

Alert | Intellectual Property Litigation



September 2017

New Patent Infringement Cases Provide Guidance on Analyzing Venue in the Wake of *TC Heartland*

On May 22, 2017, the Supreme Court issued a watershed decision in *TC Heartland LLC v. Kraft Food Group Brands LLC*, 137 S. Ct. 1514 (2017), analyzing venue for patent infringement cases under 28 U.S.C. § 1400(b). The Supreme Court issued a clear and unanimous mandate that venue is proper in a patent action only where a defendant resides (*i.e.*, is incorporated), or where it has committed acts of infringement and maintains a regular and established place of business. *TC Heartland*, however, did not provide any guidance as to what constitutes an “act of infringement” or “a regular and established place of business” within the meaning of § 1400(b). Two recent Delaware decisions by Chief Judge Stark, *Boston Scientific Corp. et al., v. Cook Group Inc., et al.*, C.A. No. 15-980, D.I. 315 (Sept. 11, 2017) and *Bristol-Myers Squibb Co., et al. v. Mylan Pharms. Inc.*, C.A. No. 17-379, D.I. 36 (Sept. 11, 2017) provide useful guideposts for analyzing venue under § 1400(b).

Notable takeaways from these decisions include: (1) in the Third Circuit, defendants bear the burden of proving that venue is improper; (2) *TC Heartland* was an intervening change in law, but a defendant may still have waived the venue defense through litigation conduct; (3) a “regular and established place of business” in Delaware requires a physical place of business in the district; and (4) the filing of an Abbreviated New Drug Application (ANDA) satisfies the “acts of infringement” requirement of § 1400(b) in every district in which the generic company intends to sell its product upon final FDA approval.

Factual Background

Boston Scientific is a patent infringement action alleging infringement of a medical device. Plaintiffs are incorporated in Delaware and Minnesota and have their principal places of business in Massachusetts and

Minnesota, respectively. Defendants are Indiana corporations with principal places of business in Indiana.

Bristol-Myers is a patent infringement action brought under the Hatch-Waxman Act, alleging the prospective infringement of Plaintiffs' Eliquis® pharmaceutical product by Defendant's proposed generic version. Plaintiffs in this action are incorporated in Delaware with their principal places of business in New Jersey and New York. Defendant is a West Virginia corporation, having its principal place of business in West Virginia.

Defendants Bear the Burden of Proof of Proving Improper Venue

Judge Stark first determined that Third Circuit law, not Federal Circuit law, controlled which party bears the burden of proof with respect to venue. Judge Stark found this issue to be purely procedural and not a question unique to patent law. Based on Third Circuit precedent, Judge Stark concluded that defendants bear the burden of proving that venue is improper. *See Myers v. Am. Dental Ass'n*, 695 F.2d 716, 724 (3d Cir. 1982).

***TC Heartland* was an Intervening Change in Law Precluding Waiver**

Generally, a defendant will waive any challenge to venue by failing to object to venue in a responsive pleading or raising it in a motion. Waiver does not apply when an intervening decision from a superior court changes the controlling law. A number of district courts have addressed whether *TC Heartland* was an intervening change in law, with courts split on the issue. Although the majority of courts (including at least one other Delaware Judge) have held that *TC Heartland* was not an intervening change in law, Judge Stark followed the minority and concluded that *TC Heartland* "did effect an intervening change in the law, creating an exception to the general rule of waiver." *Boston Scientific*, C.A. No. 15-980, D.I. 315 at 15. The court reached this conclusion for two principal reasons. First, Judge Stark found that *TC Heartland* addressed a question never before the Supreme Court – whether the Federal Circuit had erred on an issue of statutory interpretation in *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574 (Fed. Cir. 1990). Second, the court found that *VE Holding* "control[led] patent venue law for the 27 years leading up to *TC Heartland*," and any challenge to this holding "would have been an exercise in futility." *Boston Scientific*, C.A. No. 15-980, D.I. 315 at 16.

