

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 “Orchid”), 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. 9,359,302 (“the ’302 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 Pharma 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 (“Orchid’s generic products”) prior to the expiration of the asserted patent.

### **JURISDICTION AND VENUE**

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

8. 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, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Orchid Pharma Ltd. purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district and this judicial district is a likely destination of Orchid's generic products. 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](http://orchidpharma.com/downloads/annualreports/orchid_ar_15.pdf) (accessed September 14, 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.

9. Upon information and belief, this Court additionally has jurisdiction over Orchid Pharma 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 April 4, 2016, that “[t]his Offer of Confidential Access Agreement shall be governed by the laws of the State of New Jersey.”

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. 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. 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](http://orchidpharma.com/worldwide_operations.aspx#subsidiaries) (accessed September 14, 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).

12. 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](http://orchidpharma.com/downloads/annualreports/orchid_ar_15.pdf) (accessed September 14, 2016).

13. 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](http://www.orchidpharma.com/ir_factsheet.aspx) (accessed September 14, 2016). Upon information and belief, Orchid Pharma and Orgenus Pharma share a common corporate director.

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

#### **FIRST COUNT FOR PATENT INFRINGEMENT**

15. The U.S. Patent and Trademark Office ("PTO") issued the '302 patent on June 7, 2016, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '302 patent is attached as Exhibit A.

16. Otsuka is the owner of the '302 patent by virtue of assignment.

17. The '302 patent expires on September 25, 2022, excluding any pediatric exclusivity.

18. The '302 patent is directed to and claims, *inter alia*, aripiprazole crystals, pharmaceutical compositions and methods of treatment.

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

20. Otsuka lists the '302 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

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

22. Upon information and belief, Orchid Pharma Ltd. submitted ANDA No. 202683 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 generic products containing 2, 5, 10, 15, 20 and 30 mg of aripiprazole ("Orchid's tablet generic products") in the United States.

23. Otsuka received a letter from Orchid Pharma Ltd., dated August 4, 2016, purporting to include a Notice of Certification for ANDA No. 202683 under 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1) as to the '302 patent. Otsuka also received a letter from Orchid Pharma Ltd. dated August 4, 2016, purporting to include a Notice of Certification for ANDA No. 202547 under 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1) as to the '302 patent. Both letters are referred to collectively herein as "Orchid Pharma Ltd.'s letter."

24. Orchid Pharma Ltd.'s letter alleges that the active ingredient in Orchid's tablet generic products for which it seeks approval is aripiprazole.

25. Upon information and belief, Orchid's tablet generic products will, if approved and marketed, infringe at least one claim of the '302 patent.

26. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Orchid Pharma Ltd. has infringed at least one claim of the '302 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 Orchid's generic products before the expiration date of the '302 patent.

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

**SECOND COUNT FOR PATENT INFRINGEMENT**

28. Otsuka realleges and incorporates in full herein paragraphs 15-18, 23.

29. Otsuka is the holder of NDA No. 21-279 for orally disintegrating tablets (ODT) containing aripiprazole, which the FDA approved on June 7, 2006.

30. Otsuka lists the '302 patent in the Orange Book for NDA No. 21-729.

31. Upon information and belief, Orchid Pharma Ltd. submitted ANDA No. 202547 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 generic products containing 10 and 15 mg of aripiprazole ("Orchid's ODT generic products") in the United States.

32. Orchid Pharma Ltd.'s letter purports 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 '302 patent.

33. Orchid Pharma Ltd.'s letter alleges that the active ingredient in Orchid's ODT generic products for which it seeks approval is aripiprazole.

34. Upon information and belief, Orchid's ODT generic products will, if approved and marketed, infringe at least one claim of the '302 patent.

35. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Orchid Healthcare has infringed at least one claim of the '302 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 Orchid's ODT generic products before the expiration date of the '302 patent.

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

**WHEREFORE**, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Orchid 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), Orchid has infringed at least one claim of the '302 patent through Orchid Pharma Ltd.'s submission of ANDA No. 202683 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Orchid's tablet generic products in the United States before the expiration of the '302 patent;
- 2) order that the effective date of any approval by the FDA of Orchid's tablet generic products be a date that is not earlier than the expiration of the '302 patent, or such later date as the Court may determine;
- 3) enjoin Orchid from the manufacture, use, import, offer for sale and sale of Orchid's tablet generic products until the expiration of the '302 patent, or such later date as the Court may determine;
- 4) enjoin Orchid and all persons acting in concert with Orchid from seeking, obtaining or maintaining approval of Orchid's ANDA No. 202683 until expiration of the '302 patent;
- 5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Orchid has infringed at least one claim of the '302 patent through Orchid Pharma Ltd.'s submission of ANDA



No. 202547 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Orchid's ODT generic products in the United States before the expiration of the '302 patent;

- 6) order that the effective date of any approval by the FDA of Orchid's ODT generic products be a date that is not earlier than the expiration of the '302 patent, or such later date as the Court may determine;
- 7) enjoin Orchid from the manufacture, use, import, offer for sale and sale of Orchid's ODT generic products until the expiration of the '302 patent, or such later date as the Court may determine;
- 8) enjoin Orchid and all persons acting in concert with Orchid from seeking, obtaining or maintaining approval of Orchid's ANDA No. 202547 until expiration of the '302 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,

s/ Melissa A. Chuderewicz  
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