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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff, v. MYLAN PHARMACEUTICALS, INC., Defendant.	Civil Action No._____

COMPLAINT

Plaintiff Bristol-Myers Squibb Company ("BMS"), 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") No. 208177 filed by Mylan with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 208177, Mylan seeks approval to market 150 mg, 200 mg, and 300 mg capsules of atazanavir sulfate, generic versions of BMS's Reyataz® drug product (the "Mylan ANDA products"), prior to expiration of U.S. Patent No. 6,087,383 ("the 383 patent").

PARTIES

3. BMS is a Delaware corporation having places of business in New Brunswick, New Jersey, Princeton, New Jersey, Hopewell, New Jersey, Plainsboro Township, New Jersey and New York, New York. BMS 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 HIV and AIDS. BMS markets and sells its Reyataz® capsules in this judicial district and throughout the United States.

4. 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. On information and belief, Mylan is registered to do business in New Jersey and has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey as its registered agent for the receipt of service of process.

JURISDICTION AND VENUE

5. 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.

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

7. This Court has jurisdiction over Mylan because, *inter alia*, this action arises from actions of Mylan directed toward New Jersey, and because Mylan has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey. Mylan regularly and continuously transacts business within the State of New

Jersey, including by selling pharmaceutical products in New Jersey, either on its own or through its affiliates. Upon information and belief, Mylan Specialty L.P., an affiliate of Mylan, is located and doing business in Basking Ridge, New Jersey. Upon information and belief, Mylan derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within the State of New Jersey.

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

9. 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.

PATENT-IN-SUIT

10. On July 11, 2000, the U.S. Patent and Trademark Office duly and legally issued the 383 patent, titled "Bisulfate Salt of HIV Protease Inhibitor." A true and correct copy of the 383 patent is attached hereto as Exhibit A. The claims of the 383 patent are valid and enforceable. BMS is the owner of the 383 patent and has the right to enforce it. The expiration date of the 383 patent is December 21, 2018.

11. BMS is the holder of New Drug Application ("NDA") No. 021567, by which the FDA granted approval for the marketing and sale of 150 mg, 200 mg, and 300 mg strength atazanavir sulfate capsules. BMS markets atazanavir sulfate capsules in the United States, under the trade name "Reyataz®." The FDA's official publication of approved drugs (the "Orange Book") includes Reyataz® together with the 383 patent.

INFRINGEMENT BY MYLAN

12. By letter sent by overnight mail on February 3, 2015, Mylan notified BMS that Mylan had submitted ANDA No. 208177 to the FDA under Section 505(j) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("the Reyataz Notice Letter"). BMS received the Reyataz Notice Letter no earlier than February 4, 2015.

13. The Reyataz Notice Letter states that Mylan seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Mylan ANDA products before the expiration of the 383 patent. Upon information and belief, Mylan intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Mylan ANDA products promptly upon receiving FDA approval to do so.

14. By filing ANDA No. 208177, Mylan has necessarily represented to the FDA that the Mylan ANDA products have the same active ingredient as Reyataz®, have the same method of administration, dosage form, and strengths as Reyataz®, and are bioequivalent to Reyataz®.

15. Upon information and belief, the Mylan ANDA products contain atazanavir bisulfate.

16. Upon information and belief, the Mylan ANDA products will be manufactured by, or at the direction of, Mylan.

17. In the Reyataz Notice Letter, Mylan states that its ANDA contains a Paragraph IV certification asserting that the 383 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of the Mylan ANDA products.

18. This Complaint is being filed before the expiration of the forty-five days from the date BMS received the Reyataz Notice Letter.

COUNT I

(INFRINGEMENT OF THE 383 PATENT)

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

20. Mylan's submission of ANDA No. 208177 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Mylan ANDA products prior to the

expiration of the 383 patent constituted a technical act of infringement. Upon information and belief, the product described in ANDA No. 208177 would infringe one or more of the claims of the 383 patent under 35 U.S.C. § 271(e)(2)(A).

21. Mylan's commercial manufacture, use, offer to sell, sale, or importation of the Mylan ANDA products prior to the expiration of the 383 patent, and its inducement of and/or contribution to such conduct, would further infringe claims 1 and 2 of the 383 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

22. Upon FDA approval of Mylan's ANDA No. 208177, Mylan will infringe claims 1 and 2 of the 383 patent by making, using, offering to sell, and selling the Mylan ANDA products in the United States and/or importing such products into the United States, or by actively inducing and contributing to infringement of the 383 patent by others, under 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

23. If Mylan's marketing and sale of the Mylan ANDA products prior to expiration of the 383 patent and all other relevant exclusivities is not enjoined, BMS will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

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

1. A judgment that the claims of the 383 patent are not invalid, are not unenforceable, and are infringed by Mylan's submission of ANDA No. 208177, and that Mylan's making, using, offering to sell, or selling in the United States, or importing into the United States the Mylan ANDA products will infringe the 383 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. 208177 shall be a date which is not earlier than the latest

expiration date of the 383 patent, including any extensions and/or additional periods of exclusivity to which BMS is or becomes entitled.

3. An order permanently enjoining Mylan, 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 the Mylan ANDA products until after the latest expiration date of the 383 patent, including any extensions and/or additional periods of exclusivity to which BMS is or becomes entitled.

4. Damages or other monetary relief to BMS if Mylan engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Mylan ANDA products prior to the latest expiration date of the 383 patent, including any extensions and/or additional periods of exclusivity to which BMS 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: March 17, 2015

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s/ Liza M. Walsh

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