

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	
)	Civil Action No.:
ORCHID PHARMA LTD., ORCHID)	
HEALTHCARE, ORCHID PHARMA, INC.)	
and ORGENUS PHARMA INC.,)	
)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Orchid Pharma Ltd. (f/k/a Orchid Chemicals & Pharmaceuticals Limited) (“Orchid Pharma Ltd.”), Orchid Healthcare (a Division of Orchid Pharma Ltd.) (“Orchid Healthcare”) Orchid Pharma, Inc. (“Orchid Pharma”) and Orgenus Pharma Inc. (“Orgenus Pharma”) (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, Orchid Pharma Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Orchid Towers, 313 Valluvar Kottam High Road, Nungambakkam, Chennai 600034, Tamil Nadu, India.

3. Upon information and belief, Orchid Healthcare is an unincorporated division of Orchid Pharma Ltd., organized and existing under the laws of India, maintaining a place of business at Plot Nos. B5(Pt.) & B6(Pt.), SIPCOT Industrial Park, Irungattukottai, Sriperumbudur 602105, Kancheepuram District, Tamil Nadu, India.

4. Upon information and belief, Orchid Pharma is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 100 Overlook Center, 2nd Floor, Princeton, NJ 08540. Upon information and belief, Orchid Pharma Ltd. is the parent company of Orchid Pharma.

5. Upon information and belief, Orgenus Pharma is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 100 Overlook Center, 2nd Floor, Princeton, NJ 08540. Upon information and belief, Orchid Pharma Ltd. is the parent company of Orgenus Pharma.

NATURE OF THE ACTION

6. This is an action for infringement of U.S. Patent No. 9,089,567 (“the ’567 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 Orchid Healthcare’s filing of Abbreviated New Drug Applications (“ANDAs”) 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, import, offer to sell and sell generic pharmaceutical products (“Defendants’ generic products”) prior to the expiration of the asserted patent.

7. Otsuka filed a separate complaint against Defendants on Friday, January 22, 2016, asserting infringement of U.S. Patent No. 8,017,615, U.S. Patent No. 8,580,796, U.S. Patent No. 8,642,760 and U.S. Patent No. 8,518,421. *See Otsuka Pharmaceutical Co., Ltd. v. Orchid*

Pharma Ltd. et al., C.A. No. 1:16-cv-00405-JBS-KMW. Otsuka is asserting those claims in a separate complaint because it believes those claims should be litigated on the same discovery track as the numerous related consolidated cases concerning those same patents. *See, e.g., Otsuka Pharmaceutical Co., Ltd. v. Torrent Pharmaceuticals Limited et al.*, C.A. No. 1:14-cv-04671-JBS-KMW (D.I. 193).

JURISDICTION AND VENUE

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

9. This Court has jurisdiction over Orchid Pharma Ltd. Upon information and belief, Orchid Pharma Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic products. Upon information and belief, Orchid Pharma Ltd., directly or through its subsidiaries, affiliates and/or agents, including Orchid Healthcare, Orgenus Pharma and Orchid Pharma, Inc., manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Orchid Pharma Ltd. has submitted, or caused to be submitted, at least 46 ANDAs and 76 Drug Master Files to the FDA. *See* http://orchidpharma.com/downloads/annualreports/orchid_ar_15.pdf (accessed January 12, 2016). Upon information and belief, Orchid Pharma Ltd. is registered to do business in New Jersey under Business I.D. No. 0100883141. Orchid Pharma 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.

10. This Court has jurisdiction over Orchid Healthcare. Upon information and belief, Orchid Healthcare is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief,

Orchid Healthcare, directly or indirectly, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Orchid Healthcare has conducted and continues to conduct business, directly or indirectly, in this judicial district and this judicial district is a likely destination of Defendants' generic products. Orchid Healthcare has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in another civil action initiated in this jurisdiction.

11. Upon information and belief, this Court additionally has jurisdiction over Orchid Healthcare because it has availed itself of the rights and benefits of this judicial district, having stated in a purported Offer of Confidential Access, dated December 9, 2015, that "[t]his Offer of Confidential Access Agreement shall be governed by the laws of the State of New Jersey."

12. This Court has jurisdiction over Orchid Pharma. Upon information and belief, Orchid Pharma is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Orchid Pharma, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and this judicial district. Upon information and belief, Orchid Pharma is Orchid Pharma Ltd.'s "US Generic Sales and Marketing Company." *See* http://orchidpharma.com/worldwide_operations.aspx#subsidiaries (accessed January 20, 2016). Upon information and belief, Orchid Pharma is registered as a manufacturer and wholesaler in the State of New Jersey (No. 5003961) under the trade name "Karalex Pharma, LLC." *See* New Jersey Drug Registration and Verification, at <http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx> (accessed January 20, 2016).

13. This Court has jurisdiction over Orgenus Pharma. Upon information and belief, Orgenus Pharma is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Orgenus Pharma, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Orgenus Pharma “provides all business development and operational services” for Orchid Pharma Ltd., including filing Drug Master Files and ANDAs with the FDA and “represent[ing] [Orchid Pharma Ltd.] for all matters relating to the review and approval of such filings by the FDA[.]” *See* http://orchidpharma.com/downloads/annualreports/orchid_ar_15.pdf (accessed January 20, 2016).

14. Upon information and belief, Orchid Pharma Ltd., Orchid Healthcare, Orchid Pharma and Orgenus Pharma 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. According to Orchid Pharma Ltd.’s website, it is a “[v]ertically integrated global pharmaceutical company” with “[e]stablished research, manufacturing and marketing capabilities” and “[f]ully integrated API and Finished Dosage Form product offerings.” *See* http://www.orchidpharma.com/ir_factsheet.aspx (accessed January 19, 2016). Upon information and belief, Orchid Pharma and Orgenus Pharma share a common corporate director.

