IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BAYER PHARMA AG, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 1:22-cv-63 (Kleeh)
MYLAN PHARMACEUTICALS INC., and MYLAN INC.,	)	
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 by Mylan Pharmaceuticals 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 Mylan Pharmaceuticals Inc. ("MPI") is a corporation organized and existing under the laws of the State of West Virginia with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, MPI is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

6. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania with its principal place of business at 1000 Mylan Blvd., Canonsburg, PA 15317. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including MPI.

7. On information and belief, MPI is a wholly owned subsidiary of Mylan Inc. MPI and Mylan Inc. are collectively referred to herein as "Mylan." Mylan has admitted in pending patent litigation concerning infringement of the '310 patent that MPI is a wholly-owned subsidiary of Mylan Inc. *See Bayer Pharma AG et al. v. Mylan Pharmaceuticals Inc. et al.*, C.A. No. 21-cv-99 (N.D.W. Va. November 1, 2021) ("Pending Infringement Action"), D.I. 53 at ¶ 7.

8. On information and belief, MPI and Mylan Inc. know and intend that upon approval of Mylan's ANDA, MPI and Mylan Inc. will manufacture, market, sell, and distribute Mylan's ANDA Product (defined below) throughout the United States, including in West Virginia. On information and belief, MPI and Mylan Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Mylan's ANDA Product, and enter into agreements that are nearer than arm's length. On information and belief, MPI and Mylan Inc. participated, assisted, and cooperated in carrying out the acts complained of herein.

9. On information and belief, MPI and Mylan Inc. acted in concert to prepare and submit ANDA No. 212220 for Mylan's 2.5 mg rivaroxaban tablets ("Mylan's ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Mylan Inc.

10. On information and belief, following any FDA approval of ANDA No. 212220, MPI and Mylan Inc. will act in concert to market, distribute, offer for sale, and sell Mylan's ANDA Product throughout the United States and within West Virginia.

JURISDICTION

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

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

13. MPI is subject to personal jurisdiction in West Virginia because, among other things, it has purposely availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here. MPI is a corporation formed under the laws of the State of West Virginia, is qualified to do business in the State of West Virginia, and has appointed a registered agent in West Virginia to accept service of process. MPI has thus consented to jurisdiction in West Virginia. In addition, on information and belief, MPI develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of West Virginia, and therefore transacts business within the State of West Virginia related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of West Virginia. Mylan has not, in particular, contested personal jurisdiction in West Virginia in related patent litigation in this district concerning infringement of the '310 Patent. *See* Pending Infringement Action, D.I. 53 at ¶ 13.

14. Mylan Inc. is subject to personal jurisdiction in West Virginia because, among other things, Mylan Inc., itself and through its wholly owned subsidiary MPI, has purposefully availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Inc., itself and through its wholly owned subsidiary MPI, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of West Virginia, and therefore transacts business within the State of West Virginia, and/or has engaged in systematic and continuous business contacts within the State of West Virginia. In addition, Mylan Inc. is subject to personal jurisdiction in West Virginia because, on information

and belief, it controls and dominates MPI, and therefore the activities of MPI in this jurisdiction are attributed to Mylan Inc. Mylan has not, in particular, contested personal jurisdiction in West Virginia in related patent litigation in this district concerning infringement of the '310 Patent. *See* Pending Infringement Action, D.I. 46 at ¶ 14.

15. In addition, this Court has personal jurisdiction over MPI and Mylan Inc. because, among other things, on information and belief: (1) MPI, acting in concert with Mylan Inc., 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 Mylan's ANDA Product in the United States, including in West Virginia; and (2) MPI and Mylan Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Mylan's ANDA Product in the United States, including in West Virginia, upon approval of ANDA No. 212220, and will derive substantial revenue from the use or consumption of Mylan's ANDA Product in the State of West Virginia. On information and belief, if ANDA No. 212220 is approved, the generic Mylan product charged with infringing the '310 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in West Virginia, prescribed by physicians practicing in West Virginia, and dispensed by pharmacies located within West Virginia, and/or used by patients in West Virginia, all of which would have a substantial effect on West Virginia.

16. On information and belief, Mylan derives substantial revenue from generic pharmaceutical products that are used and/or consumed within West Virginia, and that are manufactured by Mylan and/or for which MPI and/or Mylan Inc. is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which MPI and/or Mylan Inc. is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in West Virginia.

VENUE

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

18. Venue is proper in this district as to MPI pursuant to 28 U.S.C. § 1400(b) because, *inter alia,* MPI is a corporation organized and existing under the laws of the State of West Virginia and is subject to personal jurisdiction in this judicial district. Mylan has not, in particular, contested venue in West Virginia in related patent litigation in this district concerning infringement of the '310 Patent. *See* Pending Infringement Action, D.I. 53 at ¶ 18.

