A Threat to NJ and Del.'s Primacy as Top Venues for Hatch-Waxman Matters?

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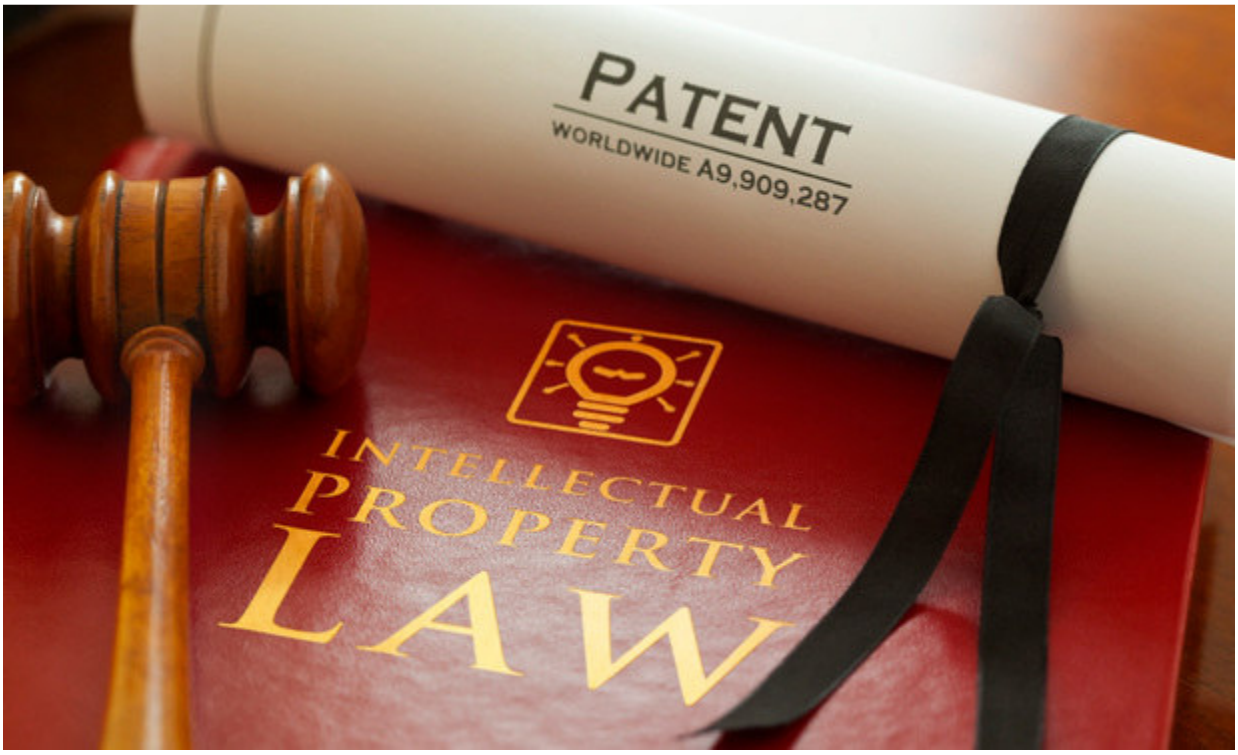
December 5, 2016



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The Districts of New Jersey and Delaware are recognized as the primary venues for Hatch-Waxman or ANDA (Abbreviated New Drug Application) litigation. As of 2015, more than three-quarters of all pending ANDA cases were filed in these two districts. But these preferred venues could be in jeopardy in light of the U.S. Supreme Court's review of the Federal Circuit's decision in Acorda Therapeutics v. Mylan Pharmaceuticals, 817 F.3d 755 (2016) , which affirmed two lower court cases holding that generic companies are subject to specific personal jurisdiction on the basis of their future intended sales of ANDA product in the jurisdiction.

Traditionally, district courts exercised personal jurisdiction in ANDA cases based on theories of general jurisdiction because there was no "real" act of infringement in any district (infringement under 35 U.S.C. §271(e)(2) being "imaginary" or "artificial") that would subject an ANDA applicant to specific personal jurisdiction. Tending to find that such "acts" of infringement did not really "occur" anywhere, courts instead relied on general jurisdiction to exercise power over a party. *See, e.g. Eli Lilly v. Sicor Pharmaceuticals,* No. 06-cv-238, (S.D. Ind. Apr. 27, 2007).

