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Hatch-Waxman Litigation and Opinion

In this Issue:

Significant Implications for Hatch-Waxman Cases Following *TC Heartland*

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The Supreme Court's 8-0 decision in *TC Heartland* will have an immediate impact on patent litigation throughout the United States. While most of the public discourse is focused on what the decision will mean for patent troll cases and the Eastern District of Texas, the effects may be felt just as strongly in the Districts of New Jersey and Delaware, which are currently home to more than 75% of Hatch-Waxman cases. Brands and generics alike will be faced with important, strategic decisions that may reshape the landscape of Hatch-Waxman litigation in the years to come.

I. An Overview of *TC Heartland*

Patent venue is proper: (1) where the defendant "resides"; and (2) where the defendant has "committed acts of infringement" and has "a regular and established place of business." 28 U.S.C. § 1400(b). Over the past twenty-five years, the former option had largely swallowed the latter, as courts interpreted § 1400(b) in view of the broader general venue statute. The general venue statute, both in its current form and as applied prior to its 2011 amendment, defines the residency of legal entities such that venue is proper wherever they are subject to personal jurisdiction. Thus, courts understood venue to be proper In patent infringement cases in essentially any district in which a defendant did business.

In *TC Heartland*, the Supreme Court resurrected its interpretation of the patent venue statue and upended the status quo. Specifically confining its decision to domestic corporations, the Court held that patent venue statute cannot be read in view of the general venue statute, and that "where the defendant resides" means only the state in which the defendant is incorporated. The Court expressly left unanswered the effects of its decision on unincorporated associations or foreign entities.

II. Looking Ahead

While the ultimate holding of *TC Heartland* is relatively straight forward—for patent cases, a domestic corporation only "resides" in the state in which it is incorporated—the rationale that led the Court to its conclusion has wide-ranging implications for Hatch-Waxman cases, such as what entities may be sued, particularly when they are unincorporated associations or foreign entities, and when joining multiple parties is acceptable.

A. History of Patent Venue

To assess the implications of *TC Heartland*, it is necessary to appreciate history of the patent venue statute, as it forms the foundation the Court's analysis. The original venue statute provided any case (including patent cases) could be brought in the district in which the defendant was an inhabitant or in which he was found when served. *Stonite Products Co. v. Melvin Lloyd Co.*, 315 U.S. 561, 563 (1942). In 1887 and 1888, Congress revised the venue statute to limit suits to the district in which the defendant was an inhabitant, or in diversity cases, in the district of either the plaintiff's residence or the defendant's residence. *Id*. at 563–64.

In 1893, the Supreme Court held that the new venue statutes did not apply to suits against an alien or foreign corporation, "especially in a suit for the infringement of a patent right." *In re Hohorst*, 14 S. Ct. 221, 225 (1893). The latter comment caused lower courts to begin to doubt whether the venue restrictions applied to patent cases at all. *Stonite*, 315 U.S. at 564. Before long, the prevailing rule was that infringers could be sued wherever they were found. Id. at 564–65. To correct this interpretation, Congress passed a statute specifically directed to venue in patent cases. The patent venue statute "was adopted to define the exact jurisdiction of the federal courts in actions to enforce patent rights." Stonite, 315 U.S. at 565.

In *Stonite*, the Supreme Court first considered the interplay between the patent venue statute and the general venue statute. There the patentee had brought suit in one district against two defendants who were residents of different districts of the same state. 315 U.S. at 562. Not unlike today, the general venue statute included a provision that in such instances venue would be proper in the district of either defendant. *Id*. The Court reversed, holding that in view of the history of the patent venue statute, "Congress did not intend the [patent venue statute] to dovetail with the general provisions relating to the venue of civil suits, but rather that it alone should control venue in patent infringement proceedings." *Id*. at 565–66.

