IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY, AND PFIZER INC., Plaintiffs, v. LUPIN LTD., 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 Lupin Ltd. ("Lupin"). This action relates to Abbreviated New Drug Application ("ANDA") No. 210119 filed by Lupin with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 210119, Lupin seeks approval to market 2.5 mg and 5 mg tablets of apixaban, generic versions of Plaintiffs' Eliquis® drug product (the "Lupin 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, Lupin is a corporation organized and existing under the laws of India, having its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400051, Maharashtra, India.

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 Lupin. Lupin, through its counsel, by e-mail dated March 17, 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 LUPIN

11. By letter sent by Federal Express and overnight mail on February 23, 2017, Lupin notified Plaintiffs that Lupin had submitted ANDA No. 210119 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 February 24, 2017.

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

13. By filing ANDA No. 210119, Lupin has necessarily represented to the FDA that the Lupin 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, Lupin is seeking approval to market the Lupin ANDA product for the same approved indications as Eliquis®.

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

16. In the Eliquis Notice Letter, Lupin offered confidential access to portions of its ANDA No. 210119 on terms and conditions set forth in the Eliquis Notice Letter ("the Lupin Offer"). Lupin requested that Plaintiffs accept the Lupin Offer before receiving access to Lupin's ANDA No. 210119. The Lupin Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the Lupin 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 work related to actions before the FDA. The Lupin Offer unreasonably restricted the ability of counsel to seek the opinions of Plaintiffs' employees and outside experts without written permission from Lupin's designated counsel; and Lupin had broad authority to reject any request by Plaintiffs to seek outside expert access to the Lupin ANDA. The restrictions Lupin has placed on access to ANDA No. 210119 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. Lupin's submission of ANDA No. 210119 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Lupin 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. Lupin's commercial manufacture, use, offer to sell, sale, or importation of the Lupin 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 Lupin's ANDA No. 210119, Lupin 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 Lupin 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 Lupin's marketing and sale of the Lupin 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 Lupin's submission of ANDA No. 210119, either literally or under the doctrine of equivalents, and that Lupin's making, using, offering to sell, or selling in the

United States, or importing into the United States the Lupin 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. 210119 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 Lupin, 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 Lupin 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 Lupin engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Lupin 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 5, 2017

Respectfully submitted,

FARNAN LLP

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