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Hatch-Waxman Litigation Venue Update Post-*Google*

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Patent litigants often fight over personal jurisdiction and venue. This battle is particularly high-stakes in Hatch-Waxman litigation, because the fight between brand name and generic drug makers arises prior to Food and Drug Administration approval and launch of the accused product. The brand often can maintain its market exclusivity during the pendency of the case; thus, even if a generic eventually wins on the merits, a slow case can effectively be a win for the brand.

Time to disposition varies widely across venues. Certain districts are known for being faster than others. The U.S. District Court for the Eastern District of Texas is a hotspot, for example, because its trial-friendly local rules lead litigants to believe that they have a much better chance of getting to trial, and getting to trial relatively quickly, compared to other venues. In the context of Hatch-Waxman litigation, a brand's ability to choose and hold venue results in almost all Hatch-Waxman cases going to federal courts in Delaware and New Jersey, which have relatively slow dockets.

This article discusses several recent decisions that may rein in a litigant's flexibility to house their case in a preferred venue—either speedy or slow. Now, it appears that Hatch-Waxman cases will proceed exclusively in the venues where generics are incorporated or are headquartered. Because litigants cannot be tied to venue through future sales, Delaware and New Jersey, where many generics are headquartered or incorporated, should continue to see a substantial portion of Hatch-Waxman litigation. Thus, although the *In re Cray* and *In re Google* are de jure venue restrictions, there should be few de facto changes to Hatch-Waxman venue analysis in their wake.

Patent Venue Precedent

In 2014, *Daimler AG v. Bauman*, 571 U.S. 117 (2014), limited general personal jurisdiction. The U.S. Supreme Court held that Daimler's contacts in California, relative to its other national and international contacts, were not sufficient to render it "at home" in the state for the purpose of general jurisdiction. Then in 2017, *TC Heartland v. Kraft Foods*, 137 S. Ct. 1514 (2017), reined in venue by distinguishing the patent venue statute from the general venue statute. The Court held that the patent venue statute cannot be read in view of the general venue statute, and that "where the defendant resides," for domestic corporations, means only the state in which the defendant is incorporated.

The patent venue statute, 28 U.S.C. §1400(b), provides that any "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." Determining whether a defendant committed "acts of infringement" or has a "regular and established place of business" in a given venue may be particularly difficult in the Hatch-Waxman context, when no sales of an accused product have taken place.

Not long after the Supreme Court's decision in *TC Heartland*, the U.S. Court of Appeals for the Federal Circuit weighed in on patent venue too. *In re Cray*, 871 F.3d 1355 (Fed. Cir. 2017), clarified what constitutes a "regular and established place of business" for patent venue purposes. To establish proper venue, *Cray* requires a physical place in the district, which "must be established," and "must be a place of the defendant."

Hatch-Waxman Venue After *Cray*

The *Cray* test still left questions regarding what constitutes an established place of business. In February 2020, the Federal Circuit tackled the second prong of *Cray* in *In re Google, LLC*, 949 F.3d 1338 (Fed. Cir. 2020). In doing so, the court bolstered recent Hatch-Waxman decisions in the districts of New Jersey and Delaware. Together, these cases indicate that Hatch-Waxman litigation is likely only proper in the venue where a generic is incorporated or headquartered.

Two 2019 cases—one in Delaware, one in New Jersey—dealt with Hatch-Waxman venue questions in the wake of *Cray*. In both cases, the court analyzed venue with respect to Mylan Pharmaceuticals Inc. under Section 1400(b). In both cases, the court determined that the plaintiffs did not establish proper venue under *Cray*.

New Jersey

Plaintiffs Valeant Pharmaceuticals, Dow Pharmaceutical Sciences, and Kaken Pharmaceutical Co., sued Mylan, among others, for patent infringement under the Hatch-Waxman Act in the District of New Jersey. *Valeant Pharms. N. Am. LLC v. Zydus Pharms. U.S.*, No. 18-cv-13635 (PGS)(LHG), 2019 BL 334375 (D.N.J. Aug. 13, 2019). Mylan is incorporated and

headquartered in West Virginia, but the plaintiffs argued that Mylan satisfied the second prong of 28 U.S.C. §1400(b) by committing an act of patent infringement in New Jersey and having a regular and established place of business in the state.

The plaintiffs pointed to the District of Delaware's decision in *Bristol-Myers Squibb v. Mylan*, No. 17-379, 2017 BL 318410, at *15 (D. Del. Sep. 11, 2017) and the District of New Jersey's holding in *Celgene v. Hetero Labs*, No. 17-3387, 2018 BL 71484, at *8 (D.N.J. Mar. 2, 2018), which found that the Hatch-Waxman Act's focus on future patent infringement following approval of a generic drug makes it appropriate to include an alleged Hatch-Waxman infringer's future acts in a venue analysis. Thus, the plaintiffs reasoned that it was appropriate to consider the alleged infringer's future intent to sell its product throughout the U.S., including in New Jersey, when analyzing venue under the second prong of 28 U.S.C. §1400(b).

The District of New Jersey, relying on the Federal Circuit's language from *In re Cray*, disagreed. The court analyzed venue over Mylan in New Jersey under the second prong of 28 U.S.C. §1400(b), focusing on the requirement that venue is proper "where the defendant has committed acts of infringement" in the district.

