IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No.: _____
	)	
ACTAVIS ELIZABETH LLC and ACTAVIS, INC.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Orexo AB and Orexo US, Inc. ("Orexo US") (collectively, "Plaintiffs"), for their Complaint against defendants Actavis Elizabeth LLC ("Actavis Elizabeth") and Actavis, Inc. (collectively "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Orexo AB is a company organized and existing under the laws of Sweden, having its principal place of business at Virdings allé 32 A, 754 50 Uppsala, Sweden.

2. Plaintiff Orexo US is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 150 Headquarters Plaza, East Tower, Morristown, NJ 07960. Orexo US is a wholly owned subsidiary of Orexo AB.

3. On information and belief, defendant Actavis Elizabeth is a company organized and existing under the laws of the state of Delaware, having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

4. On information and belief, defendant Actavis, Inc. is a corporation organized and existing under the laws of the state of Nevada, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis,

Inc. was formerly known as Watson Pharmaceuticals, Inc., which changed its corporate name to Actavis, Inc. in 2013.

5. On information and belief, Actavis Elizabeth is a wholly owned subsidiary of Actavis, Inc.

JURISDICTION AND VENUE

6. This is an action for patent infringement arising under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338.

7. This Court has personal jurisdiction over Actavis Elizabeth. Actavis Elizabeth is a Delaware company. It is registered with the Delaware Department of State: Division of Corporations under file number 0875422 and maintains a registered agent for service of process in Delaware.

8. On information and belief, Actavis Elizabeth regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Actavis Elizabeth has continuous and systematic contacts with Delaware.

9. On information and belief, Actavis Elizabeth is in the business of manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the state of Delaware. On information and belief, Actavis Elizabeth directly or through its affiliates and agents develops, formulates, manufactures, markets, and/or sells pharmaceutical products, including generic drug products, throughout the United States and in this judicial district.

10. On information and belief, Actavis Elizabeth holds an active Delaware pharmacy wholesale license (No. A4-0000069) and an active Delaware controlled substances distributor/manufacturer license (No. DS0751).

11. On information and belief, Actavis Elizabeth has availed itself of this forum by consenting to personal jurisdiction and/or asserting counterclaims in other civil actions initiated in this jurisdiction, including but not limited to *Cephalon, Inc. v. Actavis LLC et al.*, 14-cv-122-GMS (D. Del. 2014) and *Janssen Pharms., Inc. v. Actavis Elizabeth LLC, et al.*, 13-cv-04507-CCC-JAD (D. Del. 2013).

12. Actavis Elizabeth has purposefully availed itself of the privilege of conducting activities in Delaware and its conduct and connection with Delaware are such that it should reasonably anticipate being haled into court in the state.

13. This court has personal jurisdiction over Actavis, Inc. On information and belief, Actavis, Inc. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Actavis, Inc. has continuous and systematic contacts with Delaware.

14. On information and belief, Actavis, Inc. develops, formulates, manufactures, markets, and/or sells pharmaceutical products, including generic drug products, throughout the United States and in this judicial district, directly or through its affiliates and agents, including its wholly owned subsidiary Actavis Elizabeth.

15. On information and belief, Actavis, Inc. has several wholly-owned subsidiaries that are incorporated in Delaware and hold Delaware pharmacy wholesale and/or

controlled substance distributor/manufacturer licenses, including but not limited to Actavis Elizabeth and Actavis Pharma, Inc.

16. On information and belief, Actavis, Inc. has availed itself of this forum by filing lawsuits in this judicial district as a plaintiff, including but not limited to Kissei Pharm. Co. et al. v. Hetero USA Inc. et al., 13-cv-01091 (D. Del. 2013) and Kissei Pharm. Co. et al. v. Sandoz Inc., 13-cv-01092 (D. Del. 2013).

