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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

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

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Wockhardt Bio Ag, Wockhardt USA LLC, and Wockhardt Limited (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 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 Limited.

3. 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 Limited.

4. Upon information and belief, Wockhardt Limited 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 8,759,350 (“the ’350 patent”) and U.S. Patent No. 7,053,092 (“the ’092 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”) prior to the expiration of the asserted patents.

**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 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.

8. 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.

9. Upon information and belief, this Court has jurisdiction over Wockhardt Limited. because at a minimum Wockhardt Limited., 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 Limited. has previously submitted to the jurisdiction of this Court.

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

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

**FIRST COUNT FOR PATENT INFRINGEMENT**

12. The U.S. Patent and Trademark Office (“PTO”) issued the ’350 patent on June 24, 2014, entitled “Carbostyryl Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders.” A copy of the ’350 patent is attached as Exhibit A.

13. Otsuka is the owner of the ’350 patent by virtue of assignment.

14. The ’350 patent expires on March 2, 2027, subject to any supplemental patent term adjustment.

15. The ’350 patent is directed to and claims, *inter alia*, pharmaceutical compositions and methods of treatment.

16. 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 ’350 patent for NDA No. 21-713.

17. Otsuka manufactures and sells aripiprazole oral solution in the United States under the trademark Abilify<sup>®</sup>.

18. 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).

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

20. Otsuka received a letter from Wockhardt dated January 21, 2015, purporting to include a Notice of Certification for ANDA No. 205377 (“Wockhardt’s ’350 Patent 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).

21. Wockhardt’s ’350 Patent letter alleges that the active ingredient in Wockhardt’s generic product for which it seeks approval is aripiprazole.

22. Upon information and belief, Wockhardt’s generic product will, if approved and marketed, infringe at least one claim of the ’350 patent.

23. Under 35 U.S.C. § 271(e)(2)(A), Wockhardt has infringed at least one claim of the ’350 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 ’350 patent.

24. 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 Limited, Wockhardt USA LLC, and Wockhardt Bio AG.

#### **SECOND COUNT FOR PATENT INFRINGEMENT**

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

26. The PTO issued the ’092 patent on May 30, 2006, entitled “5-HT<sub>1A</sub> Receptor Subtype Agonist.” A copy of the ’092 patent is attached as Exhibit B.

27. Otsuka is the owner of the ’092 patent by virtue of assignment.

28. The ’092 patent expires on January 28, 2022.

29. The '092 patent is directed to and claims, *inter alia*, methods of treatment comprising administering aripiprazole.

30. Otsuka lists the '092 patent in the Orange Book for NDA No. 21-713.

31. Otsuka received a letter from Wockhardt dated February 20, 2015, purporting to include a Notice of Certification for ANDA No. 205377 ("Wockhardt's '092 Patent 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).

32. Wockhardt's '092 Patent letter alleges that the active ingredient in Wockhardt's generic product for which it seeks approval is aripiprazole.

33. Upon information and belief, Wockhardt's generic product will, if approved and marketed, infringe at least one claim of the '092 patent.

34. Under 35 U.S.C. § 271(e)(2)(A), Wockhardt has infringed at least one claim of the '092 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 '092 patent.

35. 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 Limited, Wockhardt USA LLC, and Wockhardt Bio AG.

**WHEREFORE**, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Wockhardt Limited, 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 '350 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 '350 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 '350 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 '350 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 '350 patent;
- 5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Wockhardt has infringed at least one claim of the '092 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 '092 patent;
- 6) 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 '092 patent, or such later date as the Court may determine;

- 7) enjoin Wockhardt from the commercial manufacture, use, import, offer for sale and/or sale of Wockhardt's generic products until the expiration of the '092 patent, or such later date as the Court may determine;
- 8) 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 '092 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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