

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

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OTSUKA PHARMACEUTICAL CO., LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	Civil Action No.:
INTAS PHARMACEUTICALS LIMITED,	)	
ACCORD HEALTHCARE, INC., ACCORD	)	
HEALTHCARE LIMITED, ASTRON	)	
RESEARCH LIMITED and HETERO LABS	)	
LIMITED,	)	
	)	
Defendants.	)	

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**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Intas Pharmaceuticals Limited (“Intas”), Accord Healthcare, Inc., Accord Healthcare Limited, Astron Research Limited and Hetero Labs Limited (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, 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, Inc. 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, Inc. is a wholly-owned subsidiary of Intas.

4. Upon information and belief, Accord Healthcare Limited is a corporation organized and existing under the laws of India, having its principal place of business at 2nd Floor, Chinubhai Centre, Ashram Road, Ahmedabad, 380009, Gujarat, India. Upon information and belief, Accord Healthcare Limited is a wholly-owned subsidiary of Intas.

5. Upon information and belief, Astron Research Limited is a corporation organized and existing under the laws of India and has a principal place of business at 10th Floor, Premier House I, Sarkhej Gandhinagar Highway, Bodakdev, Ahmedabad 380 054, Gujarat, India. Upon information and belief, Astron Research Limited is a wholly-owned subsidiary of Intas and is the Research and Development Unit of Intas.

6. 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**

7. This is an action for infringement of U.S. Patent No. 8,017,615 (“the ’615 patent”), U.S. Patent No. 8,580,796 (“the ’796 patent”), and U.S. Patent No. 8,642,760 (“the ’760 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, Inc.’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, sale, offer to sell and import generic pharmaceutical products (“Accord Healthcare, Inc.’s generic products”) prior to the expiration of the asserted patents.

### **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 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 Intas’ 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>. 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.

10. This Court has jurisdiction over Accord Healthcare, Inc. Upon information and belief, Accord Healthcare, Inc., 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>. Upon information and belief,

Intas' website states that Accord Healthcare, Inc. 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). Accord Healthcare, Inc. 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.

11. This Court has jurisdiction over Accord Healthcare Limited. Upon information and belief, Intas' website indicates that Accord Healthcare Limited is the offshore identity of Intas, and as a marketing arm of Intas in the United States, is engaged in the marketing and sales of pharmaceutical products throughout the United States and in this judicial district. *See* [http://www.intaspharma.com/index.php?option=com\\_content&view=article&id=50&Itemid=57](http://www.intaspharma.com/index.php?option=com_content&view=article&id=50&Itemid=57).

12. This Court has jurisdiction over Astron Research Limited. Upon information and belief, Astron Research Limited is a wholly-owned subsidiary of Intas, shares common corporate directors with Intas, "has been merged with Intas and now functions as its R&D unit." *See* [http://www.intaspharma.com/index.php?option=com\\_content&view=article&id=107&Itemid=89](http://www.intaspharma.com/index.php?option=com_content&view=article&id=107&Itemid=89). According to its website, Astron Research Limited's "products and technology are sold in over 50 countries, which includes . . . [the] US" and it has "45 ANDAs filed in [the] US." *See* [www.astron-research.com](http://www.astron-research.com). Intas' website indicates that "Intas's R&D (erstwhile Astron Research Limited) has developed products and technologies are supplied and/or licensed in over 50 countries, including . . . [the] US" and that the "company has filed 75 ANDAs in [the] US." *See* [http://www.intaspharma.com/index.php?option=com\\_content&view=article&id=107&Itemid=89](http://www.intaspharma.com/index.php?option=com_content&view=article&id=107&Itemid=89).

13. Upon information and belief, Intas, Accord Healthcare, Inc., Accord Healthcare Limited and Astron Research Limited operate as a single integrated business. Intas' website indicates that Accord Healthcare, Inc. 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). Accord Healthcare, Inc.'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, Inc. *See* <http://www.accord-healthcare.com/productsearch.php?gid=2&cid=1#>. Upon information and belief, Accord Healthcare Limited is the offshore identity of Intas. Upon information and belief, Astron Research Limited is the Research and Development Unit of Intas. Upon information and belief, Intas, Accord Healthcare Limited and Astron Research Limited share common corporate directors.

14. This Court has jurisdiction over Hetero Labs Limited. According to its website, "Hetero is one of the largest manufacturer and supplier of Active Pharmaceutical Ingredients (API's) catering to the ever increasing requirements of the global pharmaceutical market." *See* <http://www.heterodrugs.com/busin-API.shtml>. 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.

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 U.S. Patent and Trademark Office (“PTO”) issued the ’615 patent on September 13, 2011, entitled “Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof.” A copy of the ’615 patent is attached as Exhibit A.

17. Otsuka is the owner of the ’615 patent by virtue of assignment.

18. The ’615 patent expires on December 16, 2024 (including pediatric exclusivity).

19. The ’615 patent is directed to and claims, *inter alia*, pharmaceutical solid oral preparations, and processes for preparing pharmaceutical solid oral preparations.

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 ’615 patent in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 21-436.

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

23. Upon information and belief, Accord Healthcare, Inc. submitted ANDA No. 20-6251 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 Accord Healthcare, Inc.’s generic products in the United States.