17. On information and belief, Actavis, Inc. has also availed itself of this forum by consenting to personal jurisdiction and asserting counterclaims in numerous other civil actions initiated in this jurisdiction, including but not limited to UCB, Inc. et al. v. Watson Labs., Inc.— Florida, et al., 13-cv-01219-LPS (D. Del. 2013).

18. Actavis, Inc. has purposefully availed itself of the privilege of conducting activities in Delaware and its conduct and connection with Delaware are such that it should reasonably anticipate being haled into court in the state.

19. On information and belief, Defendants collaborate to manufacture, import, market, distribute, and/or sell pharmaceutical products (including generic drug products) throughout the United States, including in the state of Delaware.

20. On information and belief, upon approval of Actavis Elizabeth's Abbreviated New Drug Application (ANDA) No. 208450, Defendants and/or their affiliates or agents will market and sell Actavis Elizabeth's Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate Sublingual Tablets, Eq. 8.6 mg/2.1 mg and 11.4 mg/2.9 mg base (the "ANDA Products") in Delaware and throughout the United States and will derive substantial revenue therefrom. On information and belief, upon approval of Actavis Elizabeth's ANDA, Defendants will sell the ANDA Products in the state of Delaware and throughout the United

States, and Actavis, Inc. will be involved in the manufacture, distribution, and/or marketing of the ANDA Products.

21. On information and belief, upon approval of Actavis Elizabeth's ANDA, Defendants and/or their affiliates or agents will place the ANDA Products into the stream of commerce with the reasonable expectation or knowledge and the intent that such products will ultimately be purchased and used by consumers in this judicial district.

22. On information and belief, this Court further has personal jurisdiction over Defendants because Defendants regularly do or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive substantial revenue from services or things used or consumed in Delaware and committed the tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to plaintiff Orexo US, a Delaware corporation.

23. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, the above-mentioned facts.

24. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b).

THE PATENTS-IN-SUIT

25. Orexo US holds approved New Drug Application ("NDA") No. 204242 for buprenorphine hydrochloride and naloxone hydrochloride sublingual tablets, which are prescribed and sold in the United States under the trademark Zubsolv®.

26. Zubsolv® sublingual tablets are indicated for the maintenance treatment of opioid dependence and for the induction of buprenorphine maintenance therapy in patients suffering from opioid dependence.

27. United States Patent No. 8,454,996 ("the '996 patent," copy attached as Exhibit A) is titled "Pharmaceutical Compositions for the Treatment of Acute Disorders" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on June 4, 2013. The '996 patent claims, *inter alia*, methods of treatment comprising administration of pharmaceutical compositions containing buprenorphine. The '996 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Zubsolv® sublingual tablets (NDA No. 204242).

28. The named inventors of the '996 patent are Anders Pettersson and Christer Nyström. The '996 patent is assigned to Orexo AB.

29. United States Patent No. 8,940,330 ("the '330 patent," copy attached as Exhibit B) is titled "Abuse-Resistant Pharmaceutical Composition For The Treatment Of Opioid Dependence" and was duly and legally issued by the USPTO on January 27, 2015. The '330 patent claims, *inter alia*, pharmaceutical compositions containing buprenorphine and naloxone. The '330 patent is listed in the Orange Book for Zubsolv® sublingual tablets (NDA No. 204242).

30. The named inventor of the '330 patent is Andreas Fischer. The '330 patent is assigned to Orexo AB.

CLAIMS FOR RELIEF - PATENT INFRINGEMENT

31. Actavis Elizabeth submitted ANDA No. 208450 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products.

32. On information and belief, ANDA No. 208450 seeks FDA approval of the ANDA Products for the indication of maintenance treatment of opioid dependence and/or for the induction of buprenorphine maintenance therapy in patients suffering from opioid dependence.

