IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER AG and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Pharma AG, Bayer AG (Bayer AG and Bayer Pharma AG 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 and amendment 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 a generic version of Plaintiffs' 2.5 mg XARELTO® product prior to the expiration of U.S. Patent No. 10,828,310 ("the '310 patent").

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, 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 principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

Defendants

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, Teva USA and Teva Ltd. acted in concert to prepare, submit, and amend ANDA No. 212247 for Teva USA's 2.5 mg rivaroxaban tablets ("Teva's ANDA Product"), 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 Product 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 Product 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 will market, distribute, offer for sale, and sell Teva's ANDA Product throughout the United States and within Delaware.

13. On information and belief, following any FDA approval of ANDA No. 212247, Teva knows and intends that its ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

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

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

16. 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.

17. 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 Product 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 Product 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 Product in the State of Delaware. On information and belief, if ANDA No. 212247 is approved, the generic Teva product charged with infringing the '310 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.

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. 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/or it has filed counterclaims in such cases. *See e.g.*, *Acadia Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 20-986 (D.I. 12); *Arbor Pharmaceuticals, LLC v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 19-053 (D.I. 9); *Sun Pharma Global FZE et al. v. Teva Pharmaceutical Industries Ltd. et al.*, C.A. No. 18-1552 (D.I. 7).

VENUE

20. Venue is proper in this district for Teva USA pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Teva USA is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

21. Venue is proper in this district for Teva Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Teva Ltd. is a private limited company organized and existing under the laws of Israel and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

22. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor. The 2.5 mg tablet strength of XARELTO® is indicated for administration orally twice daily, in combination with aspirin (75-100 mg) once daily, 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).

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

24. The '310 patent, entitled "Reducing the Risk of Cardiovascular Events," was duly and legally issued on November 10, 2020. The '310 patent is attached as Exhibit A.

25. As set forth in greater detail in the '310 patent, the claims of the '310 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, independent claim 1 recites, "A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, comprising administering to the human patient rivaroxaban and aspirin in amounts that are clinically proven effective in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial disease, wherein rivaroxaban is administered in an amount of 2.5 mg twice daily and aspirin is administered in an amount of 75-100 mg daily."

26. Bayer Pharma AG is the assignee of the '310 patent.

27. Bayer AG is an exclusive licensee under the '310 patent.

28. Janssen is an exclusive sublicensee under the '310 patent.

29. Pursuant to 21 U.S.C. § 355, the '310 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with the 2.5 mg strength of XARELTO®.

COUNT I: INFRINGEMENT OF THE '310 PATENT

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

31. By letter dated June 15, 2021 ("Teva's Notice Letter"), Teva notified Bayer Pharma AG and Janssen that Teva USA had submitted to the FDA ANDA No. 212247 for Teva's ANDA Product and had submitted an amendment to that ANDA. This product is a generic version of the 2.5 mg strength of XARELTO®.

32. In Teva's Notice Letter, Teva indicated that, in connection with its ANDA No. 212247, Teva had filed a Paragraph IV Certification with respect to the '310 patent.

33. In Teva's Notice Letter, Teva stated that Teva's ANDA Product contains rivaroxaban.

34. On information and belief, the proposed labeling for Teva's ANDA Product directs a method of reducing 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). On information and belief, the proposed labeling for Teva's ANDA Product further directs the administration of Teva's ANDA Product and aspirin in amounts that are clinically proven effective in reducing the risk of MI, stroke or CV death in a human patient with CAD and/or PAD, wherein Teva's ANDA Product will be administered twice daily and aspirin is administered in an amount of 75-100 mg daily.

35. The purpose of ANDA No. 212247 was, *inter alia*, 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 Product with its proposed labeling prior to the expiration of the '310 patent.

36. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 212247, *i.e.*, prior to the expiration of the '310 patent.

37. On information and belief, the manufacture, use (including in accordance with and as directed by Teva's proposed labeling for Teva's ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product will infringe at least claim 1 of the '310 patent.

38. In Teva's Notice Letter, Teva did not contest that the use of Teva's ANDA Product in accordance with its proposed labeling would infringe claims 1-4 of the '310 patent.

39. Teva has knowledge of the claims of the '310 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 Product with its proposed labeling immediately and imminently upon approval of ANDA No. 212247. On information and belief, by such activities, Teva specifically intends to infringe the '310 patent.

40. On information and belief, Teva plans and intends to, and will, actively induce infringement of the '310 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, Teva knows that Teva's ANDA Product with its proposed labeling is especially made or adapted for use in infringing the '310 patent, and that Teva's ANDA Product with its proposed labeling is not suitable for substantial noninfringing use. On information and belief, Teva plans and intends to, and will, contribute to infringement of the '310 patent immediately and imminently upon approval of ANDA No. 212247.

42. Teva's submission of ANDA No. 212247 and submission of an amendment to that ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product were acts of infringement of the '310 patent under 35 U.S.C. § 271(e)(2).

43. 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 Product with its proposed labeling prior to the expiration of the '310 patent.

44. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

45. The foregoing actions by Teva constitute and/or will constitute infringement of the '310 patent, active inducement of infringement of the '310 patent, and/or contribution to the infringement by others of the '310 patent.

46. Unless Teva is enjoined from infringing the '310 patent, actively inducing infringement of the '310 patent, and contributing to the infringement by others of the '310 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

47. This action is being commenced before the expiration of forty-five days from the date Bayer and Janssen received Teva's Notice Letter.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '310 PATENT

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

49. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Teva on the other regarding Teva's liability for infringement and active inducement of infringement of the '310 patent.

50. An actual case or controversy exists between Plaintiffs and Teva with respect to Teva's liability for infringement of the '310 patent.

51. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Teva's ANDA Product will infringe and induce the infringement of the '310 patent.

* * *

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Teva has infringed the '310 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 Product, or any product or compound the use of which infringes the '310 patent, be no earlier than the expiration date of the '310 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 Product, or any product or compound the use of which infringes the

'310 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '310 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Teva's ANDA Product prior to the expiration of the '310 patent will infringe and induce the infringement of the '310 patent;

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

(f) An award of Plaintiffs' costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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