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*Otsuka Pharmaceutical Co., Ltd.*

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

_____	)	
OTSUKA PHARMACEUTICAL CO., LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	Civil Action No.: 16-cv-5743-JBS-KMW
INTAS PHARMACEUTICALS LIMITED,	)	
ACCORD HEALTHCARE, INC. and	)	
HETERO LABS LIMITED,	)	
	)	
Defendants.	)	
_____	)	

**AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint<sup>1</sup> against Defendants Intas Pharmaceuticals Limited (“Intas”), Accord Healthcare, Inc. (“Accord Healthcare”) and Hetero Labs Limited (collectively, “Defendants”), alleges as follows:

<sup>1</sup> In accordance with Fed. R. Civ. P. 15(a)(1)(B), Otsuka files this Amended Complaint within 21 days of service of the Answer to Complaint by Intas and Accord Healthcare on February 13, 2017 (D.I. 11) and the Rule 12(b) Motion filed by Hetero Labs Limited on February 14, 2017 (D.I. 14).

### **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, Intas is a corporation organized and existing under the laws of India, having its principal place of business at 2nd Floor, Chinubhai Centre, Off Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

3. Upon information and belief, Accord Healthcare is a corporation organized and existing under the laws of North Carolina, having its principal place of business at 1009 Slater Road, Suite 210B, Durham, NC 27703. Upon information and belief, Accord Healthcare is a wholly-owned subsidiary of Intas.

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. 9,359,302 (“the ’302 patent”) and U.S. Patent No. 9,387,182 (“the ’182 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 Accord Healthcare’s filing of an Abbreviated New Drug Application (“ANDA”) No. 20-6251 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 (“Defendants’ generic

products”) prior to the expiration of the asserted patent, as well as Defendants’ actual manufacture, use, sale, offer for sale and import of Defendants’ generic products upon approval of ANDA No. 20-6251.

6. Upon information and belief, the effort to seek approval for ANDA No. 20-6251 and to manufacture, import, market, and/or sell Defendants’ generic products upon approval has been a cooperative and joint enterprise and venture between Intas, Accord Healthcare and Hetero Labs Limited.

7. Upon information and belief, Intas, Accord Healthcare and Hetero Labs Limited have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing and maintaining ANDA No. 20-6251 and in commercializing Defendants’ generic products in the United States in accordance with ANDA No. 20-6251 upon approval.

8. Upon information and belief, Hetero Labs Limited has induced, contributed to and participated and assisted in the preparation, filing and maintenance of Accord Healthcare’s ANDA No. 20-6251 by directly drafting, submitting to and maintaining with the FDA Drug Master File (“DMF”) No. 22,563 for an aripiprazole drug substance used as the active ingredient in Defendants’ generic products and by authorizing, and continuing to authorize, Accord Healthcare to rely upon and incorporate the contents of DMF No. 22,563 into Accord Healthcare’s ANDA No. 20-6251 with the knowledge and intent that Accord Healthcare would submit ANDA No. 20-6251 to the FDA incorporating the contents of DMF No. 22,563.

9. Upon information and belief, DMF No. 22,563 contains information concerning the aripiprazole drug substance used as the infringing active ingredient in Defendants’ generic products, without which the submission of ANDA No. 20-6251 would not be complete and without which approval of ANDA No. 20-6251 could not have been obtained.

10. Upon information and belief, each of Intas, Accord Healthcare and Hetero Labs Limited have thus been, and continue to be, joint and prime movers in the drafting, submission, approval and maintenance of ANDA No. 20-6251.

11. Upon information and belief, Hetero Labs Limited is actively inducing and/or contributing to the commercialization of Defendants' generic products upon approval of ANDA No. 20-6251 by contributing to and participating and assisting in the maintenance of Accord Healthcare's ANDA No. 20-6251, by continuing to authorize Accord Healthcare to rely upon and incorporate the contents of DMF No. 22,563 into Accord Healthcare's ANDA No. 20-6251, and by manufacturing and selling of its aripiprazole drug substance to Intas and Accord Healthcare with knowledge and intent that its aripiprazole drug substance is incorporated into Defendants' infringing generic drug products as a material component and with knowledge and intent that Defendants' infringing generic products are being used, imported, offered for sale and/or sold in the United States by Intas and Accord Healthcare in an infringing manner.

