IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, Plaintiff, v. MYLAN PHARMACEUTICALS, INC., Defendants.	Civil Action 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 Defendant Mylan Pharmaceuticals, Inc. ("Mylan"). This action relates to Abbreviated New Drug Application ("ANDA") Nos. 205980 and 205981 filed by Mylan with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 205980, Mylan seeks approval to market 2.5 mg and 5 mg saxagliptin hydrochloride tablets, generic versions of AstraZeneca's ONGLYZA® drug product, prior to expiration of RE44,186 ("the RE'186 patent") and U.S. Patent No. 7,951,400 ("the '400 patent").

3. In ANDA No. 205981, Mylan seeks approval to market 5 mg/500mg, 2.5 mg/1000 mg and 5 mg/1000 mg saxagliptin hydrochloride and metformin hydrochloride

extended-release tablets, generic versions of AstraZeneca's KOMBIGLYZE™ XR drug product, prior to expiration of the RE'186 patent and U.S. Patent No. 8,628,799 ("the '799 patent").

PARTIES

4. 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.

5. 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.

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

7. Upon information and belief, Mylan is a company organized and existing under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

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 Mylan because, *inter alia*, this action arises from actions of Mylan directed toward Delaware and because Mylan has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Mylan regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. Upon information and belief, Mylan 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.

11. Mylan 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.

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

PATENTS-IN-SUIT

13. On April 30, 2013, the U.S. Patent and Trademark Office duly and legally reissued the RE'186 patent, titled "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.

14. On May 31, 2011, the U.S. Patent and Trademark Office duly and legally issued the '400 patent, entitled "Coated Tablet Formulation and Method." A true and correct copy of the '400 patent is attached hereto as **Exhibit B**. The claims of the '400 patent are valid and enforceable. AstraZeneca is the owner of the '400 patent by assignment and has the right to enforce it.

15. 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 C**. 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.

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 and '400 patents.

17. 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 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 MYLAN

A. Submission of ANDA No. 205980

18. By letter dated April 28, 2014, Mylan notified AstraZeneca that Mylan had submitted ANDA No. 205980 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("the Onglyza Notice Letter"). AstraZeneca received the Onglyza Notice Letter on or about April 30, 2014.

19. The Onglyza Notice Letter states that Mylan 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 and '400 patents. Upon information and belief, Mylan intends to engage in the commercial manufacture, use, and sale of its generic saxagliptin hydrochloride tablets promptly upon receiving FDA approval to do so.

20. By filing ANDA No. 205980, Mylan 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®.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.