IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, Plaintiff, v. ACTAVIS LABORATORIES FL, INC. f/k/a WATSON LABORATORIES FL, INC., 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 Actavis Laboratories FL, Inc. f/k/a Watson Laboratories, Inc., Actavis, Inc., and Actavis LLC (collectively, "Watson"). This action relates to Abbreviated New Drug Application ("ANDA") No. 207159 filed by Watson Laboratories FL, Inc. with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 207159, Watson seeks approval to market 5 mg/500 mg, 5 mg/1000 mg, and 2.5 mg/1000 mg saxagliptin hydrochloride and metformin hydrochloride tablets, generic versions of AstraZeneca's KOMBIGLYZE™ XR drug product, prior to

expiration of U.S. Patent No. RE44,186 ("the RE'186 patent") and U.S. Patent No. 8,628,799 ("the '799 patent").

PARTIES

3. 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.

4. 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.

5. 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 KOMBIGLYZE™ XR in this judicial district and throughout the United States.

6. Upon information and belief, Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories FL, Inc.) is a corporation organized under the laws of Florida, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. Upon information and belief, Actavis Laboratories FL, Inc. is an indirect wholly owned subsidiary of Actavis, Inc.

8. 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.

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

10. 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.

11. 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 Actavis, Inc.

JURISDICTION AND VENUE

12. 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.

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

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

15. 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.

16. 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.

17. 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.

PATENTS-IN-SUIT

18. 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.

19. On January 14, 2014, the U.S. Patent and Trademark Office duly and legally issued the '799 patent, entitled "Coated Tablet Formulation and Method." A true and correct copy of the '799 patent is attached hereto as **Exhibit B**. The claims of the '799 patent are valid and enforceable. AstraZeneca is the owner of the '799 patent by assignment and has the right to enforce it.

20. AstraZeneca is the holder of New Drug Application ("NDA") No. 200678, by which the FDA granted approval for the marketing and sale of 5 mg/500 mg, 5 mg/1000 mg and 2.5 mg/1000 mg strength saxagliptin hydrochloride and metformin hydrochloride extended

release tablets as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate. AstraZeneca markets saxagliptin hydrochloride and metformin hydrochloride tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trade name "KOMBIGLYZE™ XR." The FDA's official publication of approved drugs (the "Orange Book") includes 5 mg/500 mg strength KOMBIGLYZE™ XR together with the RE'186 and '799 patents. The Orange Book includes 5 mg/1000 mg and 2/5 mg/1000 mg strength KOMBIGLYZE™ XR together with the RE'186 patent.

INFRINGEMENT BY WATSON

21. By letter dated September 24, 2014 ("the Notice Letter"), Watson notified AstraZeneca and AstraZeneca Pharmaceuticals LP, that Watson Laboratories FL, Inc. had submitted ANDA No. 207159 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 September 25, 2014.

22. The Notice Letter states that Watson seeks approval from the FDA to engage in the commercial manufacture, use, and sale of generic saxagliptin hydrochloride and metformin hydrochloride tablets before the expiration of the RE'186 and '799 patents. Upon information and belief, Watson intends to engage in the commercial manufacture, use, and sale of its generic saxagliptin hydrochloride and metformin hydrochloride tablets after receiving FDA approval to do so.

23. By filing ANDA No. 207159, Watson has necessarily represented to the FDA that its generic saxagliptin hydrochloride and metformin hydrochloride tablets have the same active

ingredient as KOMBIGLYZE™ XR, have the same method of administration, dosage form, and strengths as KOMBIGLYZE™ XR, and are bioequivalent to KOMBIGLYZE™ XR.

24. In the Notice Letter, Watson notified AstraZeneca and AstraZeneca Pharmaceuticals LP that its ANDA contained a "paragraph IV certification" asserting that the RE'186 and '799 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Watson's generic saxagliptin hydrochloride and metformin hydrochloride tablets.

25. 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)

26. Each of the preceding paragraphs 1 to 25 is incorporated as if fully set forth herein.

27. Watson's submission of ANDA No. 207159 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic saxagliptin hydrochloride and metformin 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. 207159 would infringe one or more of the claims of the RE'186 patent under 35 U.S.C. § 271(e)(2)(A).

28. Upon information and belief, upon FDA approval of Watson's ANDA No. 207159, 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 and metformin 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.

29. If Watson's marketing and sale of generic saxagliptin hydrochloride and metformin 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.

COUNT II (INFRINGEMENT OF THE '799 PATENT)

30. Each of the preceding paragraphs 1 to 29 is incorporated as if fully set forth herein.

31. Watson's submission of ANDA No. 207159 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic saxagliptin hydrochloride and metformin hydrochloride tablets prior to the expiration of the '799 patent constituted a technical act of infringement. Upon information and belief, the product described in ANDA No. 207159 would infringe one or more of the claims of the '799 patent under 35 U.S.C. § 271(e)(2)(A).

32. Upon information and belief, upon FDA approval of Watson's ANDA No. 207159, Watson will further infringe at least one claim of the '799 patent by making, using, offering to sell, and selling at least one dosage strength of its generic saxagliptin hydrochloride and metformin 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.

33. If Watson's marketing and sale of generic saxagliptin hydrochloride and metformin hydrochloride tablets prior to expiration of the '799 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 and '799 patents are not invalid, not unenforceable, and are infringed by Watson's submission of ANDA No. 207159, 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 and metformin hydrochloride tablets will infringe the RE'186 and with regard to at least one dosage strength of Watson's generic saxagliptin hydrochloride and metformin hydrochloride extended release tablets, the '799 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. 207159 shall be a date which is not earlier than the latest expiration date of the RE'186 and '799 patents, 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 and metformin hydrochloride tablets until after the latest expiration date of the RE'186 and '799 patents, 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 and metformin hydrochloride tablets prior to the

latest expiration date of the RE'186 and '799 patents, 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: October 31, 2014

McCarter & English, LLP

/s/ Daniel M. Silver

Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com

Charles E. Lipsey
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
11955 Freedom Drive
Reston, VA 20190
(571) 203-2700
(202) 208-4400 (fax)
Charles.Lipsey@finnegan.com

James B. Monroe
Robert F. Shaffer
Maximilienne Bishop
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
901 New York Ave., N.W.
Washington, D.C. 20001
(202) 408-4000
(202) 408-4400 (fax)
James.Monroe@finnegan.com
Robert.Shaffer@finnegan.com
Max.Bishop@finnegan.com

Attorneys for Plaintiff
AstraZeneca AB