Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION,	:	
Plaintiff,	:	**Civil Action No. 17-3387 (ES) (MAH)**
v.	:	**MEMORANDUM**
HETERO LABS LIMITED, et al.,	:	
Defendants.	:	

SALAS, DISTRICT JUDGE

Pending before the Court is Defendants Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V.'s (collectively, "Mylan" or "Mylan Defendants") motion to dismiss for improper venue, lack of subject-matter jurisdiction, and failure to state a claim under Federal Rules of Civil Procedure 12(b)(3), 12(b)(1), and 12(b)(6), respectively. (D.E. No. 56). The Court has considered the parties' submissions and decides the matter without oral argument. See Fed. R. Civ. P. 78(b). For the following reasons, Mylan's motion is DENIED without prejudice.

I. Improper Venue under Rule 12(b)(3)

a. Legal Standard

Mylan seeks dismissal for improper venue under Rule 12(b)(3). (D.E. No. 56-1 ("Mylan Mov. Br.") at 1). Courts are divided on which party bears the burden on a Rule 12(b)(3) motion in a patent case. Compare Galderma Labs., L.P. v. Teva Pharm. USA, Inc., No. 17-1076, 2017 WL 6505793, at *3 (N.D. Tex. Nov. 17, 2017) (plaintiff bears the burden), with Mallinckrodt IP v. B. Braun Med. Inc., No. 17-365, 2017 WL 6383610, at *2 (D. Del. Dec. 14, 2017) (party opposing venue bears the burden); see also 14D Wright & Miller, Federal Practice & Procedure

§ 3826 (4th ed. 2017) ("There are many cases—predominantly, but not exclusively, from the Third and Fifth Circuits—holding that the burden is on the objecting defendant to establish that venue is improper, because venue rules are for the convenience and benefit of the defendant.").

Mylan argues that Federal Circuit law governs the burden-of-proof inquiry. (D.E. No. 110 ("Mylan Reply Br.") at 6-7).[1] Mylan relies on Federal Circuit precedent that instructs:

> a procedural issue that is not itself a substantive patent law issue is nonetheless governed by Federal Circuit law if the issue pertains to patent law, if it bears an essential relationship to matters committed to [the Federal Circuit's] exclusive control by statute or if it clearly implicates the jurisprudential responsibilities of [the Federal Circuit] in a field within its exclusive jurisdiction.

(Id. at 6) (citing Midwest Indus. v. Karavan Trailers, 175 F.3d 1356, 1359 (Fed. Cir. 1999)). According to Mylan, § 1400(b) is a patent-specific statute, which triggers the application of Federal Circuit law. (See id. at 6-7). And in Mylan's view, Federal Circuit law places the burden as to venue on the plaintiff. (Id. at 7) (citing Hoover Grp., Inc. v. Custom Metalcraft, Inc., 84 F.3d 1408, 1410 (Fed. Cir. 1996)).[2]

Celgene argues that Third Circuit law governs the burden-of-proof inquiry. (D.E. No. 88 ("Celgene Opp. Br.") at 3). For support, Celgene relies on several cases,[3] including a post-TC Heartland Hatch-Waxman case from this Circuit. (See id.) (citing BMS, 2017 WL 3980155, at

---

[1] Mylan concedes that, "at the very least, there is a split of authority as to who bears the burden of proof on an objection to venue." (Mylan Reply Br. at 7 n.3).

[2] The Hon. Chief Judge Leonard P. Stark, U.S.D.J., recently rejected this reading of Hoover. See Bristol-Myers Squibb Co. v. Mylan Pharm. Inc. ("BMS"), No. 17-379, 2017 WL 3980155, at *4 (D. Del. Sept. 11, 2017) ("In Hoover, the Federal Circuit did not make clear whether it was applying Federal Circuit law or regional-circuit law. Nor did Hoover make any statement as to which party bears the burden of proof on venue issues. Thus, there appears to be no binding Federal Circuit decision on these points.").

[3] See Great W. Mining & Mineral Co. v. ADR Options, Inc., 434 F. App'x 83, 86 (3d Cir. 2011) ("Because improper venue is an affirmative defense, the burden of proving lack of proper venue remains—at all time—with the defendant."); *Myers v. Am. Dental Ass'n*, 695 F.2d 716, 724 (3d Cir. 1982), cert. denied, 462 U.S. 1106 (1983); Koninklijke Philips N.V. v. ASUSTeK Comput. Inc., No. 15-1125, 2017 WL 3055517, at *2 (D. Del. July 19, 2017).

