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ANDA Applicant Dismissed for Lack of Venue Under § 1400(b) as District of New Jersey Departs from its own and the District of Delaware's Prior Rulings

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On August 13, 2019, the United States District Court for the District of New Jersey, in *Valeant Pharmaceuticals N. Am. LLC v. Mylan Pharmaceuticals Inc.*, No. 18-cv-14305, held that venue was not proper in New Jersey over Mylan in a patent infringement action arising from Mylan's submission of an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of the drug, Julia®.

Following Mylan Pharmaceuticals Inc.'s ANDA submission to FDA, plaintiffs, Valeant Pharmaceuticals, Dow Pharmaceutical Sciences, and Kaken Pharmaceutical Co., sued Mylan Pharmaceuticals Inc. ("MPI") along with its parent corporation, Mylan Inc., and its sister corporation, Mylan Laboratories Ltd. ("MLL"), for patent infringement under the Hatch-Waxman Act in the District of New Jersey. Plaintiffs subsequently filed an identical protective suit against the Mylan defendants in Northern District of West Virginia, which that court stayed pending the resolution of the Mylan entities' motion to dismiss for lack of venue under the patent venue statute, 28 U.S.C. § 1400(b). The Mylan entities argued that venue is not appropriate under § 1400(b) because no defendant resides in New Jersey, and no act of infringement under the Hatch-Waxman Act has yet occurred in that state because MPI filed the ANDA from West Virginia with FDA in Maryland.

Despite the presence of at least one Mylan subsidiary and employees in New Jersey, not named as defendants in the instant suit, plaintiffs did not argue under the first prong of § 1400(b) that any of the named Mylan defendants resides (i.e., is incorporated) in New Jersey. MPI is incorporated and headquartered in West Virginia, Mylan Inc. is incorporated in Pennsylvania, and MLL is incorporated and located in India. Instead, plaintiffs argued that Mylan satisfied the second prong of § 1400(b) by committing an act of patent infringement in New Jersey and having a regular and established place of business in the state. Plaintiffs pointed to the District of Delaware's decision in *Bristol-Myers Squibb v. Mylan*, No. 17-cv-00379 (see our prior coverage of a subsequent ruling on the "regular and established place of business" § 1400(b) element in that case, here) and the District of New Jersey's holding in *Celgene v. Hetero Labs*, No. 17-cv-03387 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 is appropriate to consider the alleged infringer's future intent to sell its ANDA product throughout the United States, including in New Jersey, when analyzing venue under the second prong of § 1400(b).

The District of New Jersey disagreed, instead relying on the Federal Circuit's cautionary language from In re ZTE (USA) Inc., 890 F.3d 1008, 1014 (Fed. Cir. 2018), holding that patent venue requirements are specific and should not be given a liberal construction. Accordingly, the court found that the only prior act of infringement under the Hatch-Waxman Act, MPI's submission of the ANDA, was made from West Virginia to FDA in Maryland – not New Jersey. Without an act of infringement in New Jersey, the first part of the second § 1400(b) prong was not met and the court ordered dismissal of plaintiffs' infringement claims.

The court also declined the plaintiffs' request to retain the remaining claims requesting a declaratory judgment of infringement, which plaintiffs argued are governed by the general venue statute, 28 U.S.C. § 1391(c), not § 1400(b). The court held that, even if § 1391(c) were the appropriate standard, it would decline to retain the declaratory judgment claims because they would be largely duplicative of the infringement claims that would proceed in the plaintiffs' protective suit in West Virginia. By dismissing all claims, the court sought to conserve the parties' and court's resources as well as avoid potentially inconsistent rulings that may result from proceeding in both forums.

As the latest contribution to an evolving area of patent venue jurisprudence, the court's decision also creates a split within the 3rd Circuit regarding the impact of the Hatch-Waxman Act's framework on the second prong of the patent venue statute.

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