

for the Federal Circuit recently held, “[t]he Supreme Court changed the controlling law when it decided *TC Heartland*[¹] in May 2017.” *In re Micron Tech., Inc.*, __ F.3d __, 2017 WL 5474215, at *6 (Fed. Cir. Nov. 15, 2017). Therefore, “[t]he venue objection was not available until the Supreme Court decided *TC Heartland* because, before then, it would have been improper, given controlling precedent, for the district court to dismiss or to transfer for lack of venue.” *Id.* at *3. Hence, Mylan did not waive its challenge to venue by failing to press it until after *TC Heartland*. *See id.*

The Venue Defense Was Not Forfeited

Nor does the Court find that Mylan forfeited its challenge to venue due to its conduct in this litigation; and Mylan is not otherwise estopped from prevailing on this challenge. *See Micron*, 2017 WL 5474215, at *7 (“[D]istrict courts have authority to find forfeiture of a venue objection.”); *Boston Sci. Corp. v. Cook Grp. Inc.*, 2017 WL 3996110, at *9 (D. Del. Sept. 11, 2017) (“It may well be that in any particular case the Court, after excusing waiver based on *TC Heartland*, should next proceed by assessing whether, in any event, a defendant should not be permitted to press its effort to change venue. Prototypical examples of where the Court might reach such a conclusion include whether a defendant raises venue for the first time on the eve of trial, or many months (or years) after *TC Heartland* was handed down, or where dismissal or transfer would unduly prejudice a plaintiff. Or a party may have taken affirmative steps in the litigation that should, in particular circumstances, be viewed as essentially estopping that party from prevailing on an improper [venue] defense.”) (internal citations omitted).

Plaintiffs Javelin Pharmaceuticals, Inc., Hospira, Inc., and Janssen Pharmaceutica N.V.

¹*TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017).

(“Plaintiffs”) filed their complaint on April 4, 2016. (D.I. 1) In its answer, filed on June 13, 2016, Mylan contended that venue was not proper in this District (D.I. 15 at 18, 29), which put Plaintiffs (and the Court) on notice that Mylan believed it should not have to litigate this case in Delaware. Consistent with the then-governing legal precedent, *see VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574 (Fed. Cir. 1990), over the next 14 months Mylan complied with the Court’s scheduling order (D.I. 21) and rules of procedure and actively participated in this litigation – which included the claim construction process (*see, e.g.*, D.I. 44, 48, 53), leading to the Court’s issuance of a claim construction opinion and order (D.I. 91, 92). Then, on August 7, 2017, less than three months after *TC Heartland* was decided, Mylan filed its pending motion to dismiss or transfer, due to improper venue, pursuant to Federal Rule of Civil Procedure 12(b)(3). Trial in this case is not scheduled to begin until April 9, 2018 (D.I. 21 at 11) and the 30-month stay on FDA approval of Mylan’s ANDA for its generic drug product does not expire until August 2018 (D.I. 3).

The Court discerns nothing in Mylan’s participation in this litigation that should be deemed as having forfeited a now potentially-meritorious venue objection. *See Micron*, 2017 WL 5474215, at *7-8 (identifying non-exclusive bases on which forfeiture of venue challenge may be found, including “untimeliness or consent,” “submission through conduct,” and where objection “was not made until long after” change in law “took effect”) (internal quotation marks omitted). Nor does the Court’s conclusion of no forfeiture threaten Plaintiffs with any undue prejudice, particularly given that the Court is not modifying the trial date and given that a parallel action is pending in the District of West Virginia, with trial scheduled at approximately the same date as the trial scheduled by this Court. (*See* D.I. 59 at 1-2) Regardless of which side has the

burden with respect to waiver, forfeiture, and estoppel, the Court finds that none of these doctrines here precludes Mylan from proceeding with its challenge to venue in this case.²

Defendants Are Not Delaware Residents for Purposes of Patent Venue

Venue in a patent case is governed exclusively by 28 U.S.C. § 1400(b), *TC Heartland*, 137 S.Ct. at 1516, which provides: “[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.” For purposes of § 1400(b), a defendant which is a domestic corporation “resides” only in its state of incorporation. *See TC Heartland*, 137 S.Ct. at 1517. It is undisputed that MLL, Inc., and MPI – which are, respectively, incorporated in India, Pennsylvania, and West Virginia (D.I. 15 at 3-4) – do not “reside” in Delaware.