By 1957, a circuit split had developed over whether the general venue statute's definition of residence for a corporation should be read as supplementing the patent venue statute. In *Fourco Glass Co. v. Transmirra Products Corp*., 353 U.S. 222 (1957), the Supreme Court reiterated "that 28 U.S.C. § 1400(b) is the sole and exclusive provision controlling venue in patent infringement actions." 353 U.S. at 229; *see also id.* at 228 ("§ 1400(b) is a special venue statute applicable, specifically, to all defendants in a particular type of actions, i.e., patent infringement actions.").

These strong pronouncements resurrected the question of venue for alien defendants in patent cases, particularly in view of Congress enacting § 1391(d), which expressly provided that an alien was subject to suit in any district. If § 1400(b) was the exclusive venue statute for "all defendants" in patent cases, not to be supplemented in any way by the general venue statute, then arguably a foreign defendant that did not "reside" or have "a regular and established place of business" in the United States might not be subject to venue anywhere.

The Supreme Court avoided that result in *Brunette Mach. Works Ltd. v. Kockum Indus., Inc.,* 406 U.S. 706 (1972), by explaining that § 1391(d) was not really "an appendage to the general venue statutes." 406 U.S. at 713. It was "not derived from the general venue statutes that s 1400(b) was intended to replace." *Id*. Rather, it was merely a reflection of "the longstanding rule that suits against alien defendants are outside those statutes." *Id*. "[S]uits against aliens are wholly outside the operation of all the federal venue laws, general and special." *Id*. at 714.

In 1988, Congress amended the general venue statute, which the Federal Circuit interpreted as having affected the meaning of the patent venue statute. *See TC Heartland*, slip op. at 6–7 (discussing *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1564 (1990)). The patent venue itself, however,

had remained unchanged. *Id*. at 7. Thus, the Supreme Court reversed the Federal Circuit, and reiterated that "[a]s applied to domestic corporations, 'reside[nce]' in § 1400(b) refers only to the State of incorporation." *Id*. at 10 (modification in original).

B. Venue Based on "Reside[nce]"

Under the Federal Circuit interpretation of § 1400(b), a defendant legal entity was subject to venue wherever it was subject to personal jurisdiction. In Hatch-Waxman cases, the effect was defendants were subject to venue almost anywhere in the United States, traditionally under principles of general jurisdiction based on their marketing products throughout the country. Even after *Daimler AG v. Bauman,* 134 S. Ct. 746 (2014), reined in general jurisdiction, prevailing specific jurisdiction theories suggested that ANDA or 505(b)(2) filers were arguably amenable to venue where an NDA holder was located or in district in which the filer intended to eventually sell product. See generally *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

Thus, Hatch-Waxman plaintiffs had substantial flexibility in where they chose to file suit against ANDA or 505(b)(2) filers, and most often selected New Jersey or Delaware. In case with multiple filers, they often chose to join filers relying on the same reference listed drug into groups of common cases. In view of *TC Heartland*, not only is residence-based venue for domestic corporations limited to the state of the entity's incorporation, but residence-based venue for other entities is now arguably less certain that previously assumed.

1. Venue for Domestic Pharmaceutical Corporations

For all the questions *TC Heartland* raises in other contexts, it provides a clear answer for domestic corporations: "where the defendant resides" means only the state in which the defendant is incorporated. It is not enough to have a principal place of business in the forum. Nearly 75% of all Hatch-Waxman cases are filed in either the District of Delaware or the District of New Jersey. While many pharmaceutical companies are incorporated in Delaware or New Jersey, there are many that are not. For those companies, Delaware and New Jersey are no longer proper venue under a residence-based venue theory. Thus, *TC Heartland* will have an immediate effect on the number of cases filed in each jurisdiction and the defendants against which such cases are filed.

2. Venue for Unincorporated Domestic Pharmaceutical Entities

In *TC Heartland*, the Court expressly declined to address the treatment of unincorporated associations. See slip op. at 2 n.2. The general venue statute does not distinguish between incorporated and unincorporated entities for residency purposes. *See* 28 U.S.C. § 1391(c)(2).

