UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. ACTAVIS ELIZABETH LLC, ACTAVIS, INC., ACTAVIS PLC, JUBILANT LIFE SCIENCES LIMITED, JUBILANT GENERICS LIMITED and JUBILANT LIFE SCIENCES (USA) INC., Defendants.	Civil Action No.: 14-cv-7106-JBS-KMW

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Actavis Elizabeth LLC ("Actavis Elizabeth"), Actavis, Inc., Actavis plc, Jubilant Life Sciences Limited ("Jubilant Life Sciences"), Jubilant Generics Limited ("Jubilant Generics") and Jubilant Life Sciences (USA) Inc. ("Jubilant USA") (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, Actavis Elizabeth is a single member limited liability company organized and existing under the laws of the State of Delaware, having a place

of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202. Upon information and belief, Actavis Elizabeth is a wholly-owned subsidiary of Actavis, Inc.

3. Upon information and belief, Actavis, Inc. (f/k/a Watson Pharmaceuticals, Inc.) is a corporation organized and existing under the laws of the State of Nevada, having its headquarters and principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis, Inc. is a wholly-owned subsidiary of Actavis plc.

4. Upon information and belief, Actavis plc is a publicly-traded company organized and existing under the laws of Ireland, having its corporate headquarters at 1 Grand Canal Square, Docklands Dublin 2, Ireland, and U.S. administrative headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis plc is the global parent of, *inter alia*, Actavis Elizabeth LLC and Actavis, Inc.

5. Upon information and belief, Jubilant Life Sciences, formerly known as Jubilant Organosys Limited, is a corporation organized and existing under the laws of India, having its principal place of business at 1A, Sector 16A, Noida - 201301, Uttar Pradesh, India.

6. Upon information and belief, Jubilant Generics is a corporation organized and existing under the laws of India, having its principal place of business at 1A, Sector 16A, Noida - 201301, Uttar Pradesh, India. Upon information and belief, Jubilant Generics is a wholly-owned subsidiary of Jubilant Life Sciences.

7. Upon information and belief, Jubilant USA is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at One Crossroads Drive, Building A, Second Floor, Bedminster, New Jersey 07921. Upon information and belief, Jubilant USA is a wholly-owned subsidiary of Jubilant Life Sciences.

NATURE OF THE ACTION

8. This is an action for infringement of 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 Actavis Elizabeth'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, sell and offer to sell generic pharmaceutical products ("Defendants' generic products") prior to the expiration of the asserted patents.

JURISDICTION AND VENUE

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

10. This Court has jurisdiction over Actavis Elizabeth. Upon information and belief, Actavis Elizabeth is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Actavis Elizabeth, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Actavis Elizabeth purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district, and this judicial district is a likely destination of Defendants' generic products. Upon information and belief, Actavis Elizabeth is registered to do business in New Jersey under Business I.D. No. 0600272818. Upon information and belief, Actavis Elizabeth is registered as a Manufacturer and Wholesaler in the State of New Jersey (No. 5003329) under the trade name "Actavis Elizabeth LLC." *See* New Jersey Drug Registration and Verification, at http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx. Actavis Elizabeth 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 Actavis, Inc. Upon information and belief, Actavis, Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Actavis, Inc., directly or indirectly, develops, manufactures, imports, markets, sells and distributes generic pharmaceutical products throughout the United States and in this judicial district. Upon information and belief, Actavis, Inc. is registered to do business in New Jersey under Business I.D. No. 0101005391. Upon information and belief, Actavis, Inc. is registered as a Manufacturer and Wholesaler in the State of New Jersey (No. 5003854) under the trade name "Actavis, Inc." *See* New Jersey Drug Registration and Verification, at http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx. Upon information and belief, Actavis Elizabeth is a wholly-owned subsidiary of Actavis, Inc. Upon information and belief, Actavis, Inc. directs, authorizes, cooperates, participates and/or assists Actavis Elizabeth with the marketing, selling and/or distributing of its pharmaceutical products throughout the United States and in this judicial district. Actavis, 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.