Venue Is Potentially Proper Here Under the Second Prong of § 1400(b)

Venue is proper in this District unless Mylan can show that the second prong of § 1400(b) is not satisfied. *See Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, 2017 WL 3980155, at *5 (D. Del. Sept. 11, 2017) (“*BMS*”) (holding that burden is on party opposing venue). That is, Delaware is a proper venue for this lawsuit unless Mylan can meet its burden to show either that (i) a defendant has not committed acts of infringement in Delaware, or (ii) a defendant does not have a regular and established place of business in Delaware. If Mylan can show either of the foregoing is true with respect to one or more of the Defendants, then venue

²Should Mylan ultimately choose to renew its venue challenge after the period of venue-related discovery being ordered, Mylan will not be deemed to have forfeited its venue objection based solely on its compliance with discovery orders or its (required) participation in all aspects of this litigation during the venue-discovery period.

here is improper with respect to such Defendant(s), and the Court will have to dismiss or transfer this case (at least as to one or more Defendants). Mylan contends it has met its burden with respect to both requirements of this second prong of § 1400(b).

The First Requirement: Acts of Infringement

Mylan has failed to show that any of the Defendants has not committed acts of infringement in Delaware, given the Court's understanding of the meaning of this statutory requirement in the context of Hatch-Waxman litigation. *See BMS*, 2017 WL 3980155, at *12 (holding that "acts of infringement" in this 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"). Mylan gives the Court no persuasive reason to reconsider this determination.

The Second Requirement: Regular and Established Place of Business

Venue-Related Discovery

Turning to whether one or more of the Defendants lacks a regular and established place of business in Delaware, the Court concludes that the record, at present, does not permit it to make a finding. Therefore, the Court will allow Plaintiffs to take venue-related discovery.

As the Federal Circuit recently explained in *In re Cray*, 871 F.3d 1355, 1362 (Fed. Cir. 2017), "[t]hree general requirements [are] relevant to the [regular and established place of business] 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. If any statutory requirement is not satisfied, venue is improper under § 1400(b)."

"In 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.* The Federal Circuit “stress[ed] that no one fact is controlling” and all facts must be “taken together” in determining whether venue is proper. *Id.* at 1366. This suggests that, at 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.

Related Mylan Entities May Be Relevant to the
Regular and Established Place of Business Inquiry

While Defendants contend that “there is no evidence to establish the Mylan Defendants have a regular and established place of business here” (D.I. 73 at 2), the Court finds Plaintiffs’ theory – that the “places” of any Mylan entity, including Mylan affiliates, subsidiaries, parents, or alter egos, may be attributable to the named Mylan Defendants for purposes of venue – is not frivolous and justifies some limited venue-related discovery.³

Defendants declare: “[n]one of Mylan Inc., MPI, or MLL . . . maintain any offices, warehouses, manufacturing plants, or other real property in Delaware;” nor do they “have a mailing address or telephone listing in Delaware,” “have any employees or officers working in Delaware,” or “advertise or represent that they have any place of business in Delaware.” (D.I. 60 at 2-3) Plaintiffs contend, however, that MPI and MLL are wholly-owned subsidiaries of Inc.,

³Contrary to Mylan’s contentions, the record here is not “replete with sworn facts proving that th[e] three requirements [of *Cray*] are not met with respect to Defendants.” (D.I. 75 at 2) Plaintiffs alleged in their Complaint that Defendants “collaborated in the development of Mylan’s Product and preparation and filing of Mylan’s ANDA” and if the ANDA is approved, Defendants “plan to and will act in concert to manufacture, distribute, import, offer for sale and/or sell Mylan’s Product throughout the United States, including within the State of Delaware.” (D.I. 1 ¶¶ 15, 20)

and that Inc. has at least 20 subsidiaries incorporated in the State of Delaware.⁴ (D.I. 1 ¶ 36) In Plaintiffs' view, it is possible that through Inc.'s various Delaware subsidiaries, one or more of the named Defendants may be found to have a regular and established place of business in this District.

