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Attorney for Plaintiff
Otsuka Pharmaceutical Co., Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

_____)	
OTSUKA PHARMACEUTICAL CO., LTD.)	
)	
Plaintiff,)	
)	
v.)	
)	Civil Action No.: 14-cv-1078-JBS-KMW
TORRENT PHARMACEUTICALS)	
LIMITED, TORRENT PHARMA INC. and)	
HETERO LABS LIMITED,)	
)	
)	
Defendants.)	
_____)	

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

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

4. Upon information and belief, Hetero Labs Limited is a corporation organized and existing under the laws of India, having its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018, Andhra Pradesh, India.

NATURE OF THE ACTION

5. This is an action for infringement of U.S. Patent No. 8,017,615 (“the ’615 patent”) and U.S. Patent No. 8,580,796 (“the ’796 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 certain generic pharmaceutical products (“Torrent Ltd.’s generic products”) prior to the expirations of the asserted patents, as well as Defendants’ actual manufacture, use, sale, offer for sale and import of Torrent Ltd.’s generic products upon approval of its ANDA.

JURISDICTION AND VENUE

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

7. 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 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.

8. 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 January 4, 2014, that “[Torrent Ltd.] 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.”

9. 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.

10. 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#, 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.”

11. This Court has jurisdiction over Hetero Labs Limited. According to its website, “Hetero offers a proven history providing reliable supply of both drug substance and drug product to most of the top 20 global pharmaceutical companies.” *See* <http://www.heteroworld.com/pages/why-hetero/>. Upon information and belief, Hetero Labs Limited, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Hetero Labs Limited maintains continuous and systematic contacts with New Jersey through its authorized U.S. agent, PharmaQ, Inc., located at Water View Plaza, 20001 Route 46, Suite 105, Parsippany, NJ 07054-1315.

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

FIRST COUNT FOR PATENT INFRINGEMENT

13. The U.S. Patent and Trademark Office (“PTO”) issued the ’615 patent on September 13, 2011, entitled “Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof.” A copy of the ’615 patent is attached as Exhibit A.

14. Otsuka is the owner of the ’615 patent by virtue of assignment.

15. The ’615 patent expires on June 16, 2024, and pediatric exclusivity relating to the ’615 patent expires on December 16, 2024.

16. The ’615 patent is directed to and claims, *inter alia*, pharmaceutical solid oral preparations, as well as processes for preparing pharmaceutical solid oral preparations.

17. Otsuka is the holder of New Drug Application (“NDA”) No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002. Otsuka lists the ’615 patent in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 21-436.

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

19. 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, sell, offer to sell and import Torrent Ltd.’s generic products in the United States.

20. Otsuka received a letter from Torrent Ltd. dated January 4, 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 20-1519 letter”) as to the ’615 patent.

21. Torrent Ltd.’s 20-1519 letter alleges that the “name for the drug product that is the subject of the Torrent ANDA is aripiprazole tablet, for oral administration.”

22. Upon information and belief, Torrent Ltd.'s generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

23. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-1519 seeking approval to manufacture, use, sell, offer to sell and import Torrent Ltd.'s generic products before the expiration date of the '615 patent.

24. 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., Torrent Ltd. and Hetero Labs Limited.

SECOND COUNT FOR PATENT INFRINGEMENT

25. The PTO issued the '796 patent on November 12, 2013, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '796 patent is attached as Exhibit B.

26. Otsuka is the owner of the '796 patent by virtue of assignment.

27. The '796 patent expires on September 25, 2022, and pediatric exclusivity relating to the '796 patent expires on March 25, 2023.

28. The '796 patent is directed to and claims, *inter alia*, aripiprazole crystals.

29. Otsuka is the holder of NDA No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002. Otsuka lists the '796 patent in the Orange Book for NDA No. 21-436.

30. Otsuka markets various dosage forms of aripiprazole tablets in the United States under the trademark Abilify®.

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

32. Torrent Ltd.'s 20-1519 letter purports 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 as to the '796 patent.

33. Upon information and belief, Torrent Ltd.'s generic products will, if approved and marketed, infringe claims 1-2 of the '796 patent.

34. Torrent Ltd.'s generic products contain aripiprazole, as shown in the approved labeling for Torrent Ltd.'s generic products. *See* <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3988e66f-339c-451e-9f8a-9d0c0a2a381b> (accessed January 11, 2016).

35. Upon information and belief, Torrent Ltd.'s generic products contain Anhydrous Aripiprazole Crystals B of low hygroscopicity as claimed in the '796 patent.

36. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed claims 1-2 of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-1519 seeking approval to manufacture, use, sell, offer to sell and import Torrent's generic product before the expiration date of the '796 patent.

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

THIRD COUNT FOR PATENT INFRINGEMENT

38. Otsuka realleges, and incorporates in full herein, paragraphs 25-37.

39. Torrent Ltd.'s ANDA No. 20-1519 was approved by the FDA on April 28, 2015.

40. Upon information and belief, Defendants are currently manufacturing, marketing, importing, using, selling and offering for sale Torrent Ltd.'s generic products in connection with ANDA No. 20-1519.

41. Upon information and belief, Defendants are infringing claims 1-2 of the '796 patent under 35 U.S.C. § 271(a) by their manufacture, market, import, use, sale and offer for sale of Torrent Ltd.'s generic products.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants 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), Defendants have infringed at least one claim of the '615 patent through Torrent Ltd.'s submission of ANDA No. 20-1519 to the FDA to obtain approval to manufacture, use, sell, offer to sell and import Torrent Ltd.'s generic products in the United States before expiration of the '615 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 '615 patent, or such later date as the Court may determine;
- 3) enjoin Defendants from the manufacture, use, sale, offer for sale and import of Torrent Ltd.'s generic products until the expiration of the '615 patent, or such later date as the Court may determine;
- 4) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Torrent Ltd.'s ANDA No. 20-1519 until expiration of the '615 patent;

- 5) enter judgment that, under 35 U.S.C. § 271 (e)(2)(A), Defendants have infringed at least one claim of the '796 patent through Torrent Ltd.'s submission of ANDA No. 20-1519 to the FDA to obtain approval to manufacture, use, sell, offer to sell and import Torrent Ltd.'s generic products in the United States before expiration of the '796 patent;
- 6) 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 '796 patent, or such later date as the Court may determine;
- 7) enjoin Defendants from the manufacture, use, sale, offer for sale and import of Torrent Ltd.'s generic products until the expiration of the '796 patent, or such later date as the Court may determine;
- 8) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Torrent Ltd.'s ANDA No. 20-1519 until expiration of the '796 patent;
- 9) enter judgment that, under 35 U.S.C. § 271(a), Defendants have infringed at least one claim of the '796 patent through Defendants' manufacture, market, import, use, sale and offer for sale of Torrent Ltd.'s generic products in the United States before the expiration of the '796 patent;
- 10) award Otsuka all available and legally permissible damages sufficient to compensate Otsuka for Defendants' infringement of the '796 patent by their manufacture, market, import, use, sale and offer for sale of Torrent Ltd.'s generic products, together with interest, in an amount to be determined at trial;

- 11) find Defendants' infringement to have been willful and award Otsuka enhanced damages for this willful infringement;
- 12) 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
- 13) award Otsuka such further and additional relief as this Court deems just and proper.

Date: March 23, 2016

Respectfully submitted,

s/ Melissa A. Chuderewicz
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