*5 (holding that the law of the regional circuit controls who bears the burden, and explaining that under Third Circuit law, the burden is on the defendant to prove improper venue)).

After the parties briefed Mylan's motion, other district courts in the Third Circuit followed the reasoning in BMS and applied Third Circuit law to determine—as a procedural matter—which party bears the burden on a venue challenge in a patent case. See Koninklijke KPN N.V. v. Kyocera Corp., No. 17-87, 2017 WL 6447873, at *2 (D. Del. Dec. 18, 2017).[4] The Court will follow the reasoning in BMS and hold that "the issue of which party bears the burden of proof on a venue challenge is a procedural, non-patent issue controlled by the law of the regional circuit." See 2017 WL 3980155, at *4. Thus, Mylan—as the party opposing venue—bears the burden here. See Great W. Mining & Mineral Co., 434 F. App'x at 86 (3d Cir. 2011).[5]

b. Analysis

Venue in a patent case is governed exclusively by a special patent-venue statute, which provides that, "[a]ny civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business." 28 U.S.C. § 1400(b); see TC Heartland LLC v. Kraft Foods Grp. Brands LLC, 137 S. Ct. 1514, 1515 (2017); see also In re Cray, 871 F. 3d

[4] See also Infinity Computer Prods., Inc. v. Oki Data Americas, Inc., No. 12-6797 (consolidated), 2018 WL 1035793, at *3 (E.D. Pa. Feb. 23, 2018); 3G Licensing, S.A. v. HTC Corp., No. 17-83, 2017 WL 6442101, at *1 (D. Del. Dec. 18, 2017); Mallinckrodt IP, 2017 WL 6383610, at *2; Javelin Pharm., Inc. v. Mylan Labs. Ltd., No. 16-224, 2017 WL 5953296, at *2 (D. Del. Dec. 1, 2017); UCB, Inc. v. Mylan Techs., Inc., No. 17-322, 2017 WL 5985559, at *2 (D. Del. Dec. 1, 2017); Paltalk Holdings, Inc. v. Valve Corp., No. 16-1239, 2017 WL 4570301, at *2 (D. Del. Oct. 13, 2017), report and recommendation adopted, No. 16-1239, 2018 WL 692928 (D. Del. Feb. 2, 2018).

[5] The Court is mindful that another court in this District appeared to have placed the burden of proof in a patent-venue challenge on the plaintiff. See Telebrands Corp. v. Seasonal Specialties, LLC, No. 17-3390, 2017 WL 3895558, at *3 (D.N.J. Sept. 6, 2017). Although the parties raised the burden-of-proof issue in their briefing (see id. at D.E. Nos. 11-1, 14 & 15), the Telebrands court did not address the issue. Rather, it stated, without discussion or citation, that the plaintiff "has not met its burden of raising evidence to demonstrate that the venue of this patent infringement action properly lies within the District of New Jersey pursuant to Section 1400(b)." Given the Telebrands court's lack of discussion of this issue, the Court is inclined to follow the weight of authority in this Circuit and Judge Stark's well-reasoned analysis in BMS.

1355, 1360 (Fed. Cir. 2017) (holding that "Federal Circuit law, rather than regional circuit law, governs [the] analysis of what § 1400(b) requires."). Thus, Mylan must demonstrate that (1) it does not "reside" in New Jersey and (2) it either (a) has not committed "acts of infringement" in New Jersey, or (b) does not have a "regular and established place of business" in New Jersey. See BMS, 2017 WL 3980155, at *5-6. In other words, if Mylan "resides" in New Jersey, then venue is proper here. If Mylan does not "reside" in New Jersey, but has committed "acts of infringement" in New Jersey and has a "regular and established place of business" in New Jersey, then venue is proper here.

1. *Does Mylan "Reside" in New Jersey*?

