

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

ASTRAZENECA AB,)	
)	
Plaintiff,)	
)	
v.)	
)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC.,)	
)	
Defendant.)	
)	
)	

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 defendant Teva Pharmaceuticals USA, Inc. (“Teva”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 207678 filed by Teva with the U.S. Food and Drug Administration (“FDA”) for approval to market 5 mg/500 mg saxagliptin hydrochloride and metformin hydrochloride extended-release tablets, generic versions of AstraZeneca’s KOMBIGLYZE™ XR drug product, prior to expiration of U.S. Patent No. 8,628,799 (“the ’799 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 2 diabetes. Through its subsidiary, AstraZeneca Pharmaceuticals LP, AstraZeneca markets and sells KOMBIGLYZE™ XR in this judicial district and throughout the United States.

5. Upon information and belief, Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

JURISDICTION AND VENUE

6. 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.

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

8. This Court has jurisdiction over Teva because, upon information and belief, Teva is a Delaware corporation.

9. This Court also has jurisdiction over Teva because, *inter alia*, this action arises from activities of Teva directed toward Delaware, and Teva has purposefully availed itself of the

rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Teva regularly and continuously transacts business within the state of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through affiliates. Upon information and belief, Teva derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

10. Teva has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertion of counterclaims and by filing suits in Delaware.

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

PATENT-IN-SUIT

12. 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 A**. 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.

13. 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 extended-release

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 ’799 patent and U.S. Patent No. RE44’186, which covers the composition of saxagliptin.

INFRINGEMENT BY TEVA

14. By letter dated August 31, 2015 (“the Notice Letter”), Teva notified AstraZeneca and AstraZeneca Pharmaceuticals LP that Teva had submitted ANDA No. 207678 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 1, 2015.

15. The Notice Letter states that Teva seeks approval from the FDA to engage in the commercial manufacture, use, and sale of generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets (5 mg/500 mg strength) before the expiration of the ’799 patent. Upon information and belief, Teva intends to engage in the commercial manufacture, use, and sale of its generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets after receiving FDA approval to do so.

16. By filing ANDA No. 207678, Teva has necessarily represented to the FDA that its generic saxagliptin hydrochloride and metformin hydrochloride extended-release 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.

17. In the Notice Letter, Teva notified AstraZeneca that its ANDA contained a “Paragraph IV certification” asserting that the ’799 patent is invalid, unenforceable, and/or will

not be infringed by the commercial manufacture, use, and sale of Teva's generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets.

18. 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 '799 PATENT)

19. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth herein.

20. Teva's submission of ANDA No. 207678 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets (5 mg/500 mg strength) prior to the expiration of the '799 patent constituted a technical act of infringement. Upon information and belief, the product described in ANDA No. 207678 would infringe one or more of the claims of the '799 patent under 35 U.S.C. § 271(e)(2)(A).

21. Upon information and belief, upon FDA approval of Teva's ANDA No. 207678, Teva will further infringe at least one claim of the '799 patent by making, using, offering to sell, and selling its generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. § 271(a) unless enjoined by the Court.

22. If Teva's marketing and sale of generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets (5 mg/500 mg strength) 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 '799 patent are not invalid, not unenforceable, and are infringed by Teva's submission of ANDA No. 207678, and that Teva's making, using, offering to sell, or selling in the United States, or importing into the United States Teva's generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets will infringe 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. 207678 shall be a date which is not earlier than the latest expiration date of the '799 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.
3. An order permanently enjoining Teva, 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 Teva's generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets until after the latest expiration date of the '799 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 Teva engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Teva's generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets prior to the latest expiration date of the '799 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: October 9, 2015

McCarter & English, LLP

/s/ Daniel M. Silver

Michael P. Kelly (#2295)

Daniel M. Silver (#4758)

McCarter & English, LLP

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) Giannelli

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

M. David Weingarten
Finnegan, Henderson, Farabow, Garrett &
Dunner, L.L.P.
3500 SunTrust Plaza
303 Peachtree Street, NE
Atlanta, GA 30308
(404) 653-6400
(202) 408-4400 (fax)
david.weingarten@finnegan.com

Eric E. Grondahl
McCarter & English, LLP
CityPlace I
185 Asylum St.
Hartford, CT 06103
(860) 275-6704
egrondahl@mccarter.com

*Attorneys for Plaintiff
AstraZeneca AB*