

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

BRISTOL-MYERS SQUIBB COMPANY
AND PFIZER INC.,

Plaintiffs,

v.

IMPAX LABORATORIES, INC.,

Defendant.

Civil Action No. _____

COMPLAINT

Plaintiffs Bristol-Myers Squibb Company (“BMS”) and Pfizer Inc. (“Pfizer”) (BMS and Pfizer, collectively, “Plaintiffs”), by their attorneys, hereby allege 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 Impax Laboratories, Inc. (“Impax”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 209810 filed by Impax with the U.S. Food and Drug Administration (“FDA”).

2. In ANDA No. 209810, Impax seeks approval to market 2.5 mg and 5 mg tablets of apixaban, generic versions of Plaintiffs’ Eliquis[®] drug product (the “Impax ANDA product”), prior to expiration of U.S. Patent No. 9,326,945 (the “’945 patent” or “patent-in-suit”).

PARTIES

3. BMS is a corporation organized and existing under the laws of Delaware, having a place of business at Route 206 and Province Line Road, Princeton, New Jersey 08540.

4. Pfizer is a corporation organized and existing under the laws of Delaware, having its principal place of business at 235 East 42nd Street, New York, New York 10017.

5. Plaintiffs are engaged in the business of creating, developing, and bringing to market revolutionary pharmaceutical products to help patients prevail against serious diseases, including treatments for thromboembolic disorders. Plaintiffs sell Eliquis[®] in this judicial district and throughout the United States.

6. Upon information and belief, Impax is a corporation organized and existing under the laws of Delaware, having its principal place of business at 30831 Huntwood Avenue, Hayward, CA 94544.

JURISDICTION AND VENUE

7. 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.

8. This Court has jurisdiction over Impax because, *inter alia*, Impax has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, both Delaware corporations, in Delaware. For example, on information and belief, following approval of ANDA No. 209810, Impax will make, use, import, sell, and/or offer for sale the Impax ANDA product in the United States, including in Delaware, prior to the expiration of the patent-in-suit.

9. This Court also has jurisdiction over Impax because, *inter alia*, this action arises from actions of Impax directed toward Delaware, and because Impax 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, Impax is a corporation organized and existing

under the laws of Delaware. Upon information and belief, Impax regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware. Upon information and belief, Impax derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

10. Impax has previously been sued in this judicial district and has availed itself of Delaware courts through the assertion of claims and counterclaims in suits brought in Delaware including *Impax Laboratories, Inc. v. Par Pharmaceutical Inc.*, 1:16-cv-00856.

11. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), including because, *inter alia*, Impax is subject to personal jurisdiction in this district, as set forth above, has committed an act of infringement and will commit further acts of infringement in this judicial district, as set forth in more detail in paragraph 8 above, and, upon information and belief, has a regular and established place of business in this judicial district. Further, venue is proper in this Court because Impax is organized under the laws of Delaware, is registered in Delaware, and does business in Delaware.

12. For these reasons, and for other reasons that will be presented to the Court if jurisdiction and/or venue are challenged, the Court has personal jurisdiction over Impax, and venue in this judicial district is proper.

PATENT-IN-SUIT

13. On May 3, 2016, the U.S. Patent and Trademark Office duly and legally issued the '945 patent, titled "Apixaban Formulations." A true and correct copy of the '945 patent is attached hereto as Exhibit A. The claims of the '945 patent are valid, enforceable, and not expired. Plaintiffs are the joint owners of the '945 patent and have the right to enforce it.

14. BMS is the holder of New Drug Application ("NDA") No. 202155, by which the FDA granted approval for the marketing and sale of 2.5 mg and 5 mg strength apixaban tablets.

Plaintiffs market apixaban tablets in the United States, under the trade name “Eliquis[®].” The FDA’s official publication of approved drugs (the “Orange Book”) includes Eliquis[®] together with the patent-in-suit. Eliquis[®] is a factor Xa inhibitor indicated: (1) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (2) for the prophylaxis of deep vein thrombosis (“DVT”), which may lead to pulmonary embolism (“PE”), in patients who have undergone hip or knee replacement surgery; and (3) for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy. A copy of the complete prescribing information for Eliquis[®] approved in NDA No. 202155 is attached as Exhibit B.

INFRINGEMENT BY IMPAX

15. By letter sent Federal Express mail on March 3, 2017, Impax notified Plaintiffs that Impax had submitted ANDA No. 209810 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) (“the Eliquis Notice Letter”). Plaintiffs received the Eliquis Notice Letter no earlier than March 6, 2017.

16. The Eliquis Notice Letter states that Impax seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Impax ANDA product before the expiration of the patent-in-suit. Upon information and belief, Impax intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Impax ANDA product promptly upon receiving FDA approval to do so.

17. By filing ANDA No. 209810, Impax has necessarily represented to the FDA that the Impax ANDA product has the same active ingredient as Eliquis[®], has the same dosage form and strength as Eliquis[®], and is bioequivalent to Eliquis[®].

18. Upon information and belief, Impax is seeking approval to market the Impax ANDA product for the same approved indications as Eliquis[®].

19. In the Eliquis Notice Letter, Impax states that its ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the patent-in-suit is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of the Impax ANDA product.

20. In the Eliquis Notice Letter, Impax made no offer of confidential access to all or part of its ANDA No. 209810.

21. This Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the Eliquis Notice Letter.

COUNT I

(INFRINGEMENT OF THE '945 PATENT)

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

23. Impax's submission of ANDA No. 209810 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Impax ANDA product prior to the expiration of the '945 patent constituted a technical act of infringement of at least one of the claims of the '945 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 9-12, 20-23, 25, 27, 29, 31, 33, 35, and 37, under 35 U.S.C. § 271(e)(2)(A).

24. Impax's commercial manufacture, use, offer to sell, sale, or importation of the Impax ANDA product prior to the expiration of the '945 patent, and its inducement of and/or contribution to such conduct, would further infringe at least one of the claims of the '945 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 9-12, 20-23, 25, 27, 29, 31, 33, 35, and 37, under 35 U.S.C. §§ 271(a), (b) and/or (c).

25. Upon FDA approval of Impax's ANDA No. 209810, Impax will infringe one or more claims of the '945 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 9-12, 20-23, 25, 27, 29, 31, 33, 35, and 37, by making, using, offering to

sell, and selling the Impax ANDA product in the United States and/or importing said product into the United States, or by actively inducing and contributing to infringement of the '945 patent by others, under 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

26. If Impax's marketing and sale of the Impax ANDA product prior to expiration of the '945 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

1. A judgment that the claims of the patent-in-suit are not invalid, are not unenforceable, and are infringed by Impax's submission of ANDA No. 209810, either literally or under the doctrine of equivalents, and that Impax's making, using, offering to sell, or selling in the United States, or importing into the United States the Impax ANDA product will infringe the claims of the patent-in-suit, either literally or under the doctrine of equivalents.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 209810 shall be a date which is not earlier than the latest expiration date of the patent-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

3. An order permanently enjoining Impax, 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 Impax ANDA product until after the latest expiration date of the patent-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

4. Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, to Plaintiffs if Impax engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Impax ANDA product prior to the latest expiration date of the patent-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

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

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