UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: AURYXIA (FERRIC CITRATE) PATENT LITIGATION MDL No. 2896

TRANSFER ORDER

Before the Panel: Plaintiffs and patentholders Keryx Biopharmaceuticals, Inc., Panion & BF Biotech, Inc., and Chen Hsing Hsu (together, Keryx) move under 28 U.S.C. § 1407 to centralize pretrial proceedings in this litigation in the District of Delaware. This litigation consists of four actions pending in two districts, as listed on Schedule A. The Panel has been notified that plaintiffs have filed another two potentially related actions in the District of Delaware.[1] Responding generic manufacturer defendants do not oppose the motion.[2]

Keryx filed these actions after the 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 Auryxia (ferric citrate), which is used in the treatment of adults with chronic kidney disease. The actions on the motion are a series of Hatch-Waxman[3] patent infringement lawsuits, in which Keryx alleges that each of the defendants

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[1] These and any other related actions are potential tag-along actions. *See* Panel Rules 1.1(h), 7.1, and 7.2.

[2] Mylan Pharmaceuticals Inc.; Chemo Research S.L.; and Insud Pharma S.L.U.; Lupin Atlantis Holdings SA; and Lupin Limited. Defendant Teva Pharmaceuticals USA, Inc., did not respond to the motion and, therefore, is deemed to acquiesce to the relief sought. *See* Panel Rule 6.1(c).

[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

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has infringed thirteen or fourteen U.S. Patents[4] by filing ANDAs seeking FDA approval to market generic Auryxia in the United States.

After considering all arguments, 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 identical claims that defendants infringed the Auryxia patents. Centralization is warranted to prevent inconsistent rulings (particularly with respect to claim construction and issues of patent validity) and overlapping pretrial obligations, reduce costs, and create efficiencies for the parties, courts, and witnesses.

We recently centralized a similar litigation, finding that because of "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, placing all actions before a single judge should foster the efficient resolution of all of the actions." *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. All but one of the six related actions are pending in this district. We are confident that the Honorable Leonard P. Stark, who is well-versed in complex patent litigation, will steer this matter on a prudent course.

IT IS THEREFORE ORDERED that the actions listed on Schedule A and pending outside the District of Delaware are transferred to the District of Delaware and, with the consent of that court, assigned to the Honorable Leonard P. Stark for coordinated or consolidated pretrial proceedings.

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[3](...continued)
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).

[4] The patents are U.S. Patent Nos. 7,767,851; 8,093,423; 8,299,298; 8,338,642; 8,609,896; 8,754,257; 8,754,258; 8,846,976; 8,901,349; 9,050,316; 9,328,133; 9,757,416; and 9,387,191. Plaintiffs have also asserted U.S. Patent No. 5,753,706 against every defendant except Teva.

PANEL ON MULTIDISTRICT LITIGATION

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SCHEDULE A

District of Delaware

KERYX BIOPHARMACEUTICALS, INC., ET AL. v. LUPIN LTD., ET AL., C.A. No. 1:18-01968
KERYX BIOPHARMACEUTICALS, INC., ET AL. v. TEVA PHARMACEUTICALS USA, INC., C.A. No. 1:18-02012
KERYX BIOPHARMACEUTICALS, INC., ET AL. v. CHEMO RESEARCH S.L., ET AL., C.A. No. 1:19-00220

Northern District of West Virginia

KERYX BIOPHARMACEUTICALS, INC., ET AL. v. MYLAN PHARMACEUTICALS INC., C.A. No. 1:19-00040