UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

VALEANT PHARMACEUTICALS NORTH AMERICA LLC, et al., *Plaintiffs*, v. ZYDUS PHARMACEUTICALS (USA) INC., et al., *Defendants*.	**MEMORANDUM AND ORDER** Civil Action No. 18-cv-13635 (PGS)(LHG)
VALEANT PHARMACEUTICALS NORTH AMERICA, LLC, et al., *Plaintiffs*, v. MYLAN PHARMACEUTICALS INC., et al., *Defendants*.	Civil Action No. 18-cv-14305 (PGS)(LHG)

SHERIDAN, U.S.D.J.

This is a patent infringement action brought by Plaintiffs Valeant Pharmaceuticals North America LLC ("Valeant"), Valeant Pharmaceuticals Ireland Ltd. ("Valeant Ireland"), Dow Pharmaceutical Sciences, Inc. ("Dow"), and Kaken Pharmaceutical Co., Ltd. ("Kaken") (collectively, "Plaintiffs") against Defendants Mylan Pharmaceuticals Inc. ("MPI"), Mylan Laboratories Ltd. ("MLL"), and Mylan Inc. (collectively, the "Mylan Defendants"). (Compl., ECF No. 1). Dow is the holder of a New Drug Application ("NDA") No. 203567 for Jublia

(Efinaconazole topical solution, 10%), and several patents that generally claim methods for treating onychomycosis by administering efinaconazole, and pharmaceutical compositions for the treatment of disorders of the nail or nail bed.[1] (*Id.* at ¶¶ 19-28). Plaintiff Valeant is a limited liability company organized and existing under the laws of Delaware, and with its principal place of business located in Bridgewater, New Jersey. (*Id.* at ¶ 1). Plaintiff Valeant Ireland is a company existing under the laws of Ireland, with its principal place of business located in Dublin, Ireland. (*Id.* at ¶ 2). Plaintiff Dow is a corporation organized and existing under the laws of Delaware with its principal place of business located in California. (*Id.* at ¶ 3). Plaintiff Kaken is a corporation organized and existing under the laws of Japan, with its principal place of business located in Tokyo, Japan. (*Id.* at ¶ 4).

Defendant MPI is a corporation organized and existing under the laws of West Virginia, with its principal place of business located in West Virginia. (*Id.* at ¶ 5). MLL is a corporation organized and existing under the laws of India, with a place of business in Hyderabad, India. (*Id.* at ¶ 6). Finally, Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, having a place of business in Pennsylvania. (*Id.* at ¶ 7). Mylan Inc. is a parent corporation to several subsidiaries, including Agila Specialties Inc., which is located in New Jersey. (Ex. A, ECF No. 19-2). Plaintiffs allege that MPI and MLL are a wholly-owned subsidiaries of Mylan Inc. (*Id.* at ¶¶5-6).

Plaintiffs brought this patent infringement action against Defendants after MPI filed Abbreviated New Drug Application (ANDA) No. 212064 with the FDA, seeking approval to sell

[1] United States Patent Nos. 7,214,506 ("the'506 patent"), 8,039,494 ("the '494 patent"), 8,486,978 ("the '978 patent"), 9,302,009 ("the '009 patent"), 9,566,272 ("the '272 patent"), 9,662,394 ("the '394 patent"), 9,861,698 ("the '698 patent") and 9,877,955 ("the '955 patent").

a generic efinaconazole topical solution; a generic version of Jublia. (*Id.* at ¶¶ 29-30). Plaintiffs allege it received Defendants' notice letter on August 13, 2018, that included a Notice of Certification under 505(j)(2)(B)(ii) and (iv), 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) that included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). (*Id.* at ¶ 31).

