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CLIENT ALERT

Venue Is Proper Only in Districts Where Actions Related to the Submission of an ANDA Occur

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Valeant Pharmaceuticals North America LLC et al. v. Mylan Pharmaceuticals Inc. et al., No. 2019-2402 (Fed. Cir. November 5, 2020)

Patentee filed suit in the District of New Jersey against two U.S.-based and one foreign corporation arising out of the submission of an ANDA. The alleged infringers moved to dismiss the complaint against the U.S.-based entities under FRCP 12(b)(3) for improper venue, because the only act of infringement—submission of the ANDA—did not occur in New Jersey. The alleged infringers also moved to dismiss the foreign corporation for failure to state a claim under FRCP 12(b)(6). The district court granted the motion to dismiss as to all the alleged infringers for improper venue. On appeal, the Federal Circuit affirmed the dismissal of the two U.S.-based corporations, but reversed and remanded the dismissal of the foreign corporation.

The question before the Federal Circuit was "where 'acts of infringement' under § 1400(b) occur with respect to infringement claims brought pursuant to the Hatch-Waxman Act." The court held that in cases brought under 35 U.S.C. § 271(e)(2)(A), "infringement occurs for venue purposes only in districts where actions related to the submission of an [ANDA] occur, not in all locations where future distribution of the generic products specified in the ANDA is contemplated." The Federal Circuit reasoned that there was no dispute that § 1400(b) "requires a past act of infringement." And under a plain reading of § 271(e)(2), "the only past infringing act is the ANDA submission, which creates the right to bring suit in the first instance." The court further observed that the "result of virtually all Hatch-Waxman litigation is [] that no post-submission infringement happens." Although patentee argued that policy concerns should dictate a different result, the Federal Circuit noted that "venue is not one of those vague principles, which, in the interest of some overriding policy, is to be given a liberal construction."

With respect to the foreign corporation, it was undisputed that venue was proper in any judicial district, including the District of New Jersey. The Federal Circuit found that it was "incongruous" to dismiss the complaint as to all of the alleged infringers on the basis of venue, and thus remanded for the district court to determine whether patentee "plausibly alleged sufficient involvement on the part of" the foreign entity to survive a 12(b)(6) motion to dismiss.

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