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IP CASE OF THE WEEK

Where's ANDA?: A New Frontier for Hatch-Waxman Litigation

***Valeant Pharm. N. Am. LLC v. Mylan Pharm. Inc.*, No. 2019-2402, 2020 WL 6495091 (Fed. Cir. Nov. 5, 2020)**

By: Lisa Holubar & Manon Burns | November 20, 2020

Changing the future of Hatch-Waxman litigation, the Federal Circuit held as a matter of first impression that for purposes of venue under Hatch-Waxman Act claims, acts of infringement occur where actions related to the Abbreviated New Drug Application (ANDA) submission occur. Thus, a plaintiff has only two options to file suit (1) where the pharmaceutical defendant is incorporated or (2) where it performed actions related to its ANDA submission. The Federal Circuit thus affirmed the dismissal of claims based on improper venue.

The Supreme Court's holding in *T.C. Heartland* narrowed possible patent venues to two: (1) where a corporation is incorporated and (2) where acts of infringement occur and the corporation has a regular and established place of business. For Hatch-Waxman litigation, the question then arose as to where infringing acts occur under the patent venue statute.

In September of 2018, Valeant filed suit against Mylan in the District of New Jersey due to Mylan's ANDA submission to market a generic version of the drug "Jublia." The ANDA submission was sent from Mylan's West Virginia office to the FDA. Valeant alleged several connections between Mylan and New Jersey. The next day, Valeant also filed suit in the Northern District of West Virginia. Mylan moved to dismiss the New Jersey suit on the basis of improper venue, because no Mylan defendant resided in New Jersey, and the only infringing act—the ANDA submission—did not occur in New Jersey. Valeant argued that an act of infringement under the patent venue statute should not be limited to an ANDA submission—rather, the court should also consider the alleged infringer's planned future infringing conduct.

The district court agreed with Mylan. Because the ANDA was submitted from West Virginia, proper venue was in West Virginia. Further, planned future acts are not relevant to unambiguous wording of the patent venue statute. On appeal, the Federal Circuit considered past district court decisions grappling with the question. Under the Hatch-Waxman Act, an act of infringement is defined as submitting an ANDA for a drug claimed in a patent if the purpose of the ANDA is to get approval to manufacture, use, and sell the drug. Thus, the only act of infringement in the Hatch-Waxman context is the ANDA submission, and the litigation does not "turn potential future acts into past infringement."

With the Federal Circuit further narrowing potential venue choices under the Hatch-Waxman Act, pharmaceutical companies will be forced to bring their claims in only two possible locations: where the alleged generic infringer is incorporated or where the submitter commits actions related to its ANDA submission. Previously, the majority of such litigations were instituted in New Jersey and Delaware, where most giant pharmaceutical companies are located. Now, however, this case provides generic companies the opportunity to control venue of a possible lawsuit by deliberately and thoughtfully choosing where they engage in any ANDA-related activities. As such, this case potentially opens the door for more and varied law to be created by the new courts that likely will be asked to weigh in on Hatch-Waxman issues.