UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. LUPIN LIMITED, LUPIN ATLANTIS HOLDING SA, and LUPIN PHARMACEUTICALS, INC., Defendants.	)	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Lupin Limited ("Lupin Ltd."), Lupin Atlantis Holding SA ("Lupin Atlantis") and Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") (collectively "Lupin"), 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, Lupin Ltd. is a corporation organized and existing under the laws of the India, having its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400051, Maharashtra, India.

3. Upon information and belief, Lupin Atlantis is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Durachweg 13, 8200 Schaffhuasen, Switzerland. Upon information and belief, Lupin Atlantis is a wholly-owned subsidiary of Lupin Ltd.

4. Upon information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the Commonwealth of Virginia, having its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, MD 21202. Upon information and belief, Lupin Pharmaceuticals is a wholly-owned subsidiary of Lupin Ltd.

NATURE OF THE ACTION

5. 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"), U.S. Patent No. 8,642,760 ("the '760 patent") and U.S. Patent No. 8,759,350 (the '350 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 Lupin Atlantis' 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, import, offer to sell and sell generic pharmaceutical products ("Lupin's generic products") 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. This court has jurisdiction over Lupin Ltd. Upon information and belief, Lupin Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic products. Upon information and belief, Lupin Ltd., directly or

through its wholly-owned subsidiaries, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. According to Lupin Ltd.'s Annual Report, Effective Date March 31, 2014, Lupin Ltd. "has 93 ANDAs pending for approval and launch, addressing a total market size of over USD 80 billion." Upon information and belief, Lupin Ltd. "is one of the most competitive quality players in the API space globally" and has filed in total "149 DMF[s]." *Id.* Upon information and belief, Lupin Ltd. is "the 7th largest generic pharmaceutical company in the world by market capitalization and the 10th largest generic pharmaceutical company by revenues" and its "global formulations business contributes 90% of Lupin's global revenues with formulations sales in excess of USD 1.65 billion." *See* http://lupin.com/formulations.php. Upon information and belief, Lupin Ltd. "has significant market share in key markets" such as the CNS therapy segment. *See* http://lupinworld.com/corporate-overview.htm. Lupin 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.

8. This court has jurisdiction over Lupin Atlantis. Upon information and belief, Lupin Atlantis is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Lupin Atlantis, directly or through its parent, subsidiaries, affiliates and/or agents, including Lupin Ltd. and Lupin Pharmaceuticals, manufactures, markets, imports, and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Lupin Atlantis purposefully has conducted and continues to conduct business, directly or through its parent, subsidiaries, affiliates and/or agents, including Lupin Ltd. and Lupin Pharmaceuticals, in this judicial district and this judicial district is a likely destination of Lupin's generic products.

This Court has personal jurisdiction over Lupin Atlantis at least under Federal Rule of Civil Procedure 4(k)(2).

9. This Court has jurisdiction over Lupin Pharmaceuticals. Upon information and belief, Lupin Pharmaceuticals is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products, throughout the United States and in this judicial district. Upon information and belief, since 2003 Lupin Pharmaceuticals has "received more than 75 FDA approvals and ha[s] become one of the fastest growing pharmaceutical companies in the US." *See* http://www.lupinpharmaceuticals.com/generics.htm. Upon information and belief, Lupin Pharmaceuticals is "the 5th largest and fastest growing top 5 generics player in the US with a 5.4% market share by prescriptions" and as of March 2014, "31 of [its] 63 generic products marketed . . . in the US ranked No. 1 by market share and 53 of [its] 63 are in the top 3 by Market share[.]" *See* http://lupin.com/business-usa.php#global2. Upon information and belief, Lupin Pharmaceuticals is "dedicated to delivering high-quality branded and generic medicines across the US" and "has built strong relationships in the US wholesale and retail channels[.]" *See* http://lupin.com/business-usa.php#global1. Upon information and belief, "[Lupin Pharmaceuticals] is the exclusive US distributor for all of the products developed and manufactured by its parent company, Lupin Ltd., and other affiliate companies." *See* http://www.pharmacytimes.com/publications/supplement/2014/Generic-Supplement-2014/Lupin-Pharmaceuticals-Inc. Upon information and belief, Lupin Pharmaceuticals is registered in the State of New Jersey (No. 5004060). *See* New Jersey Drug Registration and Verification, at http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx. Upon information and belief, Lupin Pharmaceuticals and Lupin Ltd. share a common corporate director. Lupin Pharmaceuticals 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. Upon information and belief, Lupin Ltd., Lupin Atlantis and Lupin Pharmaceuticals 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. Upon information and belief, Lupin Ltd. and its subsidiaries are "a fully integrated pharmaceutical company with an unrivaled position in the US[.]" *See* http://lupinworld.com/the-lupin-story.htm. Upon information and belief, Lupin Pharmaceuticals' website markets to the United States numerous generic products identifying Lupin Ltd. as the product manufacturer. *See* https://www.lupinpharmaceuticals.com/products1.htm.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § l400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

12. 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.

13. Otsuka is the owner of the '615 patent by virtue of assignment.

14. The '615 patent expires on December 16, 2024 (including pediatric exclusivity).

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

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

17. Otsuka lists the '615 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

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

19. Upon information and belief, Lupin Atlantis submitted ANDA No. 205589 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 Lupin's generic products in the United States.

20. Otsuka received a letter from Lupin Atlantis dated September 19, 2014, purporting to include a Notice of Certification for ANDA No. 205589 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) ("Lupin Atlantis' 205589 letter") as to the '615 patent.

