

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NOVARTIS PHARMACEUTICALS	:	
CORPORATION,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 18-1043-LPS
	:	
ACCORD HEALTHCARE INC., et al.,	:	
	:	
Defendants.	:	

MEMORANDUM ORDER

Defendant MPI Pharmaceutical Inc. (“Defendant” or “MPI”) has moved to dismiss this action as against it due to improper venue. (D.I. 118) Plaintiff Novartis Pharmaceuticals Corporation (“Novartis” or “Plaintiff”) sued MPI and 22 additional groups of generic drug makers, all of whom had filed abbreviated new drug applications (“ANDAs”) related to the drug fingolimod, pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(j). The parties and the Court have coordinated discovery and scheduling for all of the related cases. (*See* D.I. 216) (joint scheduling order)¹

MPI, a West Virginia corporation, filed its motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(3). After the matter was fully briefed, this Court issued its decision in *Bristol-Meyers Squibb Co. v. Aurobindo Pharma USA Inc.*, 2018 WL 5109836 (D. Del. Oct. 18, 2018) (“*BMS II*”), which dismissed a different Hatch-Waxman action against MPI based on improper venue here in the District of Delaware. The Court then ordered supplemental briefing,

¹ In the time since MPI filed its motion, multiple defendants have settled with Novartis. (*See, e.g.,* D.I. 170, 235)

to permit the parties to address the impact of *BMS II* on MPI's motion here. (*See* D.I. 209; *see also* D.I. 119, 163, 206, 219, 220, 224, 225) In its supplemental briefing, Novartis insisted MPI's motion should still be denied and also sought, in the alternative, venue-related discovery (a request it had also made in its original briefing) and leave to file an amended complaint. MPI argued that the *BMS II* decision only strengthened the basis for dismissal here.

Having carefully considered all of the materials before the Court, **IT IS HEREBY ORDERED THAT** MPI's motion (D.I. 118) is **GRANTED** and Plaintiff's request for discovery and to file an amended complaint is **DENIED**.

Generally, "venue provisions are designed, not to keep suits out of the federal courts, but merely to allocate suits to the most appropriate or convenient federal forum." *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 710 (1972). When a party feels it has been sued in an improper federal venue, it may move to dismiss or transfer venue under Rule 12(b)(3). *See also* 28 U.S.C. § 1406(a) (stating that court granting Rule 12(b)(3) motion based on improper venue "shall dismiss, or if it be in the interest of justice, transfer such case to any district or division in which it could have been brought"). When such a motion is filed, the Court must determine whether venue is proper in accordance with the applicable statutes. *See Albright v. W.L. Gore & Assocs., Inc.*, 2002 WL 1765340, at *3 (D. Del. July 31, 2002).

In a patent infringement action, venue is governed solely and exclusively by the patent venue statute, 28 U.S.C. § 1400(b) ("Section 1400(b)"). *See TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1516 (2017). The general venue statute, 28 U.S.C. § 1391 ("Section 1391"), does not have any application in a patent case. *See id.* at 1521. Section 1400(b) provides: "Any civil action for patent infringement may be brought in the judicial

district [i] where the defendant resides, or [ii] where the defendant has committed acts of infringement and has a regular and established place of business” (internal numbering added).

Generally, “it is not necessary for the plaintiff to include allegations in his complaint showing that venue is proper.” *Great W. Mining & Mineral Co. v. ADR Options, Inc.*, 434 F. App’x 83, 86-87 (3d Cir. 2011). However, “upon motion by the Defendant challenging venue in a patent case, the Plaintiff bears the burden of establishing proper venue.” *In re ZTE (USA) Inc.*, 890 F.3d 1008, 1013 (Fed. Cir. 2018). The Court will accept any venue-related allegations in the complaint as true, unless they are contradicted by the defendant’s evidence. *See Bockman v. First Am. Mktg. Corp.*, 459 F. App’x 157, 158 n.1 (3d Cir. 2012); *In re First Solar, Inc. Derivative Litig.*, 2013 WL 817132, at *2 (D. Del. Mar. 4, 2013). In addition, the Court may consider affidavits. *See Bockman*, 459 F. App’x at 161 (affirming dismissal of complaint “because Defendants satisfied their burden of showing improper venue by offering evidence that the wrongful acts alleged in the Complaint did not occur in Pennsylvania, and Plaintiffs failed to rebut that evidence”).

