IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff, v. CIPLA USA, INC., and CIPLA LIMITED, Defendants.	)	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 Defendants Cipla USA, Inc. and Cipla Limited (collectively, "Cipla"). This action relates to Abbreviated New Drug Application ("ANDA") No. 200626 filed by Cipla Limited with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 200626, Cipla Limited seeks approval to market 100 mg, 150 mg, 200 mg, and 300 mg capsules of atazanavir sulfate, generic versions of BMS's Reyataz® drug product (the "Cipla ANDA products"), prior to expiration of U.S. Patent No. 6,087,383 ("the '383 patent").

PARTIES

3. BMS is a Delaware corporation having a place of business at 345 Park Avenue, New York, New York.

4. 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.

5. Upon information and belief, Cipla USA, Inc. is a company organized and existing under the laws of Delaware, having a principal place of business at 9100 S. Dadeland Blvd., Suite 1500, Miami, Florida 33156.

6. Upon information and belief, Cipla Limited is a company organized and existing under the laws of India, having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai – 400 013, Maharashtra, India.

7. Upon information and belief, Cipla USA, Inc. is a wholly owned subsidiary of Cipla Limited, as well as an agent in the United States, authorized to accept service of process for Cipla Limited.

8. Upon information and belief, Cipla is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market.

JURISDICTION AND VENUE

9. 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.

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

11. This Court has jurisdiction over Cipla USA, Inc. because, upon information and belief, Cipla USA, Inc. is a company organized and existing under the laws of Delaware. Upon

information and belief, Cipla USA, Inc. directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States and in this judicial district.

12. This Court has jurisdiction over Cipla Limited because, upon information and belief, Cipla USA, Inc. is a Delaware corporation and is acting as the agent of Cipla Limited, at least with respect to ANDA 200626.

13. In the alternative, this Court has jurisdiction over Cipla Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

14. This Court also has jurisdiction over Cipla Limited because, inter alia, this action arises from actions of Cipla Limited directed toward Delaware, and because Cipla Limited 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, Cipla Limited regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. Upon information and belief, Cipla Limited derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

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

PATENT-IN-SUIT

16. 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. BMS also was awarded a period of pediatric exclusivity through June 21, 2019.

17. 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 CIPLA

18. By letter sent by regular mail on December 31, 2015, Cipla USA, Inc. notified BMS that Cipla Limited had submitted ANDA No. 200626 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 January 7, 2016.

19. The Reyataz Notice Letter states that Cipla Limited seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Cipla ANDA products before the expiration of the '383 patent. Upon information and belief, Cipla Limited intends to—directly or indirectly through Cipla USA, Inc. and/or other subsidiaries, affiliates, and distributors—engage in the commercial manufacture, use, and sale of the Cipla ANDA products promptly upon receiving FDA approval to do so.

20. By filing ANDA No. 200626, Cipla Limited has necessarily represented to the FDA that the Cipla 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®.

21. Upon information and belief, the Cipla ANDA products contain atazanavir bisulfate.

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

23. In the Reyataz Notice Letter, Cipla USA, Inc. states that the Cipla 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 Cipla ANDA products.

24. 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)

25. Each of the preceding paragraphs 1 to 24 is incorporated as if fully set forth herein.

26. Cipla’s Limited’s submission of ANDA No. 200626 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Cipla 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. 200626 would infringe one or more of the claims of the ’383 patent under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Cipla USA, Inc. was also involved in the submission of ANDA No. 200626.

27. Cipla’s commercial manufacture, use, offer to sell, sale, or importation of the Cipla 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).

28. Upon FDA approval of Cipla’s ANDA No. 200626, Cipla Limited and Cipla USA, Inc. will each infringe claims 1 and 2 of the ’383 patent by making, using, offering to sell, and selling the Cipla ANDA products, which comprise atazanavir bisulfate, 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.

29. If Cipla's marketing and sale of the Cipla 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 Cipla Limited's submission of ANDA No. 200626, and that Cipla's making, using, offering to sell, or selling in the United States, or importing into the United States the Cipla 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. 200626 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 Cipla, 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 Cipla 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, including, but not limited to, costs and pre- and post-judgment interest, to BMS if Cipla engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Cipla 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: February 11, 2016

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

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