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Federal Circuit Clarifies Scope of Personal Jurisdiction in Hatch-Waxman Cases

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On March 18, 2016, a panel of the Federal Circuit issued its decision in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.* and *AstraZeneca AB v. Mylan Pharms. Inc.*, holding that Mylan is subject to specific personal jurisdiction in Delaware by virtue of its filing of a Abbreviated New Drug Application ("ANDA"), coupled with specific plans to sell the generic pharmaceutical products in Delaware. This ruling is likely to be well received by innovator pharmaceutical manufacturers and, if not overturned, would significantly reduce the recent trend of generic companies challenging personal jurisdiction in Hatch-Waxman litigation.

Mylan's Motions to Dismiss in the District Court of Delaware

In each of the two cases considered by the Federal Circuit, on appeal from the District of Delaware, Mylan had filed a motion to dismiss on the grounds that Delaware lacked both general and specific personal jurisdiction. Personal jurisdiction refers to a court's ability to rule on issues brought before it and to enforce its decisions against the parties. Broadly speaking, specific personal jurisdiction exists when a defendant has sufficient minimum contacts with a forum state that relate and give rise to the claim at issue, whereas general personal jurisdiction in a forum over a defendant exists independently of any suit-related contacts.

In ruling on Mylan's motions below, Chief Judge Stark (in *Acorda*) and Judge Sleet (in *AstraZeneca*) disagreed about whether Delaware could exercise general personal jurisdiction over Mylan. Their disagreement focused on the impact of the Supreme Court's 2014 decision in *Daimler AG v. Bauman*, which limited general jurisdiction to situations where a company's contact with a forum is so continuous as to render the company "essentially at home" there. In light of *Daimler*, Chief Judge Stark and Judge Sleet differed on whether Mylan's registration to do business in Delaware pursuant to a state statute (which required appointment of a registered agent for service of process) constituted a valid form of consent to general personal jurisdiction. Notwithstanding their disagreement, however, both Chief Judge Stark and Judge Sleet found that Delaware could adequately exercise specific personal jurisdiction over Mylan.

The Federal Circuit Majority Panel Opinion

Writing for a Federal Circuit panel that included Judges Newman and O'Malley, Judge Taranto agreed with both Chief Judge Stark and Judge Sleet that Delaware could exercise specific personal jurisdiction. The court noted that Mylan's ANDA filings "constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." The fact that "Mylan intends to direct sales of its drugs into Delaware . . . once it has the requested FDA approval to market them" was of particular importance to the panel. Mylan would "undisputedly" engage in marketing of its ANDA product in Delaware, and Mylan's planned marketing was "suit-related." As a result, the court held that "it suffices for Delaware to meet the minimum-contacts requirement in the present cases that Mylan's ANDA filings and its distribution channels establish that Mylan plans to market its proposed drugs in Delaware and the lawsuit is about patent constraints on such in-State marketing."

After finding sufficient minimum contacts, the court went on to review (and ultimately find unpersuasive) the other due process factors that may defeat specific personal jurisdiction: "the burden on the defendant," "the forum State's interest in adjudicating the dispute," "the plaintiff's interest in obtaining convenient and effective relief," and "the interstate judicial systems' interest in obtaining the most efficient resolution of controversies." With respect to the

burden on Mylan, the court found it "modest" because Mylan is a "large generic manufacturer" that has litigated numerous Hatch-Waxman lawsuits in Delaware. With respect to the other factors, the court found that Delaware has an interest in resolving the case because of the future sales of products in the jurisdiction, and that upholding personal jurisdiction in Delaware would serve the interests of the plaintiffs and the judicial system because multiple lawsuits against other generic manufacturers were pending in Delaware on the same patents. Notably, while the general intent to market analysis might arguably support specific personal jurisdiction in virtually any forum nationwide, the majority's analysis of these more case-specific due process factors focuses on the propriety of Delaware in particular as a forum with sufficient jurisdictional contacts.

Judge O'Malley's Concurring Opinion

Judge O'Malley authored a separate opinion to discuss the issue of general personal jurisdiction, which the majority Federal Circuit opinion declined to address. Judge O'Malley also wrote to explain that although she concurred with the majority's judgment finding specific personal jurisdiction over Mylan in Delaware, she did so under a separate legal theory.

