

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

BRISTOL-MYERS SQUIBB COMPANY and)	
PFIZER INC.,)	
)	
Plaintiffs and Counterclaim-Defendants)	
)	
v.)	C.A. No. 17-374-LPS
)	(CONSOLIDATED)
AUROBINDO PHARMA USA INC. and)	
AUROBINDO PHARMA LTD.,)	
)	
Defendants and Counterclaim-Plaintiffs.)	

BRISTOL-MYERS SQUIBB COMPANY)	
and PFIZER INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 17-379-LPS
)	
MYLAN PHARMACEUTICALS INC.,)	
)	
Defendant.)	

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MEMORANDUM OPINION

October 18, 2018
Wilmington, Delaware


STARK, U.S. District Judge:

This is a pharmaceutical patent case brought by Bristol-Myers Squibb Company and Pfizer Inc. (“BMS” or “Plaintiffs”) pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(j). (C.A. No. 17-374 D.I. 1)¹ Presently before the Court is Defendant Mylan Pharmaceuticals Inc.’s (“MPI” or “Defendant”) renewed motion to dismiss or transfer under 28 U.S.C. § 1406(a) for improper venue. (C.A. No. 17-374 D.I. 178) In its initial motion to dismiss for improper venue, filed on July 25, 2017, MPI contended that venue was improper in this District based on the Supreme Court’s decision in *TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S. Ct. 1514, 1519 (2017), which held that § 1400(b) is the “sole and exclusive provision controlling venue in patent infringement actions.” (C.A. No. 17-379 D.I. 15 at 3-4) On September 11, 2017, the Court denied MPI’s initial motion without prejudice, as the Court could not determine based on the record then before it whether venue was proper in Delaware. (*See* C.A. No. 17-379 D.I. 36 at 38) The Court, therefore, ordered what it intended to be expedited, venue-related discovery on the question of whether MPI has a “regular and established place of business” under the second prong of § 1400(b). (*See id.* at 39, 43, 45)

On May 17, 2018, after eight months of limited discovery and three discovery dispute teleconferences, MPI renewed its motion to dismiss, maintaining that venue is improper in this District. The parties submitted briefing (*see* C.A. No. 17-374 D.I. 179, 192, 213) and the Court heard oral argument on July 18, 2018 (*see* Transcript (“Tr.”) (C.A. No. 17-374 D.I. 233)).

For the reasons set forth below, the Court will grant MPI’s motion.

¹The instant action is part of a consolidated action involving Plaintiffs and other generic pharmaceutical filers.

I. LEGAL STANDARDS

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). Federal Rule of Civil Procedure 12(b)(3) authorizes a party to move to dismiss a lawsuit for improper venue. 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). Venue in a patent infringement action is governed solely and exclusively by the patent venue statute, 28 U.S.C. § 1400(b). *See TC Heartland*, 137 S. Ct. at 1516. The general venue statute, 28 U.S.C. § 1391(c), does not have any application in a patent case. *See id.* at 1521.

“[U]pon 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). If the Court grants a Rule 12(b)(3) motion based on improper venue, the Court “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.” 28 U.S.C. § 1406(a).

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). Hence, when confronted with a motion to dismiss for improper venue, the Court may consider both the complaint and evidence outside the complaint. *See* 14D Wright & Miller, *Federal Practice & Procedure* § 3826 (4th ed. 2017). The Court will accept any venue-related allegations in the complaint as true, unless those allegations are contradicted by the

defendant's affidavits. *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 submitted by the plaintiff. *See Bockman*, 459 F. App'x at 161 (affirming District Court's 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").

II. DISCUSSION

The patent venue statute, 28 U.S.C. § 1400(b), provides:

Any civil action for patent infringement may be brought in the judicial district [1] where the defendant resides, or [2] where the defendant has committed acts of infringement and has a regular and established place of business.

It is undisputed that MPI is incorporated in West Virginia (*see* C.A. No. 17-379 D.I. 1 at ¶ 2; C.A. No. 17-374 D.I. 179 at 1) and, therefore, does not "reside" in Delaware. *See TC Heartland*, 137 S. Ct. at 1517 ("[A] domestic corporation 'resides' only in its State of incorporation for purposes of the patent venue statute."). Plaintiffs have proposed alternative bases on which venue here may, nonetheless, be proper.