Plaintiffs subsequently filed the present complaint, bringing the following allegations: (1) Infringement of the '506 Patent under § 271(e)(2); (2) Declaratory Judgment of Infringement of the '506 Patent; (3) Infringement of the '494 Patent under § 271(e)(2); (4) Declaratory Judgment of Infringement of the '494 Patent; (5) Infringement of the '978 Patent under § 271(e)(2); (6) Declaratory Judgment of Infringement of the '978 Patent; (7) Infringement of the '009 Patent under § 271(e)(2); (8) Declaratory Judgment of Infringement of the '009 Patent; (9) Infringement of the '272 Patent under § 271(e)(2); (10) Declaratory Judgment of Infringement of the '272 Patent; (11) Infringement of the '394 Patent under § 271(e)(2); (12) Declaratory Judgment of Infringement of the '394 Patent; (13) Infringement of the '698 Patent under § 271(e)(2); (14) Declaratory Judgment of Infringement of the '698 Patent; (15) Infringement of the '955 Patent under § 271(e)(2); and (16) Declaratory Judgment of Infringement of the '955 Patent.

The parties have indicated that there is an identical, protective suit filed in the United States District Court for the Northern District of West Virginia. (Pl. br., ECF No. 23, at 5); *see also Valeant Pharmaceuticals North America, et al. v. Mylan Pharmaceuticals, Inc., et al.*, No. 18-184. That matter is stayed pending this Court's decision on the propriety of venue in this District. *Valeant Pharmaceuticals North America, et al. v. Mylan Pharmaceuticals, Inc., et al.*, No. 18-184, ECF No. 67.

For the reasons expressed herein, Defendants' motion to dismiss Counts 1, 3, 5, 7, 9, 11, 13, and 15 (the Hatch-Waxman infringement counts) for improper venue is granted. Counts 2, 4,

6, 8, 10, 12, 14, and 16 (the declaratory judgment counts) are dismissed, as this Court declines to extend declaratory judgment jurisdiction for those counts.

I

Pursuant to Fed. R. Civ. P. 12(b)(3), a party may move to dismiss a claim for improper venue. 28 U.S.C. § 1400(b) is the "sole and exclusive provision controlling venue in patent infringement actions . . . and is not to be supplemented . . . by §1391(c)." *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1519 (2017). Under §1400(b), venue is proper in a patent action only where "where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business." "[A] domestic corporation 'resides' only in its State of incorporation for purposes of the patent venue statute." *TC Heartland*, 137 S. Ct. at 1517. Plaintiffs bear the burden of establishing that venue is proper in this judicial district. *See In re ZTE (USA) Inc.*, 890 F.3d 1008, 1013 (Fed. Cir. 2018).

Here, Plaintiffs do not argue that any of these Defendants reside in New Jersey, and therefore must instead show "*both* that Defendants committed acts of infringement in New Jersey, *and* that Defendants have a regular and established place of business in New Jersey." *Metuchen Pharm. LLC v. Empower Pharm. LLC*, No. 18-11406, 2018 U.S. Dist. LEXIS 187105, at *4-5 (D.N.J. Nov. 1, 2018) (citing *Telebrands Corp. v. Ill. Indus. Tool, Inc.*, No. 17-3411, 2017 U.S. Dist. LEXIS 151421, at *1 (D.N.J. Sept. 18, 2017)).

Plaintiffs allege that venue is appropriate in this judicial district and that this Court has jurisdiction over the Defendants, because Defendant MPI has taken steps to engage in future activities that will be purposefully directed at New Jersey, and that the ANDA filing constitutes "formal acts that reliably indicate plans to engage in marketing of the proposed generic drug." (*Id.* at ¶ 11). Accordingly, Plaintiffs argue that venue in this District is proper because:

> (a) Mylan has committed acts of infringement in New Jersey through its submission of its ANDA; and (b) Mylan has a regular and established place of business in New Jersey at minimum because its enterprise of related companies, commonly referred to as "One Mylan," has a physical presence in this Judicial District, including the offices of its subsidiaries, clinical trial sites, and the homes of at least fourteen employees, whom Mylan admits work in New Jersey on behalf of Mylan.

(Pl. br., ECF No. 23, at 8-9).