12. This Court has jurisdiction over Actavis plc. Upon information and belief, Actavis plc is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Actavis plc, 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 Actavis

plc's Form 10-K, filed February 25, 2014, "Actavis is a leading integrated global specialty pharmaceutical company engaged in the development, manufacturing, marketing, sale and distribution of generic, branded generic, brand name [], biosimilar and over-the-counter [] pharmaceutical products" and "had more than 195 ANDAs on file in the U.S." as of December 31, 2013; its U.S. portfolio contains approximately 250 generic pharmaceutical product families; and it owns properties at least in Elizabeth, New Jersey. This Court has personal jurisdiction over Actavis plc at least under Federal Rule of Civil Procedure 4(k)(2).

13. Upon information and belief, Actavis Elizabeth, Actavis, Inc. and Actavis plc operate as a single integrated business. Upon information and belief, Actavis plc's Form 10-K indicates that it files a single financial report to the SEC for itself and its subsidiaries. Upon information and belief, Actavis Elizabeth and Actavis, Inc. share at least one director and at least one officer.

14. This Court has jurisdiction over Jubilant Life Sciences. Upon information and belief, Jubilant Life Sciences is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Jubilant Life Sciences, directly or indirectly, manufactures, markets, imports and sells generic drug products throughout the United States and in this judicial district. According to Jubilant Life Sciences' website, Jubilant Life Sciences "provides Life Science Products and Services across the pharmaceutical value chain, serving customers across 75 countries with ground presence in India, North America, Europe and China." *See* http://www.jubl.com/uploads/downloads/api-product-list1.pdf. Jubilant Life Sciences "has **27 commercial APIs focusing on . . . CNS . . .** which are marketed to leading generics companies. Jubilant's forward integration into generics, 65 US **DMFs** to its credit, and excellent track record

has [*sic*] given the Company momentum in key markets like North America…." (emphases original). *See* http://www.jubl.com/uploads/downloads/78down_A_Jubilant_Life_Sciences _Brochure.pdf. at 11. According to its website, Jubilant Life Sciences has thirty-one commercial products and fifty-eight ANDAs in the United States. *See id.* Further, Jubilant Life Sciences' website states that Jubilant Life Sciences has filed a Drug Master File for aripiprazole and offers aripiprazole for sale. *See* http://www.jubl.com/uploads/downloads/api-product-list1.pdf.

15. This Court has jurisdiction over Jubilant Generics. Upon information and belief, Jubilant Generics is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Jubilant Generics, directly or indirectly, manufactures, markets, imports and sells generic drug products throughout the United States and in this judicial district.

16. This Court has jurisdiction over Jubilant USA. Upon information and belief, Jubilant USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Jubilant USA, directly or indirectly, manufactures, markets, imports and sells generic drug products throughout the United States and in this judicial district. Upon information and belief, Jubilant USA is registered to do business in New Jersey under Business I.D. No. 0101009869. Upon information and belief, Jubilant USA is the marketing office for Jubilant Life Sciences and Jubilant Generics in the United States.

17. Upon information and belief, Jubilant Life Sciences Jubilant Generics and Jubilant USA, acting as an integrated unit, maintain continuous and systematic contacts with New Jersey, including through Jubilant Life Sciences' other wholly-owned subsidiary, Jubilant Clinsys Inc., located at One Crossroads Drive, Building A, Second Floor, Bedminster, New

Jersey 04921. According to Jubilant Life Sciences' website, it is "[a]n integrated Pharmaceutical and Life Sciences Company **offering end-to-end solutions** across pharmaceutical value chain." (emphases original). *See* http://www.jubl.com/uploads/downloads/78down_A_Jubilant _Life_Sciences_Brochure.pdf. at 2. Upon Information and belief, Jubilant Life Sciences and Jubilant Generics share multiple corporate directors.

