

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BAYER INTELLECTUAL PROPERTY
GMBH, BAYER AG, and JANSSEN
PHARMACEUTICALS, INC.,

Plaintiffs,

V.

CHANGZHOU PHARMACEUTICAL
FACTORY,

Defendant.

: Civil Action No.: _____

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 Changzhou Pharmaceutical Factory (“Changzhou”), 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’ 10 mg, 15 mg, and 20 mg 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.

Changzhou

5. Upon information and belief, Changzhou is a corporation organized and existing under the laws of China, having a principal place of business at No. 518 Laodong East Road Changzhou, Jiangsu, 213018 China.

6. Upon information and belief, Changzhou 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, Changzhou 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, Changzhou 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.

7. Upon information and belief, Changzhou prepared and submitted ANDA No. 216995 for Changzhou's 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Changzhou's ANDA Products").

8. Upon information and belief, following any FDA approval of ANDA No. 216995, Changzhou will market, distribute, offer for sale, and sell Changzhou's ANDA Products throughout the United States, including within New Jersey.

9. Upon information and belief, following any FDA approval of ANDA No. 216995, Changzhou knows and intends that Changzhou's ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States, including in New Jersey.

JURISDICTION

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

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

12. This Court has personal jurisdiction over Changzhou because, among other things, upon information and belief: (1) Changzhou 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 Changzhou's ANDA Products in the United States, including in New Jersey; (2) Changzhou will market, distribute, offer for sale, and/or sell Changzhou's ANDA Products in the United States, including in New Jersey, upon approval of ANDA No. 216995, and will derive substantial revenue from the use or consumption of Changzhou's ANDA Products in the State of New Jersey; and (3)

with respect to its Paragraph IV Certification for ANDA No. 216995, Changzhou designated as an agent for service of process a person located in this District, namely, Andrew J. Miller of Windels Marx Lane & Mittendorf, LLP, 1 Giralda Farms, Suite 100, Madison, NJ 07940. Upon information and belief, if ANDA No. 216995 is approved, the generic Changzhou products charged with infringing the '218 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in New Jersey, prescribed by physicians practicing in New Jersey, and dispensed by pharmacies located within New Jersey, and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

13. If Changzhou's connections with New Jersey are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Changzhou is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Changzhou in New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2). Relatedly, Changzhou sent the Changzhou Notice Letter (defined below) to Janssen in the United States, specifically in this district. In this Notice Letter, Changzhou provided an agent for service "[p]ursuant to 21 C.F.R. 314.95(c)(9)," which applies "[i]f the applicant does not reside or have a place of business in the United States."

VENUE

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

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

FACTUAL BACKGROUND

16. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor indicated (i) to reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation; (ii) for treatment of deep vein thrombosis (DVT); (iii) for treatment of pulmonary embolism (PE); (iv) for the reduction in the risk of recurrence of DVT and/or PE in adult 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 adult patients undergoing knee or hip replacement surgery; (vi) for the prophylaxis of venous thromboembolism (VTE) and VTE related death during hospitalization and post hospital discharge in adult patients admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE and not at high risk of bleeding; (vii) in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular death, myocardial infarction, and stroke) in adult patients with coronary artery disease (CAD); (viii) in combination with aspirin, to reduce the risk of major thrombotic vascular events (myocardial infarction, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in adult patients with peripheral artery disease (PAD), including patients who have recently undergone a lower extremity revascularization due to symptomatic PAD; (ix) for the treatment of VTE and the reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years after at least 5 days of initial parenteral anticoagulant treatment; (x) for thromboprophylaxis in pediatric patients aged 2 years and older with congenital heart disease who have undergone the Fontan procedure. XARELTO® is available as tablets in 2.5 mg, 10 mg, 15 mg, and 20 mg dosage strengths.

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

The '218 Patent

18. 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.

19. 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.”

20. BIP is the assignee of the ’218 patent.

21. Bayer AG is an exclusive licensee under the ’218 patent.

22. Janssen is an exclusive sublicensee under the ’218 patent.

23. Pursuant to 21 U.S.C. § 355, the ’218 patent is listed in the Orange Book in connection with XARELTO® tablets in 10 mg, 15 mg, and 20 mg dosage strengths.