24. Otsuka received a letter from Accord Healthcare, Inc. dated May 7, 2014, purporting 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)(1) (“Accord Healthcare, Inc.’s 20-6251 letter”) as to the ’615 patent.

25. Accord Healthcare, Inc.'s 20-6251 letter alleges that the "established name of the drug product that is subject of the Accord ANDA is aripiprazole tablets."

26. Upon information and belief, Accord Healthcare, Inc.'s generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

27. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-6251 seeking approval to manufacture, use, import, offer to sell and sell Accord Healthcare, Inc.'s generic products before the expiration date of the '615 patent.

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

29. Upon information and belief, Intas, Accord Healthcare Limited, Astron Research Limited and Hetero Labs Limited will actively aid, abet, encourage and induce Accord Healthcare, Inc. and others in the manufacture, use, import, offer for sale and sale of Accord Healthcare, Inc.'s generic products before the expiration date of the '615 patent.

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

30. Otsuka realleges, and incorporates in full herein, paragraphs 20, 22 and 23.

31. The PTO issued the '796 patent on November 12, 2013, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '796 patent is attached as Exhibit B.

32. Otsuka is the owner of the '796 patent by virtue of assignment.

33. The '796 patent expires on March 25, 2023 (including pediatric exclusivity).

34. The '796 patent is directed to and claims, *inter alia*, aripiprazole crystals.

35. Otsuka lists the '796 patent in the Orange Book for NDA No. 21-436.

36. Accord Healthcare, Inc.'s 20-6251 letter purports 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)(1) as to the '796 patent.

37. Upon information and belief, Accord Healthcare, Inc.'s generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

38. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-6251 seeking approval to manufacture, use, import, offer to sell and sell Accord Healthcare, Inc.'s generic products before the expiration date of the '796 patent.

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

40. Upon information and belief, Intas, Accord Healthcare Limited, Astron Research Limited and Hetero Labs Limited will actively aid, abet, encourage and induce Accord Healthcare, Inc. and others in the manufacture, use, import, offer for sale and sale of Accord Healthcare, Inc.'s generic products before the expiration date of the '796 patent.

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

41. Otsuka reallages, and incorporates in full herein, paragraphs 20, 22 and 23.



42. The PTO issued the '760 patent on February 4, 2014, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '760 patent is attached as Exhibit C.

43. Otsuka is the owner of the '760 patent by virtue of assignment.

44. The '760 patent expires on March 25, 2023 (including pediatric exclusivity).

45. The '760 patent is directed to and claims, *inter alia*, aripiprazole drug substance.

46. Otsuka lists the '760 patent in the Orange Book for NDA No. 21-436.

47. Accord Healthcare, Inc.'s 20-6251 letter purports 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)(1) as to the '760 patent.

48. Upon information and belief, Accord Healthcare, Inc.'s generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

49. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-6251 seeking approval to manufacture, use, import, offer to sell and sell Accord Healthcare, Inc.'s generic products before the expiration date of the '760 patent.

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

51. Upon information and belief, Intas, Accord Healthcare Limited, Astron Research Limited and Hetero Labs Limited will actively aid, abet, encourage and induce Accord

Healthcare, Inc. and others in the manufacture, use, import, offer for sale and sale of Accord Healthcare, Inc.'s generic products before the expiration date of the '760 patent.

**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 '615 patent through Accord Healthcare, Inc.'s submission of ANDA No. 20-6251 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Accord Healthcare, Inc.'s generic products in the United States before the expiration of the '615 patent;
- 2) order that the effective date of any approval by the FDA of Accord Healthcare, Inc.'s generic products be a date that is not earlier than the expiration of the '615 patent, or such later date as the Court may determine;
- 3) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Accord Healthcare, Inc.'s generic products until the expiration of the '615 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, Inc.'s ANDA No. 20-6251 until expiration of the '615 patent;
- 5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '796 patent through Accord Healthcare, Inc.'s submission of ANDA No. 20-6251 to the FDA to obtain approval to manufacture, use, import,

- offer to sell and sell Accord Healthcare, Inc.'s generic products in the United States before the expiration of the '796 patent;
- 6) order that the effective date of any approval by the FDA of Accord Healthcare, Inc.'s generic products be a date that is not earlier than the expiration of the '796 patent, or such later date as the Court may determine;
  - 7) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Accord Healthcare's generic products until the expiration of the '796 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 Accord Healthcare, Inc.'s ANDA No. 20-6251 until expiration of the '796 patent;
  - 9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '760 patent through Accord Healthcare, Inc.'s submission of ANDA No. 20-6251 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Accord Healthcare, Inc.'s generic products in the United States before the expiration of the '760 patent;
  - 10) order that the effective date of any approval by the FDA of Accord Healthcare, Inc.'s generic products be a date that is not earlier than the expiration of the '760 patent, or such later date as the Court may determine;
  - 11) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Accord Healthcare, Inc.'s generic products until the expiration of the '760 patent, or such later date as the Court may determine;

- 12) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Accord Healthcare, Inc.'s ANDA No. 20-6251 until expiration of the '760 patent;
- 13) 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
- 14) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

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