IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY AND PFIZER INC., Plaintiffs, v. SIGMAPHARM LABORATORIES, LLC., 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 Sigmapharm Laboratories, LLC. ("Sigmapharm"). This action relates to Abbreviated New Drug Application ("ANDA") No. 210053 filed by Sigmapharm with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 210053, Sigmapharm seeks approval to market 2.5 mg and 5 mg tablets of apixaban, generic versions of Plaintiffs' Eliquis® drug product (the "Sigmapharm 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").

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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, Sigmapharm is a corporation organized and existing under the laws of Pennsylvania, having its principal place of business at 3375 Progress Drive, Bensalem, Pennsylvania 19020.

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 Sigmapharm. Sigmapharm, through its counsel, by e-mail dated March 30, 2017, agreed that it does not contest jurisdiction or venue in this Court in this matter.

PATENTS-IN-SUIT

9. 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

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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.

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 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.

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 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 SIGMAPHARM

12. By letter sent by Federal Express on March 7, 2017, Sigmapharm notified Plaintiffs that Sigmapharm had submitted ANDA No. 210053 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 8, 2017.

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

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directly or indirectly – engage in the commercial manufacture, use, and sale of the Sigmapharm ANDA product promptly upon receiving FDA approval to do so.

14. By filing ANDA No. 210053, Sigmapharm has necessarily represented to the FDA that the Sigmapharm 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, Sigmapharm is seeking approval to market the Sigmapharm ANDA product for the same approved indications as Eliquis®.

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

17. In the Eliquis Notice Letter, Sigmapharm offered confidential access to portions of its ANDA No. 210053 on terms and conditions set forth in the Eliquis Notice Letter ("the Sigmapharm Offer"). Sigmapharm requested that Plaintiffs accept the Sigmapharm Offer before receiving access to Sigmapharm's ANDA No. 210053. The Sigmapharm Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the Sigmapharm 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 work before or involving the FDA. The Sigmapharm Offer unreasonably restricted the ability of counsel to seek the opinions of Plaintiffs' employees and outside experts without written permission from Sigmapharm's designated counsel; Sigmapharm had broad authority to reject any such request for access to the Sigmapharm ANDA. The restrictions Sigmapharm has placed on

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access to ANDA No. 210053 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 '208 PATENT)

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

20. Sigmapharm's submission of ANDA No. 210053 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Sigmapharm 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).

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

22. Sigmapharm's commercial manufacture, use, offer to sell, sale, or importation of the Sigmapharm 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

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