IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, BAYER AG and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SUNSHINE LAKE PHARMA CO., LTD. and HEC PHARM USA INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Intellectual Property GmbH ("BIP"), Bayer AG (Bayer AG and BIP are collectively referred to herein as "Bayer"), and Janssen Pharmaceuticals, Inc. ("Janssen") (Bayer and Janssen are collectively referred to herein as "Plaintiffs"), by their attorneys, for their Complaint, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Sunshine Lake Pharma Co., Ltd. and HEC Pharm USA Inc. of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of Plaintiffs' XARELTO® products prior to the expiration of U.S. Patent No. 9,539,218.

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim am Rhein, Germany.

3. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

4. Plaintiff Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

Defendants

5. Upon information and belief, defendant Sunshine Lake Pharma Co., Ltd. ("Sunshine Ltd.") is a corporation organized and existing under the laws of China, with a place of business at Northern Industry Road 1#, Song Shan Lake, Dongguan 523000 Guangdong, China.

6. Upon information and belief, HEC Pharm USA Inc. ("HEC") is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 116 Village Blvd, Suite 200, Princeton, NJ 08540.

7. Upon information and belief, HEC is a wholly-owned subsidiary of Sunshine Ltd., and is controlled and dominated by Sunshine Ltd.

8. Upon information and belief, Sunshine Ltd. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug

products. As a part of this business, upon information and belief, Sunshine Ltd, acting in concert with HEC, files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. Upon information and belief, as part of these ANDAs, Sunshine Ltd., acting in concert with HEC, files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

9. Upon information and belief, Sunshine Ltd. and HEC acted in concert to prepare and submit ANDA No. 213348 for Sunshine Ltd.'s 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Sunshine's ANDA Products").

10. Upon information and belief, Sunshine Ltd. and HEC are agents of one another, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Sunshine's ANDA Products at issue.

11. Upon information and belief, following any FDA approval of ANDA No. 213348, Sunshine Ltd. and HEC will act in concert to market, distribute, offer for sale, and sell Sunshine's ANDA Products throughout the United States and within Delaware. These two entities—Sunshine Ltd. and HEC—are hereafter collectively referred to as "Sunshine."

12. Upon information and belief, following any FDA approval of ANDA No. 213348, Sunshine knows and intends that Sunshine's ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States, including in Delaware.

JURISDICTION

13. Plaintiffs incorporate each of the preceding paragraphs as if each fully set forth herein.

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over Sunshine Ltd. and HEC because, among other things, upon information and belief: (1) Sunshine Ltd., acting in concert with HEC, has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sunshine's ANDA Products in the United States, including in Delaware; and (2) Sunshine Ltd and HEC, acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Sunshine's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 213348, and will derive substantial revenue from the use or consumption of Sunshine's ANDA Products in the State of Delaware. Upon information and belief, if ANDA No. 213348 is approved, the generic Sunshine products charged with infringing the '218 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

16. Alternatively, if Sunshine Ltd.'s connections with Delaware are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Sunshine Ltd. is

not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Sunshine Ltd. in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

17. Upon information and belief, Sunshine Ltd. and HEC have consented to jurisdiction in Delaware in a prior case arising out of the filing of their ANDAs, and each filed counterclaims in that case.

FACTUAL BACKGROUND

18. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor indicated: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT); (iii) for the treatment of pulmonary embolism (PE); (iv) for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months; (v) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery; and (vi) in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI) and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD). XARELTO® is available as tablets in 2.5 mg, 10 mg, 15 mg, and 20 mg dosage strengths.

19. Janssen is the holder of New Drug Application No. 022406 for XARELTO®, which has been approved by the FDA.

20. U.S. Patent No. 9,539,218 ("the '218 patent"), entitled "Prevention and Treatment of Thromboembolic Disorders," was duly and legally issued on January 10, 2017. The '218 patent is attached as Exhibit A.

21. As set forth in greater detail in the '218 patent, the claims of the '218 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, claim 1 recites, "A method of treating a thromboembolic disorder comprising administering a direct factor Xa inhibitor that is 5-Chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl}methyl)-2-thiophenecarboxamide no more than once daily for at least five consecutive days in a rapid-release tablet to a patient in need thereof, wherein the thromboembolic disorder is selected from the group consisting of pulmonary embolisms, deep vein thromboses, and stroke."

22. BIP is the assignee of the '218 patent.

23. Bayer AG is an exclusive licensee under the '218 patent.

24. Janssen is an exclusive sublicensee under the '218 patent.

25. Pursuant to 21 U.S.C. § 355, the '218 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with XARELTO® tablets in 10mg, 15 mg, and 20 mg dosage strengths.

