

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

**BAYER PHARMA AG, BAYER AG, and
JANSSEN PHARMACEUTICALS, INC.,**

Plaintiffs,

V.

MYLAN PHARMACEUTICALS INC., and
MYLAN INC.,

Defendants.

C.A. No. 1:22-cv-63 (Kleeh)

ELECTRONICALLY
FILED
8/5/2022
U.S. DISTRICT COURT
Northern District of WV

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.



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