Under § 1400(b), a defendant that is a domestic corporation "resides" only in its state of incorporation. See TC Heartland, 137 S.Ct. at 1517. Mylan asserts that it does not "reside" in New Jersey because none of the Mylan Defendants are incorporated in New Jersey. (Mylan Mov. Br. at 2, 6). Celgene does not appear to challenge Mylan's assertion. (See generally Celgene Opp. Br.) (addressing only second prong under § 1400(b)). The Court has reviewed Mylan's submissions, including the Meckstroth Declaration (D.E. No. 56-2) and the Jenkins Declaration (D.E. No. 56-3), and is satisfied that the Mylan Defendants do not "reside" in New Jersey for purposes of § 1400(b). See BMS, 2017 WL 3980155, at *3 ("[W]hen confronted with a motion to dismiss for improper venue, the Court may consider both the complaint and evidence outside the complaint.").

2. *Has Mylan Committed "Acts of Infringement" in New Jersey?*

Section 1400(b) asks whether the defendant "has committed acts of infringement" in the judicial district where the suit is brought. The rub here is whether § 1400(b) references only past "acts of infringement." Mylan argues that it does: "[t]he express language of the statute—'where

the defendant has committed acts of infringement'—refers to an act committed in the past. The Congressional intent of that language is unambiguous." (Mylan Mov. Br. at 3). Celgene argues that it does not: "in Hatch-Waxman cases, 'has committed' in § 1400(b) necessarily includes prospective acts that would constitute ordinary patent infringement if, after FDA approval, the generic drug product is launched." (Celgene Opp. Br. at 5).

Celgene's argument follows Judge Stark's reasoning in BMS. (See id. at 4) (citing 2017 WL 3980155, at *9, 11-15, 22). There, the court observed that Congress's use of the past tense in § 1400(b) "creates an almost impenetrable problem in the particular context of Hatch–Waxman patent litigation . . . 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." BMS, 2017 WL 3980155, at *6 (emphasis in original). The court held that "acts of infringement" in the Hatch-Waxman context include acts "the ANDA applicant non-speculatively intends to take if its ANDA receives final FDA approval, plus steps already taken by the applicant indicating its intent to market the ANDA product in this District." Id. at 12.

Mylan attempts to distinguish BMS because it issued before Cray, the Federal Circuit's recent decision clarifying TC Heartland. (See Mylan Reply Br. at 18 n.6). Mylan contends that BMS "relied heavily on case law regarding personal jurisdiction for purposes of its venue analysis," but Cray mandates that "venue is independent of and separate from personal jurisdiction." (Id.). To that end, Mylan has a point: Cray explicitly instructed district courts to "be careful not to conflate showings that may be sufficient for other purposes, e.g., personal jurisdiction or the general venue statute, with the necessary showing to establish proper venue in patent cases." 871 F.3d at 1361.

Mylan's argument would be stronger, however, if other district courts in this Circuit did not follow BMS after Cray issued. See Mallinckrodt IP, 2017 WL 6383610 (adopting holding from BMS for "acts of infringement"); Javelin Pharm., Inc., 2017 WL 5953296 (same); UCB, Inc., 2017 WL 5985559 (same).[6] And Mylan has not persuaded the Court to depart from this view. Further, because Mylan does not offer any arguments, in the alternative or otherwise, concerning future "acts of infringement" (or lack thereof), the Court finds that Mylan has failed to meet its burden to show that it has not committed "acts of infringement" in New Jersey for purposes of § 1400(b).

3. Does Mylan *have a "Regular and Established* Place of Business*" in New Jersey?*

In Cray, the Federal Circuit provided significant guidance about the meaning of "regular and established place of business" under § 1400(b). 871 F. 3d 1355. The Federal Circuit clarified that there are "three general requirements relevant to the inquiry: (1) there must be a physical place in the district; (2) it must be a regular and established place of business; and (3) it must be the place of the defendant." Id. at 1360. "If any statutory requirement is not satisfied, venue is improper under § 1400(b)." Id. And "[i]n deciding whether a defendant has a regular and established place of business in a district, no precise rule has been laid down and each case depends on its own facts." Id. at 1362.

