IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY, AND PFIZER INC., Plaintiffs, v. SUNSHINE LAKE PHARMA CO., LTD.; SUNSHINE LAKE LLC; AND HEC PHARM USA 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 Sunshine Lake Pharma Co., Ltd. ("Sunshine Ltd."), Sunshine Lake LLC ("Sunshine LLC"), and HEC Pharm USA Inc. ("HEC") (collectively "Defendants"). This action relates to Abbreviated New Drug Application ("ANDA") No. 209944 filed by Sunshine Ltd. with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 209944, Sunshine Ltd. seeks approval to market 2.5 mg and 5 mg tablets of apixaban, generic versions of Plaintiffs' Eliquis® drug product (the "Sunshine 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, Sunshine Ltd. is a corporation organized and existing under the laws of China, having its principal place of business at Northern Industry Road 1#, Song Shan Lake, Dongguan 523000 Guangdong, China.

7. Upon information and belief, Sunshine LLC is a business organized and existing under the laws of Delaware, and is registered to do business in Delaware (File Number 4110345).

8. Upon information and belief, HEC is a corporation organized and existing under the laws of New Jersey, having its principle place of business at 116 Village Blvd, Suite 200, Princeton, NJ 08540.

9. Upon information and belief, Sunshine Ltd., HEC, and Sunshine LLC are subsidiaries and/or corporate affiliates of HEC Pharma, a private company based in China which is active in pharmaceuticals. Upon information and belief, based in part on information on HEC Pharma's website at http://www.hecpharm.com/en/investor.aspx?AboutCateId=54, Sunshine Ltd. is responsible for oral dosage forms of pharmaceutical products for the European Union and United States regions. Upon information and belief, HEC and Sunshine LLC are the U.S. agents for and/or constitute the U.S. operations for, Sunshine Ltd.

JURISDICTION AND VENUE

10. 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.

11. This Court has jurisdiction over Defendants because, *inter alia*, Defendants have committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intend a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, both Delaware corporations, in Delaware. For example, on information and belief, following approval of ANDA No. 209944, Defendants will make, use, import, sell, and/or offer for sale the Sunshine ANDA product in the United States, including in Delaware, prior to the expiration of the patent-in-suit.

12. This Court also has jurisdiction over Defendants because Sunshine LLC is a Delaware limited liability company and, upon information and belief, along with HEC, is the agent of and/or constitutes the U.S. operations of Sunshine Ltd. Upon information and belief, Sunshine LLC acts in concert with Sunshine Ltd. and HEC with respect to Sunshine Ltd.'s ANDA products in the United States.

13. This Court also has jurisdiction over Defendants because, *inter alia*, this action arises from actions of Defendants directed toward Delaware, and because Defendants have purposefully availed themselves of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Defendants regularly and continuously transact business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies, including Sunshine LLC, a business organized and existing under the laws of Delaware. Upon information and

belief, Defendants derive substantial revenue from the sale of those products in Delaware and have availed themselves of the privilege of conducting business within Delaware.

14. In the alternative, this Court has jurisdiction over Sunshine Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

15. HEC has previously been sued in this judicial district and has availed itself of Delaware courts through the assertion of counterclaims in suits brought in Delaware including *Novartis AG v. HEC Pharm Co., Ltd.*, 1:15-cv-00151-LPS.

16. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), including because, *inter alia*, Defendants are subject to personal jurisdiction in this district, as set forth above, have committed an act of infringement and will commit further acts of infringement in this judicial district, as set forth in more detail in paragraph 11 above, and, upon information and belief, have a regular and established place of business in this judicial district. In addition, venue is proper in this Court as to Sunshine Ltd. under 28 U.S.C. § 1391(c)(3), because Sunshine Ltd., upon information and belief, is not a resident of the United States and may thus be sued in any judicial district. Further, venue is proper in this Court as to Sunshine LLC because it is organized under the laws of Delaware, is registered in Delaware, and does business in Delaware.

17. For these reasons, and for other reasons that will be presented to the Court if jurisdiction and/or venue are challenged, the Court has personal jurisdiction over Defendants, and venue in this judicial district is proper.

PATENT-IN-SUIT

18. 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.

19. 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 DEFENDANTS

20. By letter sent by certified mail and Federal Express March 6, 2017, Sunshine Ltd. notified Plaintiffs that Sunshine Ltd. had submitted ANDA No. 209944 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 7, 2017.

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

22. By filing ANDA No. 209944, Sunshine Ltd. has necessarily represented to the FDA that the Sunshine ANDA product has the same active ingredient as Eliquis®, has the same dosage form and strength as Eliquis®, and is bioequivalent to Eliquis®.

23. Upon information and belief, Sunshine Ltd. is seeking approval to market the Sunshine ANDA product for the same approved indications as Eliquis®. Upon information and belief, Sunshine LLC and HEC will serve as the distributor for the Sunshine ANDA product in the U.S. upon FDA approval.

24. In the Eliquis Notice Letter, Sunshine Ltd. 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 Sunshine ANDA product.

25. In the Eliquis Notice Letter, Sunshine Ltd. offered confidential access to portions of its ANDA No. 209944 on terms and conditions set forth in the Eliquis Notice Letter ("the Sunshine Offer"). Sunshine Ltd. requested that Plaintiffs accept the Sunshine Offer before receiving access to Sunshine's ANDA No. 209944. The Sunshine Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the Sunshine 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 Sunshine Offer unreasonably restricted the ability of counsel to seek the opinions of Plaintiffs' employees and outside experts without written permission from Sunshine Ltd.'s designated counsel; and Sunshine Ltd. had broad authority to reject any request by Plaintiffs to seek outside expert access to the Sunshine ANDA. The restrictions Sunshine Ltd. has placed on access to ANDA No. 209944 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).

26. 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)

27. Each of the preceding paragraphs 1 to 26 is incorporated as if fully set forth herein.

28. Sunshine Ltd.'s submission of ANDA No. 209944 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Sunshine 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). Upon information and belief, Sunshine LLC and/or HEC are acting as the U.S. agents for Sunshine Ltd. with respect to Sunshine Ltd.'s ANDA products, including with respect to ANDA No. 209944.

29. Defendants' commercial manufacture, use, offer to sell, sale, or importation of the Sunshine 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).

30. Upon FDA approval of ANDA No. 209944, Defendants 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 Sunshine 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.

31. If Defendants’ marketing and sale of the Sunshine 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 Sunshine Ltd.’s submission of ANDA No. 209944, either literally or under the doctrine of equivalents, and that Defendants’ making, using, offering to sell, or selling in the United States, or importing into the United States the Sunshine 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. 209944 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 Defendants, their affiliates, subsidiaries, and each of their 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 Sunshine 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 Defendants engage in commercial manufacture, use, offers

to sell, sale, or importation in or into the United States of the Sunshine 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

/s/ Michael J. Farnan

Joseph J. Farnan, Jr. (Bar No. 100245)
Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 N. Market Str., 12th Floor
Wilmington, DE 19801
Tel: (302) 777-0300
Fax: (302) 777-0301
farnan@farnanlaw.com
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Counsel for Plaintiffs Bristol-Myers Squibb Company and Pfizer Inc.

Of Counsel:

Amy K. Wigmore
Gregory H. Lantier
Tracey C. Allen
Heather M. Petruzzi
Jeffrey T. Hantson
Wilmer Cutler Pickering Hale and Dorr LLP
1875 Pennsylvania Ave, NW
Washington, DC 20006
202-663-6000
202-663-6363