33. On information and belief, Actavis, Inc. actively participated in and/or directed activities related to the submission of ANDA No. 208450 and the development of the ANDA Products, was actively involved in preparing the ANDA, and/or intends to directly benefit from and has a financial stake in the approval of the ANDA. On information and belief, upon approval of Actavis Elizabeth's ANDA, Actavis, Inc. will be involved in the manufacture, distribution, and/or marketing of the ANDA Products.

34. By letter dated September 18, 2015, and pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95, Actavis Elizabeth notified Plaintiffs that it had submitted ANDA No. 208450 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products before the expiration of the '996 patent, the '330 patent, and U.S. Patent Nos. 8,470,361 and 8,658,198 (the '361 and '198 patents, respectfully).

35. In its September 18, 2015 letter, Actavis Elizabeth notified Plaintiffs that, as a part of its ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") with respect to the '996 patent, the '330 patent, the '361 patent, and the '198 patent.

COUNT I
Infringement of U.S. Patent No. 8,454,996 Under 35 U.S.C. § 271

36. Plaintiffs repeat and reallege paragraphs 1 through 35 as if fully set forth herein.

37. By submitting ANDA No. 208450 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products throughout the United States prior to the

expiration of the '996 patent, Actavis Elizabeth committed an act of infringement of the '996 patent under 35 U.S.C. § 271(e)(2).

38. The commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, for which Actavis Elizabeth seeks approval in ANDA No. 208450, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '996 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

39. Actavis Elizabeth's ANDA Products will have the same clinical instructions on use, be administered in the same manner, and achieve the same results as Zubsolv® sublingual tablets. Actavis Elizabeth's Proposed ANDA Product label will instruct doctors, caregivers, and/or patients to practice one or more of the methods claimed in the '996 patent.

40. Defendants were aware of the '996 patent at the time the ANDA was submitted and deliberately and intentionally submitted the ANDA with knowledge that one or more claims of the '996 patent covered the ANDA Products or their use.

41. Plaintiffs will be irreparably harmed by Defendants' infringing activities and do not have an adequate remedy at law.

COUNT II
Infringement of U.S. Patent No. 8,940,330 Under 35 U.S.C. § 271

42. Plaintiffs repeat and reallege paragraphs 1 through 41 as if fully set forth herein.

43. By submitting ANDA No. 208450 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products throughout the United States prior to the

expiration of the '330 patent, Defendants committed an act of infringement of the '330 patent under 35 U.S.C. § 271(e)(2).

44. The commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, for which Actavis Elizabeth seeks approval in ANDA No. 208450, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '330 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

45. Defendants were aware of the '330 patent at the time the ANDA was submitted and deliberately and intentionally submitted the ANDA with knowledge that one or more claims of the '330 patent covered the ANDA Products or their use.

46. Plaintiffs will be irreparably harmed by Defendants' infringing activities and do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendants and respectfully request the following relief:

A. A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '996 patent by submitting ANDA No. 208450 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products before the expiration of the '996 patent;

B. A judgment that the manufacture, use, offer for sale, sale, and/or importation of the ANDA Products will infringe the '996 patent under 35 U.S.C 271(a), 271(b), and/or 271(c).

C. A judgment declaring that the '996 patent remains valid and enforceable;

D. A permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from

engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products until the expiration of the '996 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

E. An order that the effective date of any approval of Actavis Elizabeth's ANDA No. 208450 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration of the '996 Patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

F. A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '330 patent by submitting ANDA No. 208450 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products before the expiration of the '330 patent;

G. A judgment that the manufacture, use, offer for sale, sale, and/or importation of the ANDA Products will infringe the '330 patent under 35 U.S.C §§ 271(a), 271(b), and/or 271(c).

H. A judgment declaring that the '330 patent remains valid and enforceable;

I. A permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products until the expiration of the '330 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

J. An order that the effective date of any approval of Actavis Elizabeth's ANDA No. 208450 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.

§ 355(j)) shall be a date that is not earlier than the expiration of the '330 Patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

K. A determination that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

L. Costs and expenses in this action; and

M. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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