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. _____
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
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 Teva Pharmaceuticals 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.

Teva

5. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 1090 Horsham Road, North Wales, Pennsylvania, and having designated its registered agent for the State of Delaware as Corporate Creations Network Inc., 3411 Silverside Road, #104 Rodney Building, Wilmington, Delaware.

6. On information and belief, Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israeli limited company organized under the laws of Israel and has a principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

7. On information and belief, Defendant Teva USA is a wholly owned subsidiary of Teva Ltd. and is controlled and dominated by Teva Ltd.

8. On information and belief, Teva USA 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, Teva USA, acting in concert with Teva Ltd., 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, Teva USA, acting in concert with Teva Ltd., 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. On information and belief, and consistent with their practice with respect to other generic products, Teva USA and Teva Ltd. acted in concert to prepare and submit ANDA No. 212247 for Teva USA's 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Teva's ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Teva Ltd.

10. On information and belief, Teva USA and Teva Ltd. 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 Teva's ANDA Products at issue.

11. On information and belief, following any FDA approval of ANDA No. 212247, Teva USA and Teva Ltd. will act in concert to market, distribute, offer for sale, and sell Teva's ANDA Products throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Teva."

12. On information and belief, following any FDA approval of ANDA No. 212247, Teva 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 AND VENUE

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 Teva USA because, among other things, Teva USA is a corporation formed under the laws of the State of Delaware, has registered to do business in the State of Delaware, and has appointed a registered agent in Delaware to accept service of process. Teva USA has thus consented to jurisdiction in Delaware.

16. In addition, this Court has personal jurisdiction over Teva USA and Teva Ltd. because, among other things, on information and belief: (1) Teva USA, acting in concert with Teva Ltd., 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 Teva's ANDA Products in the United States, including in Delaware; and (2) Teva USA and Teva Ltd., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Teva's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 212247, and

will derive substantial revenue from the use or consumption of Teva's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 212247 is approved, the generic Teva 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.

17. Teva USA and Teva Ltd. have 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.

18. Alternatively, if Teva Ltd.'s connections with Delaware, including its connections with Teva USA, are found to be insufficient to confer personal jurisdiction, then upon information and belief, Teva Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Teva Ltd. in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

19. Venue is proper in this district pursuant to 28 U.S.C. §1400(b) because Teva USA is incorporated in Delaware, and pursuant to 28 U.S.C. § 1391(c)(3) because Teva Ltd. is a defendant not resident in the United States.

FACTUAL BACKGROUND

20. 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.

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

22. 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.

23. 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."

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

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

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

27. 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 Teva

28. By letter dated October 22, 2018 (the “Notice Letter”), Teva USA notified BIP and Janssen that Teva had submitted to the FDA ANDA No. 212247 for Teva’s ANDA Products. These products are generic versions of XARELTO®.

29. In the Notice Letter, Teva stated that Teva’s ANDA Products contain rivaroxaban.

30. In the Notice Letter, Teva stated that the dosage form of Teva’s ANDA Products is tablets. On information and belief, the dosage form of Teva’s ANDA Products satisfies the “rapid-release tablet” requirement of claim 1 of the ’218 patent.

31. On information and belief, the proposed labeling for Teva’s ANDA Products directs the use of Teva’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. On information and belief, the proposed labeling for Teva’s ANDA Products further directs the use of Teva’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.

32. In the Notice Letter, Teva did not substantively contest infringement of any claim of the ’218 patent.

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

34. In the Notice Letter, Teva indicated that, in connection with its ANDA No. 212247, Teva had filed Paragraph IV Certifications with respect to the ’218 patent.

35. The purpose of ANDA No. 212247 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 Teva’s ANDA Products with their proposed labeling prior to the expiration of the ’218 patent.

36. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 212247, *i.e.*, prior to the expiration of the ’218 patent.

37. Teva has knowledge of the claims of the ’218 patent. Notwithstanding this knowledge, Teva has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 212247. On information and belief, by such activities, Teva specifically intends to infringe the ’218 patent.

38. On information and belief, Teva 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.

39. On information and belief, Teva knows that Teva’s ANDA Products are especially made or adapted for use in infringing the ’218 patent, and that Teva’s ANDA Products are not suitable for substantial noninfringing use. On information and belief, Teva plans and intends to, and will, contribute to infringement of the ’218 patent immediately and imminently upon approval of ANDA No. 212247.

40. The foregoing actions by Teva 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.

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

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

CLAIM FOR RELIEF
(Infringement of the ’218 Patent)

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

44. Teva’s submission of ANDA No. 212247 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva’s ANDA Products was an act of infringement of the ’218 patent under 35 U.S.C. § 271(e)(2).

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

46. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 212247, *i.e.*, prior to the expiration of the '218 patent.

47. The foregoing actions by Teva 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.

48. Unless Teva 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 Teva has infringed the '218 patent;

(b) A judgment ordering that the effective date of any FDA approval for Teva to make, use, offer for sale, sell, market, distribute, or import Teva'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 Teva, and all persons acting in concert with Teva, from making, using, selling, offering for sale, marketing, distributing, or importing Teva'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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December 5, 2018