This is effectively an adoption of the Supreme Court's decision in *Denver & Rio Grande W.R. Co. v. Brotherhood of Railroad Trainmen*, 378 U.S. 556 (1967), in which it ruled that a labor union ought to be treated like a corporation for residency purposes, such that venue was proper wherever the entity was "doing business." Incorporated and unincorporated entities were treated in parity for purposes of the general venue statute until it was amended in 1988 to provide that corporations were residents of wherever they were subject to personal jurisdiction. Thereafter, the courts were divided on whether unincorporated entities were also subject to venue wherever they were subject to person jurisdiction, or whether the standard as set out in *Denver & Rio Grande* controlled.

The amendment of the general venue statute in 2011 returned incorporated and unincorporated to parity and eliminated the confusion. But while *TC Heartland* avoids the question of unincorporated association, the principles and history that support its holding suggest that the general venue statute cannot be relied upon to define residency regardless of whether the defendant is a corporation or an unincorporated association.

The leading authority, then, appears to be *Sperry Products v. Association of American Railroads*, 132 F.2d 408 (2nd Cir. 1942), which determined that the residency of an unincorporated association for the purposes of the patent venue statute was its principal place of business. Although the patent venue statute at the time was drafted differently, *see Stonite,* 315 U.S. at 562 n.1, it effectively meant the same as it does today. *See Fourco Glass*, 353 U.S. at 226–28 ("[W]e hold that 28 U.S.C. s

1400(b) made no substantive change from [the patent venue statute] as it stood and was dealt with in the Stonite case.").

Sperry would appear to be good law today. Indeed, the Supreme Court relied on its rationale in reaching its own conclusion in *Denver & Rio Grande*. 387 U.S. at 560–61. And just as the Supreme Court presumed Congress would have been aware of *Sperry* when amending the general venue statute in 1948 to support its conclusion that incorporated and unincorporated should be treated in parity, similar reasoning would suggest that the conversion of the patent venue statute to its modern form—without any substantive changes, *see Fourco Glass,* 353 U.S. at 226–28—reflects a similar endorsement of treatment of residency for both incorporated and unincorporated entities in the context of the patent venue statute.

Therefore, an unincorporated pharmaceutical company is most likely "resident" for patent venue purposes in the state in which it has its principal place of business. Just as with domestic pharmaceutical corporations, this is likely to have an immediate impact on the district in which Hatch-Waxman plaintiffs file cases.

3. Venue for Foreign Pharmaceutical Corporations

As noted above, the Court expressly declined to reach the issue of foreign entities in *TC Heartland*, but had previously considered the issue in Brunette, in which it held that foreign entities were subject to venue in any district.

The Federal Courts Jurisdiction and Venue Clarification Act of 2011 revised and reorganized the general venue statute, and § 1391(d) is no longer the alien venue statute. Instead, the general venue statute now provides at § 1391(c) a definition of residency "[f]or all venue purposes," which includes that "an entity with the capacity to sue and be sued in its common name under applicable law, whether or not incorporated, shall be deemed to reside, if a defendant, in any judicial district in which such defendant is subject to the court's personal jurisdiction with respect to the civil action in question," 28 U.S.C. § 1391(c)(1), and "a defendant not resident in the United States may be sued in any judicial district, and the joinder of such a defendant shall be disregarded in determining where the action may be brought with respect to other defendants." 28 U.S.C. § 1391(c)(2).

Discussing the effect of these revisions, the House Committee Report stated that "[n]ew paragraph 1391(a)(1) would follow current law in providing the general requirements for venue choices, but would not displace the special venue rules that govern under particular Federal statutes." H.R. Rep. No. 112-10 at 18. The Report further observed that "there are over 200 specialized venue statutes in the United States Code. These specialized statutes would continue to govern within their respective fields, and the general venue statute would govern diversity and Federal question litigation outside these special areas." *Id*. at 18 n.8. The Report suggested the changes regarding venue for aliens were deliberate and intended to carry significance. *Id*. at 22–23 ("[T]he first clause of proposed paragraph 1391(c)(3) would change venue law by shifting the focus from 'alienage' of a defendant to whether the defendant has his or her 'residence' outside the United States.")