Infringement by Defendants

26. By letter dated June 24, 2019 (the "Sunshine Notice Letter"), Sunshine notified BIP and Janssen that Sunshine had submitted to the FDA ANDA No. 213348 for Sunshine's ANDA Products. These products are generic versions of XARELTO®.

27. In the Sunshine Notice Letter, Sunshine stated that Sunshine's ANDA Products contain rivaroxaban.

28. In the Sunshine Notice Letter, Sunshine stated that the dosage form of Sunshine's ANDA Products is tablets. Upon information and belief, the dosage form of

Sunshine's ANDA Products satisfies the "rapid-release tablet" requirement of claim 1 of the '218 patent.

29. Upon information and belief, the proposed labeling for Sunshine's ANDA Products directs the use of Sunshine's ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT); (iii) for the treatment of pulmonary embolism (PE); (iv) for the reduction in the risk of recurrence DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months; and (v) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery. Upon information and belief, the proposed labeling for Sunshine's ANDA Products further directs the use of Sunshine's ANDA Products in a manner that satisfies the "no more than once daily for at least five consecutive days" requirement of claim 1 of the '218 patent.

30. In the Sunshine Notice Letter, Sunshine did not contest infringement of any claim of the '218 patent.

31. Upon information and belief, the manufacture, use (including in accordance with and as directed by Sunshine's proposed labeling for Sunshine's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Sunshine's ANDA Products will infringe at least claim 1 of the '218 patent.

32. In the Sunshine Notice Letter, Sunshine indicated that, in connection with its ANDA No. 213348, Sunshine had filed Paragraph IV Certifications with respect to the '218 patent.

33. The purpose of ANDA No. 213348 was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Sunshine's ANDA Products with their proposed labeling prior to the expiration of the '218 patent.

34. Sunshine intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sunshine's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 213348, *i.e.*, prior to the expiration of the '218 patent.

35. Sunshine has knowledge of the claims of the '218 patent. Notwithstanding this knowledge, Sunshine has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sunshine's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 213348. Upon information and belief, by such activities, Sunshine specifically intends to infringe the '218 patent.

36. Upon information and belief, Sunshine plans and intends to, and will, actively induce infringement of the '218 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

37. Upon information and belief, Sunshine knows that Sunshine's ANDA Products are especially made or adapted for use in infringing the '218 patent, and that Sunshine's ANDA Products are not suitable for substantial noninfringing use. Upon information and belief, Sunshine plans and intends to, and will, contribute to infringement of the '218 patent immediately and imminently upon approval of ANDA No. 213348.

38. The foregoing actions by Sunshine constitute and/or will constitute infringement of the ’218 patent, active inducement of infringement of the ’218 patent, and/or contribution to the infringement by others of the ’218 patent.

39. An actual case or controversy exists between Plaintiffs and Sunshine with respect to infringement of the ’218 patent.

40. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Sunshine Notice Letter.

CLAIM FOR RELIEF
(Infringement of the ’218 Patent)

41. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

42. Sunshine’s submission of ANDA No. 213348 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Sunshine’s ANDA Products was an act of infringement of the ’218 patent under 35 U.S.C. § 271(e)(2).

43. Upon information and belief, Sunshine has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Sunshine’s ANDA Products with their proposed labeling prior to the expiration of the ’218 patent.

44. Sunshine intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sunshine’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 213348, *i.e.*, prior to the expiration of the ’218 patent.

45. The foregoing actions by Sunshine constitute and/or will constitute infringement of the ’218 patent, active inducement of infringement of the ’218 patent, and/or contribution to the infringement by others of the ’218 patent.

46. Unless Sunshine is enjoined from infringing the ’218 patent, actively inducing infringement of the ’218 patent, and contributing to the infringement by others of the ’218 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Sunshine has infringed the ’218 patent;

(b) A judgment ordering that the effective date of any FDA approval for Sunshine to make, use, offer for sale, sell, market, distribute, or import Sunshine’s ANDA Products, or any product or compound the use of which infringes the ’218 patent, be no earlier than the expiration date of the ’218 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Sunshine, and all persons acting in concert with Sunshine, from making, using, selling, offering for sale, marketing, distributing, or importing Sunshine’s ANDA Products, or any product or compound the use of which infringes the ’218 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’218 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A declaration that this is an exceptional case and an award of attorneys’ fees for Plaintiffs pursuant to 35 U.S.C. § 285;

(e) An award of Plaintiffs’ costs and expenses in this action; and

(f) Such further and other relief as this Court may deem just and proper.

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