IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civil Action No. 1:17-CV-55

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 Mylan Pharmaceuticals Inc. ("Mylan"). This action relates to Abbreviated New Drug Application ("ANDA") No. 210128 filed by Mylan with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 210128, Mylan seeks approval to market 2.5 mg and 5 mg tablets of apixaban, generic versions of Plaintiffs' Eliquis® drug product (the "Mylan ANDA product"), prior to expiration of U.S. Patent Nos. 6,967,208 (the "'208 patent") and 9,326,945 (the "'945 patent") (collectively, the "patents-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, Mylan is a corporation organized and existing under the laws of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

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 personal jurisdiction over Mylan because, *inter alia*, Mylan has purposefully availed itself of the rights and benefits of West Virginia law by engaging in systematic and continuous contacts with West Virginia. Upon information and belief, Mylan is a corporation organized and existing under the laws of West Virginia and has its principal place of business in West Virginia. Upon information and belief, Mylan regularly and continuously transacts business within West Virginia, including by selling pharmaceutical products in West Virginia. Upon information and belief, Mylan derives substantial revenue from the sale of those products in West Virginia and has availed itself of the privilege of conducting business within West Virginia.

9. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), including because, *inter alia*, Mylan is subject to personal jurisdiction in this district, as set forth above, has

committed an act of infringement under 35 U.S.C. § 271(e)(2) and will commit further acts of infringement in this judicial district, 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 Mylan is organized under the laws of West Virginia and has its principal place of business in West Virginia.

PATENTS-IN-SUIT

10. On November 22, 2005, the U.S. Patent and Trademark Office duly and legally issued the '208 patent, titled "Lactam-Containing Compounds and Derivatives thereof as Factor Xa Inhibitors." A true and correct copy of the '208 patent is attached hereto as Exhibit A. The claims of the '208 patent are valid, enforceable, and not expired. BMS is the owner of the '208 patent and has the right to enforce it.

11. 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 B. 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.

12. 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 patents-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 C.

INFRINGEMENT BY MYLAN

13. By letter sent by Federal Express on March 2, 2017, Mylan notified Plaintiffs that Mylan had submitted ANDA No. 210128 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 3, 2017.

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

15. By filing ANDA No. 210128, Mylan has necessarily represented to the FDA that the Mylan ANDA product has the same active ingredient as Eliquis®, has the same dosage form and strength as Eliquis®, and is bioequivalent to Eliquis®.

16. Upon information and belief, Mylan is seeking approval to market the Mylan ANDA product for the same approved indications as Eliquis®.

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

18. In the Eliquis Notice Letter, Mylan offered confidential access to portions of its ANDA No. 210128 on terms and conditions set forth in the Eliquis Notice Letter ("the Mylan Offer"). Mylan requested that Plaintiffs accept the Mylan Offer before receiving access to

Mylan's ANDA No. 210128. The Mylan Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. The Mylan Offer unreasonably restricted the ability of counsel to seek the opinions of Plaintiffs' employees and outside experts; and Mylan did not provide any means of gaining permission to seek outside expert access to the Mylan ANDA. The restrictions Mylan has placed on access to ANDA No. 210128 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, ***as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information***" (emphasis added).

19. 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 '208 PATENT)

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

21. Mylan's submission of ANDA No. 210128 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Mylan ANDA product prior to the expiration of the '208 patent constituted a technical act of infringement of at least one of the claims of the '208 patent, either literally or under the doctrine of equivalents, including but not limited to claims 8, 13, 26-27, and 55-61, under 35 U.S.C. § 271(e)(2)(A).

22. Mylan's commercial manufacture, use, offer to sell, sale, or importation of the Mylan ANDA product prior to the expiration of the '208 patent, and its inducement of and/or contribution to such conduct, would further infringe, either literally or under the doctrine of equivalents, at least one of the claims of the '208 patent, including but not limited to claims 8, 13, and 26-27, under 35 U.S.C. §§ 271(a), (b) and/or (c).

23. Mylan's commercial manufacture, use, offer to sell, sale, or importation of the Mylan ANDA product for the same treatment claimed in the '208 patent prior to the expiration of the '208 patent, and its inducement of and/or contribution to such conduct, would further infringe, either literally or under the doctrine of equivalents, at least one of the claims of the '208 patent, including but not limited to claims 55-61, under 35 U.S.C. §§ 271(a), (b) and/or (c).

24. Upon FDA approval of Mylan's ANDA No. 210128, Mylan will infringe, either literally or under the doctrine of equivalents, at least one of the claims of the '208 patent, including but not limited to claims 8, 13, 26-27, and 55-61, by making, using, offering to sell, and selling the Mylan 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 '208 patent by others, under 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

25. If Mylan's marketing and sale of the Mylan ANDA product prior to expiration of the '208 patent and all other relevant exclusivities are not enjoined, BMS will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II

(INFRINGEMENT OF THE '945 PATENT)

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

27. Mylan's submission of ANDA No. 210128 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Mylan 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).

28. Defendant's commercial manufacture, use, offer to sell, sale, or importation of the Mylan 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).

29. Upon FDA approval of Mylan's ANDA No. 210128, Mylan 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 Mylan 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.

30. If Defendant's marketing and sale of the Mylan 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 patents-in-suit are not invalid, are not unenforceable, and are infringed by Mylan's submission of ANDA No. 210128, either literally or under the doctrine of equivalents, and that Mylan's making, using, offering to sell, or selling in the United States, or importing into the United States the Mylan ANDA product will infringe the claims of the patents-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. 210128 shall be a date which is not earlier than the latest expiration date of the patents-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become 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 product until after the latest expiration date of the patents-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 Mylan engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Mylan ANDA product prior to the latest expiration date of the patents-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.

Dated: April 12, 2017

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