During a March 9, 2018 teleconference, the Court identified three open venue questions it believed were implicated in this case: (1) under the first prong of § 1400(b), whether the residency of one entity can be imputed to another; (2) under the second prong of § 1400(b), what, if any, degree of fraud or abuse of the corporate form is required in order for two entities to have an alter-ego relationship or to in any way impute a regular and established place of business of

one entity to another; and (3) assuming some degree of fraud or abuse of corporate form is necessary, whether a corporate entity or corporate family's structuring of its business relationships can rise to that level of fraud or abuse. (*See* C.A. No. 17-374 D.I. 119 at 60)

MPI contends that dismissal is appropriate because MPI is not incorporated in Delaware and neither performed the alleged act of infringement in Delaware nor maintains a regular and established place of business in Delaware. (*See* C.A. No. 17-374 D.I. 179 at 6)² In addition, MPI argues that the residences and activities of non-party affiliates of MPI are irrelevant because statutes and common law-doctrines regarding “alter egos” and “piercing the corporate veil” cannot supplement § 1400(b). (*See id.*) It would follow that the Court may not, in any circumstance, impute the residence or regular and established business of one entity to another for purposes of § 1400(b). (*See id.*) Even if such doctrines were relevant to § 1400(b), in MPI's view Plaintiffs have failed to meet their burden to prove the requisite fraud by clear and convincing evidence. (*See id.*)

BMS responds that the Delaware residency of an MPI subsidiary, Mylan Securitization LLC (“Mylan Securitization”), may be imputed to MPI due to an alleged alter ego relationship between these two entities and, thus, MPI's motion should be denied. (*See* C.A. No. 17-374 D.I. 192 at 1-2) BMS does not, at this time, contend that venue is proper under the second prong of § 1400(b) – where the inquiry is “whether MPI maintains a ‘regular and established place of business’ in this District” – as BMS asserts that MPI provided insufficient discovery on this

²While MPI's motion is structured as a motion to dismiss or transfer, at oral argument the parties agreed that if the Court did not find venue appropriate in this District, it should dismiss, not transfer, the case. (*See* Tr. at 74-75) A related action is pending in the Northern District of West Virginia. (*See id.* at 74; *see also Bristol-Myers Squibb Co. et al v. Mylan Pharm. Inc.*, 1:17-CV-00055 (N.D. W. Va.))

issue. (*See id.* at 2 n.2; *see also* Tr. at 44) In the alternative, BMS contends that, because this is a Hatch-Waxman action, venue should be governed by § 1391 and, under that statute, there can be no dispute that venue is proper in Delaware.

A. Venue Under § 1400(b)

BMS has failed to meet its burden to show that venue is proper in this District. *See ZTE*, 890 F.3d at 1013.

As an initial matter, the Court must address whether the residency of one entity may be imputed to another for purposes of satisfying § 1400(b). MPI contends that under *TC Heartland*, the venue statute may not be supplemented with other statutory or common-law doctrines. (C.A. No. 17-374 D.I. 179 at 12) BMS counters that under common law, which has not been abrogated by *TC Heartland*, the residency of one entity may be imputed to another when the entities are corporate affiliates that have freely disregarded their separateness. (C.A. No. 17-374 D.I. 192 at 7) The Court agrees with BMS that residency may be imputed under the first prong of the venue statute. *See Minn. Mining & Mfg. v. Eco Chem, Inc.* (“3M”), 757 F.2d 1256, 1265 (Fed. Cir. 1985) (“[P]iercing the corporate veil is appropriate in order to establish venue under the patent venue statutes.”); *Leach Co. v. Gen. Sani-Can Mfg. Corp.*, 393 F.2d 183, 186 (7th Cir. 1968) (finding venue in patent infringement case proper as to corporation based on acts of its affiliate); *Xodus Med., Inc. v. Allen Med. Sys., Inc.*, 2018 WL 2338763, at *1 (W.D. Pa. May 22, 2018) (piercing of corporate veil is available for establishing proper venue under second prong of § 1400(b)); *Unity Opto Tech. Co. v. Lowe’s Home Centers, LLC*, 2018 WL 2087250, at *2 (W.D. Wis. May 4, 2018) (same). The Supreme Court’s decision in *TC Heartland* did not overrule 3M – which was decided in the context of § 1400(b). *See* 757 F.2d at 1261 n.8.