The Hatch-Waxman Act treats the filing of an ANDA as an act of infringement, 35 U.S.C. § 271(e)(2), accordingly, because MPI electronically submitted the at issue ANDA in West Virginia, MPI committed an act of infringement in West Virginia. (Decl. of Keith Meckstroth, ECF No. 19-1, at ¶ 26). Defendants and Plaintiffs disagree on whether "planned, future acts" of infringement shall be considered in determining whether a party has committed acts of infringement under § 1400(b). According to Defendants, the venue statute itself was drafted in the past tense, "a civil action for patent infringement may be brought where the defendant *has committed* acts of infringement." Defendants argue that no act of infringement occurred in New Jersey because the only act of infringement alleged in Plaintiff's complaint is MPI's electronic submission of the ANDA, which occurred in West Virginia, and not in New Jersey. (Decl. of Keith Meckstroth, ECF No. 19-1, at ¶ 26). Neither Mylan, Inc. nor MLL participated in the electronic submission of the ANDA to the FDA. (*Id.* at ¶¶ 32, 42).

In contrast, Plaintiffs argue that courts must consider whether Defendants have any planned or future acts of infringement to determine whether an act of infringement occurred in New Jersey. Plaintiffs rely on the court's decision in *Bristol-Myers Squibb Co. v. Mylan Pharm., Inc.*, where the court explained

> Congress' choice of verb tense in the patent venue statute creates an almost impenetrable problem in the particular context of Hatch-Waxman patent litigation. This is because the temporal focus of the Hatch-Waxman infringement analysis is the future, not — as is true in essentially all other patent infringement suits — the past, or even the present. In a Hatch-Waxman suit, the subject of the dispute is the

> generic drug product that the defendant will manufacture and sell and offer for sale in the future (after obtaining FDA approval); a Hatch-Waxman suit is not about a generic product the defendant has sold or is selling.

Bristol-Myers Squibb Co. v. Mylan Pharm., Inc., No. 17-379, 2017 U.S. Dist. LEXIS 146372, at *15 (D. Del. Sep. 11, 2017) (citing *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 760 (Fed. Cir. 2016)). Accordingly, the court determined "an ANDA filer's future, intended acts must be included as part of the 'acts of infringement' analysis for purposes of determining if venue is proper under the patent venue statute." *Id.* at *18; *see also Celgene Corp. v. Hetero Labs Ltd.*, No. 17-3387, 2018 U.S. Dist. LEXIS 34025, at *8 (D.N.J. Mar. 2, 2018).

However, the Federal Circuit recently reiterated that courts must be mindful that "[t]he requirement of venue is specific and unambiguous; it is not one of those vague principles which, in the interests of some overriding policy, is to be given a liberal construction." *In re ZTE (USA) Inc.*, 890 F.3d 1008, 1014 (Fed. Cir. 2018) (citing *In re Cray Inc.*, 871 F.3d 1355, 1361 (Fed. Cir. 2017)). Here, Plaintiffs argue that, should the FDA approve Defendant MPI's ANDA, each Defendant will stand to benefit from such approval, and that MPI will direct product sales into New Jersey. (Pl. br. at 11). However, Plaintiff fails to show specifically how MLL and Mylan, Inc., as separate corporate entities, committed any act of infringement in New Jersey.[2]

Regarding defendant MPI, the Court is not persuaded that the ANDA filer's future, intended acts are included in the acts of infringement analysis. The Federal Circuit has cautioned against

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[2] Plaintiffs argue that venue is proper in this District pursuant to 28 U.S.C. § 1391 for Defendant MLL, a corporation organized and existing under the laws of India, with a place of business in Hyderabad, India. (*Id.* at ¶ 6). 28 U.S.C. § 1391(c)(3) states "a defendant not resident in the United States may be sued in any judicial district, and the joinder of such a defendant shall be disregarded in determining where the action may be brought with respect to other defendants." 28 U.S.C. § 1391(c)(3). As such, the Court will not consider Defendant MLL in determining whether venue is appropriate in New Jersey. Moreover, the Court notes that because MLL may be sued in any judicial district, venue is also proper in West Virginia, where Plaintiff's protective suit was filed.

liberally construing the patent venue statute, and on its face, the patent venue statute states "a civil action for patent infringement may be brought *where* the defendant *has committed* acts of infringement." *See* §1400(b) (emphasis added). *Bristol-Myers Squibb Co.*'s interpretation of that statute does not follow from a plain reading of the statute, which is clear: only where a defendant has committed an act of infringement may a party bring a patent suit. Here, it is undisputed that defendant MPI submitted its ANDA application in West Virginia, to the FDA in Maryland. None of these actions occurred in New Jersey. Accordingly, Plaintiff has not met its burden of showing that an act of infringement occurred in New Jersey, which is necessary for venue to be proper in New Jersey. Counts 1, 3, 5, 7, 9, 11, 13, and 15 (the Hatch-Waxman infringement counts) are dismissed.