As Congressman Lamar Smith, the Judiciary Committee Chairman and the sponsor of the bill that became the Federal Courts Jurisdiction and Venue Clarification Act of 2011, explained: "This legislation contains a number of revisions to Federal jurisdictional and venue law," including clarification of "the definition of citizenship for foreign corporations and domestic corporations doing business abroad." 157 Cong. Rec. H1369. Congresswoman Jackson Lee, another proponent of the bill, also characterized the bill as "[m]ore clearly defin[ing] 'citizenship' for foreign corporations . . . ." *Id*.

Given these changes, it remains to be seen whether "the longstanding rule that suits against alien defendants are outside" both general and special venue statutes still stands. If courts were to find that Congress intended to replace the old alienage rule with a new formulation based on a definition of citizenship supplied by § 1391(c), then there may call into a question the availability of venue for foreign defendants in patent infringement cases, given that §1400(b) is not to be interpreted as supplemented by the general venue statue. Consequently, there may not be a "judicial district where the defendant resides" when the ANDA or 505(b)(2) filer is a foreign entity. It seems unlikely, however, that Courts will find that there is no proper venue for a foreign Hatch-Waxman defendant.

C. Venue Based on "Acts of Infringement" and a "Regular and Established Place of Business"

With the limitation on "where the defendant resides," analysis is likely to shift to whether a defendant is amenable to venue based on "where the defendant has committed acts of infringement and has a regular and established place of business." Here, too, question may be particularly complicated for Hatch-Waxman cases.

1. "Acts of Infringement".

To subject a defendant to jurisdiction outside the district in which it resides, the plaintiff must identify acts of infringement in that district. This may be difficult enough in a traditional patent case, but it is particularly so in Hatch-Waxman cases. As it is often observed, the filing of an ANDA or a 505(b)(2) application is "a technical act of infringement." F*erring B.V. v. Watson Laboratories, Inc.-Florida,* 764 F.3d 1401, 1408 (Fed. Cir. 2014); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661,678 (1990) (noting that § 271 (e)(2) creates "a highly artificial act of infringement that consists of submitting an ANDA . . . containing the fourth type of certification").

Where, then, does a "technical" or "artificial" act occur? In their divided panel decision, Judges Gajarsa and Rader suggested the "submission" or "filing" of a drug application itself to the FDA was the "act" of infringement—in other words, at the FDA's offices in Beltsville or Rockville, Maryland, depending on the type of application being filed—though each ultimately concluded (for different reasons) that it could not be relied upon to establish personal jurisdiction. *Zeneca Ltd. v. Mylan Pharms, Inc.,* 173 F.3d 829, 832–34 (Fed. Cir. 1999).

The Federal Circuit's recent decision finding specific jurisdiction based on a filer's intent to engage in post-approval marketing of the drug product, *Acorda Therapeutics,* 817 F.3d at 761–64, could arguably be extended to venue. But while future activities may be the basis for exercising specific jurisdiction, § 1400(b) speaks of "where the defendant **has committed** acts of infringement," 28 U.S.C. § 1400(b)(emphasis added), and as the Supreme Court has counseled, "[t]he requirement of venue is specific and unambiguous; it is not one of those vague principles which, in the interest of some overriding policy, is to be given a 'liberal' construction." *Schnell v. Peter Eckrich & Sons, Inc.*, 365 U.S. 260, 264 (1961).

If the courts adopt the rationale of *Acorda Therapeutics* to "acts of infringement" analyses, patent venue in Hatch-Waxman cases may boil down to where is the plaintiff's principal place of business, or from where did the defendant submit the ANDA. At present, however, there seems to be a significant question whether and where a pharmaceutical company will have engaged in an act of patent infringement for purposes of § 1400(b).