While related corporate entities are generally legally distinct, piercing the corporate veil, and imputing one entity's residence to another, may be appropriate in circumstances where one corporation acts as the alter ego of the other. *See id.* at 1265. Even MPI, ultimately, appears to acknowledge this possibility, while emphasizing the rarity of the applicable requirements being satisfied. (*See* Tr. at 24-25; *see also* C.A. No. 17-374 D.I. 213 at 4 (MPI reply brief seemingly recognizing that “two distinct entities” may be “treat[ed] . . . as one for venue purposes” where there is “some compelling reason to do so”))

The Court is not holding that one entity necessarily *is* a resident of two places; for instance, there is no dispute that MPI resides solely in West Virginia. (*See* Tr. at 59) Instead, the Court is allowing for the possibility that, for the purposes of venue in patent cases, there are circumstances under which it is appropriate to impute the residence of one entity to another entity – where there is an alter ego relationship or piercing of the corporate veil – and in those circumstances the law allows the Court to treat one entity *as if* it were a resident in a second district.³ *See generally In Re BigCommerce*, 890 F.3d 978, 986 (Fed. Cir. 2018) (holding that

³A contrary conclusion – that, under no circumstances, may the residency status of one entity be imputed to another – would seem to create an opportunity to flout the policies underlying the Hatch-Waxman Act and allow for intentional corporate malfeasance. At the hearing, BMS' counsel put it this way:

[W]e have to think about the equitable impact of this. People could set up shell[] [corporations] and just say, well, we can't be a residen[t] of two places and therefore you can't get at us. That would be very inconsistent with the objectives with federal policy, with the whole notion of the Hatch-Waxman framework

Here, we have an entity that has set up . . . subsidiaries and affiliates in Delaware. They shouldn't be allowed, if we can show, which we have, that there is an alter-ego[,] to avoid venue here just because they have elected to incorporate somewhere else.

“for purposes of determining venue under § 1400(b) in a state having multiple judicial districts, a corporate defendant *shall be considered* to ‘reside’ only in the single judicial district within that state where it maintains a principal place of business) (emphasis added).

Having concluded that the residency of one entity may be imputed to another, the Court must next consider the showing necessary to impute venue under § 1400(b). The presumption of corporate separateness may only be overcome by a showing of fraud, injustice, or unfairness. *See Trustees of Nat. Elevator Indus. Pension, Health Benefit & Educ. Funds v. Lutyk*, 332 F.3d 188, 194 (3d Cir. 2003) (“[P]iercing of the corporate veil is an equitable remedy, and therefore the situation must present an element of injustice or fundamental unfairness.”) (internal citation and quotation marks omitted); *see also Blair v. Infineon Techs. AG*, 720 F. Supp. 2d 462, 471 (D. Del. 2010) (“While the list of factors is not exhaustive and no single factor is dispositive, some combination is required, and an overall element of fraud, injustice, or unfairness must always be present.”).⁴

The Third Circuit considers multiple non-exclusive factors in evaluating an alleged alter ego relationship,⁵ including:

gross undercapitalization, failure to observe corporate formalities,
nonpayment of dividends, insolvency of debtor corporation,
siphoning of funds from the debtor corporation by the dominant

(Tr. at 60-61)

⁴The parties agree that Third Circuit law governs, as corporate-veil piercing does not present questions unique to patent law. (*See* Tr. at 45-46, 55)

⁵“Although the tests employed to determine when circumstances justifying ‘veil-piercing’ exist are variously referred to as the ‘alter ego,’ ‘instrumentality,’ or ‘identity’ doctrines, the formulations are generally similar, and courts rarely distinguish them.” *Pearson v. Component Tech. Corp.*, 247 F.3d 471, 485 n.2 (3d Cir. 2001)

stockholder, nonfunctioning of officers and directors, absence of corporate records, and whether the corporation is merely a facade for the operations of the dominant stockholder.