II

Plaintiffs argue that venue is proper in this district over the declaratory judgement claims because "[i]t has long been held that a declaratory judgment action alleging that a patent is invalid and not infringed . . . is governed by the general venue statutes, not by § 1400(b)." *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1583 (Fed. Cir. 1990). However, no party here is seeking invalidation of the patents, instead, Plaintiffs seek declaratory judgment that Defendants *infringed* on its patents. The parties have not reconciled the holding in *Ve Holding Corp.* with the Supreme Court's holding in *TC Heartland LLC*, that 28 U.S.C. § 1400(b) is the "sole and exclusive provision controlling venue in patent infringement actions . . . and is not to be supplemented . . . by §1391(c)." Accordingly, because venue is improper for the infringement claims, the Court finds that venue is improper for the declaratory judgment claims as well.

However, even if venue is proper for these claims, it is within the Court's discretion to decline declaratory judgment jurisdiction. *Noven Therapeutics, LLC v. Actavis Labs. FL, Inc.*, No.

14-6414, 2015 U.S. Dist. LEXIS 175628, at *2 (D.N.J. Feb. 20, 2015) (citing *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008)); *see also 3M v. Norton Co.*, 929 F.2d 670, 672 (Fed. Cir. 1991). A court may exercise jurisdiction over declaratory judgment actions "(1) when the judgment will serve a useful purpose in clarifying and settling the legal relations in issue, and (2) when it will terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding." *3M*, 929 F.2d at 672-73.

Defendants argue that this Court lacks subject matter jurisdiction to determine these claims, because the present circumstances lack any immediacy. In general, "[t]he foundation of a declaratory action is that 'the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *AIDS Healthcare Found., Inc. v. Gilead Scis., Inc.*, 890 F.3d 986, 991-92 (Fed. Cir. 2018) (quoting *MedImmune Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)). "The immediacy requirement is concerned with whether there is an immediate impact on the plaintiff and whether the lapse of time creates uncertainty." *Id.* (quoting *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014)).

The parties have indicated that there is an identical protective suit filed in the United States District Court for the Northern District of West Virginia. (Pl. br. at 5). The West Virginia court stayed that matter until this Court decided whether venue is proper in this District. (*Id.*; *see also Valeant Pharmaceuticals North America, et al. v. Mylan Pharmaceuticals, Inc., et al.*, No. 18-184, ECF No. 67). Having decided venue is improper in this District, as a practical matter, it is unlikely that upon this Court's decision, the parties will continue to litigate solely the declaratory judgment action in this District, while there is an identical case proceeding simultaneously in the Northern District of West Virginia. Even move, if this Court were to adjudicate the declaratory judgment

action, while the West Virginia Court litigated the Hatch-Waxman action, the parties and the Courts would essentially be litigating and deciding the same issues, as both the declaratory judgment action and the Hatch-Waxman actions seek the same result: infringement and declaratory judgment of infringement. Adjudication of the declaratory judgment claims while there are identical claims proceeding in the Northern District of West Virginia will not "serve a useful purpose in clarifying and settling the legal relations" nor will it "terminate and afford relief from . . . uncertainty, insecurity, and controversy." *3M*, 929 F.2d at 672-73. For these reasons, the Court declines to exercise declaratory judgment jurisdiction, and Counts 2, 4, 6, 8, 10, 12, 14, and 16 (the declaratory judgment counts) are dismissed.

ORDER

THIS MATTER having been opened to the Court by Defendant's motion to dismiss (ECF No. 18 [18-14305]); and the Court having fully considered the submissions in support thereof, and any opposition thereto; and having considered the arguments of counsel; and for good cause shown;

IT IS on this 13 day of August, 2019,

ORDERED that Defendants' motion to dismiss (ECF No. 18 [18-14305]) is **GRANTED**.

Peter G. Sheridan

PETER G. SHERIDAN, U.S.D.J.