Here, then, the burden is on Novartis to demonstrate that venue in this District is proper either because [i] MPI resides in Delaware or [ii] MPI has a regular and established place of business in Delaware and has committed infringing acts here. MPI contends that Novartis has failed to make the required showing under either prong of Section 1400(b). (*See* D.I. 119 at 4-6)

Novartis first responds that MPI is urging the Court to undertake an incorrect analysis. To Novartis, the general venue statute, Section 1391, and not the patent venue statute, Section 1400(b), governs venue in Hatch-Waxman cases. (D.I. 163 at 7-15; D.I. 220 at 1) Specifically, Novartis asserts that “a Hatch-Waxman case under 35 U.S.C. § 271(e) is not a ‘civil action for patent infringement’ under Section 1400(b),” because it “provides for unique forms of regulatory

relief prior to actual infringement.” (D.I. 163 at 9-10) Novartis likens Hatch-Waxman claims to suits for a declaratory judgment, arguing that “[n]o principled reason exists to treat those two sorts of claims differently for venue purposes.” (*Id.* at 11-12) In making this argument, Novartis emphasizes the disconnect between the word choice of the patent venue statute – “has committed” acts of infringement – and Hatch-Waxman cases, in which the proposed infringing product has not yet been marketed or sold. (*Id.* at 13) (citing *Bristol-Myers Squibb Co. v. MPI Pharm. Inc.*, 2017 WL 3980155, at *6 (D. Del. Sept. 11, 2017)) Novartis concludes that using Section 1391 leads to the most efficient outcome of permitting it to litigate its similar patent disputes against all ANDA-filing defendants in a single action in a single District, thus “encouraging the uniform determination of patent rights.” (*Id.* at 14-15)

After Novartis filed its answering brief, but before MPI filed its reply brief, this Court issued its decision in *BMS II*, rejecting the patentee’s argument there that Section 1391, and not Section 1400(b), governs venue in Hatch-Waxman cases. *See BMS II* at *5-6. In its supplemental briefing, Novartis asks the Court to “reconsider its decision” in *BMS II*. (D.I. 220 at 3) While Novartis’ briefing on the issue is far more extensive than *BMS*’ had been, it does not persuade the Court to reach a different conclusion.

As in *BMS II*, the Court finds that the instant action is “incontestably a ‘civil action for patent infringement,’ governed solely and exclusively by § 1400(b).” *BMS II* at *6. Novartis, like *BMS*, expressly alleged in its complaint that it was filing a “patent infringement” action against MPI and cited solely Section 1400(b) as the statutory basis for venue. Novartis’ cause of action arises under Section 271(e)(2)(A), which makes it an “act of patent infringement” to do as MPI is alleged to have done here: file an ANDA with the U.S. Food and Drug Administration seeking approval of a pharmaceutical product that reads on a valid, enforceable, unexpired

patent. Under *TC Heartland*, the proper venues for such patent infringement actions are determined solely and exclusively by Section 1400(b).