The court noted that under *Cray*, patent venue requirements are specific and should not be given a liberal construction. The court found that the only act of infringement under the Hatch-Waxman Act, Mylan's submission of its abbreviated new drug application (ANDA), was made from West Virginia to the FDA in Maryland—not New Jersey. Without an act of infringement in New Jersey, the first part of the second Section 1400(b) prong was not met. Therefore, the court ordered dismissal of the plaintiffs' infringement claims.

Delaware

In the Delaware case, Novartis sued Mylan and over 20 other groups of generic ANDA filers for patent infringement under the Hatch-Waxman Act in the District of Delaware. *Novartis Pharmaceuticals Corp. v. Accord Healthcare Inc.*, No. 18-1043-LPS, 2019 USPQ2d 221773 (D. Del. June 17, 2019). As an initial matter, the court determined that the patent-specific venue statute, 28 U.S.C. §1400(b), not the general venue statute, 28 U.S.C. §1391, applies to Hatch-Waxman patent infringement cases. The court then analyzed Mylan's forum contacts under 28 U.S.C. §1400(b).

As a West Virginia corporation, Mylan did not "reside" in Delaware as the first prong of 28 U.S.C. §1400(b) requires. That left the court to analyze venue over Mylan in Delaware under the second prong of 28 U.S.C. §1400(b), "where the defendant has committed acts of infringement and has a regular and established place of business." The court noted that the Federal Circuit has provided guidance regarding application of this prong in *Cray*, which requires a physical place in the district, which must be established, and must be a place of the defendant.

Novartis argued that the presence of one Mylan employee in Delaware supported venue in that forum. The court disagreed on the basis that it had seen no evidence that Mylan: stored materials at that employees' home; owned, controlled, or established that employee's home; or required that employee to live in Delaware. The court rejected Novartis's emphasis on a Mylan employee's social media presence as a basis for finding a regular and established place of business. The court determined that merely doing business in Delaware did not suffice to establish venue and dismissed the case.

Federal Circuit: Venue Requires Employee Presence

The U.S. Court of Appeals for the Federal Circuit, in *In re Google*, bolstered the case law from Delaware and New Jersey. In *In re Google LLC*, 949 F.3d 1338 (Fed. Cir. 2020), the Federal Circuit reversed the Eastern District of Texas's ruling that venue was proper because Google maintained servers in the district. Consistent with its analysis in *Cray*, and consistent with the above cases from Delaware and New Jersey, the Federal Circuit found that venue was not proper.

The Eastern District of Texas ruled that Google was subject to venue in the district based on the presence of Google's servers. The servers were located in data centers owned by third-party internet service providers (ISPs). Google appealed. Interestingly, this was the second time in a year that Google petitioned the Federal Circuit to tackle a venue issue from the Eastern District of Texas. The Federal Circuit first denied Google's writ of mandamus in October 2018, and then denied a rehearing en banc in February 2019.

In February 2020, however, and despite its earlier determination that Google had not shown that the district court's ruling implicated the "special circumstances justifying mandamus review," the Federal Circuit concluded that mandamus was now appropriate. The Federal Circuit noted that after its first denial of mandamus, similar legal issues had "percolate[d] in the district courts." The resulting decisions, although conflicting, added clarity as to whether Google's servers could constitute

a regular and established place of business. The court ultimately concluded that, consistent with its analysis in *In re Cray*, and under the present facts, they could not.

In *In re Google*, like in *Novartis*, the court found the second factor of *Cray*, the "physical place must be established" test, was not met, because a "place of business" requires the regular, physical presence of an employee or other agent of the defendant conducting the defendant's business. The Federal Circuit acknowledged that Google has many millions of customers in the district and markets its goods and services directly to consumers in the district. Google also owned very large servers located within the district, particularly designed to serve customers within the district. But the Federal Circuit clarified that while the servers qualify for the physicality requirement, they are not a "place of business." According to the court, a "place of business" must have an "employee or agent" conducting business in the location—Google's AI is not sufficient, nor is a theory that an ISP functions as an "agent" of Google.

In making this "employee or agent" requirement, the court looked to the patent-law service-of-process statute 28 U.S.C. §1694. The statute indicates that service may be made upon a defendant's "agent or agents conducting such business" at the regular and establish place of business. The court explained that "the service statute plainly assumes that the defendant will have a 'regular and established place of business' within the meaning of the venue statute" only if the defendant also has an agent engaged in conducting such business. Likewise, the provision that service "may be made by service upon the agent" and the "regular and established" character of the business assumes the regular, physical presence of an agent at the place of business. Absent a contrary indication, the court ruled, these assumptions govern the venue statute as well.

The court also stated that "the venue statute should be read to exclude agents' activities, such as maintenance, that are merely connected to, but do not themselves constitute, the defendant's conduct of business in the sense of production, storage, transport, and exchange of goods or services."

Conclusion

Cray and *In re Google* help provide clarity to patent venue by identifying what is required to show that a defendant has a "regular and established place of business." These decisions, along with the precedent from the districts of New Jersey and Delaware, indicate that Hatch-Waxman cases will only be properly venued in a jurisdiction where the generic is incorporated or where the generic's headquarters are located.