Pearson, 247 F.3d at 485. “The test, whether or not a particular version requires an element of fraudulent intent, . . . is demonstrably an inquiry into whether the debtor corporation is little more than a legal fiction.” *Id.* “Alter ego must be shown by clear and convincing evidence.” *Lutyk*, 332 F.3d at 194 (internal quotation marks omitted).⁶

Plaintiffs have failed to meet their heavy burden. *See Pearson*, 247 F.3d at 485 (burden to establish alter ego relationship “is notoriously difficult for plaintiffs to meet”). BMS contends that Mylan Securitization, an accounts-receivable securitization entity, is an alter ego of MPI. Based on the information it received over several months of discovery, BMS asserts an alter ego relationship exists because Mylan Securitization: (1) is wholly-owned by MPI; (2) does not have its own employees, revenue, profits, Delaware tax filings, or facilities; (3) is represented by the same counsel as MPI in transactions with MPI; (4) has “tiny” costs of operations; and (5) shares one overlapping director with MPI. (C.A. No. 17-374 D.I. 192 at 10-11; *see also* Tr. at 48-50) In addition, BMS reads Mylan Securitization’s status as a special purpose vehicle (“SPV”) as meaning that Mylan Securitization is “designed to try to insulate [MPI] from liability in a bankruptcy-type situation” by “isolat[ing] assets in a different entity.” (Tr. at 49)

While these factors may show a close relationship between MPI and Mylan Securitization, they are insufficient to pierce the corporate veil or render one entity the alter ego of the other. As MPI explains, there is nothing improper about forming a wholly-owned limited

⁶The parties agree that the applicable standard of proof is clear and convincing evidence. (*See* Tr. at 55; *see also* C.A. No. 17-374 D.I. 179 at 3)

liability company for tax purposes. (*See* Tr. at 65; *see also* C.A. No. 17-374 D.I. 214-18) While BMS attempts to show undercapitalization or insolvency of MPI due to its relationship with Mylan Securitization, it has produced no evidence to support these allegations. Similarly, the fact that MPI and Mylan Securitization share one overlapping director does not demonstrate that corporate formalities have been ignored. While BMS makes much of the fact that MPI and Mylan Securitization were represented by the same counsel in the transaction creating Mylan Securitization (*see* Tr. at 50-51), MPI correctly observes that the transaction is not secret, nor is there evidence to suggest it was a sham or the result of a fraudulent negotiation. Mylan Securitization's status as an SPV is likewise not nefarious. As BMS itself described, the corporate structure is designed to accelerate the provision of cash to MPI (which should make it easier, not harder, to recover damages from MPI, were it found to be monetarily liable). (*See also* C.A. No. 17-374 D.I. 193-14 at 76-77) (testimony from knowledgeable witness describing how Mylan Securitization pays cash to MPI for MPI receivables and then securitizes receivables and sells securities to investors) In sum, Plaintiffs have failed to produce any evidence showing that corporate formalities were ignored or that anything illegal or improper occurred in setting up Mylan Securitization. To the contrary, the record evidence shows that the two entities maintain corporate separateness, that Mylan Securitization is a registered LLC with its own books and records, and that all of its documents are publicly available.

Even considering all of these factors together and in the light most favorable to BMS, they do not support disregarding MPI's separate corporate status, as Plaintiffs have not shown *any* evidence of fraud, unfairness, or injustice. *See Cannon Mfg. Co. v. Cudahy Packing Co.*, 267 U.S. 333, 334-35 (1925) (control of subsidiary operations by parent corporation and shared

business purpose were insufficient to impute venue absent companies' disregard of corporate separateness); *see also Sovereign IP, LLC v. AT&T, Inc.*, 2017 WL 5126158, at *1 (E.D. Tex. Oct. 31, 2017), *adopted*, 2017 WL 6452802 (E.D. Tex. Dec. 18, 2017) (holding that "[e]ven if venue-related discovery revealed an interdependence between AT&T Services and AT&T Inc., . . . this would not be sufficient to impute any AT&T Services place of business to AT&T Inc.," given uncontradicted sworn declaration that "corporate form has not been disregarded").