The Supreme Court's decisions in *Goodyear* and *Daimler* in 2011 and 2014, respectively, cast doubt as to the applicability of general jurisdiction. The Supreme Court held in those cases that general jurisdiction requires contact with a state that is so pervasive it makes the defendant "essentially at home" or "comparable to a domestic enterprise." Although many Hatch-Waxman litigants may do business throughout the country, they are not subject to general jurisdiction wherever they have substantial sales. To hold otherwise would essentially subject them to jurisdiction everywhere, a conclusion the majority in *Daimler* found "unacceptably grasping." Instead, the *Daimler* court explained that the place of incorporation or the principal place of business, though not exhaustive, should be the basis for general jurisdiction.

The Mylan Jurisdiction Cases

In light of these two Supreme Court decisions, Mylan, incorporated and headquartered in Pennsylvania, and Mylan Pharmaceuticals, incorporated and headquartered in West Virginia, began testing the limits of *Goodyear* and *Daimler* by challenging personal jurisdiction in several ANDA litigations filed in the District of Delaware and the District of New Jersey. Two notable cases, *AstraZeneca AB v. Mylan Pharms.,* 14-cv-0696 (D. Del. Nov. 5, 2014) (Sleet, J.) and *Acorda Therapeutics v. Mylan Pharms.,* 14-cv-0935 (D. Del. Jan. 14, 2015) (Stark, J.), resulted in the Federal Circuit's *Acorda* decision, which essentially subjects generic ANDA applicants to jurisdiction in every state unless and until the Supreme Court says otherwise. In the cases below, the District of Delaware considered two issues: (1) general jurisdiction based on a theory of consent by virtue of the generic defendants having registered to do business in the state, and (2) specific jurisdiction based on the Paragraph IV notifications sent by the generic defendants to plaintiffs in the state.

In *Acorda v. Mylan*, Judge Stark found general jurisdiction under a theory of consent based on the state's long arm statutes and Mylan's registration to do business under the state's registration statutes. But in *AstraZeneca v. Mylan,* Judge Sleet did not find general jurisdiction, explaining that most states have similar registration statutes and that compliance with those statutes to satisfy jurisdiction "would expose companies with a national presence (such as Mylan) to suit all over the country, a result specifically at odds with *Daimler*." *AstraZeneca v. Mylan,* 14-cv-0696 at 15.

The Delaware court in both cases found specific personal jurisdiction based on the fact that Mylan sent its Paragraph IV notifications to plaintiffs in Delaware. On appeal, the Federal Circuit affirmed the lower courts' decisions in both cases with respect to specific personal jurisdiction on the basis that the minimum-contacts requirement was met by Mylan's plan "to market its proposed drugs in Delaware and the lawsuit is about patent constraints on such in-state marketing." *Acorda v. Mylan,* 14-cv-0935 at 18. Although the Federal Circuit pointed out that the two cases came to separate conclusions with respect to general jurisdiction, the Federal Circuit did not address the issue.

On Sept. 19, Mylan filed a petition for writ of certiorari seeking the Supreme Court's review of personal jurisdiction jurisprudence in the Hatch-Waxman context. The Generic Pharmaceutical Association recently filed amici briefs urging the Supreme Court to hear the case, explaining that the Federal Circuit's decision runs contrary to the limitations placed on jurisdiction in *Daimler*

and has created an "ANDA exception" not found in the Hatch-Waxman Act. If the Supreme Court grants certiorari in *Acorda v. Mylan*, what are the potential consequences for New Jersey and Delaware as preferred ANDA litigation venues?

Possible Effects of Supreme Court Decision Overturning Acorda v. Mylan

Even if the Supreme Court were to reverse and find that a generic applicant's anticipated future sales in a state does not create specific jurisdiction, Delaware will likely remain a favored jurisdiction because it is the state of incorporation for so many companies, including a number of generic pharmaceutical companies. Similarly, many generics have their principle place of business in New Jersey, and thus are subject to general jurisdiction there. But for those generics that are neither incorporated in nor have principle places of business in these jurisdictions, brand companies may be forced to file suit in the generics' home states. This could result in multiple suits being filed in multiple jurisdictions, with different time tables for fact and expert discovery, competing claim constructions and different trials (with the possibility of differing outcomes on similar issues).

While multidistrict rules may allow for pre-trial consolidation, it will not solve the issue of trials occurring in multiple jurisdictions. Many ANDA litigations involve multiple defendants who participate in joint defense groups to create efficiencies and coordinate the litigation. A single-defendant litigation in a different venue may impact the group as a whole. Multidistrict litigation may result in contradictory rulings, or an early ruling from a jurisdiction with a single defendant may affect the litigation in a separate jurisdiction with multiple defendants. Until the issue of where a generic applicant is subject to personal jurisdiction is fully resolved, it remains to be seen how ANDA litigation may be affected going forward.