IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: Sitagliptin Patent Litigation	MDL No. _____

MEMORANDUM IN SUPPORT OF MOTION
TO TRANSFER ACTION TO THE DISTRICT OF DELAWARE

Pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, Merck Sharp & Dohme Corp. ("Merck") hereby moves to transfer *Merck Sharp & Dohme Corp. v. Mylan Pharmaceuticals Inc., and Mylan Inc.*, Case No. 1:19-cv-00101-IMK, pending in the U.S. District Court for the Northern District of West Virginia, to Judge Andrews in the U.S. District Court for the District of Delaware for coordinated and consolidated pretrial proceedings with thirteen actions already pending before Judge Andrews in the District of Delaware.

BACKGROUND

Sitagliptin phosphate was the first dipeptidyl peptidase-IV ("DPP-IV") inhibitor approved by the U.S. Food & Drug Administration ("FDA") for the treatment of type 2 diabetes and 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. Merck owns U.S. Patent No. 7,326,708 ("the '708 patent") and U.S. Patent No. 8,414,921 ("the '921 patent"), 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. Merck has listed the '708 patent in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for JANUVIA®, JANUMET®, and JANUMET XR®, and has listed the '921 patent for JANUMET®.

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To date, Merck has received notice of at least twenty-six Abbreviated New Drug Applications ("ANDAs"), filed by various generic pharmaceutical drug companies, seeking FDA approval to market generic versions of JANUVIA®, JANUMET®, and JANUMET XR® prior to the expiration of Merck's patents. According to these notice letters, the ANDAs contain certifications under the Hatch-Waxman Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '708 and '921 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the respective generic products. In response, Merck filed fourteen separate actions in the U.S. District Court for the District of Delaware alleging that submission of the these ANDAs constituted infringement of the '708 and '921 patents (collectively, the "patents-in-suit"). *See* note 1, *infra*.

On March 21, 2019, Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan") moved to dismiss Merck's action against Mylan in Delaware for improper venue. *See* Case No. 1:19-cv-00315-RGA, D.I. 10 (D. Del. Mar. 21, 2019). Seeking to obviate the need for venue discovery, expedite pretrial matters, and preserve judicial resources and the resources of the parties, Merck refiled its complaint against Mylan in the U.S. District Court for the Northern District of West Virginia, where Mylan concedes that venue is proper. Case No. 1:19-cv-00101-IMK, D.I. 1 (N.D. W. Va. May 2, 2019). Merck and Mylan subsequently entered into a stipulation voluntarily dismissing Merck's Delaware action without prejudice. *See* Case No. 1:19-cv-00315-RGA, D.I. 21, 22 (D. Del. May 10, 2019).

As of the filing of this motion, there are thirteen actions pending in Delaware (the "Delaware Actions") and one action pending in West Virginia (the "West Virginia Action"). In these actions, Merck has asserted the '708 patent against 23 defendants (organized into 13 defendant groups based on corporate affiliation), and has further asserted the '921 patent against 3 of those

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defendant groups, including Mylan. All fourteen actions are at an early stage, and one defendant has yet to answer Merck's complaint. No conferences have been held with any of the courts, no discovery has taken place, and no substantive orders have been issued.

ARGUMENT

The Panel may centralize actions pursuant to 28 U.S.C. § 1407 if the movant establishes: (1) that there are "common questions of fact" between the actions; (2) that centralization will "be for the convenience of [the] parties and witnesses"; and (3) that centralization "will promote the just and efficient conduct of [the] actions." Transferring the West Virginia Action to Judge Andrews in the District of Delaware satisfies all three statutory criteria, and centralization is warranted under the Panel's previous decisions in Hatch-Waxman cases. *See* note 1, *infra*.