Here, the Court concludes that the record, at present, does not permit it to make a finding. The Court will therefore allow Celgene to take venue-related discovery. In the Court's view, venue-related discovery is especially appropriate in this case because Mylan moved before

[6] But see Galderma Labs., L.P., 2017 WL 6505793, at *5 (addressing BMS but holding that, although "the Delaware court's opinion [in BMS] is very thorough, there are several issues with the decision that counsel this Court away from adopting the holding that an act of infringement occurs in any district where the ANDA filer intends to market the ANDA product after it receives FDA approval").

the Federal Circuit issued Cray. See, e.g., Galderma Labs., L.P., 2017 WL 6505793, at *3 (permitting venue-related discovery because the parties' briefed the defendant's 12(b)(3) motion before Cray issued). As the Hon. Chief Judge Barbara M.G. Lynn, U.S.D.J., noted in Galderma Labs, Cray clarifies that the venue analysis is "particularly fact-specific." Id. Other courts, too, have ordered venue-related discovery in similar circumstances. See, e.g., Mallinckrodt IP, 2017 WL 6383610, at *5; Javelin Pharm., Inc., 2017 WL 5953296, at *2-3; UCB, Inc., 2017 WL 5985559, at *2-3; see also Intellectual Ventures II LLC v. FedEx Corp., No. 16-0980, 2017 WL 5630023, at *4 (E.D. Tex. Nov. 22, 2017) (finding that venue-related discovery would have been appropriate but for the defendants' waiver); but see Telebrands, 2017 WL 3895558, at *2-3 (declining to order venue-related discovery because the defendant, "in no uncertain times," did not have a regular and established place of business in New Jersey).

The Court's decision to permit venue-related discovery is also based on the strength of the parties' arguments. See Javelin Pharm., Inc., 2017 WL 5953296, at *3 ("[A]t least in a difficult case, the Court should permit venue-related discovery, to allow the adversarial process to aid the Court in making a fact-specific decision on a well-developed factual record."). Thus, Celgene may take discovery on these matters, and Mylan may renew, should it wish to do so, its challenge to the propriety of venue in this District. See id. at *4.

II. Lack of Subject-Matter Jurisdiction under Rule 12(b)(1)

a. Legal Standard

Generally, dismissal for lack of subject-matter jurisdiction under Rule 12(b)(1) "is a procedural question not unique to patent law," and is therefore governed by regional circuit law. Toxgon Corp. v. BNFL, Inc., 312 F.3d 1379, 1380 (Fed. Cir. 2002). That said, "[w]hether an actual case or controversy exists so that a district court may entertain an action for a

declaratory judgment of non-infringement and/or invalidity is governed by Federal Circuit law." MedImmune, Inc. v. Centocor, Inc., 409 F.3d 1376, 1378 (Fed. Cir.2005), overruled on other grounds, 549 U.S. 118 (2007).

b. Analysis

Mylan argues that the Court lacks subject-matter jurisdiction over Celgene's claims under 35 U.S.C. §§ 271(a)-(c). (See Mylan Mov. Br. at 12-14). Celgene counters that it does not have any claims under §§ 271(a)-(c). (See Celgene Opp. Br. at 23). Rather, Celgene states that it included references to §§ 271(a)-(c) "to provide clarity and detail as to the nature of the future infringing activities that Mylan will engage in if Mylan's Proposed Products are approved by the FDA." (Id. at 24).

The Court will deny Mylan's motion at this time. Celgene concedes that it has no standalone claims under §§ 271(a)-(c). (Id. at 23-24) (stating that "the paragraphs in the Complaint concerning §§ 271(a)-(c) do not stand alone or allege any cause of action separate or apart from the claims brought under § 271(e)(2)"). To the extent this issue resurfaces later in this litigation, Mylan may move at the appropriate time.

III. Failure to State a Claim under Rule 12(b)(6)

In light of the Court's decision to permit venue-related discovery in connection with Mylan's Rule 12(b)(3) motion, the Court will deny as moot Mylan's motion to dismiss under Rule 12(b)(6). See Mallinckrodt IP, 2017 WL 6383610, at *1 (denying Rule 12(b)(6) motion as moot pending venue-related discovery). Mylan may renew its motion following the venue-related discovery.

IV. Conclusion

For the foregoing reasons, the Court DENIES Mylan's motion without prejudice. The Court will permit Celgene to take venue-related discovery. Thereafter, Mylan may renew its venue challenge and its 12(b)(6) motion, should it wish to do so. An appropriate Order accompanies this Memorandum.

s/Esther Salas
Esther Salas, U.S.D.J.