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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

OTSUKA PHARMACEUTICAL CO., LTD.	)	Civil Action No.:
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
WOCKHARDT LTD., WOCKHARDT USA	)	
LLC AND WOCKHARDT BIO AG	)	
	)	
Defendants.	)	
	)	
	)	
	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Wockhardt Ltd., Wockhardt USA LLC, and Wockhardt BIO AG (collectively “Wockhardt”), 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, Wockhardt USA LLC is a corporation organized under the laws of the State of Delaware, and its principal place of business is located at 20 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054. Upon information and belief, Wockhardt USA LLC is a wholly-owned subsidiary of Wockhardt Ltd.

3. Upon information and belief, Wockhardt BIO AG is a corporation organized under the laws of Switzerland, and its principal place of business is located at Baarerstrasse 43, 6300 Zug, Switzerland. Upon information and belief, Wockhardt BIO AG is a wholly-owned subsidiary of Wockhardt Ltd.

4. Upon information and belief Wockhardt Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai, 400051, India.

#### **NATURE OF THE ACTION**

5. This is an action for infringement of United States Patent Number 6,977,257 (“the ’257 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 Wockhardt BIO AG’s filing, through its U.S. agent Wockhardt USA LLC, 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 market a generic pharmaceutical product (“Wockhardt’s generic product”).

#### **JURISDICTION AND VENUE**

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

7. Upon information and belief, this Court has jurisdiction over Wockhardt USA LLC because at a minimum it (1) is registered to do business in New Jersey, (2) has its headquarters in New Jersey, (3) directly, or indirectly, manufactures, markets, sells, and distributes generic drugs throughout the United States and in this judicial district, (4) purposefully has conducted and continues to conduct business in this judicial district, and (5) this judicial district is a likely destination of its generic products. Upon information and belief, Wockhardt USA LLC has previously submitted to the jurisdiction of this Court.

8. Upon information and belief, this Court has jurisdiction over Wockhardt BIO AG because at a minimum Wockhardt BIO AG, itself and through its affiliate Wockhardt USA LLC, (1) directly, or indirectly, manufactures, markets, sells, and distributes generic drugs throughout the United States and in this judicial district, (2) purposefully has conducted and continues to conduct business in this judicial district, and (3) this judicial district is a likely destination of its generic products. Upon information and belief, Wockhardt BIO AG has previously submitted to the jurisdiction of this Court.

9. Upon information and belief, this Court has jurisdiction over Wockhardt Ltd. because at a minimum Wockhardt Ltd., itself and through its subsidiaries Wockhardt AG and Wockhardt USA LLC, (1) directly, or indirectly, manufactures, markets, sells, and distributes generic drugs throughout the United States and in this judicial district, (2) purposefully has conducted and continues to conduct business in this judicial district, and (3) this judicial district is a likely destination of its generic products. Upon information and belief, Wockhardt Ltd. has previously submitted to the jurisdiction of this Court.

10. Otsuka received a letter from Wockhardt dated September 18, 2013, purporting to include an Offer of Confidential Access. Upon information and belief, this Court

additionally has jurisdiction over Wockhardt because it has availed itself of the rights and benefits of this judicial district, having stated in its Offer of Confidential Access that “[t]his Agreement shall be governed in accordance with the laws of the state of New Jersey.”

11. Upon information and belief, Wockhardt Ltd., Wockhardt USA LLC and Wockhardt BIO AG hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic products.

12. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

### **COUNT FOR PATENT INFRINGEMENT**

13. The U.S. Patent and Trademark Office (“PTO”) issued the ’257 patent on December 20, 2005, entitled “Aripiprazole Oral Solution.” A copy of the ’257 patent is attached as Exhibit A.

14. The ’257 patent is assigned to Otsuka. Otsuka is the owner of the ’257 patent as recorded by the PTO at Reel 017586, Frame 0036.

15. The ’257 patent expires on October 24, 2022 (including pediatric exclusivity).

16. The ’257 patent claims, *inter alia*, oral aripiprazole solutions.

17. Otsuka is the holder of NDA No. 21-713 for aripiprazole oral solution, which the FDA approved on December 10, 2004. The Orange Book lists the ’257 patent for NDA No. 21-713.

18. Otsuka manufactures and sells aripiprazole oral solution in the United States under the trademark Abilify®.

19. Upon information and belief, Wockhardt filed with the FDA ANDA No. 205377, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

20. Upon information and belief, Wockhardt's ANDA No. 205377 seeks FDA approval to sell in the United States Wockhardt's generic product.

21. Otsuka received a letter from Wockhardt dated September 18, 2013, purporting to include a Notice of Certification for ANDA No. 205377 ("Wockhardt's 205377 letter") under 21 U.S.C. § 355(j)(2)(B)(ii), Section 505(j)(2)(B)(ii), § 355(j)(2)(A)(vii)(IV), and § 355(j)(2)(B)(iv).

22. Wockhardt's 205377 letter alleges that the active ingredient in Wockhardt's generic product for which it seeks approval is aripiprazole.

23. Upon information and belief, Wockhardt's generic product will, if approved and marketed, infringe at least one claim of the '257 patent.

24. Under 35 U.S.C. § 271(e)(2)(A), Wockhardt has infringed at least one claim of the '257 patent by submitting, or causing to be submitted to the FDA, ANDA No. 205377 seeking approval for the commercial marketing of Wockhardt's generic product before the expiration date of the '257 patent.

25. Upon information and belief, Wockhardt's actions relating to Wockhardt's ANDA No. 205377 complained of herein were done with the cooperation, participation, and assistance, and for the benefit, of Wockhardt Ltd., Wockhardt USA LLC, and Wockhardt BIO AG.

**WHEREFORE**, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Wockhardt Ltd., Wockhardt USA LLC, and

Wockhardt BIO AG 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), Wockhardt has infringed at least one claim of the '257 patent through Wockhardt's submission of ANDA No. 205377 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Wockhardt's generic product before the expiration of the '257 patent;

2. order that the effective date of any approval by the FDA of Wockhardt's generic product be a date that is not earlier than the expiration of the '257 patent, or such later date as the Court may determine;

3. enjoin Wockhardt from the commercial manufacture, use, import, offer for sale and/or sale of Wockhardt's generic products until the expiration of the '257 patent, or such later date as the Court may determine;

4. enjoin Wockhardt and all persons acting in concert with Wockhardt, from seeking, obtaining or maintaining approval of Wockhardt's ANDA No. 205377 until the expiration of the '257 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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Dated: October 31, 2013

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