I. There Are Common Questions of Fact

The fourteen pending actions are parallel Hatch-Waxman patent cases that, by their very nature, will inevitably raise common questions of fact. As the Panel has recognized on numerous occasions, patent infringement actions asserting the same or closely related patents will necessarily "share common factual and legal questions concerning such matters as the technology underlying the patents, prior art, claim construction and issues of infringement involving the patents." *In re PharmaStem Therapeutics, Inc., Patent Litig.*, 360 F. Supp. 2d 1362, 1364 (J.P.M.L. 2005). The common questions that will likely arise in the pending actions can be grouped roughly into the following four categories.

First, based on their notice letters, all defendants intend to litigate the validity of at least claim 1 of the '708 patent on the grounds of obviousness under 35 U.S.C. § 103. Obviousness is thus a legal issue common to all fourteen cases that, under controlling case law, will require the resolution of numerous common factual issues. These issues include, without limitation, the level of ordinary skill in the art, the scope and content of prior art, whether the person of ordinary

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skill ("POSA") would have been motivated to the combine prior art references, whether the POSA would have had a reasonable expectation of success in achieving the claimed invention, and the consideration of any objective indicia of nonobviousness. *See, e.g., Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1343 (Fed. Cir. 2017) (setting forth the factual determinations underlying the obviousness inquiry).

Second, each of the ANDA filers has submitted an application to the FDA for approval to market generic versions of JANUVIA®, JANUMET®, and/or JANUMET XR® using a product label mirroring Merck's. Accordingly, common questions will be presented as to whether these regulatory submissions constitute infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2), including at least claim 1 of the '708 patent, and whether the proposed ANDA products will directly or indirectly infringe Merck's patents under other provisions of 35 U.S.C. § 271. *See Fering B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1382, 1387–88 (Fed. Cir. 2014); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997).

Third, both validity and infringement may require the predicate, pretrial resolution of claim construction disputes. Claim construction is a question of law that may require the district court to resolve subsidiary factual questions. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). Moreover, the Panel has repeatedly observed that centralization is necessary to prevent inconsistent pretrial rulings "particularly on claim construction issues." *See, e.g., In re RAH Color Techs. LLC Patent Litig.*, 347 F. Supp. 3d 1359, 1360 (J.P.M.L. 2018); *In re Nebivolol ('040) Patent Litig.*, 867 F. Supp. 2d 1354, 1355 (J.P.M.L. 2012).

Fourth, in addition to requesting a reset of the approval date of each ANDA to the expiry of the '708 and/or '921 patents, Merck is seeking permanent injunctive relief to preclude the ANDA filers from marketing their infringing products prior to the expiration of the patents-in-

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suit. Whether Merck is entitled to permanent injunctive relief will turn on common questions of fact. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391–92 (2006) (observing that to obtain a permanent injunction, "[a] plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction"). Additionally, in the event that any defendants attempt to market their ANDA products before these cases are decided, Merck may seek preliminary injunctive relief, the availability of which will also turn on common questions of fact. *See, e.g.*, *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1363–64 (Fed. Cir. 2017).

II. Transfer Will Serve the Convenience of the Parties and Witnesses

Centralization of the actions before Judge Andrews will serve the convenience of the parties and witnesses by ensuring a common pretrial schedule, common fact and expert discovery, and a "streamlined" and consistent approach to scheduling, motions practice, claim construction, and summary judgment. *In re Fenofibrate Patent Litig.*, 787 F. Supp. 2d 1352, 1354 (J.P.M.L. 2011). It will also obviate the need for witnesses to appear and participate in more than one proceeding. *See PharmaStem*, 360 F. Supp. 2d at 1364 ("[T]ransfer under Section 1407 has the benefit of placing all actions . . . before a single judge who can structure pretrial proceedings to consider all parties' legitimate discovery needs while ensuring that common parties and witnesses are not subjected to discovery demands which duplicate activity that has already occurred or is occurring in other actions.").

Centralization in the District of Delaware will maximize these benefits, as thirteen of the fourteen actions have been assigned to Judge Andrews in that District. Other than Mylan, no Defendant has contested the propriety of Delaware as a venue to litigate this action. All of the par-

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