IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY AND PFIZER INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, 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 Teva Pharmaceuticals USA, Inc. ("Teva"). This action relates to Abbreviated New Drug Application ("ANDA") No. 210142 filed by Teva with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 210142, Teva seeks approval to market 2.5 mg and 5 mg tablets of apixaban, generic versions of Plaintiffs' Eliquis® drug product (the "Teva ANDA product"), prior to expiration of U.S. Patent No. 9,326,945 (the "'945 patent") (the "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, Teva is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

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. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), and this Court has personal jurisdiction over Teva. Teva, through its counsel, via written agreement on March 28, 2017, agreed that it does not contest jurisdiction or venue in this Court in this matter.

PATENT-IN-SUIT

9. 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.

10. 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 TEVA

11. By letter sent by Express Mail and Federal Express on March 10, 2017, Teva notified Plaintiffs that Teva had submitted ANDA No. 210142 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 13, 2017.

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

13. By filing ANDA No. 210142, Teva has necessarily represented to the FDA that the Teva ANDA product has the same active ingredient as Eliquis®, has the same dosage form and strength as Eliquis®, and is bioequivalent to Eliquis®.

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

15. In the Eliquis Notice Letter, Teva 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 Teva ANDA product.

16. In the Eliquis Notice Letter, Teva offered confidential access to portions of its ANDA No. 210142 on terms and conditions set forth in the Eliquis Notice Letter ("the Teva Offer"). Teva requested that Plaintiffs accept the Teva Offer before receiving access to Teva's ANDA No. 210142. The Teva Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the Teva Offer contained a broad patent prosecution bar, which, among other things, does not have a carve-out for inter-partes reviews or other adversarial proceedings, and a broad bar on any work related to actions before the FDA. The Teva Offer did not allow access to ANDA No. 210142 by outside experts or even contain a mechanism for obtaining outside expert access. The restrictions Teva has placed on access to ANDA No. 210142 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).

17. 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)

18. Each of the preceding paragraphs 1 to 17 is incorporated as if fully set forth herein.

19. Teva's submission of ANDA No. 210142 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva 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).

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

21. Upon FDA approval of Teva’s ANDA No. 210142, Teva 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 Teva 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.

22. If Teva’s marketing and sale of the Teva 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 Teva’s submission of ANDA No. 210142, either literally or under the doctrine of equivalents, and that Teva’s making, using, offering to sell, or selling in the United States, or importing into the United States the Teva 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. 210142 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 Teva, 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 Teva 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 Teva engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Teva 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.

Dated: April 10, 2017

Respectfully submitted,

FARNAN, LLP

/s/ Michael J. Farnan

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