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Federal Circuit Limits Venue Options for Hatch-Waxman Litigation

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Nearly three and a half years after the Supreme Court's landmark patent venue decision in *TC Heartland*, the Court of Appeals for the Federal Circuit continues to grapple with the fallout. The latest iteration came on Thursday, November 5, when the Federal Circuit confronted the question of where "acts of infringement" under 28 U.S.C. § 1400(b) occur with respect to patent infringement claims brought pursuant to the Hatch-Waxman Act.

In what may be seen as a win for generic drug manufacturers, the court (in an opinion by Judge O'Malley, joined by Judges Newman and Taranto) held that, for cases brought under 35 U.S.C. § 271(e)(2), infringement occurs for venue purposes *only* in districts where "actions related to the submission of an Abbreviated New Drug Application ('ANDA')" occur. The court rejected a broader interpretation of the statute, refusing to read "acts of infringement" as referring to future, contemplated distribution of the generic product specified in the ANDA. A petition for rehearing seems likely, and the case may ultimately be headed for the Supreme Court.

Background

The patent venue statute, 28 U.S.C. § 1400(b), provides two ways to establish proper venue in a patent infringement suit. First, venue is proper where a defendant "resides." In *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017), the Supreme Court reiterated that § 1400(b) is the exclusive provision controlling venue in patent cases. The Court also held that, for corporations, "resides" in § 1400(b) refers only to the state of incorporation. Therefore, if a plaintiff wants to bring suit in a venue outside of a defendant's state of incorporation, it must use the second prong of § 1400(b), which requires showing a defendant has (1) a "regular and established place of business" *and* (2) committed "acts of infringement" in the chosen venue.

In the Hatch-Waxman Act, it is an "act of infringement" under 35 U.S.C. § 271(e)(2) to submit an ANDA "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."

In its November 5 decision in *Valeant Pharms. N. Am., LLC v. Mylan Pharms. Inc.*, the Federal Circuit addressed where an act infringement occurs under 35 U.S.C. § 271(e)(2) for the purposes of establishing proper venue under the second prong of 28 U.S.C. § 1400(b).

Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.

Mylan Pharmaceuticals Inc. ("MPI") filed an ANDA seeking approval to market a generic version of Julia®, a drug used to treat fungal infections in toenails. MPI submitted that ANDA from its West Virginia office to the FDA in Maryland. The ANDA included a Paragraph IV certification that the nine Orange Book-listed patents for Julia® are invalid, unenforceable, or would not be infringed by the ANDA product. MPI then notified Valeant of the ANDA submission.

After this notice, three Valeant entities filed suit in the District of New Jersey against three Mylan entities, though none of the defendants were incorporated in the state of New Jersey. The defendants were MPI, incorporated in West Virginia; Mylan Inc., incorporated in Pennsylvania; and Mylan Laboratories Ltd. ("MLL"), incorporated in India.

The New Jersey district court granted the Mylan defendants' motion to dismiss the complaint against all three defendants based on improper venue, finding that the ANDA was submitted from West Virginia – therefore, the "acts of infringement" in the second prong of 28 U.S.C. § 1400(b) occurred there, not in New Jersey.

In its precedential ruling on appeal, the Federal Circuit first held that venue in patent infringement cases must be predicated on *past* acts of infringement – *i.e.*, acts that occurred *before* the action alleging infringement was filed. Accordingly, acts of infringement in Hatch-Waxman litigation – where no product has been sold – occur only in venues where "actions related to the ANDA submission occur."

The Federal Circuit then addressed Valeant's arguments for a broader interpretation of where infringement occurs for venue purposes. First, the court dismissed Valeant's suggestion that the "act of infringement" must include planned, future infringing conduct. In the court's opinion, this interpretation would be contrary to the plain language of 35 U.S.C. § 271(e)(2), judicial precedent on patent venue, and Congressional intent for both patent venue and Hatch-Waxman litigation. Second, the court rejected Valeant's interpretation of an ANDA submission as a "nationwide act of infringement" because "such a broad interpretation of the infringing act, without any textual hook in the statute, would be a bridge too far." Finally, the court found Valeant's policy arguments unpersuasive. While acknowledging that Valeant's concern that a generic drug company could "game" the system by strategically choosing the venue from which it made an ANDA submission was "intuitively persuasive," the court nevertheless concluded that statutory questions concerning venue are "not amenable to such policy concerns" and left it to Congress to address them.

In a footnote, the Federal Circuit left two critical questions open. First, it declined to decide if the District of Maryland – the location of the FDA office where ANDA submissions are sent – might be a proper venue as a location where an "act of infringement" occurs. Second, the court left unresolved which acts involved in the preparation and submission of an ANDA are relevant for venue purposes. The Federal Circuit did agree with the district court, however, that acts protected by the safe harbor provisions in 35 U.S.C. § 271(e)(1) are not sufficient to trigger venue.

Last, the Federal Circuit noted that the district court decision clearly articulates, and it is undisputed, that the foreign entity MLL is properly subject to venue in any judicial district, including the District of New Jersey. Moreover, the court noted that the salient issue to be addressed on remand is whether MLL's involvement in the ANDA submission is sufficient for it to be considered a "submitter," and, thus, amenable to suit. Specifically, for purposes of a Rule 12(b)(6) motion, the district court must decide whether Valeant plausibly alleged sufficient involvement by MLL in the preparation of the ANDA.

Implications

As noted by the Federal Circuit in its discussion of policy considerations, this decision hands generic drug manufacturers some control over the venue in which suit may be brought. For example, a generic manufacturer can prevent Hatch-Waxman litigation in certain venues by avoiding any acts "related to the submission" of an ANDA in those venues. Of course, this control is unavailable to foreign corporations and may be limited by subsequent judicial interpretation of what activities are "related to the submission" of an ANDA for venue purposes and other business considerations.

A petition for panel rehearing or rehearing en banc seems likely, as this would provide interested parties and industry groups with an opportunity to weigh in via amicus briefing.

If you would like to discuss the foregoing or any related patent litigation matter, please contact the Ropes & Gray attorney with whom you regularly work or any attorney in our IP litigation practice.