

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

|                                  |   |                   |
|----------------------------------|---|-------------------|
| OTSUKA PHARMACEUTICAL CO., LTD., | ) |                   |
|                                  | ) |                   |
| Plaintiff,                       | ) |                   |
|                                  | ) |                   |
| v.                               | ) |                   |
|                                  | ) |                   |
| TORRENT PHARMACEUTICALS LIMITED  | ) | Civil Action No.: |
| and TORRENT PHARMA INC.,         | ) |                   |
|                                  | ) |                   |
|                                  | ) |                   |
| Defendants.                      | ) |                   |
|                                  | ) |                   |
|                                  | ) |                   |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Torrent Pharmaceuticals Limited (“Torrent Ltd.”) and Torrent Pharma Inc. (“Torrent Inc.”) (collectively, “Torrent”), alleges as follows:

**THE PARTIES**

1. 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. Otsuka is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Torrent Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Torrent House, Off Ashram Road, Ahmedabad, 380009, Gujarat, India.

3. Upon information and belief, Torrent Inc. is a wholly-owned subsidiary of Torrent Ltd. Upon information and belief, Torrent Inc. is a corporation organized and existing

under the laws of Delaware with its corporate headquarters at 150 Allen Road, Suite 102, Basking Ridge, New Jersey 07920.

**NATURE OF THE ACTION**

4. This is an action for infringement of U.S. Patent No. 8,642,760 (“the ’760 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 Torrent Ltd.’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to manufacture, use, sell, offer to sell and import generic pharmaceutical products (“Torrent Ltd.’s generic products”) prior to the expiration of the asserted patent.

**JURISDICTION AND VENUE**

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

6. This Court has jurisdiction over Torrent Ltd. Torrent Ltd. is in the business of manufacturing, importing, marketing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Torrent Ltd., directly or through its wholly-owned subsidiaries (primarily Torrent Inc.), manufactures, imports, markets and sells generic drug products throughout the United States and in this judicial district. Upon information and belief, Torrent Ltd. purposefully has conducted and continues to conduct business directly, or through its wholly-owned subsidiaries (primarily Torrent Inc.), in this judicial district, and this judicial district is a likely destination of Torrent Ltd.’s generic products. Torrent Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

7. Upon information and belief, this Court additionally has jurisdiction over Torrent Ltd. because it has availed itself of the rights and benefits of this judicial district, having stated in a purported Offer of Confidential Access, dated June 11, 2014, that “[t]he Company agrees that any claims for breach of this Agreement must be brought exclusively in the courts located in the State of New Jersey and consents to the jurisdiction and venue of such courts for any such claims.”

8. This Court has jurisdiction over Torrent Inc. Upon information and belief, Torrent Inc.’s corporate headquarters are in New Jersey. Torrent Inc., directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Torrent Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

9. Upon information and belief, Torrent Ltd. and Torrent Inc. operate as a single, integrated business, and share a website, <http://www.torrentpharma.com>, in which Torrent Inc. is identified as “general inquiries contact” and “business development contact” regarding Torrent operations in the United States. The website, [http://www.torrentpharma.com/int\\_usa.php#](http://www.torrentpharma.com/int_usa.php#), also states that: “The world’s 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.”

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

**FIRST COUNT FOR PATENT INFRINGEMENT**

11. The U.S. Patent and Trademark Office (“PTO”) issued the ’760 patent on February 4, 2014, entitled “Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof.” A copy of the ’760 patent is attached as Exhibit A.

12. Otsuka is the owner of the ’760 patent by virtue of assignment.

13. The ’760 patent expires on March 25, 2023 (including pediatric exclusivity).

14. The ’760 patent is directed to and claims, *inter alia*, aripiprazole drug substance.

15. Otsuka is the holder of New Drug Application (“NDA”) No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002.

16. Otsuka lists the ’760 patent in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 21-436.

17. Otsuka markets aripiprazole tablets in the United States under the trademark Abilify®.

18. Upon information and belief, Torrent Ltd. submitted ANDA No. 20-1519 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, import, offer to sell and sell Torrent Ltd.’s generic products in the United States.

19. Otsuka received a letter from Torrent Ltd. dated June 11, 2014, purporting to include a Notice of Certification for ANDA No. 20-1519 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (“Torrent Ltd.’s June 11, 2014 letter”) as to the ’760 patent.

20. Torrent Ltd.’s June 11, 2014 letter alleges that the “name for the drug product that is the subject of the Torrent ANDA is aripiprazole tablet, for oral administration.”

21. Upon information and belief, Torrent Ltd.’s generic products will, if approved and marketed, infringe at least one claim of the ’760 patent.

22. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Torrent Ltd. has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-1519 seeking approval to manufacture, use, import, offer to sell and sell Torrent Ltd.'s generic products before the expiration date of the '760 patent.

23. Upon information and belief, Torrent Ltd.'s actions relating to Torrent Ltd.'s ANDA No. 20-1519 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Torrent Inc. and Torrent Ltd.

**WHEREFORE**, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Torrent Ltd. and Torrent Inc. on the patent infringement claims set forth above and respectfully requests that this Court:

- 1) enter judgment that, under 35 U.S.C. § 271 (e)(2)(A), Torrent has infringed at least one claim of the '760 patent through Torrent Ltd.'s submission of ANDA No. 20-1519 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Torrent Ltd.'s generic products in the United States before expiration of the '760 patent;
- 2) order that the effective date of any approval by the FDA of Torrent Ltd.'s generic products be a date that is not earlier than the expiration of the '760 patent, or such later date as the Court may determine;
- 3) enjoin Torrent from the manufacture, use, import, offer for sale and sale of Torrent Ltd.'s generic products until the expiration of the '760 patent, or such later date as the Court may determine;

- 4) enjoin Torrent and all persons acting in concert with Torrent, from seeking, obtaining or maintaining approval of Torrent Ltd.'s ANDA No. 20-1519 until expiration of the '760 patent;
- 5) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Otsuka costs, expenses and disbursements in this action, including reasonable attorney fees; and
- 6) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

*s/ John F. Brenner* \_\_\_\_\_

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