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. _____
TARO PHARMACEUTICAL INDUSTRIES LTD., TARO PHARMACEUTICALS U.S.A., 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 Taro Pharmaceutical Industries Ltd. 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.

Taro

5. On information and belief, Defendant Taro Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of the State of Israel, with a place of business at 14 Hakitor Street, Haifa Bay 2624761, Israel.

6. On information and belief, Defendant Taro Pharmaceuticals U.S.A., Inc. is a corporation organized and existing under the laws of the State of New York, with a place of business at 3 Skyline Drive, Hawthorne, NY 10532.

7. On information and belief, Taro Pharmaceuticals U.S.A., Inc. is the agent for service of process in the United States for Taro Pharmaceutical Industries Ltd.

8. On information and belief, Taro Pharmaceuticals U.S.A., Inc. is a wholly-owned subsidiary of Taro Pharmaceutical Industries Ltd., and is controlled and dominated by Taro Pharmaceutical Industries Ltd.

9. On information and belief, Taro Pharmaceutical Industries 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, on information and belief, Taro Pharmaceutical Industries Ltd., acting in concert with Taro Pharmaceuticals U.S.A., Inc., 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. On information and belief, as part of these ANDAs, Taro Pharmaceutical Industries Ltd., acting in concert with Taro Pharmaceuticals U.S.A., Inc., 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.

10. On information and belief, Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. acted in concert to prepare and submit ANDA No. 208557 for Taro Pharmaceutical Industries Ltd.'s 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Taro's ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Taro Pharmaceutical Industries Ltd.

11. On information and belief, Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. are agents of each other, 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 Taro's ANDA Products at issue.

12. On information and belief, following any FDA approval of ANDA No. 208557, Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. will act in concert to market, distribute, offer for sale, and sell Taro's ANDA Products throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Taro."

13. On information and belief, Taro prepared and submitted ANDA No. 208557 for Taro's 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Taro's ANDA Products").

14. On information and belief, following any FDA approval of ANDA No. 208557, Taro will market, distribute, offer for sale, and sell Taro's ANDA Products throughout the United States and within Delaware.

15. On information and belief, following any FDA approval of ANDA No. 208557, Taro knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

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

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

18. Taro, through its counsel, has represented that Taro agrees to personal jurisdiction in Delaware for purposes of this case.

19. In addition, this Court has personal jurisdiction over Taro because, among other things, on information and belief: (1) Taro 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

Taro's ANDA Products in the United States, including in Delaware; and (2) Taro will market, distribute, offer for sale, and/or sell Taro's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 208557, and will derive substantial revenue from the use or consumption of Taro's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 208557 is approved, the generic Taro 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.

20. Taro has consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases.

VENUE

21. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

22. 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), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery. XARELTO® is available as tablets in 10 mg, 15 mg, and 20 mg dosage strengths.

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

24. 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.

25. 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."

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

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

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

29. 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®.

Infringement by Taro

30. By letter dated March 8, 2017 (the "Taro Notice Letter"), Taro notified BIP and Janssen that Taro had submitted to the FDA ANDA No. 208557 for Taro's ANDA Products. These products are generic versions of XARELTO®.

31. In the Taro Notice Letter, Taro stated that Taro's ANDA Products contain rivaroxaban.

32. In the Taro Notice Letter, Taro stated that the dosage form of Taro's ANDA Products is tablets. On information and belief, the dosage form of Taro's ANDA Products satisfies the "rapid-release tablet" requirement of claim 1 of the '218 patent.

33. On information and belief, the proposed labeling for Taro's ANDA Products directs the use of Taro'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), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery. On information and belief, the proposed labeling for Taro's ANDA Products further directs the use of Taro'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.

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

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

36. In the Taro Notice Letter, Taro indicated that, in connection with its ANDA No. 208557, Taro had filed a Paragraph IV Certification with respect to the '218 patent.

37. The purpose of ANDA No. 208557 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 Taro's ANDA Products with their proposed labeling prior to the expiration of the '218 patent.

38. Taro intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208557, *i.e.*, prior to the expiration of the '218 patent.

39. Taro has knowledge of the claims of the '218 patent. Notwithstanding this knowledge, Taro has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208557. On information and belief, by such activities, Taro specifically intends to infringe the '218 patent.

40. On information and belief, Taro 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.

41. On information and belief, Taro knows that Taro's ANDA Products are especially made or adapted for use in infringing the '218 patent, and that Taro's ANDA Products are not suitable for substantial noninfringing use. On information and belief, Taro plans and intends to, and will, contribute to infringement of the '218 patent immediately and imminently upon approval of ANDA No. 208557.

42. The foregoing actions by Taro 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.

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

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

CLAIM FOR RELIEF
(Infringement of the ’218 Patent)

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

46. Taro’s submission of ANDA No. 208557 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Taro’s ANDA Products was an act of infringement of the ’218 patent under 35 U.S.C. § 271(e)(2).

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

48. Taro intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208557, *i.e.*, prior to the expiration of the ’218 patent.

49. The foregoing actions by Taro 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.

50. Unless Taro 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 Taro has infringed the ’218 patent;

(b) A judgment ordering that the effective date of any FDA approval for Taro to make, use, offer for sale, sell, market, distribute, or import Taro’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 Taro, and all persons acting in concert with Taro, from making, using, selling, offering for sale, marketing, distributing, or importing Taro’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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