVOX CR® 100 and 150 mg capsules.

29. By letter dated September 9, 2011 (the "Torrent Letter"), the Torrent Defendants advised Plaintiffs that they had submitted ANDA No. 203240 seeking approval to manufacture, use, or sell generic Fluvoxamine Maleate Extended-Release Capsules prior to the expiration of the '462 patent.

30. The Torrent Letter also advised Plaintiffs that the Torrent Defendants' ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetics Act), that, in the Torrent Defendants' opinion, the manufacture, use or sale of the proposed generic Fluvoxamine Maleate Extended-Release Capsules described in its ANDA will not infringe the '462 patent, and/or that the '462 patent is invalid and/or unenforceable.

COUNT I

31. Plaintiffs incorporate each of the preceding paragraphs 1 to 30 as if fully set forth herein.

32. By submitting ANDA No. 203240 to the FDA for the purpose of obtaining approval for the commercial manufacture, use, or sale of its Fluvoxamine Maleate Extended Release Capsules before the expiration date of the '462 Patent, the Torrent Defendants have committed an act of infringement of one or more claims of the '462 Patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

33. The commercial manufacture, use or sale of the Torrent Defendants' proposed generic Fluvoxamine Maleate Extended-Release Capsules in the United States before the expiration of the '462 patent would infringe one or more claims of that patent.

34. On information and belief, the Torrent Defendants were aware of the existence of the '462 patent and were aware that the filing of its ANDA and certification with respect to the '462 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

35. Plaintiffs incorporate by reference paragraphs 1 through 34 of this Complaint as if fully set forth herein.

36. On information and belief, Torrent Inc. jointly filed and/or was actively involved in submitting ANDA No. 203240 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale throughout the United States, including the State of Delaware, of the Torrent Defendants' generic Fluvoxamine Maleate Extended-Release Capsules prior to the expiration of the '462 patent. Upon information and belief, Torrent Inc. will participate in the manufacture, marketing, and sale of the Torrent Defendants' generic Fluvoxamine Maleate Extended-Release Capsules if they are approved by the FDA. Torrent Inc. thus actively induced Torrent Ltd. to submit ANDA No. 203240 to the FDA.

37. The commercial manufacture, use or sale of the Torrent Defendants' proposed generic Fluvoxamine Maleate Extended-Release Capsules in the United States before the expiration of the '462 patent would infringe one or more claims of that patent.

38. By actively inducing submission of ANDA No. 203240, Torrent Inc. has committed an act of infringement with respect to the '462 patent under 35 U.S.C. § 271(b).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the Torrent Defendants individually and/or collectively have infringed the '462 patent;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(a) that the effective date of any approval of the Torrent Defendants' ANDA No. 203240 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), be a date which is not earlier than the expiration date of the '462 patent or any extension of exclusivity to which Plaintiffs are or become entitled;

C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining the Torrent Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from infringement of the '462 patent for the full term thereof;

D. A judgment that Torrent Inc. induced Torrent Ltd. to infringe the '462 patent;

E. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

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