Having rejected Novartis' contention that Section 1391, and not Section 1400(b), should govern the venue analysis in this Hatch-Waxman infringement action, the Court next turns to whether Novartis has met its burden to show that venue is proper in this District under Section 1400(b). MPI is not incorporated in Delaware and, therefore, indisputably does not reside here. Nevertheless, Novartis contends that it should be given an opportunity to pursue venue-related discovery, which would, it insists, likely yield sufficient evidence that some MPI-related entity is incorporated in Delaware and/or maintains a regular and established place of business here, and these contacts might be imputable to MPI itself. (D.I. 163 at 17-19)²

“[W]here issues arise as to jurisdiction or venue, discovery is available to ascertain the facts bearing on such issues.” *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 n.13 (1978). In the context of jurisdictional discovery, the Third Circuit has instructed that “unless a plaintiff’s claim is ‘clearly frivolous,’ jurisdictional discovery should be allowed.” *Rocke v. Pebble Beach Co.*, 541 Fed. Appx. 208, 212 (3d Cir. 2013). The law is equally clear, however, that a plaintiff may not “undertake a fishing expedition based only upon bare allegations, under the guise of jurisdictional discovery.” *Eurofins Pharma U.S. Holdings v. BioAlliane Pharma SA*, 623 F.3d 147, 157 (3d Cir. 2010). To show that discovery is warranted, a party must, at a minimum, state a non-frivolous basis for venue and do so with “reasonable particularity.” *Eastman Chem. Co. v. AlphaPet, Inc.*, 2011 WL 6004079, at *2 (D. Del. Nov. 4, 2011).

² Novartis also seeks discovery into other possible venues. (D.I. 163 at 19) The Court sees no reason to provide such discovery under the circumstances of this case.

In *BMS II*, this Court found that, after a year of discovery directed at (in part) MPI, any further discovery would amount to a fishing expedition. *See BMS II* at *5. There, the parties debated the relevance of the “relationship between MPI and [MPI] Securitization” (a sister company incorporated in Delaware), which the Court found not to be a basis for venue. *Id.* at *4-5. Importantly, this Court also found no “evidence of fraud, unfairness, or injustice,” nor any likelihood that further discovery would reveal such evidence. (*Id.* at *5) (citing *Cannon Mfg. Co. v. Cudahy Packing Co.*, 267 U.S. 333, 334-35 (1925))

Before *BMS II* was issued, Novartis had requested discovery into MPI Securitization under a veil-piercing theory. (D.I. 163 at 16-17) Since Novartis did not refer to this request in its post-*BMS II* supplemental briefing, the Court assumes Novartis is no longer seeking discovery on the theory that the MPI-MPI Securitization relationship could give rise to a basis for venue to be proper in this District.³ Even were Novartis still seeking such discovery, the Court would not permit it, as it appears at this point to be an improper fishing expedition. Novartis has not articulated, with reasonable particularity, a plausible basis to believe that the discovery would lead to evidence allowing the Court to find that MPI resides in or has a regular and established place of business in this District for purposes of Section 1400(b).

In denying the request for discovery, the Court has considered – and rejected – Novartis’ contention that venue may turn out to be proper in this District based on the existence of a single MPI employee who lives and works in Delaware.⁴ Novartis contends that discovery may reveal

³ Novartis’ position is not entirely clear. In a supplemental brief, it wrote that it was not “interested in relitigating the issues already decided in *BMS II*, such as the veil-piecing theories the court rejected there (though the record of what was already exchanged between the parties in *BMS II* should be produced).” (D.I. 225 at 2)

⁴ In the course of litigating MPI’s motion, the parties reached an impasse as to whether information about MPI’s sole Delaware employee should be redacted from case filings. (*See*,

evidence that the employee's home is used to conduct MPI's business and, therefore, may be determined to be a regular and established place of MPI's business. *See In re Cray*, 871 F.3d 1355, 1362-63 (Fed. Cir. 2017); *see also Regenlab USA LLC v. Estar Tech. Ltd.*, 335 F.Supp.3d 526 (S.D.N.Y. 2018) (finding that presence of even single work-at-home employee may

e.g., D.I. 286, 296) The Court heard argument on this issue during a teleconference on December 21, 2018. (*See* D.I. 308 at 39-46) While the Court will itself refrain from using the employee's name in this Memorandum Order – as her specific identity adds nothing pertinent to the analysis – the Court also finds that MPI has failed to show good cause for its proposed redactions relating to the employee. *See Publicker Indus. v. Cohen*, 733 F.2d 1059, 1070-71 (3d Cir. 1984) (“The party seeking . . . the sealing of [part of the judicial record] bears the burden of showing that the material is the kind of information that courts will protect and that there is good cause for the order to issue. Good cause is established on showing that disclosure will work a clearly defined and serious injury to the party seeking closure.”).