12. Upon information and belief, the commercialization of Defendants' infringing generic products in the United States is being done for the joint pecuniary benefit of each of Intas, Accord Healthcare and Hetero Labs Limited.

13. Upon information and belief, the commercialization of Defendants' generic products would not be possible without the joint cooperation, participation and ongoing assistance of each of Intas, Accord Healthcare and Hetero Labs Limited, and thus each have an equal right to control the occurrence of infringement.

14. Upon information and belief, each of Intas, Accord Healthcare and Hetero Labs Limited have thus been, and continue to be, joint and prime movers in the commercialization of Defendants' generic products.

### **JURISDICTION AND VENUE**

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

16. This Court has jurisdiction over Intas. Intas is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Intas, directly or through its wholly-owned subsidiaries, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Intas purposefully has conducted and continues to conduct business, directly or through its wholly-owned subsidiaries, in this judicial district, and this judicial district is a likely destination of Defendants' generic products. Upon information and belief, Intas is registered as a Manufacturer in the State of New Jersey (No. 5003815) under the trade name "Accord Healthcare Inc." *See* New Jersey Drug Registration and Verification, at <http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx>. (Accessed September 16, 2016). Intas 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.

17. This Court has jurisdiction over Accord Healthcare. Upon information and belief, Accord Healthcare, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. According to its website, "Accord has been servicing the needs of the US healthcare industry since 2009[]" and its "business in the USA . . . currently accounts for more that [sic] USD 100 million in revenue." *See* <http://www.accord-healthcare.com/global-presence-usa.html>. (Accessed September 16, 2016). Upon information and belief, Intas' website states that Accord Healthcare is "the preferred supplier for leading distributors and retail pharma chains" in the United States. *See* [http://www.intaspharma.com/index.php?option=com\\_content&view=article&id=56&Itemid=63](http://www.intaspharma.com/index.php?option=com_content&view=article&id=56&Itemid=63).

(Accessed September 16, 2016). Accord Healthcare 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.

18. Upon information and belief, Intas and Accord Healthcare operate as a single integrated business. Intas' website indicates that Accord Healthcare is Intas' operations in the United States with "more than 36 ANDAs approvals" and "about 30+ ANDAs awaiting approval." *See* [http://www.intaspharma.com/index.php?option=com\\_content&view=article&id=56&Itemid=63](http://www.intaspharma.com/index.php?option=com_content&view=article&id=56&Itemid=63). (Accessed September 16, 2016). Accord Healthcare's website also indicates that it markets at least 22 oral dosage forms in the United States, all of which are manufactured by Intas for Accord Healthcare. *See* <http://www.accord-healthcare.com/productsearch.php?gid=2&cid=1#>. (Accessed September 16, 2016).

19. This Court has jurisdiction over Hetero Labs Limited. According to its website, "Hetero is the leading global supplier of APIs . . . to the pharmaceutical companies who manufacture formulations and new-generation products." *See* <http://heteroworld.com/pages/business-api>. (Accessed September 16, 2016). 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 systemic contacts with New Jersey through its authorized U.S. agent, PharmaQ, Inc., located at Water View Plaza, 2001 Route 46, Suite 405, Parsippany, NJ 07054-1315.

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

**FIRST COUNT FOR PATENT INFRINGEMENT**

21. Otsuka realleges, and incorporates in full herein, each preceding paragraph.
22. 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.
23. Otsuka is the owner of the ’302 patent by virtue of assignment.
24. The ’302 patent expires on September 25, 2022, excluding any pediatric exclusivity.
25. The ’302 patent is directed to and claims, inter alia, aripiprazole crystals, pharmaceutical compositions and methods of treatment.
26. Otsuka is the holder of New Drug Application (“NDA”) No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002.
27. Otsuka lists the ’302 patent in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 21-436.
28. Otsuka markets aripiprazole tablets in the United States under the trademark Abilify®.
29. Upon information and belief, Accord Healthcare submitted ANDA No. 206251 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 (“Defendants’ generic products”) in the United States.
30. Otsuka received a letter from Accord Healthcare dated August 5, 2016, (“Accord Healthcare’s letter”), purporting to include a Notice of Certification for ANDA No. 206251 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(6) as to the ’302 patent.

