IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY AND PFIZER INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC., Defendants.	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 Defendants Dr. Reddy's Laboratories, Ltd. ("Dr. Reddy's Ltd.") and Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's Inc.," and together with Dr. Reddy's Ltd., "DRL"). This action relates to Abbreviated New Drug Application ("ANDA") No. 210082 filed by DRL with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 210082, DRL seeks approval to market 2.5 mg and 5 mg tablets of apixaban, generic versions of Plaintiffs' Eliquis® drug product (the "DRL 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, Dr. Reddy's Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Door No. 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, 500034, Andhra Pradesh, India.

7. Upon information and belief, Dr. Reddy's Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

8. 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.

9. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), and this Court has personal jurisdiction over DRL. DRL, through its counsel, by e-mail dated March 27, 2017, agreed that it does not contest jurisdiction or venue in this Court in this matter.

PATENT-IN-SUIT

10. 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.

11. 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 DRL

12. By letter sent by UPS Next Day Air on March 9, 2017, DRL notified Plaintiffs that DRL had submitted ANDA No. 210082 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 10, 2017.

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

in the commercial manufacture, use, and sale of the DRL ANDA product promptly upon receiving FDA approval to do so.

14. By filing ANDA No. 210082, DRL has necessarily represented to the FDA that the DRL ANDA product has the same active ingredient as Eliquis®, has the same dosage form and strength as Eliquis®, and is bioequivalent to Eliquis®.

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

16. In the Eliquis Notice Letter, DRL 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 DRL ANDA product.

17. In the Eliquis Notice Letter, DRL offered confidential access to portions of its ANDA No. 210082 on terms and conditions set forth in the Eliquis Notice Letter ("the DRL Offer"). DRL requested that Plaintiffs accept the DRL Offer before receiving access to DRL's ANDA No. 210082. The DRL Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the DRL 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 restriction barring access by outside counsel who engage in any FDA counseling, litigation, or other work before or involving the FDA. The DRL Offer unreasonably restricted the ability of counsel to seek the opinions of outside experts without written permission from DRL's designated counsel, and DRL had broad authority to reject any request by Plaintiffs to seek outside expert access to the DRL ANDA. The restrictions DRL has placed on access to ANDA No. 210082 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).

18. 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)

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

20. DRL's submission of ANDA No. 210082 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the DRL 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).

21. DRL's commercial manufacture, use, offer to sell, sale, or importation of the DRL 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).

22. Upon FDA approval of DRL ANDA No. 210082, DRL 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 DRL ANDA product in the United States and/or importing said product into the

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