2. "Regular and Established Place of Business"

Having a "regular and established place of business" in a district likely requires "a permanent and continuous presence there." *In re Cordis Corp.*, 769 F.2d 733, 737 (Fed. Cir. 1985). The contours of when this standard is satisfied appear highly fact dependent. Regardless the precise contours that develop, established venue will likely be more difficult for Hatch-Waxman defendants than for traditional patent infringement defendants because the place of business will need to coincide with the illusive "act" of infringement. For example, if the "act" is limited to the filing in Maryland, then defendants without regular and established places of business in Maryland may not be amenable to venue under the second prong. Even if the "act" is defined more broadly, venue will be much more limited that before.

D. Other Venue Theories

Given the uncertainty around § 1400(b), Hatch-Waxman plaintiffs may attempt to assert alternative venue theories. For example, some recent case filings have alleged proper venue in the home district of the Hatch-Waxman plaintiff based on a theory that the district would be the only proper venue under 21 U.S.C. § 355(j)(5)(C)(i)(II)—that is, the statute permitting declaratory judgment actions for patent certainty. This theory appears weak given in filing suit that it invokes a statutory provision that only applies in the absence of an affirmative suit. It remains to be seen how the Courts will react to such novel venue theories, as well as what additional theories Hatch-Waxman plaintiffs may develop.

E. Venue in Multi-Defendant Hatch-Waxman Cases

TC Heartland is likely not only to change the districts in which Hatch-Waxman plaintiffs may file cases, but it is also likely to change the manner in which they are litigated. Often, more than one company files an ANDA or a 505(b)(2) application referencing the same previously approved drug. Sometimes these multiple filers are effectively simultaneous, such as when multiple applications are filed on the date one year prior to the expiration of New Chemical Entity exclusivity (the "NCE-1" date). Other times they are not simultaneous, but they are relatively close in time.

In either scenario, it is common for a Hatch-Waxman plaintiff to sue all of the filers in the same district. Often, courts coordinate those cases, grouping them in one or more waves, and potentially consolidating them for purposes of pre-trial or trial. Such coordination arguably may result in benefits and drawbacks both for Hatch-Waxman plaintiffs and defendants. To the extent this coordination is less likely to be an option in the future, it is likely to change numerous variables for Hatch-Waxman litigants. Cases may be more or less expensive to litigate. The risks and rewards may increase or decrease.

TC Heartland is also likely to reduce the practice of suing multiple, related entities belonging to a common corporate family. For example, although one entity may file an ANDA or 505(b)(2) application, a Hatch-Waxman plaintiff may also sue a parent entity or a related entity it believes will be responsible for marketing the drug product once approved. If these entities are residents of different districts, Hatch-Waxman plaintiffs may no longer be able to file one case against the multiple entities.

On the other hand, this may signal an uptick in the use of multidistrict litigation in Hatch-Waxman cases. "When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings." 28 U.S.C. § 1407. Section 1400(b) would not appear to impose any legal restrictions on the district to which a multidistrict litigation could be transferred. *See In re Peanut Crop Ins. Litig.*, 342 F. Supp. 2d 1353, 1354 (M.D.L. 2004).

Practically speaking, the Panel tends to transfer cases to a district in which one of the cases is already pending, often preferring the one that will be the most convenient for the witnesses and the parties, and most efficient for the courts. Thus, with many pharmaceutical companies centered in the Mid-Atlantic Region, courts in New Jersey and Delaware may frequently be the venue for pretrial proceedings. The transfer is, however, a temporary one—cases are remanded to their original courts for trial. 28 U.S.C. § 1407 ("Each action so transferred shall be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred."); *see also In re Brand-Name Prescription Drugs Antitrust Litig.*, 264 F. Supp. 2d 1372, 1377 (M.D.L. 2003) (suggesting parties may be capable of waiving the remand requirement).

III. Conclusion

Ultimately, *TC Heartland* presents a bevy of new challenges and opportunities for brands and generic companies alike. Strategic decisions about corporate form, the identity of a filer, the location of related offices and entities, may all affect ANDA and 505(b)(2) filing strategies.

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