21. Lupin Atlantis' 205589 letter alleges that the name of the drug product that is subject of the Lupin Atlantis ANDA is "Aripiprazole Tablets, 2-mg, 5-mg, 10-mg, 15-mg, 20-mg, and 30-mg."

22. Upon information and belief, Lupin's generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

23. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin Atlantis has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 205589 seeking approval to manufacture, use, import, offer to sell and sell Lupin's generic products before the expiration date of the '615 patent.

24. Upon information and belief, Lupin Atlantis' actions relating to Lupin Atlantis' ANDA No. 205589 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Lupin Ltd., Lupin Atlantis and Lupin Pharmaceuticals.

SECOND COUNT FOR PATENT INFRINGEMENT

25. Otsuka realleges, and incorporates in full herein, paragraphs 16–21.

26. 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.

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

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

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

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

31. Lupin Atlantis' 205589 letter purports to include a Notice of Certification for ANDA No. 205589 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the '796 patent.

32. Upon information and belief, Lupin's generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

33. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin Atlantis has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 205589 seeking approval to manufacture, use, import, offer to sell and sell Lupin's generic products before the expiration date of the '796 patent.

34. Upon information and belief, Lupin Atlantis' actions relating to Lupin Atlantis' ANDA No. 205589 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Lupin Ltd., Lupin Atlantis and Lupin Pharmaceuticals.

THIRD COUNT FOR PATENT INFRINGEMENT

35. Otsuka realleges, and incorporates in full herein, paragraphs 16–21.

36. 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.

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

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

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

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

41. Lupin Atlantis' 205589 letter purports to include a Notice of Certification for ANDA No. 205589 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the '760 patent.

42. Upon information and belief, Lupin's generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

43. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin Atlantis has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 205589 seeking approval to manufacture, use, import, offer to sell and sell Lupin's generic products before the expiration date of the '760 patent.

44. Upon information and belief, Lupin Atlantis' actions relating to Lupin Atlantis' ANDA No. 205589 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Lupin Ltd., Lupin Atlantis and Lupin Pharmaceuticals.

FOURTH COUNT FOR PATENT INFRINGEMENT

45. Otsuka realleges, and incorporates in full herein, paragraphs 16–21.

46. The U.S. Patent and Trademark Office ("PTO") issued the '350 patent on June 24, 2014, entitled "Carbostyril Derivatives and Serotonin Reuptake Inhibitors for Treatment of

Mood Disorders." A copy of the '350 patent is attached as Exhibit D.

47. Otsuka is the owner of the '350 patent by virtue of assignment.

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

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

50. Otsuka lists the '350 patent in the Orange Book for NDA No. 21-436.

51. Lupin Atlantis' 205589 letter purports to include a Notice of Certification for ANDA No. 205589 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the '350 patent.

52. Upon information and belief, Lupin's generic products will, if approved and marketed, infringe at least one claim of the '350 patent.

53. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 205589 seeking approval to manufacture, use, import, offer to sell and sell Lupin's generic products before the expiration of the '350 patent.

54. Upon information and belief, Lupin Atlantis' actions relating to Lupin Atlantis' ANDA No. 205589 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Lupin Ltd. and Lupin Pharmaceuticals.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Lupin 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), Lupin has infringed at least one claim of the '615 patent through Lupin Atlantis' submission of ANDA No. 205589 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Lupin'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 Lupin'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 Lupin from the manufacture, use, import, offer for sale and sale of Lupin's generic products until the expiration of the '615 patent, or such later date as the Court may determine;

4) enjoin Lupin and all persons acting in concert with Lupin, from seeking, obtaining or maintaining approval of Lupin Atlantis' ANDA No. 205589 until expiration of the '615 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '796 patent through Lupin Atlantis' submission of ANDA No. 205589 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Lupin'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 Lupin'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 Lupin from the manufacture, use, import, offer for sale and sale of Lupin's generic products until the expiration of the '796 patent, or such later date as the Court may determine;

8) enjoin Lupin and all persons acting in concert with Lupin, from seeking, obtaining or maintaining approval of Lupin Atlantis' ANDA No. 205589 until expiration of the '796 patent;

9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '760 patent through Lupin Atlantis' submission of ANDA No. 205589 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Lupin'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 Lupin'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 Lupin from the manufacture, use, import, offer for sale and sale of Lupin's generic products until the expiration of the '760 patent, or such later date as the Court may determine;

12) enjoin Lupin and all persons acting in concert with Lupin, from seeking, obtaining or maintaining approval of Lupin Atlantis' ANDA No. 205589 until expiration of the '760 patent;

13) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '350 patent through Lupin Atlantis' submission of ANDA No. 205589 to the FDA to obtain approval to manufacture, use, import, offer to sell and

sell Lupin's generic products in the United States before the expiration of the '350 patent;

14) order that the effective date of any approval by the FDA of Lupin's generic products be a date that is not earlier than the expiration of the '350 patent, or such later date as the Court may determine;

15) enjoin Lupin from the manufacture, use, import, offer for sale and sale of Lupin's generic products until the expiration of the '350 patent, or such later date as the Court may determine;

16) enjoin Lupin and all persons acting in concert with Lupin, from seeking, obtaining or maintaining approval of Lupin Atlantis' ANDA No. 205589 until expiration of the '350 patent;

17) 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

18) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

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