As this legal theory was not addressed by *Cray*, the Court sees no basis on which to find that Plaintiffs' theory as to how the named Defendants might be found to have a regular and established place of business in Delaware, based on other Mylan entities having a regular and established place of business here, to be frivolous. It does not appear that *Cray* disturbed the prior holding of the Federal Circuit in *Minnesota Mining & Manufacturing Co. v. Eco Chemicals, Inc.*, 757 F.2d 1256, 1265 (Fed. Cir. 1985), that "venue in a patent infringement case [may be] proper with regard to one corporation by virtue of the acts of another, intimately connected, corporation."

In fact, *Cray* can be read as having provided further support to the viability of Plaintiffs' theory. In *Cray*, the Federal Circuit found that a defendant's employee's home may, in some circumstances, constitute a "place of the defendant." See 871 F.3d at 1363. *Cray* approvingly cites the Federal Circuit's prior decision *In re Cordis Corp.*, 769 F.2d 733, 735 (Fed. Cir. 1985), where an employee's home was found to support a finding that the named-defendant employer had a regular and established place of business in a district. Where an employee's home is used "to store its [i.e., the named defendant's] literature, documents, and products . . . that the employees then directly took to its [the named defendant's] clients," that home may be found to

⁴Mylan admitted that "certain subsidiaries of Mylan Inc. are incorporated in the State of Delaware," but did not address the number of subsidiaries. (D.I. 15 at 14)

be a regular and established place of business of the named defendant. *Cray*, 871 F.3d at 1362.

It may be more likely with respect to corporate entities than it is with respect to employees for a regular and established place of business to be properly treated, for venue purposes, as a regular and established place of business of a named defendant. Several of the reasons given in *Cray* for why the employee's home there was *not* a regular and established place of the employer's business seem less applicable to relationships within a corporate family. As *Cray* observed, "[e]mployees change jobs. Thus, the defendant must establish or ratify the place of business. It is not enough that the employee does so on his or her own." *Id.* at 1363. It seems likely that a corporate subsidiary or other corporate affiliate cannot extricate itself from a corporate family as easily as an employee can generally depart his job, or as easily as an employee may keep her job but change her personal residence. Further, unlike employees, who typically live in homes of their own choice in locations that are not at all "ratified" by their employer, it is likely more common for corporate parents to "establish" or "ratify" the place of business of their subsidiaries or other related corporate entities (with whom, for instance, they might share space). *See id.*

In the Court's view, it follows from *Cray* that the "place" of a corporate affiliate or subsidiary of a named defendant may, in at least some circumstances, and similar to the place of a defendant's employee, be treated as a "place of the defendant." Among the pertinent circumstances to be considered is whether the formalities of corporate separateness are preserved.⁵ Plaintiffs suggest that formal corporate separateness among the various Mylan

⁵*See generally* *Soverain IP, LLC v. AT&T, Inc.*, 2017 WL 5126158, at *1-2 (E.D. Tex. Oct. 31, 2017) (finding place of subsidiary could not be imputed to parent-defendant because formal corporate separateness was maintained); *Post Consumer Brands, LLC v. Gen. Mills, Inc.*,

entities may not have been preserved. (D.I. 65 at 14) This is a topic on which Plaintiffs will be permitted to take discovery.

The record presently before the Court does not establish, one way or the other, whether any entity related to Mylan – be it a parent, subsidiary, affiliate, agent, or alter ego – has any regular and established place of business in Delaware. Nor does it address the formal corporate separateness between, or the interrelationships among, the named defendants and the related Mylan entities, including the Delaware subsidiaries. It is appropriate, then, for Plaintiffs to have an opportunity to take discovery on these matters, and for Defendants thereafter to renew, should they wish to do so, their challenge to the propriety of venue in this District.

Physical Place in the District

As stated above, the first requirement of *Cray* is that there “must be a physical place in the district, . . . *i.e.*, a building or a part of a building set apart for any purpose or quarters of any kind from which business is conducted.” 871 F.3d at 1362 (internal quotation marks omitted). While a “virtual space” or “electronic communications from one person to another” will not suffice, the “‘place’ need not be a ‘fixed physical presence in the sense of a formal office or store.’” *Id.* All that is required is that there is a “physical, geographical location in the district from which the business of the defendant is carried out.” *Id.* Under Plaintiffs’ theory, which could attribute physical places in Delaware of any Mylan affiliate to one or more of the named Defendants in this case, it is possible that discovery of the relationships amongst the various

2017 WL 4865936, at *2 (E.D. Mo. Oct. 27, 2017) (denying venue discovery where there was no suggestion that formal corporate separateness was not preserved); *Symbology Innovations, LLC v. Lego Sys., Inc.*, 2017 WL 4324841, at *10-11 (E.D. Va. Sept. 28, 2017) (finding formal corporate separateness prevented imputing place of subsidiary to parent-defendant).

