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UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

19 Md 2884
FILED
APR - 4 2019
U.S. DISTRICT COURT-WVND
WHEELING, WV 26003

IN RE: KERYDIN (TAVABOROLE) TOPICAL SOLUTION 5% PATENT LITIGATION

MDL No. 2884

TRANSFER ORDER

Before the Panel:[*] Plaintiff and patentholder Anacor Pharmaceuticals, Inc., invokes 28 U.S.C. § 1407 to seek centralization of this patent infringement litigation in the District of Delaware. This litigation consists of three actions pending in two districts, as listed on Schedule A. Generic manufacturer defendants[2] in two D. Delaware actions do not oppose centralization in the District of Delaware. Mylan Inc., and Mylan Pharmaceuticals Inc. (collectively, Mylan), which are defendants in the Northern District of West Virginia action, oppose centralization.

Anacor filed these actions after 22 generic drug manufacturers submitted a total of fourteen Abbreviated New Drug Applications (ANDAs) seeking approval by the U.S. Food and Drug Administration (FDA) to make and sell generic versions of Kerydin (tavaborole) topical solution 5%, a topical antifungal that is used to treat toenail fungus. The actions on the motion are a series of Hatch-Waxman[3] patent infringement lawsuits, in which Anacor alleges that each of the 22 total

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[*] Judge Ellen Segal Huvelle did not participate in the decision of this matter.

[2] Aleor Dermaceuticals Limited, Apotex Corp., Apotex Inc., Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Cadila Healthcare Ltd., Cipla Limited, Cipla USA, Inc., Perrigo Company plc, Perrigo Pharma International DAC, Taro Pharmaceutical Industries, Ltd., Taro Pharmaceuticals U.S.A., Inc., Zydus Pharmaceuticals (USA) Inc., Encube Ethicals Pvt. Ltd., Glasshouse Pharmaceuticals Limited Canada, Lupin Limited, and Lupin Pharmaceuticals, Inc.

[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

(continued...)

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defendants has infringed four U.S. Patents[4] by filing ANDAs seeking FDA approval to market generic tavaborole in the United States.

On the basis of the papers filed and hearing held, 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. All actions involve substantially identical claims that defendants infringed the four Kerydin 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.

Mylan opposes centralization, arguing that there are too few actions to justify centralization and that informal coordination among the parties and involved judges is an adequate alternative to formal centralization. We are not persuaded by these arguments. Even though only three actions are pending in this litigation, we have long acknowledged that "actions involving the validity of complex pharmaceutical patents and the entry of generic versions of the patent holder's drugs are particularly well-suited for transfer under Section 1407." *In re: Alfuzosin Hydrochloride Patent Litig.*, 560 F. Supp. 2d 1372, 1372 (J.P.M.L. 2008). For that reason, we have centralized litigation consisting of only two Hatch-Waxman Act cases.[5] Given 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.

We select the District of Delaware as the appropriate transferee district for these actions. The claims of thirteen of the fourteen ANDA filers are pending in this district. We are confident that Judge Richard G. Andrews, who is well-versed in complex patent litigation, will steer this matter on a prudent course.

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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 No. 9,459,938, U.S. Patent No. 9,566,289, U.S. Patent No. 9,566,290, and U.S. Patent No. 9,572,823.

[5] *See, e.g., In re: Armodafinil Patent Litig.*, 755 F. Supp. 2d 1359 (J.P.M.L. 2010) (centralizing two Hatch-Waxman cases); *In re: Brimonidine Patent Litig.*, 507 F. Supp. 2d 1381 (J.P.M.L. 2007) (same); *In re: Metoprolol Succinate Patent Litig.*, 329 F. Supp. 2d 1368 (J.P.M.L. 2004) (same).

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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 Richard G. Andrews for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION

Sarah Vance

Sarah S. Vance
Chair

Lewis A. Kaplan
Catherine D. Perry
Nathaniel M. Gorton

R. David Proctor
Karen K. Caldwell

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SCHEDULE A

District of Delaware

ANACOR PHARMACEUTICALS, INC. v. LUPIN LIMITED, ET AL., C.A. No. 1:18-01606
ANACOR PHARMACEUTICALS, INC. v. ASCENT PHARMACEUTICALS, INC., ET AL., C.A. No. 1:18-01673

Northern District of West Virginia

ANACOR PHARMACEUTICALS, INC. v. MYLAN PHARMACEUTICALS INC., ET AL., C.A. No. 1:18-00202

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