3. The parties shall proceed with discovery according to this Court's scheduling order. ECF No. 10.

SO ORDERED on August 21, 2019.

IN RE: SITAGLIPTIN PHOSPHATE ('708 & '921) PATENT LITIGATION

MDL No. 2902

United States Judicial Panel on Multidistrict Litigation.

August 8, 2019

Before SARAH S. VANCE, Chair, LEWIS A. KAPLAN, R. DAVID PROCTOR, CATHERINE D. PERRY, KAREN K. CALDWELL, NATHANIEL M. GORTON, Judges of the Panel.

TRANSFER ORDER

SARAH S. VANCE, Chair

Before the Panel:* Plaintiff and patentholder Merck Sharp & Dohme Corporation moves under 28 U.S.C. § 1407 to centralize pretrial proceedings in this patent infringement litigation in the District of Delaware. This litigation consists of fourteen actions pending in two districts, as listed on Schedule A. Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, Mylan), which are defendants in the Northern District of West Virginia action, do not oppose the motion. Generic manufacturer defendants [1] in thirteen District of Delaware actions take no position on centralization, but if it is ordered, suggest that the District of Delaware serve as the transferee district.

Merck filed these actions after generic drug manufacturers submitted a total of 26 Abbreviated New Drug Applications (ANDAs) seeking approval by the U.S. Food and Drug Administration (FDA) to make and sell generic versions of sitagliptin phosphate drugs, which are popular diabetes medications known as dipeptidyl peptidase-IV (DPP-IV) inhibitors. Sitagliptin phosphate is the active ingredient of Merck's Januvia (sitagliptin phosphate), Janumet (metformin hydrochloride; sitagliptin phosphate), and Janumet XR (metformin hydrochloride; sitagliptin phosphate extended release tablets) drug products. The actions on the motion are a series of Hatch-Waxman [2] patent infringement law-

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

1. Alvogen Pine Brook LLC f/k/a Alvogen Pine Brook, Inc. and Alvogen Malta Operations Ltd.; Anchen Pharmaceuticals, Inc. and Par Pharmaceutical, Inc.; Sandoz Inc.; Apotex Inc. and Apotex Corp.; Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd.; Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.; Watson Laboratories, Inc. and Teva Pharmaceuticals USA, Inc.; Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd.; Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.; Wockhardt Bio AG and Wockhardt USA LLC; and Lupin Ltd. and Lupin Pharmaceuticals, Inc.

2. 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

suits, in which Merck alleges that each of the defendants has infringed two U.S. Patents [3] by filing an ANDA seeking FDA approval to market generic sitagliptin phosphate 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 two Merck patents. Centralization is warranted to prevent inconsistent rulings (particularly with respect to claim construction and issues of patent validity) and overlapping pretrial obligations, to reduce costs, and to create efficiencies for the parties, courts, and witnesses.

Although the cases in this litigation are pending in only two districts, 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). Given the complexity of the allegations and regulatory framework governing Hatch-Waxman cases, as well as the need for swift progress in this litigation that involves the potential entry of generic diabetes drugs into the market, placing all actions before a single judge should foster the efficient resolution of all the actions.

We select the District of Delaware as the appropriate transferee district for these actions. Thirteen of the fourteen actions 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.

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.

SCHEDULE A

MDL No. 2902 — **IN RE: SITAGLIPTIN PHOSPHATE ('708 & '921) PATENT LITIGATION**

District of Delaware

MERCK SHARP & DOHME CORP. v. ALVOGEN PINE BROOK LLC, ET AL., C.A. No. 1:19–00310

MERCK SHARP & DOHME CORP. v. ANCHEN PHARMACEUTICALS, INC., ET AL., C.A. No. 1:19–00311

MERCK SHARP & DOHME CORP. v. SANDOZ INC., C.A. No. 1:19–00312

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, 110 S.Ct. 2683, 110 L.Ed.2d 605 (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).

3. The patents are U.S. Patent Nos. 7,326,708 and 8,414,921, which disclose and claim, *inter alia*, sitagliptin phosphate and various polymorphic forms of the molecule, as well as formulations combining sitagliptin phosphate with metformin, another diabetes drug, respectively.

SCHEDULE A—Continued

MERCK SHARP & DOHME CORP. v. APOTEX INC., ET AL., C.A. No. 1:19–00313

MERCK SHARP & DOHME CORP. v. ZYDUS PHARMACEUTICALS (USA) INC., ET AL., C.A. No. 1:19–00314

MERCK SHARP & DOHME CORP. v. MACLEODS PHARMACEUTICALS LIMITED, ET AL., C.A. No. 1:19–00316

MERCK SHARP & DOHME CORP. v. WATSON LABORATORIES, INC., ET AL., C.A. No. 1:19–00317

MERCK SHARP & DOHME CORP. v. TEVA PHARMACEUTICALS USA, INC., C.A. No. 1:19–00318

MERCK SHARP & DOHME CORP. v. SUN PHARMA GLOBAL FZE, ET AL., C.A. No. 1:19–00319

MERCK SHARP & DOHME CORP. v. TORRENT PHARMACEUTICALS LIMITED, ET AL., C.A. No. 1:19–00320

SCHEDULE A—Continued

MERCK SHARP & DOHME CORP. v. WOCKHARDT BIO AG, ET AL., C.A. No. 1:19–00321

MERCK SHARP & DOHME CORP. v. LUPIN LIMITED, ET AL., C.A. No. 1:19–00347

MERCK SHARP & DOHME CORP. v. TORRENT PHARMACEUTICALS LIMITED, ET AL., C.A. No. 1:19–00872

Northern District of West Virginia

MERCK SHARP & DOHME CORP. v. MYLAN PHARMACEUTICALS, INC., ET AL., C.A. No. 1:19–00101