



THINK FORWARD

Federal Circuit Hears Arguments in Hatch-Waxman Personal Jurisdiction Challenge: Mylan Argues Brands Should Sue Them in West Virginia

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On Monday January 4, the Federal Circuit heard oral arguments in a pair of appeals—*Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, No. 15-1456, and *AstraZeneca AB v. Mylan Pharmaceuticals Inc.*, No. 15-1460—that may potentially clarify how personal jurisdiction in litigation under the Hatch-Waxman Act is impacted by the Supreme Court’s recent decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014). This is the first time the Federal Circuit has had the opportunity to address whether there is sufficient personal jurisdiction for branded pharmaceutical companies to bring consolidated Hatch-Waxman patent infringement suits against generic manufactures in a single jurisdiction, such as Delaware.

District Court Proceedings

The two appeals stem from suits filed in Delaware by AstraZeneca and Acorda under the Hatch-Waxman Act based on Mylan’s filing of Abbreviated New Drug Applications (“ANDA”) seeking FDA approval to market drug products containing saxagliptin, which AstraZeneca markets under the brand names Onglyza® and Kombiglyze® for treatment of type 2 diabetes, and dalfampridine, which Acorda markets as the multiple sclerosis drug, Ampyra®. Mylan moved to dismiss each suit arguing a lack of personal jurisdiction under *Daimler*. Mylan contended that Delaware lacked general personal jurisdiction because Mylan is incorporated in and headquartered in West Virginia and thus is not at “home” in Delaware as required for general jurisdiction under *Daimler*. Mylan also argued that no specific personal jurisdiction existed over Mylan in Delaware because its suit-related conduct did not create a substantial connection with Delaware.

The District of Delaware denied Mylan’s motions to dismiss for lack of jurisdiction in both cases, but for different reasons. In the *AstraZeneca* case, U.S. District Judge Gregory Sleet agreed with Mylan that no general jurisdiction existed in Delaware under *Daimler*. Judge Sleet, however, denied Mylan’s motion to dismiss because specific personal jurisdiction existed as a result of Mylan sending a Paragraph IV certification notice letter to AstraZeneca’s Delaware office as is required under the Hatch Waxman Act. In contrast, U.S. District Judge Leonard Stark denied Mylan’s motion to dismiss in *Acorda* on the basis of general personal jurisdiction, holding that Mylan had “consented to jurisdiction” by registering as a business in Delaware in 2010.

Appellate Argument

At argument, Judges Pauline Newman, Kathleen O’Malley and Richard Taranto grappled with the interplay between the requirements for personal jurisdiction and the artificial act of infringement that occurs under 35 U.S.C. § 271(e)(2) upon filing an ANDA containing a certification that a patent is invalid

or not infringed under 21 U.S.C. § 355(b)(2)(A)(iv).

During the arguments, Judge Taranto immediately directed Mylan to the issue of specific personal jurisdiction and noted that Mylan “plan[s] to compete in Delaware.” He inquired, “Why isn’t that enough?” and further questioned why if Mylan’s conduct were sufficient for an Article III case or controversy under the 35 U.S.C. § 271(e)(2), it would not suffice for specific personal jurisdiction. At argument, Mylan noted that it had “not purposely availed [itself] of Delaware” and that all of Mylan’s pre-litigation activities were performed in West Virginia, prompting questions from Judge O’Malley as to whether the types of activities that are protected from suit for infringement under the safe harbor of 35 U.S.C. § 271(e)(1), such as preparing the ANDA, can form the basis for specific jurisdiction. By contrast, appellees took the position that the ANDA filing creates nationwide contacts because the “generic manufacturer is seeking . . . to essentially declare nationwide war on the rights of a brand name manufacturer” and entreated the court to rule that specific jurisdiction exists nationwide upon filing of an ANDA subject to the limitations of fairness and reasonableness.

With respect to general jurisdiction, the court engaged counsel in a lengthy discussion of Delaware’s requirement that any corporation conducting business in Delaware register and appoint an agent for service of process under Del. Code tit. 8, § 371(b). That certificate of registration states that Mylan intended to engage in pharmaceutical manufacturing, distribution, and sales in Delaware. At argument, Mylan portrayed the registration and accompanying statement as “compulsory” and posited that only voluntary conduct can establish general jurisdiction under *Daimler*. Judge O’Malley countered, “*Daimler* never had the opportunity to address consent via registration,” because that case involved jurisdiction in California. She also questioned why “choosing to do business in the state” is not a voluntary act. By contrast, the appellees portrayed the Delaware statute as a sufficient basis for conferring personal jurisdiction over Mylan.

Potential Impact

Mylan alone has filed over a dozen motions to dismiss for lack of personal jurisdiction in Hatch-Waxman suits since the Supreme Court decided *Daimler*. And Mylan is not alone. Several other generic manufacturers have also challenged personal jurisdiction in Delaware and other venues such as the Eastern District of Texas. Decisions on many of these dismissal motions may be impacted by the outcome of the early *Acorda* and *AstraZeneca* appeals.

It may be possible for the Federal Circuit to decide both the *Acorda* and *AstraZeneca* appeals on bases that might limit the impact of the court’s holding such as finding that Mylan’s Delaware corporate registration establishes general jurisdiction over Mylan or that specific jurisdiction exists in the *AstraZeneca* action based on the fact that Mylan sent its notice letter to AstraZeneca’s Delaware offices. However, both parties entreated the court to provide a broader ruling that would clarify the parameters of general and specific personal jurisdiction in Hatch-Waxman cases.

If you have any questions or wish to discuss how this decision impacts your business, please contact one of our [Brinks Attorneys](#).