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

FIRST COUNT FOR PATENT INFRINGEMENT

16. The PTO issued the '567 patent on July 28, 2015, entitled "Method of Treating Cognitive Impairments and Schizophrenias." A copy of the '567 patent is attached as Exhibit A.

17. Otsuka is the owner of the '567 patent by virtue of assignment.

18. The '567 patent expired on January 28, 2022, subject to any supplemental patent term adjustment.

19. The '567 patent is directed to and claims, *inter alia*, methods of treatment of schizophrenia.

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

21. Otsuka lists the '567 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

22. Defendants have actual knowledge of the '567 patent.

23. Otsuka markets aripiprazole tablets in the United States under the trademark Abilify[®].

24. Upon information and belief, Orchid Healthcare submitted ANDA No. 202683 to the FDA, under Section 505(j), seeking approval to manufacture, use, import, offer to sell and sell generic products containing 2, 5, 10, 15, 20 and 30 mg of aripiprazole ("Defendants' tablet generic products") in the United States.

25. Otsuka received a letter from Orchid Healthcare, dated December 9, 2015, purporting to include a Notice of Certification for ANDA No. 202683 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '567 patent. Otsuka also received a letter from Orchid Healthcare dated December 9, 2015, purporting to include a Notice of Certification

for ANDA No. 202547 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '567 patent. Both letters are referred to collectively herein as "Orchid Healthcare's letter."

26. Orchid Healthcare's letter alleges that Defendants' tablet generic products are "Aripiprazole Tablets 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg."

27. Upon information and belief, the manufacture, use, import, offer for sale and sale of Defendants' tablet generic products will, if approved and marketed, directly infringe at least one claim of the '567 patent.

28. Upon information and belief, Defendants have taken active steps to intentionally induce infringement of the '567 patent.

29. Upon information and belief, Defendants have taken active steps to encourage the sale and use of Defendants' tablet generic products by physicians, pharmacists and/or patients in accordance with the methods of treatment claimed in the '567 patent by providing information and instructions in Defendants' tablet package insert encouraging the use of aripiprazole in those methods of treatment.

30. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '567 patent by submitting, or causing to be submitted to the FDA, ANDA No. 202683 seeking approval to manufacture, use, import, offer to sell and sell Defendants' tablet generic products before the expiration date of the '567 patent.

31. Upon information and belief, Orchid Healthcare's actions relating to Orchid Healthcare's ANDA No. 202683 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Orchid Pharma Ltd., Orchid Healthcare, Orchid Pharma and Orgenus Pharma.

SECOND COUNT FOR PATENT INFRINGEMENT

32. Otsuka realleges, and incorporates in full herein, paragraphs 16-19, 22 and 25.

33. Otsuka is the holder of NDA No. 21-729 for orally disintegrating tablets (“ODT”) containing aripiprazole, which the FDA approved on June 7, 2006.

34. Otsuka lists the ’567 patent in the Orange Book for NDA No. 21-729.

35. Upon information and belief, Orchid Healthcare submitted ANDA No. 202547 to the FDA, under Section 505(j), seeking approval to manufacture, use, import, offer to sell and sell generic products containing 10 and 15 mg of aripiprazole (“Defendants’ ODT generic products”) in the United States

36. Orchid Healthcare’s letter purports to include Notice of Certification for ANDA No. 202547 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the ’567 patent.

37. Orchid Healthcare’s letter alleges that Defendants’ ODT generic products are “Aripiprazole Orally Disintegrating Tablets 10 mg and 15 mg.”

38. Upon information and belief, the manufacture, use, import, offer for sale and sale of Defendants’ ODT generic products will, if approved and marketed, directly infringe at least one claim of the ’567 patent.

39. Upon information and belief, Defendants have taken active steps to intentionally induce infringement of the ’567 patent.

40. Upon information and belief, Defendants have taken active steps to encourage the sale and use of Defendants’ ODT generic products by physicians, pharmacists and/or patients in accordance with the methods of treatment claimed in the ’567 patent by providing information and instructions in Defendants’ ODT package insert encouraging the use of aripiprazole in those methods of treatment.

41. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '567 patent by submitting, or causing to be submitted to the FDA, ANDA No. 202547 seeking approval to manufacture, use, import, offer to sell and sell Defendants' ODT generic products before the expiration date of the '567 patent.

42. Upon information and belief, Orchid Healthcare's actions relating to Orchid Healthcare's ANDA No. 202547 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Orchid Pharma Ltd., Orchid Healthcare, Orchid Pharma and Orgenus Pharma.

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 '567 patent through Orchid Healthcare's submission of ANDA No. 202683 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' tablet generic products in the United States before the expiration of the '567 patent;
- 2) order that the effective date of any approval by the FDA of Defendants' tablet generic products be a date that is not earlier than the expiration of the '567 patent, or such later date as the Court may determine;
- 3) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' tablet generic products until the expiration of the '567 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 Orchid Healthcare's ANDA No. 202683 until expiration of the '567 patent;
- 5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '567 patent through Orchid Healthcare's submission of ANDA No. 202547 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' ODT generic products in the United States before the expiration of the '567 patent;
- 6) order that the effective date of any approval by the FDA of Defendants' ODT generic products be a date that is not earlier than the expiration of the '567 patent, or such later date as the Court may determine;
- 7) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' ODT generic products until the expiration of the '567 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 Orchid Healthcare's ANDA No. 202547 until expiration of the '567 patent;
- 9) 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
- 10) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

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