IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY AND PFIZER INC., Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES INC. AND SUN PHARMA GLOBAL FZE, Defendants.	C.A. No. 17-cv-409-LPS

FIRST AMENDED 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 Sun Pharmaceutical Industries Inc. ("Sun Pharmaceutical") and Sun Pharma Global FZE ("Sun FZE") (Sun Pharmaceutical and Sun FZE, collectively, "Sun"). This action relates to Abbreviated New Drug Application ("ANDA") No. 210171 filed by Sun with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 210171, Sun seeks approval to market 2.5 mg and 5 mg tablets of apixaban, generic versions of Plaintiffs' Eliquis® drug product (the "Sun 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, Sun Pharmaceutical is a corporation organized and existing under the laws of Michigan, having its principal place of business at 1 Commerce Drive, Cranbury, New Jersey 08512.

7. Upon information and belief, Sun FZE is a company organized and existing under the laws of Sharjah, United Arab Emirates, having a principal place of business at 704, Jumeirah Business Center 1, Cluster G, Jumeirah Lakes Towers, P.O. Box #643561, Dubai United Arab Emirates.

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 Sun. Sun, through its counsel, by e-mails dated March 14 and April 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 SUN

12. By letter sent by overnight delivery on February 28, 2017, Sun Pharmaceutical notified Plaintiffs that Sun Pharmaceutical had submitted ANDA No. 210171 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 1, 2017.

13. On April 18, 2017, Sun informed Plaintiffs that Sun Pharmaceutical is not the owner of ANDA No. 210171 but, rather, is acting as the U.S. agent for Sun FZE, the owner of ANDA No. 210171.

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

15. By filing ANDA No. 210171, Sun has necessarily represented to the FDA that the Sun ANDA product has the same active ingredient as Eliquis®, has the same dosage form and strength as Eliquis®, and is bioequivalent to Eliquis®.

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

17. In the Eliquis Notice Letter, Sun 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 Sun ANDA product.

18. In the Eliquis Notice Letter, Sun offered confidential access to portions of its ANDA No. 210171 on terms and conditions set forth in the Eliquis Notice Letter ("the Sun Offer"). Sun requested that Plaintiffs accept the Sun Offer before receiving access to Sun's ANDA No. 210171. The Sun Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the Sun 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 Sun Offer unreasonably restricted the ability of counsel to seek the opinions of Plaintiffs' employees and outside experts without written permission from Sun's

designated counsel; and Sun had broad authority to reject any request by Plaintiffs to seek outside expert access to the Sun ANDA. The restrictions Sun has placed on access to ANDA No. 210171 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).

19. The original Complaint was filed before the expiration of forty-five days from the date Plaintiffs received the Eliquis Notice Letter. Sun confirmed by e-mail on April 27, 2017, that it does not dispute that the filing of the original Complaint in this matter on April 10, 2017, triggered a stay of FDA approval of Sun's ANDA No. 210171, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), for 30 months from December 28, 2017.

COUNT I

(INFRINGEMENT OF THE '945 PATENT)

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

21. Sun's submission of ANDA No. 210171 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Sun 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).

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

23. Upon FDA approval of Sun's ANDA No. 210171, Sun 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 Sun 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.

24. If Sun's marketing and sale of the Sun 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 Sun's submission of ANDA No. 210171, either literally or under the doctrine of equivalents, and that Sun's making, using, offering to sell, or selling in the United States, or importing into the United States the Sun 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. 210171 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 Sun, 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 Sun 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 Sun engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Sun 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 28, 2017

Respectfully submitted,

FARNAN LLP

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