

Federal Circuit Finds Personal Jurisdiction over Mylan in Two Hatch-Waxman Appeals

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On Friday, March 18, the Court of Appeals for the **Federal Circuit** affirmed two District of *Delaware* rulings that non-resident defendant generic ANDA filer, Mylan, is subject to personal jurisdiction in two Hatch-Waxman suits filed in the state. (See [Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.](#), No. 14-935-LPS (D. Del. Jan. 14, 2015); [AstraZeneca AB v. Mylan Pharmaceuticals Inc.](#), No. 14-696-GMS (D. Del. Nov. 5, 2014)). The Federal Circuit found that specific personal jurisdiction exists over Mylan in Delaware because Mylan's ANDA filings reliably indicate its intent to engage in actions that will harm plaintiffs' patent rights in the jurisdiction. The court did not reach the issue on appeal of whether Mylan's compliance with Delaware's registration statute established consent to general personal jurisdiction in the state, an issue on which the lower court opinions split. However, Judge Kathleen M. O'Malley, concurring in the majority's judgement, would also have found Mylan consented to general personal jurisdiction in light of Delaware's interpretation of its registration statute.

Filing an ANDA Satisfies the Minimum Contacts Requirement of Specific Personal Jurisdiction

The court held that "the particular actions Mylan has already taken—its ANDA filings—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in Delaware" satisfy the minimum contacts with Delaware required to establish specific personal jurisdiction. Maj. Op. at 8-9. The court began by observing that, if Mylan had already begun the generic drug marketing activities for which it seeks permission by filing an ANDA, "there is no doubt that it could be sued for infringement in Delaware," and elsewhere that it seeks to market the generic ANDA products. Id. at 8. Mylan's ANDA filings, in turn, are "formal acts that reliably indicate plans to engage in" that same infringing activity. Id. at 9. Thus, the ANDA filings, like the contemplated marketing acts they seek approval for, establish personal jurisdiction over Mylan in Delaware.

The court found support for its holding from a number of sources. The Hatch-Waxman Act itself establishes how "tightly tied" an ANDA filing is to the "real-world" marketing acts that ANDA approval will allow. Congress itself, the court observed, stressed the purpose of the ANDA to "obtain approval . . . to engage in the commercial manufacture, use or sale of a drug" – concrete acts of infringement. Id. The fact that ANDA applications require significant financial expenditure also supports the court's conclusion that ANDA filers have "reliably confirmed a plan to engage in real-world marketing." Id. at 11. The ANDA filing alone is over \$76,000 and related application costs can total millions of dollars. Id. Moreover, precedent finding that ANDA litigation satisfies the Article III case or controversy requirement, as well as courts' hearing of injunctive actions to prevent harmful future conduct both further bolster the court's holding. Id. at 11-14.

Having found that Mylan's ANDA filing established sufficient minimum contacts with Delaware, the court quickly



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determined that this exercise of personal jurisdiction was not unconstitutionally unreasonable. Mylan's large size and many prior ANDA litigations, including in Delaware, render the burden of litigating there modest, at most. *Id.* at 16. Furthermore, Delaware has an interest in the sale of products in the forum, and litigating in Delaware saves juridical resources due to the forum's multiple ANDA suits involving the same branded drugs. *Id.*

The Federal Circuit's Opinion has Potentially Broad Impact on Current and Future Hatch-Waxman Litigation

Despite declining to reach the issue of registration as consent to personal jurisdiction, the holding that Mylan's ANDA filings establish specific jurisdiction in states where it is a nonresident may have an immediate and broad impact on Hatch-Waxman litigation. Mylan alone has filed numerous motions to dismiss for lack of personal jurisdiction in Hatch-Waxman suits since the Supreme Court's *Daimler AG v. Bauman* decision muddied the scope of general personal jurisdiction over nonresident defendants in Hatch-Waxman litigation. 134 S.Ct. 746 (2014).

With this straightforward ruling, generic ANDA filers will likely have a much harder time prevailing on a motion to dismiss for lack of personal jurisdiction in Hatch-Waxman litigation, regardless of whether or not the particular forum state has interpreted compliance with its foreign corporation registration statutes as consent to personal jurisdiction.

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