Accordingly, IT IS HEREBY ORDERED that the parties shall, no later than June 25, 2019, re-file any documents they previously filed that contained redactions of the employee's identity and her related information. (*See, e.g.*, D.I. 286 at 3)

The Court has reached this conclusion for two principal reasons. First, Novartis contends, and MPI does not seem to disagree, that all of the information that has been provided to the Court was, at least at one time, already publicly available, at least through the employee's own social media sites (including her Facebook page). MPI is likely correct that when the employee made her information public through Facebook she did not expect it would become the subject of extensive litigation (in this and possibly other cases), but that does not negate the fact that she chose to make all of this information public. MPI has failed to show good cause for why the Court should now take the affirmative step of depriving the public of one iteration (i.e., the parties' filings in this action) of information that has elsewhere otherwise and already been made publicly-available.

Second, MPI chose to file its motion (as is its right), with full knowledge that it had an employee who resides in this District. In doing so, MPI had to have (or at minimum should have) reasonably foreseen that facts related to this employee's activities in Delaware, including her use of her own home, could become pertinent to whether MPI's motion should be granted. As MPI well knows, current law may render relevant where a patent infringement defendant's employees reside and what they do in their residences. If the employee has cause to be upset about public details of her personal life being amplified through high-stakes patent litigation in federal court, her concern is more properly directed at her employer than at a patentee who is pursuing arguably non-frivolous theories for bringing its case in the District of its choice.

supporting finding of regular and established place of business).⁵ Here, Novartis' contentions regarding the single employee do not justify further discovery (nor do they, based on what Novartis has discovered to date, satisfy Novartis' burden to show that venue is proper here).

In *Cray*, 871 F.3d at 1362-63, the Federal Circuit – while noting that “no precise rule has been laid down and each case depends on its own facts” – provided guidance on how to evaluate disputes concerning the regular and established place of business requirement of Section 1400(b). First, *Cray* stated, for venue to be proper under this analysis “there must be a **physical place** in the district.” *Id.* at 1362 (internal quotation marks omitted; emphasis added). Second, the physical place must be **established**, meaning it must exist with a degree of stability and permanence. *See id.* at 1363. Finally, the place must be “a place **of the defendant**, not solely a place of the defendant’s employee,” meaning “the **defendant** must establish or ratify the place of business.” *Id.* (emphasis added). “Relevant considerations include whether the defendant owns or leases the place, . . . exercises other attributes of possession or control over the place,” or conditions employment on residence and/or product storage in district. *Id.* “[I]f an employee can move his or her home out of the district at his or her own instigation, without the approval of the defendant, that would cut against the employee’s home being considered a place of business of the defendant.” *Id.*

Novartis points to no facts supporting a reasonable expectation that discovery would lead to evidence sufficient to satisfy any of *Cray*'s requirements. Novartis does not allege that MPI materials are stored at the Delaware employee's home; that her home is owned, controlled, or

⁵ This issue was originally disputed in *BMS II*, but was dropped there because – as Novartis contends and MPI does not challenge – “the parties in *BMS* had agreed that the employee’s presence in Delaware working for MPI was irrelevant to venue because she had been hired after April 2017, when the *BMS* complaint had been filed.” (D.I. 220 at 1)

otherwise established by MPI; that the employee’s employment is conditioned upon residence in Delaware; or that there is anything to stop the employee from moving out of Delaware, at any time she wishes, for any reason (without any threat to her continued employment by MPI). (See D.I. 220 at 2; D.I. 225 at 1-2)⁶