Infringement by Changzhou

24. By letter dated February 28, 2022, (the “Changzhou Notice Letter”), Changzhou notified BIP and Janssen, among others, that Changzhou had submitted to the FDA

ANDA No. 216995 for Changzhou's ANDA Products. These products are generic versions of XARELTO®.

25. In the Changzhou Notice Letter, Changzhou stated that Changzhou's ANDA Products contain rivaroxaban.

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

27. Upon information and belief, the proposed labeling for Changzhou's ANDA Products directs the use of Changzhou's ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation; (ii) for treatment of deep vein thrombosis (DVT); (iii) for treatment of pulmonary embolism (PE); (iv) for the reduction in the risk of recurrence of DVT and/or PE in adult 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 adult patients undergoing knee or hip replacement surgery; (vi) for the prophylaxis of venous thromboembolism (VTE) and VTE related death during hospitalization and post hospital discharge in adult patients admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE and not at high risk of bleeding. Upon information and belief, the proposed labeling for Changzhou's ANDA Products further directs the use of Changzhou'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.

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

29. In the Changzhou Notice Letter, Changzhou indicated that, in connection with its ANDA No. 216995, Changzhou had filed Paragraph IV Certifications with respect to the '218 patent.

30. The purpose of ANDA No. 216995 was to obtain approval under the Food Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Changzhou's ANDA Products with their proposed labeling prior to the expiration of the '218 patent.

31. Changzhou intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 216995, *i.e.*, prior to the expiration of the '218 patent.

32. Changzhou has knowledge of the claims of the '218 patent. Notwithstanding this knowledge, Changzhou has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 216995. Upon information and belief, by such activities, Changzhou specifically intends infringement of the '218 patent.

33. Upon information and belief, Changzhou 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.

34. Upon information and belief, Changzhou knows that Changzhou's ANDA Products are especially made or adapted for use in infringing the '218 patent, and that Changzhou's ANDA Products are not suitable for substantial noninfringing use. Changzhou's ANDA Products are a material part of the claimed invention. Upon information and belief, Changzhou plans and intends to, and will, contribute to infringement of the '218 patent immediately and imminently upon approval of ANDA No. 216995.

35. The foregoing actions by Changzhou 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.

36. An actual case or controversy exists between Plaintiffs and Changzhou with respect to infringement of the '218 patent.

37. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Changzhou Notice Letter (not earlier than March 2, 2022).

COUNT I
(Infringement of the '218 Patent)

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

39. Changzhou's submission of ANDA No. 216995 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of

Changzhou's ANDA Products was an act of infringement of the '218 patent under 35 U.S.C. § 271(e)(2).

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

41. Changzhou intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 216995, *i.e.*, prior to the expiration of the '218 patent.

42. The foregoing actions by Changzhou 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. Unless Changzhou 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.

COUNT II
(Declaratory Judgment of Infringement of the '218 Patent)

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

45. 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 Changzhou on the other regarding Changzhou's liability for infringement, active inducement of, and contribution to infringement of the '218 patent.

46. An actual case or controversy exists between Plaintiffs and Changzhou with respect to Changzhou's liability for infringement of the '218 patent.

47. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Changzhou's ANDA Products will infringe, induce the infringement of, and contribute to the infringement of the '218 patent.

* * *

WHEREFORE, Plaintiffs request the following relief:

- (a) A judgment that Changzhou has infringed the '218 patent;
- (b) A judgment ordering that the effective date of any FDA approval for Changzhou to make, use, offer for sale, sell, market, distribute, or import Changzhou'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 Changzhou, and all persons acting in concert with Changzhou, from making, using, selling, offering for sale, marketing, distributing, or importing Changzhou'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 judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Changzhou's ANDA Products prior to the expiration of the '218 patent will infringe and induce the infringement of the '218 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.

Dated: April 11, 2022

s/ Keith J. Miller

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, the undersigned, attorney of record for Plaintiffs, hereby certifies that to the best of my knowledge and based upon the information available to me, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: April 11, 2022

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