With respect to general personal jurisdiction, Judge O'Malley expressed the view that the Supreme Court's decision in *Daimler* "did not overrule" a line of Supreme Court cases holding that "a corporation may consent to jurisdiction over its person by choosing to comply with a state's registration statute." Applying that rule, Judge O'Malley concluded that Mylan's compliance with Delaware's registration statute constituted "voluntary, express consent" to general personal jurisdiction in Delaware. Because a finding that Mylan had consented to broad general personal jurisdiction "would obviate the need" to further consider whether the district courts below had the authority to exercise narrower specific personal jurisdiction, Judge O'Malley noted that she would have ended the court's jurisdictional discussion at that point.

Reviewing the majority panel's opinion, Judge O'Malley agreed that Delaware could properly exercise specific personal jurisdiction over Mylan and accepted the majority's minimum-contacts analysis. Judge O'Malley suggested, however, that she was not fully persuaded by predicating jurisdiction on Mylan's future intent to sell generic products. Instead, Judge O'Malley found more persuasive the minimum-contacts analysis set forth in the Supreme Court's decisions in *Calder v. Jones* (1984) and *Walden v. Fiore*(2014). Summarizing *Calder*, Judge O'Malley explained that courts may exercise specific personal jurisdiction over defendants when those defendants engage in "intentional acts expressly aimed at the forum state, knowing that those acts will harm a potential plaintiff residing in that state." Judge O'Malley further explained that this test, as clarified by *Calder*, requires courts to examine "whether the defendant's conduct connects him to the forum in a meaningful way" to meet due process requirements.

In applying the *Calder* test to the cases on appeal, Judge O'Malley concluded that both the filing of Mylan's ANDA and the harm suffered were meaningfully connected to Delaware. As an initial matter, both Acorda and AstraZeneca are Delaware corporations. Mylan, moreover, had "engage[d] in intentional acts expressly aimed at the forum state, knowing that those acts [would] harm a potential plaintiff residing in that state." Because the "targeted nature" of Mylan's ANDA filing caused "legally cognizable injuries in Delaware," specific jurisdiction over Mylan would be proper "based on the 'effects'" of Mylan's conduct there.

Looking Ahead

Because the Federal Circuit has exclusive appellate jurisdiction in Hatch-Waxman cases, the panel's decision will likely have an immediate impact on the choice of forum for plaintiffs filing new Hatch-Waxman suits and the filing of motions to dismiss based on jurisdiction. The decision puts to rest, at least for now, the existing uncertainty about where innovator pharmaceutical companies can bring suit, and the trend of bringing Hatch-Waxman suits in established jurisdictions like the District of Delaware and the District of New Jersey will likely continue.

The decision, however, leaves some questions unanswered. While the majority's conclusion expands the application of specific personal jurisdiction to ANDA filers, it remains to be seen whether generic companies will be able to successfully challenge jurisdiction in other cases on the basis of the remaining due process factors that would make exercising jurisdiction unreasonable on the facts of a given suit. And, although Judge O'Malley's concurrence

touched on the subject, the majority opinion declined to address the connection between a company's compliance with state registration statutes and consent to general personal jurisdiction. A recent opinion of the Second Circuit suggested, in contrast to Judge O'Malley, that valid consent to general jurisdiction could no longer, following *Daimler*, be inferred from registration to do business. *See Brown v. Lockheed Martin Corp.*, No. 14-4083, 2016 U.S. App. LEXIS 2763 (2d Cir. Feb. 18, 2016).

The seeming certainty provided by the panel decision may not last for long. Mylan may seek review of the panel decision by the en banc Federal Circuit, and ultimately may seek review by the Supreme Court. A petition for writ of certiorari would give the Supreme Court an opportunity to review its jurisprudence in *Daimler*, *Calder* and *Walden*, and the effect of that jurisprudence on Hatch-Waxman litigation specifically.

A copy of the Federal Circuit's decision is available here. For further information, please contact your usual Ropes & Gray attorney or the Ropes & Gray attorney listed above.