Nothing in the record supports Novartis’ assertion that “it is not happenstance that [the employee] lives in the very territory she covers.” (D.I. 225 at 1) Also, it is uncontested that Delaware is not the employee’s only territory. (D.I. 220 at 2) No evidence indicates that MPI required or even encouraged the employee to live in Delaware. Merely doing business in Delaware does not make Delaware a regular and established place of business for MPI; it follows

⁶ Everything that the Federal Circuit said in *Cray* about the employee considered there appears to be equally true here (in terms of the relationships among MPI, its employee, and Delaware):

There is no indication that Cray owns, leases, or rents any portion of Mr. Harless’s home in the Eastern District of Texas. No evidence indicates that Cray played a part in selecting the place’s location, stored inventory or conducted demonstrations there, or conditioned Mr. Harless or Mr. Testa’s employment or support on the maintenance of an Eastern District of Texas location. No evidence shows that Cray believed a location within the Eastern District of Texas to be important to the business performed, or that it had any intention to maintain some place of business in that district in the event Mr. Harless or Mr. Testa decided to terminate their residences as a place where they conducted business.

871 F.3d at 1365.

By contrast, the instant case is unlike *Regenlab*, 335 F.Supp.3d at 550, where all the defendant’s employees worked from their homes, and, for that reason, the defendant “trie[d] to hire people living within their assigned sales territory.” The other cases upon which Novartis relies also involve materially different facts. (See D.I. 220 at 2) (citing *Kranos IP Corp. v. Riddell, Inc.*, 2017 WL 3704762 (E.D. Tex. Aug. 28, 2017) (defendant employed multiple sales representatives in district, who received, stored, and showcased infringing products within district); *Invue Security Prods. Inc. v. Mobile Tech., Inc.*, 2017 WL 3595486 (W.D.N.C. Aug. 21, 2017) (defendant had home office within district and employed six part-time field technicians, whose tasks included on-site customer service, on-site training and education, emergency call response, and storage of inventory of replacement parts and specialized tools))

that if MPI, to do business in Delaware, requires an employee in Delaware, that fact, without more, is not sufficient to make Delaware a location of MPI's regular and established business. As *Cray* holds: "The statute clearly requires that venue be laid where the defendant has a regular and established place of business, not where the defendant's employee owns a home in which he carries on some of the work that he does for the defendant." 871 F.3d at 1365 (internal quotation marks and citation omitted).

Novartis places great emphasis on the employee's social media presence, observing that she "routinely posts pictures of her activities in Delaware, makes connections between customers and local businesses, and praises [MPI]." (D.I. 225 at 2) The Court is not persuaded by Novartis' contention that this one employee's personal social media activities should be viewed as advertising and marketing *by MPI*. Moreover, as *Cray* notes, marketing activities are relevant to the venue analysis only to the extent they show that the defendant has a regular and established place of business in the District. Here, the employee's social media presence does not show a regular and established place of business for MPI.

In the absence of any evidence that the employee cannot of her own free will move her home outside of the District, Novartis' request for discovery such as "tax returns (depending on how [the employee] accounted for the support she received), reimbursement forms, pay stubs, and a variety of other sources" lacks merit. (D.I. 225 at 2) Even if MPI encourages the employee to choose to make her home in Delaware, and MPI financially supports that choice, Novartis does not articulate how this encouragement and support could possibly transform the employee's chosen abode into a regular and permanent establishment by *MPI* or an *MPI* place of business here.