31. Accord Healthcare's letter alleges that the established name of the drug products that are the subject of Accord Healthcare's ANDA is "aripiprazole tablets."

32. Upon information and belief, Defendants' generic products will, if approved and marketed, infringe at least one claim of the '302 patent.

33. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Accord Healthcare has infringed at least one claim of the '302 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206251 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '302 patent.

34. Upon information and belief, Accord Healthcare's actions relating to Accord Healthcare's ANDA No. 20-6251 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Intas, Accord Healthcare and Hetero Labs Limited.

35. Upon information and belief, Hetero Labs Limited has infringed the '302 patent under 35 U.S.C. § 271(e)(2)(A) by its cooperation, participation and ongoing assistance to Accord Healthcare in the preparation, filing and maintenance of ANDA No. 20-6251 and/or by actively inducing and/or contributing to the commercialization of Defendants' generic products upon approval by its cooperation, participation and ongoing assistance to Accord Healthcare in the maintenance of ANDA No. 20-6251, by continuing to authorize Accord Healthcare to rely upon and incorporate the contents of DMF No. 22,563 into Accord Healthcare's ANDA No. 20-6251, and by its manufacturing and selling of its aripiprazole drug substance to Intas and Accord Healthcare for use as the infringing active ingredient in Defendants' generic drug products.

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

36. Otsuka realleges, and incorporates in full herein, each preceding paragraph.



37. Accord Healthcare's ANDA No. 20-6251 was approved by the FDA on December 7, 2016.

38. Upon information and belief, Defendants are currently manufacturing, marketing, importing, using, selling and offering for sale Defendants' generic products in connection with ANDA No. 20-6251.

39. Upon information and belief, Defendants are infringing at least one claim of the '302 patent under 35 U.S.C. § 271(a) by the manufacture, market, import, use, sale and offer for sale of Defendants' generic products, as well as by Defendants' joint and cooperative efforts to maintain regulatory approval of ANDA No. 20-6251.

40. Upon information and belief, Hetero Labs Limited is infringing the '302 patent under 35 U.S.C. §§ 271(b) and/or (c) by actively inducing and/or contributing to Intas' and Accord Healthcare's commercialization of Defendants' generic products by its cooperation, participation and ongoing assistance to Accord Healthcare in the maintenance of ANDA No. 20-6251, by continuing to authorize Accord Healthcare to rely upon and incorporate the contents of DMF No. 22,563 into Accord Healthcare's ANDA No. 20-6251, and by its manufacturing and selling of its aripiprazole drug substance containing anhydrous aripiprazole crystals of low hygroscopicity as claimed in the '302 patent to Intas and Accord Healthcare, with knowledge and intent that its aripiprazole drug substance is incorporated into Defendants' infringing generic drug products as a material component, and with knowledge and intent that Defendants' infringing generic products are being used, imported, offered for sale and/or sold in the United States by Intas and Accord Healthcare in an infringing manner before the expiration date of the '302 patent.

41. Upon information and belief, Hetero Labs Limited's aripiprazole drug substance containing anhydrous aripiprazole crystals of low hygroscopicity as claimed in the '302 patent remains intact as the active ingredient of Defendants' generic products and is known or should be known by Hetero Labs Limited to be a non-staple article of commerce without substantial noninfringing uses with respect to the '302 patent.

### **THIRD COUNT FOR PATENT INFRINGEMENT**

42. Otsuka realleges, and incorporates in full herein, each preceding paragraph

43. The PTO issued the '182 patent on July 12, 2016, entitled "Carbostyryl Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders." A copy of the '182 patent is attached as Exhibit B.

