UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: XARELTO (RIVAROXABAN) ('310) PATENT LITIGATION MDL No. 3017

TRANSFER ORDER

Before the Panel: Plaintiffs Bayer and Janssen[1] move under 28 U.S.C. § 1407 to centralize pretrial proceedings in this litigation in the District of Delaware.[2] This litigation consists of five actions pending in two districts, as listed on Schedule A. Defendants Mylan and Lupin do not oppose the motion for centralization. Defendants Dr. Reddy's, Taro, and Teva did not respond to the motion and, therefore, are deemed to acquiesce to it. *See* Panel Rule 6.1(c).

Bayer and Janssen filed these actions after the various generic drug manufacturer defendants submitted Abbreviated New Drug Applications (ANDAs) seeking approval by the U.S. Food and Drug Administration (FDA) to make and sell generic versions of Xarelto (rivaroxaban) 2.5 mg tablets, a prescription drug indicated for administration orally twice daily, in combination with aspirin, to reduce the risk of major cardiovascular events in patients with chronic coronary artery disease or peripheral artery disease. All of the actions are Hatch-Waxman[3] patent

[1] Bayer Pharma AG and Bayer AG (together, Bayer) and Janssen Pharmaceuticals, Inc.

[2] Defendants in this litigation are Lupin Limited and Lupin Pharmaceuticals, Inc. (Lupin); Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (Dr. Reddy's); Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (Taro); Teva Pharmaceuticals USA, Inc. (Teva); and Mylan Pharmaceuticals Inc. and Mylan Inc. (Mylan).

[3] Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act"), Congress established an incentive for companies to bring generic versions of branded drugs to market faster than they otherwise might by granting the first company to file an ANDA an "exclusivity period" of 180 days, during which the FDA may not approve for sale any competing generic version of the drug. *See Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1304-05 (D.C. Cir. 2010). Submitting an ANDA with a "paragraph IV certification" – stating that the patents listed in the FDA's Orange Book as covering the previously approved drug are invalid or will not be infringed by the generic drug – constitutes a statutory act of infringement that creates subject-matter jurisdiction for a district court to resolve any disputes regarding patent infringement or validity before the generic drug is sold. *See* 35 U.S.C. § 271(e)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-78 (1990). If the patent-holder initiates an infringement action against the ANDA filer within 45 days of receipt of the paragraph IV certification, then the FDA may not approve the ANDA until the earlier of either 30 months or the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

infringement lawsuits, in which the plaintiffs allege that each defendant has infringed one or more claims of the applicable U.S. Patent[4] by filing ANDAs seeking FDA approval to market generic Xarelto 2.5 mg tablets in the United States.

On the basis of the papers filed,[5] we find that these actions involve common questions of fact, and that centralization in the District of Delaware will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. These actions involve substantially similar claims that defendants infringed one or more claims of the same patent concerning Xarelto (rivaroxaban) 2.5 mg tablets in seeking FDA approval to market generic versions of the drug in the United States. Centralization is warranted to eliminate duplicative discovery, prevent inconsistent rulings (particularly with respect to claim construction and issues of patent validity), and conserve the resources of the parties, their counsel and the judiciary.

We recently centralized similar litigations, citing "the complexity of the allegations and regulatory framework governing Hatch-Waxman cases, as well as the need for swift progress in litigation involving the potential entry of generic drugs into the market." *See In re Entresto (Sacubitril/Valsartan) Patent Litig.*, 437 F. Supp. 3d 1372, 1373 (J.P.M.L. 2020) (quoting *In re Palbociclib Patent Litig.*, 396 F. Supp. 3d 1360, 1361-62 (J.P.M.L. 2019)); *see also In re Kerydin (Tavaborole) Topical Solution 5% Patent Litig.*, 366 F. Supp. 3d 1370, 1371 (J.P.M.L. 2019). We are persuaded that centralization of these cases similarly will lead to their efficient resolution.

We select the District of Delaware as the transferee district for these actions. The moving plaintiffs and all responding defendants support centralization in this district. Additionally, all but one of the five related actions are pending there. We are confident that the Honorable Richard G. Andrews, who is well-versed in complex patent litigation, will steer this matter on a prudent course.

IT IS THEREFORE ORDERED that the action listed on Schedule A and pending outside the District of Delaware is transferred to the District of Delaware and, with the consent of that court, assigned to the Honorable Richard G. Andrews for coordinated or consolidated pretrial proceedings.

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[4] U.S. Patent No. 10,828,310 (the '310 patent), entitled "Reducing the Risk of Cardiovascular Events."

[5] All responding parties waived oral argument.

PANEL ON MULTIDISTRICT LITIGATION

Karen K. Caldwell
Chair

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David C. Norton
Dale A. Kimball
Matthew F. Kennelly
Roger T. Benitez
Madeline Cox Arleo

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SCHEDULE A

District of Delaware

BAYER PHARMA AG, ET AL. v. LUPIN LIMITED, ET AL., C.A. No. 1:21−00314
BAYER PHARMA AG, ET AL. v. DR. REDDYS LABORATORIES, LTD., ET AL., C.A. No. 1:21−00732
BAYER PHARMA AG, ET AL. v. TARO PHARMACEUTICAL INDUSTRIES LTD., ET AL., C.A. No. 1:21−01000
BAYER PHARMA AG, ET AL. v. TEVA PHARMACEUTICALS USA, INC., C.A. No. 1:21−01001

Northern District of West Virginia

BAYER PHARMA AG, ET AL. v. MYLAN PHARMACEUTICALS, INC., ET AL., C.A. No. 1:21−00099