Mylan entities, and of the Delaware places of business of those various entities, may show that this requirement is satisfied.

Regular and Established Place of Business

Second, the place “must be a regular and established place of business.” *Id.*

To be “regular,” the business should, for example, “operate[] in a steady, uniform, orderly, and methodical manner.” *Id.* at 1362 (internal quotation marks omitted); *see also id.* at 1363 (“[A] five-year continuous presence in the district demonstrates that the business was established for purposes of venue.”) (citation omitted). Simply “conduct[ing] business” from a place in the district or engaging in “sporadic activity cannot create venue.” *Id.* at 1362, 1365-66; *see also id.* at 1363 (“[A] business that semiannually displayed its products at a trade show in the district had only a temporary presence.”) (citation omitted).

For a place of business to be “established,” it must have some degree of permanence. *See id.* (“‘[E]stablished’ . . . contains the root ‘stable,’ indicating that the place of business is not transient. It directs that the place in question must be settled certainly, or fixed permanently.”) (internal quotation marks omitted); *see also id.* at 1363 (“[W]hile a business can certainly move its location, it must for a meaningful time period be stable, established.”).

It follows that transient, sporadic visits to a District – for instance, to a courthouse to participate in litigation – are not of sufficient permanence or steadiness to be “regular” or “established.”

Still, under Plaintiffs’ theory, which could attribute the Delaware “regular and established” physical places “of business” of any Mylan affiliate to one or more of the named Defendants in this case, it is possible that discovery of the relationships amongst the various

Mylan entities, and of the Delaware places of business of those various entities, may show that this requirement is satisfied.

Of the Defendant

The third *Cray* requirement is that “the regular and established place of business must be the place of the defendant.” *Id.* The “place *of the defendant*,” therefore, must “not [be] solely a place of the defendant’s employee.” *Id.* (emphasis added). The defendant “must establish or ratify the place of business. It is not enough that the employee does so on his or her own.” *Id.*

In determining whether a place of business is a place of the defendant, “[r]elevant considerations include whether the defendant owns or leases the place, or exercises other attributes of possession or control over the place.” *Id.* Furthermore, any conditions the employer places on the employee’s location or use of the employee’s place are more likely to make that a place that may properly be considered a place of the defendant. *Id.* (“Another consideration might be whether the defendant conditioned employment on an employee’s continued residence in the district or the storing of materials at a place in the district so that they can be distributed or sold from that place.”). Further considerations include “[m]arketing or advertisements . . . , but only to the extent they indicate that the defendant itself holds out a place for its business.” *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.*

It follows that a courthouse – even one in which a defendant like Mylan litigates frequently, as a necessary and predictable part of its business, in order to obtain approval to enter the market with its generic drugs – is not a place “of the defendant.” *Id.* The courthouse is not

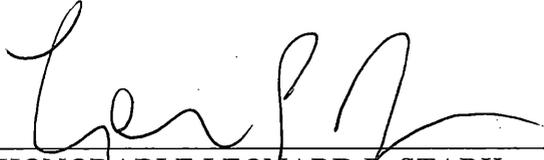
owned or leased by Mylan; nor does Mylan exercise other attributes of possession or control over the courthouse.

Still, under Plaintiffs' theory, which could attribute Delaware physical places of any Mylan affiliate to one or more of the named Defendants in this case, it is possible that discovery of the relationships amongst the various Mylan entities, and of the Delaware places of business of those various entities, may show that this requirement is satisfied.

Conclusion

Consequently, and contrary to Mylan's assertion, Plaintiffs' request for venue discovery is not "moot." (D.I. 75 at 2) Instead, as Plaintiffs describe, "Mylan essentially asks this Court to decide the motion on a one-sided factual record, without permitting the facts to be tested." (D.I. 76 at 2) The Court has determined that this would not be a reasonable and appropriate method of proceeding to resolve the important, novel venue questions that are now before it. Accordingly, after receiving specific input from the parties, the Court will order venue-related discovery, to proceed contemporaneously with the remainder of this case as it proceeds on the merits.

December 1, 2017
Wilmington Delaware


HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT COURT