Finally, the Court finds further discovery unwarranted. Expedited venue discovery was authorized more than a year ago and, since that time, the Court has handled three discovery disputes between the parties related to the subject of this motion. During the most recent discovery dispute call, the Court concluded it could see only two realistic approaches going forward: either proceed based on the discovery that had been conducted and commence briefing on a renewed motion to dismiss, or require further discovery, which could amount to a fishing expedition, and might not soon end nor ever satisfy Plaintiffs. (*See* C.A. No. 17-374 D.I. 119 at 57-58) The Court determined, over Plaintiffs' objection and despite some doubt as to whether the record was yet adequate, that additional discovery was not warranted, but warned MPI that once briefing was completed it might become clear that a fuller record was needed and the motion would have to be renewed, yet again – after more delay. Today, the Court concludes the record is sufficient and Plaintiffs have been given an adequate opportunity to show venue is proper here, and they have failed to do so.⁷ Accordingly, MPI's motion will be granted.

⁷Additionally, during oral argument, Plaintiffs advised the Court that they no longer seek additional discovery as an alternative to denial of MPI's motion. (*See* Tr. at 46-47, 58-59)

B. Venue Under § 1391

BMS alternatively contends that “the Court need not rely on § 1400(b) to deny MPI’s motion” because venue is proper under § 1391. (C.A. No. 17-374 D.I. 192 at 16) According to BMS, Hatch-Waxman actions are not governed by § 1400(b). (*See id.*) Instead, BMS insists, the text of § 1400(b), uses of the term “civil action for patent infringement” elsewhere in the U.S. Code, the patent venue statute’s legislative history, the structure of and policy behind the Hatch-Waxman Act, and general policy considerations all “support treating Hatch-Waxman actions as different from traditional infringement actions for venue purposes.” (*Id.* at 17-19) To BMS, then, “§ 1391, rather than § 1400(b), applies here.” (*Id.* at 16-17)

This argument is plainly untimely. Until briefing on MPI’s renewed motion, Plaintiffs had never proposed § 1391 as an appropriate, post-*TC Heartland* basis for venue in this case. Not once during the prior motion briefing, oral argument, or in any discovery dispute letter or teleconference – over the course of at least eight months, when venue-related discovery was ongoing – did Plaintiffs raise § 1391. Plaintiffs concede as much. (*See Tr.* at 38)

In any event, Plaintiffs’ contention is also unavailing. In *TC Heartland*, 137 S. Ct. at 1518, the Supreme Court clearly articulated that “the patent venue statute alone should control venue in patent infringement proceedings” (internal quotation marks omitted). Here, after MPI filed an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“FDA”), Plaintiffs initiated a civil action for patent infringement, contending in their complaint that MPI’s ANDA filing was an act of patent infringement. (C.A. No. 17-379 D.I. 1 at ¶ 1 (“*This is an action for patent infringement . . .*”) (emphasis added); *see also* 35 U.S.C. § 271(e)(2)(A) (“It shall be *an act of infringement* to submit an [ANDA] application . . .

for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”) (emphasis added). By filing a Hatch-Waxman patent infringement action, Plaintiffs obtained the benefit of the automatic 30-month stay of FDA approval of MPI’s ANDA, a benefit to which Plaintiffs would not have been entitled if their cause of action were anything other than a claim for patent infringement. *See* 21 U.S.C. § 355(c)(3)(C) (automatically staying FDA approval of ANDA where, among other conditions, “an action is brought for infringement of the patent” covering drug or use of drug).

As this case is incontestably a “civil action for patent infringement,” venue is governed solely and exclusively by § 1400(b). Hence, again, MPI’s motion will be granted.

III. CONCLUSION

For the reasons stated above, the Court will grant MPI’s motion to dismiss for improper venue. Consistent with the parties’ most recent positions, the Court will not transfer the case but will, instead, dismiss it. An appropriate Order follows.