44. Otsuka is the owner of the '182 patent by virtue of assignment.

45. The '182 patent expires on December 25, 2023, excluding any pediatric exclusivity.

46. The '182 patent is directed to and claims, inter alia, pharmaceutical compositions and methods of treatment.

47. Accord Healthcare's letter of August 5, 2016 purported to include a Notice of Certification for ANDA No. 20-6251 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(6) as to the '182 patent.

48. Defendants have actual knowledge of the '182 patent.

49. Upon information and belief, Defendants will infringe at least one claim of the '182 patent under 35 U.S.C. § 271(b) upon approval and marketing of Defendants' generic products that are the subject of ANDA No. 206251, including at least by taking active steps to encourage the sale and use of Defendants' generic products by physicians, pharmacists and/or

patients in accordance with the claims of the '182 patent upon approval by providing information and instructions in the packaging insert for Defendants' generic products that are the subject of ANDA No. 206251 ("Exhibit C") with knowledge and intent that Defendants' generic products will be used by physicians, pharmacists and/or patients in an infringing manner for the joint pecuniary benefit of Defendants.

50. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '182 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206251 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '182 patent and by the manufacture, sale and market of Defendants' generic drug products upon approval.

#### **FOURTH COUNT FOR PATENT INFRINGEMENT**

51. Otsuka realleges, and incorporates in full herein, each preceding paragraph.

52. Upon information and belief, physicians, pharmacists and/or patients are directly infringing the '182 patent by the sale and use of Defendants' generic products in accordance with the claims of the '182 patent.

53. Upon information and belief, Defendants are infringing at least one claim of the '182 patent under 35 U.S.C. § 271(b) by manufacturing, marketing, importing, using, selling and/or offering for sale Defendants' generic products in the United States in connection with ANDA No. 20-6251, and by taking active steps to encourage the sale and use of Defendants' generic products by physicians, pharmacists and/or patients in accordance with the claims of the '182 patent by providing information and instructions in the packaging insert for Defendants' generic products that are the subject of ANDA No. 206251 ("Exhibit C") with knowledge and

intent that Defendants' generic products will be used by physicians, pharmacists and/or patients in an infringing manner for the joint pecuniary benefit of Defendants.

**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 '302 patent through Accord Healthcare's submission of ANDA No. 20-6251 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' 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 Defendants' 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 Defendants from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '302 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 Accord Healthcare's ANDA No. 20-6251 until expiration of the '302 patent;
- 5) enter judgment that, under 35 U.S.C. §§ 271(a), (b) and/or (c), Defendants have infringed at least one claim of the '302 patent through Defendants' manufacture, market, import, use, sale and offer for sale of Defendants' generic products in the United States before the expiration of the '302 patent;

- 6) award Otsuka all available and legally permissible damages sufficient to compensate Otsuka for Defendants' infringement of the '302 patent by the manufacture, market, import, use, sale and offer for sale of Defendants' generic products, together with interest, in an amount to be determined at trial;
- 7) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '182 patent through Accord Healthcare's submission of ANDA No. 206251 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the '182 patent;
- 8) order that the effective date of any approval by the FDA of Defendants' generic products be a date that is not earlier than the expiration of the '182 patent, or such later date as the Court may determine;
- 9) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '182 patent, or such later date as the Court may determine;
- 10) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Accord Healthcare's ANDA No. 206251 until expiration of the '182 patent;
- 11) enter judgment that, under 35 U.S.C. § 271(b), Defendants have infringed at least one claim of the '182 patent through Defendants' manufacture, market, import, use, sale and offer for sale of Defendants' generic products in the United States before the expiration of the '182 patent;

- 12) award Otsuka all available and legally permissible damages sufficient to compensate Otsuka for Defendants' infringement of the '182 patent by the manufacture, market, import, use, sale and offer for sale of Defendants' generic products, together with interest, in an amount to be determined at trial;
- 13) find Defendants' infringement to have been willful and award Otsuka enhanced damages for this willful infringement;
- 14) 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
- 15) award Otsuka such further and additional relief as this Court deems just and proper.

Dated: March 6, 2017

Respectfully submitted,

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