19. Venue is proper in this district as to Mylan Inc. pursuant to 28 U.S.C. § 1400(b) because, *inter alia,* Mylan Inc. is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district, *see, e.g.*, C.A. Nos. 20-cv-52-IMK, 18-cv-202-IMK, 18-cv-193-IMK, and, on information and belief, is subject to venue in this judicial district and/or will consent to venue for the purpose of this case. Mylan Inc. is registered to do business in West Virginia, with Organization ID No. 230499. Furthermore, on information and belief, substantial preparation of ANDA No. 212220, and/or the direction of the preparation of ANDA No. 212220, took place in this district. Mylan has not, in particular, contested venue in West Virginia in related patent litigation in this district concerning infringement of the '310 Patent. *See* Pending Infringement Action, D.I. 53 at ¶ 19.

FACTUAL BACKGROUND

20. 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).

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

22. 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.

23. 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."

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

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

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

27. 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

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

29. By letter dated June 1, 2021 (the "Mylan's First Notice Letter"), Mylan notified Bayer Pharma AG and Janssen that MPI had submitted to the FDA ANDA No. 212220 for Mylan's ANDA Product. This product is a generic version of the 2.5 mg strength of XARELTO®.

30. In Mylan's First Notice Letter, Mylan also indicated that, in connection with its ANDA No. 212220, MPI had filed a Paragraph IV Certification with respect to the '310 patent.

31. In Mylan's First Notice Letter, Mylan stated that Mylan's ANDA Product contains rivaroxaban.

32. After receiving Mylan's First Notice Letter, Bayer and Janssen sued Mylan for infringement of the '310 patent on July 22, 2021 in this district. *See* Pending Infringement Action, D.I. 1.

33. The Joint Panel on Multidistrict Litigation granted Bayer and Janssen's motion to transfer the Pending Infringement Action to the U.S. District Court for the District of Delaware for consolidated pre-trial proceedings in a Hatch-Waxman Multi-District Litigation proceeding before Judge Richard A. Andrews, captioned *In re: Xarelto (Rivaroxaban) ('310) Patent Litigation*, MDL No. 21-MD-3017.

34. By letter dated June 21, 2022 ("Mylan's Second Notice Letter"), Mylan notified Bayer and Janssen that it had submitted ANDA No. 212220 "to engage in the commercial manufacture, use, or sale of the proposed rivaroxaban product before the expiration of . . . the '310 [p]atent . . . ." On information and belief, Mylan's ANDA No. 212220 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '310 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product. Mylan's Second Notice Letter indicates that Mylan seeks

approval from the FDA to engage in the commercial manufacture, use and/or sale of Mylan's ANDA Product prior to the expiration of the '310 patent.

35. On information and belief, and in light of Mylan's Second Notice Letter, the proposed labeling for Mylan'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) and/or peripheral artery disease (PAD). On information and belief, and in light of Mylan's Second Notice Letter, the proposed labeling for Mylan's ANDA Product further directs the administration of Mylan'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 Mylan's ANDA Product will be administered twice daily and aspirin is administered in an amount of 75-100 mg daily.

36. The purpose of ANDA No. 212220 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 Mylan's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

37. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 212220, *i.e.*, prior to the expiration of the '310 patent.

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

39. In Mylan's Second Notice Letter, as in Mylan's First Notice Letter, Mylan did not contest infringement of the '310 patent on any basis other than that the claims of the '310 patent were allegedly invalid.

40. Mylan now has, and has had since the date of Mylan's First Notice Letter, knowledge of the claims of the '310 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 212220. On information and belief, by such activities, Mylan specifically intends to infringe the '310 patent.

41. On information and belief, and in light of Mylan's Second Notice Letter, Mylan plans and intends to, and will, actively induce infringement of the '310 patent when its ANDA No. 212220 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

42. On information and belief, and in light of Mylan's Second Notice Letter, Mylan knows that Mylan's ANDA Product with its proposed labeling is especially made or adapted for use in infringing the '310 patent, and that Mylan's ANDA Product with its proposed labeling is not suitable for substantial noninfringing use. On information and belief, and in light of Mylan's Second Notice Letter, Mylan plans and intends to, and will, contribute to infringement of the '310 patent immediately and imminently upon approval of ANDA No. 212220.

43. Mylan's submission of ANDA No. 212220 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product was an act of infringement of the '310 patent under 35 U.S.C. § 271(e)(2).

44. On information and belief, and in light of Mylan's Second Notice Letter, Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Mylan's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

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

46. The foregoing actions by Mylan 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.

47. Unless Mylan 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.

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

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

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

50. 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 Mylan on the other regarding Mylan's liability for infringement and active inducement of infringement of the '310 patent.

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

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

* * *

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Mylan has infringed the '310 patent;

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

August 5, 2022

/s/*Chad L. Taylor*

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