The court further held that, despite its finding that *TC Heartland* was an intervening change in law, it "does not mean *per se* that nothing else a defendant has done, and nothing else about the status of a case, could **nonetheless** present a bar to that defendant prevailing on an improper venue motion." *Id.* at 18. Instead, the court should engage in an estoppel-type analysis to determine whether "a defendant should not be permitted to press its effort to change venue." *Id.* Non-limiting factors identified by the court to inform such a decision include: (1) 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; (2) whether dismissal or transfer would unduly prejudice a plaintiff; or (3) whether a party has taken affirmative steps to raise the merits of the litigation. *See id.* at 18-19.

Regular and Established Place of Business Requires a Place of Business

Because defendants in both the *Boston Scientific* and *Bristol-Myers* cases were not incorporated in Delaware, the court next considered whether venue might be proper under the “regular and established place of business” prong of § 1400(b). The court found that although a fixed physical location such as a formal office or store is not necessary, “some **physical** presence is nevertheless required,” namely a place “authorized by the defendant where some part of the defendant’s business is done.” *Id.* at 23.

Judge Stark then provided additional guidance by way of the examples of business activities that are not, without more, sufficient to establish a regular and established place of business. First, simply doing business or being registered to do business in a district is insufficient to constitute a regular and established place of business. “Second, simply demonstrating that a business entity has sufficient ‘minimum contacts’ with a district for purposes of personal jurisdiction does not necessarily mean that the entity has a regular and established place of business in the district.” *Id.* at 27. Third, maintaining a website that allows consumers to purchase a defendant’s products within the district does not, by itself, demonstrate that the defendant has a regular and established place of business in the district. Finally, simply shipping goods into a district, whether to an individual or for distribution by third parties, is not sufficient to establish a regular and established place of business. *See id.* at 27-30.

Venue-Related Discovery

In *Boston Scientific*, Judge Stark denied Plaintiffs’ request for venue-related discovery because Plaintiffs did not provide any reason to doubt the veracity of Defendant’s declarations that demonstrated they did not have a physical place of business in Delaware. *See id.* at 31-33. But, in *Bristol-Myers*, Judge Stark granted Plaintiffs’ request for expedited venue-related discovery because the extent of Defendant’s complex business operations and numerous corporate affiliates incorporated in Delaware was unclear. *See Bristol-Myers*, C.A. No. 17-379, D.I. 36 at 35-39.

“Acts of Infringement” in Hatch-Waxman Cases

In an issue of first impression, Judge Stark analyzed whether the constructive act of infringement created by the Hatch-Waxman Act was an act of infringement for purposes of venue under § 1400(b). The issue arose because of a “mismatch between the backward-looking nature of [§ 1400(b)] and the forward-looking nature of Hatch-Waxman litigation.” *Id.* at 12.

Relying on the Federal Circuit’s decision in *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016), the court found that the filing of an ANDA satisfies the act of infringement requirement of § 1400(b) in every district in which the generic company intends to sell its product upon final FDA approval. To find otherwise, according to the court, would render the second prong of § 1400(b) a nullity in Hatch-Waxman litigation. Despite the unique nature of the Hatch-Waxman Act, the court did not believe that “Congress intended for the second prong of § 1400(b) to have essentially no application in Hatch-Waxman cases or that, in Hatch-Waxman cases, Congress intended venue to be proper solely and exclusively where the defendant resides.” *Id.* at 19.

The court acknowledged a number of problems with its holding. First, it disregards the language of § 1400(b) by reading in future acts to a statute that requires having “committed acts of infringement.” *Id.* at 22. The decision also “accords a different meaning to ‘acts of infringement’ in the Hatch-Waxman context than in the non-Hatch-Waxman context.” *Id.* at 23. Finally, the court noted that the decision may not be consistent with the Supreme Court’s instruction that § 1400(b) is not to be given a liberal construction. *Id.* at 24.

Despite these shortcomings, the court found that its holding embraced the practical realities of Hatch-Waxman litigation, the purpose of the Hatch-Waxman Act, and the intent of the relevant statutes.

Conclusion

These two Delaware decisions provide relevant guideposts for Hatch-Waxman and other patent litigations for evaluating whether venue is proper under § 1400(b). However, the scope of venue-related discovery and the extent of the physical presence required to establish a “regular and established place of business” are fact-specific issues that courts will still need to address in the future.

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