

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTRAZENECA AB,)	
)	
Plaintiff,)	
)	
v.)	
)	C.A. No. _____
APOTEX CORP. and APOTEX INC.,)	
)	
Defendants.)	
)	
)	
)	

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 Apotex Corp. and Apotex Inc. (collectively, “Apotex”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 206067 filed by Apotex Corp. 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, Apotex Corp. is a corporation organized under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. Upon information and belief, Apotex Inc. is a corporation organized under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

7. Upon information and belief, Apotex Corp. is a subsidiary of Apotex Inc.

JURISDICTION AND VENUE

8. 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.

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

10. This Court has jurisdiction over Apotex Corp. because Apotex Corp. is incorporated in Delaware.

11. This Court has jurisdiction over Apotex Inc., *inter alia*, because its subsidiary and agent, Apotex Corp., is incorporated in Delaware and, upon information and belief, filed ANDA No. 206067 as Apotex Inc.'s agent and under Apotex Inc.'s direction and control.

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.

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, 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, which covers formulations of saxagliptin.

INFRINGEMENT BY APOTEX

17. By letter dated May 25, 2016 (“the Notice Letter”), Apotex notified AstraZeneca that Apotex Corp. had submitted ANDA No. 206067 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 May 26, 2016.

18. The Notice Letter states that Apotex 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, Apotex 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. 206067, Apotex 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, Apotex notified AstraZeneca that its ANDA contains 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 Apotex’s generic saxagliptin hydrochloride tablets.

21. The Complaint is being filed within forty-five days of the date AstraZeneca received the Notice Letter.

RELATED MATTERS

22. Defendants (i) Aurobindo Pharma Ltd. and Aurobindo Pharma U.S.A., Inc. (No. 14-cv-1469); (ii) Wockhardt Bio AG and Wockhardt USA LLC (No. 14-cv-667); (iii) Amneal Pharmaceuticals LLC (No. 14-cv-697); (iv) Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. (No. 14-cv-694); (iv) Mylan Pharmaceuticals, Inc. (No. 14-cv-696); and (v) Watson Laboratories, Inc. and Actavis Laboratories FL, Inc. (Nos. 14-cv-1051 and 14-cv-1356) have each been sued by AstraZeneca for infringement of claims 8, 9, 25, and 26 of the RE’186 patent. Those actions have been consolidated for pretrial and trial purposes. (Civil Action No. 1:14-cv-664-GMS, D.I. 23)

COUNT I (INFRINGEMENT OF THE RE’186 PATENT)

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

24. Apotex’s submission of ANDA No. 206067 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. 206067 would infringe, either literally or under the doctrine of equivalents, at least claims 8, 9, 25, and 26 of the RE'186 patent under 35 U.S.C. § 271(e)(2)(A).

25. Upon information and belief, upon FDA approval of Apotex's ANDA No. 206067, Apotex will further infringe, either literally or under the doctrine of equivalents, at least claims 8, 9, 25, and 26 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.

26. If Apotex'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 Apotex's submission of ANDA No. 206067, and that Apotex's making, using, offering to sell, or selling in the United States, or importing into the United States Apotex'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. 206067 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 Apotex, its affiliates, subsidiaries, and each of its 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 Apotex'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 Apotex engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Apotex'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. That this Court declare this an exceptional case and award Plaintiff its reasonable attorneys' fees, costs, and expenses in accordance with 35 U.S.C. § 285

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

DATED: July 7, 2016

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