IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC.,	)	
Plaintiff,	)	
	)	C.A. No. 17-401-LPS
v.	)	
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,	)	
Defendants.	)	

DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS

Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL" or "Defendants"), by their attorneys, for their Answer, Defenses, and Counterclaims to the Complaint filed by Bristol-Myers Squibb Company ("BMS") and Pfizer Inc. ("Pfizer") (collectively, "Plaintiffs") state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), DRL denies all allegations in Plaintiffs' Complaint except those specifically admitted below.

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").

ANSWER: DRL admits that Plaintiffs purport to bring this action for patent infringement under the patent laws of the United States. DRL further admits that this action

purports to relate to ANDA No. 210082, filed by DRL with the FDA. DRL denies any remaining allegations of paragraph 1.

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").

ANSWER: DRL admits that it filed ANDA No. 210082, which seeks FDA approval to market 2.5 mg and 5 mg tablets of apixaban prior to the expiration date of U.S. Patent No. 9,326,945 ("the '945 patent"). DRL further admits that ANDA No. 210082 identifies Eliquis® (apixaban) oral tablets, 2.5 mg and 5 mg, as the Reference Listed Drug. DRL denies any remaining allegations of paragraph 2.

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.

ANSWER: DRL lacks sufficient information to form a belief as to the truth of the allegations in paragraph 3 and therefore denies them.

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.

ANSWER: DRL lacks sufficient information to form a belief as to the truth of the allegations in paragraph 4 and therefore denies them.

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.

ANSWER: DRL lacks sufficient information to form a belief as to the truth of the allegations in paragraph 5 and therefore denies them.

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.

ANSWER: DRL Ltd. is an Indian corporation with a principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India. DRL denies any remaining allegations of paragraph 6.

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.

ANSWER: DRL admits the allegations of paragraph 7.

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.

ANSWER: The allegations set forth in paragraph 8 are legal conclusions to which no answer is required. To the extent any response is required, DRL admits for purposes of this case only that this Court has subject matter jurisdiction over the claims alleged by Plaintiffs. DRL denies any remaining allegations of paragraph 8.

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.

ANSWER: The allegations set forth in paragraph 9 are legal conclusions to which no answer is required. To the extent any response is required, DRL does not contest personal jurisdiction or venue in this judicial district solely for purposes of Plaintiffs' claims against DRL in this case and solely as they apply to the proposed product described in ANDA No. 210082. DRL denies any remaining allegations of paragraph 9.

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.

ANSWER: DRL denies every allegation set forth in this paragraph, except admits that the '945 patent is entitled "Apixaban Formulations," the face of the '945 patent indicates that it issued on May 3, 2016 and lists Bristol-Myers Squibb Company and Pfizer Inc. as its Assignees, that what appears to be a copy of the '945 patent is attached to the Complaint as Exhibit A, and on information and belief that FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") lists the expiration date of the '945 patent as February 24, 2031.

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.

ANSWER: DRL admits that the Orange Book lists Bristol Myers Squibb Co Pharmaceutical Research Institute as the holder of NDA No. 202155, which is directed to 2.5 mg and 5 mg apixaban tablets that are marketed under the trade name Eliquis®. DRL further admits that the Orange Book lists the '945 patent in relation to Eliquis®. DRL further admits that what appears to be a copy of the prescribing information for Eliquis® is attached to the Complaint as Exhibit B. DRL admits that the prescribing information for Eliquis® recites, in part:

----------INDICATIONS AND USAGE----------

ELIQUIS is a factor Xa inhibitor indicated:

- to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. (1.1)
- 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. (1.2)
- for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy. (1.3, 1.4, 1.5)

DRL denies any remaining allegations of paragraph 11.

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.

ANSWER: DRL admits the allegations of paragraph 12.

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.

ANSWER: DRL admits that its Notice Letter states that DRL seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of DRL's proposed ANDA products in ANDA No. 210082 before the expiration of the '945 patent. DRL denies any remaining allegations of paragraph 13.

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®.

ANSWER: DRL admits that ANDA No. 210082 identifies ELIQUIS® (apixaban) oral tablets, 2.5 mg and 5 mg, as the Reference Listed Drug and that ANDA No. 210082 contains

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