IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, Plaintiff, v. WATSON LABORATORIES, INC., ACTAVIS, INC., and ACTAVIS LLC, Defendants.	C.A. No. _____

COMPLAINT

Plaintiff AstraZeneca AB ("AstraZeneca"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against defendants Watson Laboratories, Inc., Actavis, Inc., and Actavis LLC (collectively, "Watson"). This action relates to Abbreviated New Drug Application ("ANDA") No. 205902 filed by Watson Laboratories, Inc. with the U.S. Food and Drug Administration ("FDA") for approval to market 2.5 mg and 5 mg saxagliptin hydrochloride tablets, generic versions of AstraZeneca's ONGLYZA® drug product, prior to expiration of U.S. Patent No. RE44,186 ("the RE'186 patent").

PARTIES

2. Plaintiff AstraZeneca is a company operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

3. Plaintiff's subsidiary, AstraZeneca Pharmaceuticals LP, is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

4. AstraZeneca is engaged in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to help patients prevail against serious diseases, including treatments for Type II diabetes. Through its subsidiary, AstraZeneca Pharmaceuticals LP, AstraZeneca markets and sells ONGLYZA® in this judicial district and throughout the United States.

5. Upon information and belief, Watson Laboratories, Inc. is a corporation organized under the laws of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. Upon information and belief, defendant Actavis, Inc. (formerly known as Watson Pharmaceuticals, Inc.) is a corporation organized under the laws of the State of Nevada, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. Upon information and belief, Watson Laboratories, Inc. is a wholly-owned subsidiary of Actavis, Inc.

8. Upon information and belief, Actavis LLC is a limited liability company organized under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis LLC

is involved in the preparation and submission of ANDA filings for the parent of Watson Laboratories, Inc., Actavis, Inc.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

10. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

11. This Court has jurisdiction over Actavis LLC because, *inter alia*, it is a Delaware limited liability company.

12. This Court also has jurisdiction over the defendants because, *inter alia*, this action arises from activities of the defendants directed toward Delaware, and the defendants have purposefully availed themselves of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, the defendants regularly and continuously transact business within the state of Delaware, including by selling pharmaceutical products in Delaware, either on their own or through affiliates. Upon information and belief, the defendants derive substantial revenue from the sale of those products in Delaware and have availed themselves of the privilege of conducting business within the State of Delaware.

13. The defendants have previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and have availed themselves of Delaware courts through the assertion of counterclaims. Watson has filed suit in Delaware courts.

14. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over the defendants.

PATENT-IN-SUIT

15. On April 30, 2013, the U.S. Patent and Trademark Office duly and legally reissued the RE'186 patent, entitled "Cyclopropyl-Fused Pyrrolidine-Based Inhibitors of Dipeptidyl Peptidase IV and Method." The RE'186 patent is a reissue of U.S. Patent No. 6,395,767 ("the '767 patent"), which issued on May 28, 2002. A true and correct copy of the RE'186 patent is attached hereto as **Exhibit A**. The claims of the RE'186 patent are valid and enforceable. AstraZeneca is the owner of the RE'186 patent by assignment and has the right to enforce it.

16. AstraZeneca is the holder of New Drug Application ("NDA") No. 022350, by which the FDA granted approval for the marketing and sale of 2.5 mg and 5 mg strength saxagliptin hydrochloride tablets as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus in multiple clinical settings. AstraZeneca markets saxagliptin hydrochloride tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trade name "ONGLYZA®." The FDA's official publication of approved drugs (the "Orange Book") includes ONGLYZA® together with the RE'186 patent and U.S. patent No. 7,951,400 ("the '400 patent").

INFRINGEMENT BY WATSON

17. By letter dated July 25, 2014 ("the Notice Letter"), Watson notified AstraZeneca and AstraZeneca Pharmaceuticals LP, that Watson Laboratories, Inc. had submitted ANDA No. 205902 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). AstraZeneca received the Notice Letter on or about July 28, 2014.

18. The Notice Letter states that Watson seeks approval from the FDA to engage in the commercial manufacture, use, and sale of generic saxagliptin hydrochloride tablets before the

expiration of the RE'186 patent. Upon information and belief, Watson intends to engage in the commercial manufacture, use, and sale of its generic saxagliptin hydrochloride tablets after receiving FDA approval to do so.

19. By filing ANDA No. 205902, Watson has necessarily represented to the FDA that its generic saxagliptin hydrochloride tablets have the same active ingredient as ONGLYZA®, have the same method of administration, dosage form, and strengths as ONGLYZA®, and are bioequivalent to ONGLYZA®.

20. In the Notice Letter, Watson notified AstraZeneca and AstraZeneca Pharmaceuticals LP that its ANDA contained a "paragraph IV certification" asserting that the RE'186 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Watson's generic saxagliptin hydrochloride tablets.

21. This Complaint is being filed before the expiration of the forty-five days from the date AstraZeneca received the Notice Letter.

COUNT I (INFRINGEMENT OF THE RE'186 PATENT)

22. Each of the preceding paragraphs 1 to 21 is incorporated as if fully set forth herein.

23. Watson's submission of ANDA No. 205902 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic saxagliptin hydrochloride tablets prior to the expiration of the RE'186 patent constituted a technical act of infringement. Upon information and belief, the product described in ANDA No. 205902 would infringe one or more of the claims of the RE'186 patent under 35 U.S.C. § 271(e)(2)(A).

24. Upon information and belief, upon FDA approval of Watson's ANDA No. 205902, Watson will further infringe at least one claim of the RE'186 patent by making, using,

offering to sell, and selling its generic saxagliptin hydrochloride tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

25. If Watson's marketing and sale of generic saxagliptin hydrochloride tablets prior to expiration of the RE'186 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AstraZeneca prays that this Court grant the following relief:

1. A judgment that the claims of the RE'186 patent are not invalid, not unenforceable, and are infringed by Watson's submission of ANDA No. 205902, and that Watson's making, using, offering to sell, or selling in the United States, or importing into the United States Watson's generic saxagliptin hydrochloride tablets will infringe the RE'186 patent.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 205902 shall be a date which is not earlier than the latest expiration date of the RE'186 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

3. An order permanently enjoining defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Watson's generic saxagliptin hydrochloride tablets until after the latest expiration date of the RE'186 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

4. Damages or other monetary relief to AstraZeneca if defendants engage in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Watson's generic saxagliptin hydrochloride tablets prior to the latest expiration date of the RE'186 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: August 15, 2014

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