Finally, Novartis included a new, additional request in its supplemental post-*BMS II* briefing. Novartis now asks for leave to file an amended complaint which would include a declaratory judgment claim against MPI, pursuant to 28 U.S.C. Section 2201. (D.I. 220 at 3) Novartis states that by seeking this amendment, it is opting to forgo “the unique regulatory remedies that [the Hatch-Waxman Act, 35 U.S.C. § 271(e)] provides,” and that it is willing to do so “in order to keep its case against MPI together with the cases against over 20 other generics in this district.” (*Id.*) According to Novartis, a declaratory judgment claim would be properly venued in Delaware because its venue would be governed by the general venue statute, Section 1391, rather than Section 1400(b). Assuming, for the sake of argument, that Novartis’ proposed amended complaint would not be futile, the Court finds that it is untimely and, if permitted, would unfairly prejudice MPI.⁷

Novartis did not include a declaratory judgment claim in its original complaint, did not seek or suggest it would seek leave to amend to add such a claim during the first two months that MPI’s motion to dismiss was pending, and only first suggested it wished to pursue this approach in supplemental briefing the Court *sua sponte* invited after issuing its *BMS II* decision. Novartis could and should have anticipated that the Court might resolve MPI’s co-pending motion to dismiss in *BMS II* in favor of MPI, and should have moved to amend substantially sooner. As

⁷ Pursuant to Fed. R. Civ. P. 15(a), at this stage a party may amend its pleading only with the opposing party’s written consent or the Court’s leave. The Third Circuit has adopted a liberal approach to the amendment of pleadings to maximize the chance that “a particular claim will be decided on the merits rather than on technicalities.” *Dole v. Arco Chem. Co.*, 921 F.2d 484, 486-87 (3d Cir. 1990) (internal citations omitted). Leave to amend should be granted absent “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of the allowance of the amendment, futility of amendment, etc.” *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Oran v. Stafford*, 226 F.3d 275, 291 (3d Cir. 2000). Futility of amendment occurs when the complaint, as amended, does not state a claim upon which relief can be granted. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997).

MPI correctly notes: “when Novartis filed its complaint, it was fully aware of MPI’s venue challenges in *BMS*. Yet, Novartis chose not to file a declaratory judgment claim,” and trying to do so in October 2018 (or any later date) is untimely. (D.I. 224 at 2)

Additionally, transforming Novartis’ case against MPI – and *only* Novartis’ case against *MPI*, but not against any of the remaining defendants in this multi-defendant consolidated action – into a declaratory judgment action would be unduly prejudicial to MPI. Among other things, to the extent Novartis’ Section 1391 venue theory may be plausible, granting the amendment would likely require the Court also to grant Novartis’ the request for discovery, necessitating the expenditure of more time and money by MPI to resolve venue issues. This would also exacerbate the Court’s challenges in managing this litigation, as all of the other remaining defendants are ready to move onto the merits of the pending preliminary injunction motion and, eventually, trial. Determining appropriate relief might also be complicated (should Novartis ultimately prevail on the merits) given that Novartis’ cause of action against MPI would differ from its cause of action against all of the other ANDA-filer defendants.

While the Court recognizes its decision today is prejudicial to Novartis, Novartis is free to file a new declaratory judgment action against MPI, in any District in which it believes it can prove venue is proper (which may include Delaware). Should such an action be filed here and assigned to the undersigned Judge, the Court will manage it in whatever manner is most reasonable and appropriate under all the circumstances. Should such an action have already been filed in another District, then Novartis plainly may seek to litigate that action in the manner it prefers. Should Novartis choose to file a new action in another District, and should venue be proper there, Novartis will have an opportunity to prove its case on the merits in that District (or

alternatively may move before the Joint Panel on Multidistrict Litigation for the creation of a multi-district litigation).

The potential inefficiencies for the federal judiciary arising from the Court's ruling are regrettable. Still, as emphasized in *TC Heartland*, MPI indisputably has the right to have this patent infringement action be litigated in a venue that is proper under Section 1400(b). This District is not such a venue for this case as it is currently pled. Accordingly, MPI's motion to dismiss is granted.

June 17, 2019
Wilmington, Delaware



HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE