UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: ENTRESTO (SACUBITRIL/VALSARTAN) PATENT LITIGATION MDL No. 2930

TRANSFER ORDER

Before the Panel:[*] Plaintiff and patentholder Novartis Pharmaceuticals Corporation (Novartis) moves 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 of one related action in the District of Delaware.[1] All responding defendants support, or do not oppose, the motion for centralization.[2]

Novartis 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 Entresto (sacubitril/valsartan), a prescription drug used in the treatment of heart failure. The actions on the motion are a series of Hatch-Waxman[3] patent infringement lawsuits, in which Novartis alleges that each of the defendants

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[*] Judge Karen K. Caldwell did not participate in the decision of this matter.

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

[2] Alembic Pharmaceuticals Limited; Alembic Global Holding SA; Alembic Pharmaceuticals, Inc.; Alkem Laboratories Ltd.; Aurobindo Pharma USA Inc.; Aurobindo Pharma Ltd.; Biocon Pharma Limited; Biocon Limited; Biocon Pharma, Inc.; Crystal Pharmaceutical (Suzhou) Co., Ltd.; Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd.; Hetero USA Inc.; Hetero Labs Limited; Hetero Labs Limited Unit III; Laurus Labs Limited; Laurus Generics Inc.; Lupin Atlantis Holdings, S.A.; Lupin Limited, Lupin Inc.; Lupin Pharmaceuticals, Inc.; Macleods Pharmaceuticals Ltd.; Macleods Pharma USA, Inc.; MSN Pharmaceuticals Inc., MSN Laboratories Private Limited; MSN Life Sciences Private Limited; Mylan Pharmaceuticals Inc.; Mylan Inc.; Mylan Laboratories Limited; Novugen Pharma (Malaysia) Sdn. Bhd.; Teva Pharmaceuticals USA, Inc.; Torrent Pharma Inc.; Torrent Pharmaceuticals Ltd.; Zydus Pharmaceuticals (USA) Inc.; and Cadila Healthcare Ltd.

[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

(continued...)

has infringed two or more of the patents covering Entresto by filing ANDAs seeking FDA approval to market generic versions of Entresto in the United States prior to expiration of the patents.

On the basis of the papers filed,[4] 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 two or more of the Entresto patents.[5] 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 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. All but one of the five 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 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

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[3](...continued)
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).

[4] All responding parties waived oral argument.

[5] The patents are U.S. Patents Nos. 8,101,659 (the '659 patent), 8,796,331 (the '331 patent), 8,877,938 (the '938 patent), and 9,388,134 (the '134 patent). Plaintiff alleges that all defendants in all actions infringed the '938 and '134 patents, and that most of the defendants also infringed the '659 and '331 patents.

assigned to the Honorable Leonard P. Stark for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION

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SCHEDULE A

District of Delaware

NOVARTIS PHARMACEUTICALS CORPORATION v. ALKEM LABORATORIES LTD., ET AL., C.A. No. 1:19-01979
NOVARTIS PHARMACEUTICALS CORPORATION v. ALEMBIC PHARMACEUTICALS LIMITED, ET AL., C.A. No. 1:19-02021
NOVARTIS PHARMACEUTICALS CORPORATION v. DR. REDDY'S LABORATORIES, INC., ET AL., C.A. No. 1:19-02053

Northern District of West Virginia

NOVARTIS PHARMACEUTICALS CORPORATION v. MYLAN PHARMACEUTICALS, INC., ET AL., C.A. No. 1:19-00201