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

FIRST COUNT FOR PATENT INFRINGEMENT

19. The U.S. Patent and Trademark Office ("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 A.

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

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

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

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

24. Otsuka lists the '796 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

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

26. Upon information and belief, Actavis Elizabeth submitted ANDA No. 90-550 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, offer to sell and sell Defendants' generic products in the United States.

27. Otsuka received a letter from Actavis dated September 26, 2014, purporting to include a Notice of Certification for ANDA No. 90-550 under 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1) ("Actavis' 90-550 letter") as to the '796 patent.

28. Actavis' 90-550 letter alleges that the "established names of the drug product that is the subject of Actavis Elizabeth's ANDA is Aripiprazole Tablets."

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

30. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Actavis Elizabeth has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-550 seeking approval to manufacture, use, offer to sell and sell Defendants' generic products before the expiration date of the '796 patent.

31. Upon information and belief, Actavis Elizabeth's actions relating to Actavis Elizabeth's ANDA No. 90-550 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Actavis Elizabeth, Actavis, Inc., Actavis plc, Jubilant Life Sciences, Jubilant Generics and Jubilant USA.

SECOND COUNT FOR PATENT INFRINGEMENT

32. Otsuka realleges, and incorporates in full herein, paragraphs 23-28.

33. 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 B.

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

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

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

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

38. Actavis Elizabeth's 90-550 letter purports to include a Notice of Certification for ANDA No. 90-550 under 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1) as to the '760 patent.

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

40. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Actavis Elizabeth has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-550 seeking approval to manufacture, use, offer to sell and sell Defendants' generic products before the expiration date of the '760 patent.

41. Upon information and belief, Actavis Elizabeth's actions relating to Actavis Elizabeth's ANDA No. 90-550 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Actavis Elizabeth, Actavis, Inc., Actavis plc, Jubilant Life Sciences, Jubilant Generics and Jubilant USA.

THIRD COUNT FOR PATENT INFRINGEMENT

42. Otsuka realleges, and incorporates in full herein, paragraphs 23-28.

43. The 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 C.

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

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

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

47. Otsuka lists the ’350 patent in the Orange Book for NDA No. 21-436.

48. Actavis Elizabeth’s 90-550 letter purports to include a Notice of Certification for ANDA No. 90-550 under 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1) as to the ’350 patent.

49. Upon information and belief, Defendants’ generic products will, if approved and marketed, infringe at least one claim of the ’350 patent.

50. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Actavis Elizabeth has infringed at least one claim of the ’350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-550 seeking approval to manufacture, use, offer to sell and sell Defendants’ generic products before the expiration date of the ’350 patent.

51. Upon information and belief, Actavis Elizabeth’s actions relating to Actavis Elizabeth’s ANDA No. 90-550 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Actavis Elizabeth, Actavis, Inc., Actavis plc, Jubilant Life Sciences, Jubilant Generics and Jubilant USA.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Actavis Elizabeth, Actavis, Inc., Actavis plc, Jubilant Life Sciences, Jubilant Generics and Jubilant USA 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 ’796 patent through Actavis Elizabeth’s submission of ANDA No. 90-550 to the FDA to obtain approval to manufacture, use, offer to sell and sell

Defendants' generic products in the United States before the expiration of the '796 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 '796 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 '796 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 Actavis Elizabeth's ANDA No. 90-550 until expiration of the '796 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '760 patent through Actavis Elizabeth's submission of ANDA No. 90-550 to the FDA to obtain approval to manufacture, use, offer to sell and sell Defendants' generic products in the United States before the expiration of the '760 patent;

6) 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 '760 patent, or such later date as the Court may determine;

7) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '760 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 Actavis Elizabeth's ANDA No. 90-550 until expiration of the '760 patent;

9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '350 patent through Actavis Elizabeth's submission of ANDA No. 90-550 to the FDA to obtain approval to manufacture, use, offer to sell and sell Defendants' generic products in the United States before the expiration of the '350 patent;

10) 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 '350 patent, or such later date as the Court may determine;

11) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '350 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 Actavis Elizabeth's ANDA No. 90-550 until expiration of the '350 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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