



# THINK FORWARD

## Federal Circuit Holds Hatch-Waxman ANDA Filing and Certification Are Sufficient Contact to Confer Personal Jurisdiction in Delaware

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On Friday March 18, the Federal Circuit issued an opinion in a pair of appeals involving the contours of personal jurisdiction in Hatch-Waxman litigation—[Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc., No. 15-1456](#), and [AstraZeneca AB v. Mylan Pharmaceuticals Inc., No. 15-1460](#). In an opinion authored by Judge Taranto and joined by Judge Newman, the court held that Mylan had minimum contacts sufficient for specific personal jurisdiction in Delaware. Judge O'Malley wrote a separate concurring opinion. We previously reported on the oral arguments for these cases [here](#). The majority's holding may have far-ranging impacts on the forums where branded pharmaceutical companies may commence consolidated litigation under the Hatch-Waxman Act.

### Majority Opinion

The majority found that the jurisdictional issues for these cases turned on whether personal jurisdiction over Mylan satisfied constitutional due process standards. According to *International Shoe Co. v. Washington*, 326 U.S. 310 (1945), a court may exercise personal jurisdiction without violating the Due Process Clause when the defendant “has certain minimum contacts with the forum such that the maintenance of the suit does not offend “traditional notions of fair play and substantial justice.”” *Id.* at 316 (citation omitted). The minimum contacts requirement focuses on whether the defendant's suit-related conduct creates a substantial connection with the forum state. The court held that minimum contacts standard was satisfied by Mylan filing an ANDA with the intent to market drugs in both actions in Delaware upon approval: “Mylan's ANDA filings constitute formal acts that reliably indicated plans to engage in marketing of the proposed generic drugs.” The majority also noted, “Mylan's ANDA filings, including its certifications regarding the patents at issue here, are thus suit-related, and they have a substantial connection with Delaware because they reliably, non-speculatively predict Delaware activities by Mylan.”

The majority dispatched the notion that finding specific personal jurisdiction might be unreasonable, noting that the litigation “burden on Mylan will be at most modest,” which “has litigated many suits in Delaware, including some that it initiated.” The Court also distinguished *Zeneca Ltd. v. Mylan Pharmaceuticals, Inc.*, 173 F.3d 829 (Fed. Cir. 1999), which it found did not address whether the location of an ANDA filer's future sales could support specific personal jurisdiction in the Hatch-Waxman litigation.

Also noteworthy are the issues left undecided by the majority. Specifically, the court declined to address the issue of general personal jurisdiction, including the impact of Mylan's registration to do business in Delaware on general jurisdiction. In addition, the majority did not rely on the site where Mylan's notice letter was received as a factor in its analysis, although that had been a primary factor in one of the

underlying district court decisions.

### **Judge O'Malley's Concurrence**

Judge O'Malley concurred with the majority that the Delaware district courts possessed personal jurisdiction over Mylan but under a different legal theory. Judge O'Malley advocated that the court should have begun its inquiry by analyzing general personal jurisdiction, which, in her view, existed over Mylan by virtue of its registration to do business in Delaware and appointment of an agent for service. Under the Delaware Supreme Court's holding in *Sternberg v. O'Neil*, 550 A.2d 1105 (Del. 1988) compliance with Delaware's registration statute constitutes consent to general personal jurisdiction. Based on Mylan's registration, Judge O'Malley reasoned "that Mylan is subject to general personal jurisdiction in Delaware by virtue of its voluntary, express consent to such jurisdiction."

With respect to specific personal jurisdiction, Judge O'Malley would not have relied on Mylan's expressions of future intent as the majority did. Instead, Judge O'Malley reasoned that Mylan's conduct connected it to Delaware in a "meaningful way" as required for specific personal jurisdiction under *Calder v. Jones*, 465 U.S. 783 (1984). She reasoned that the "nature of ANDA litigation is such that, as in *Calder*, 'the focal point both of the [filing of the ANDA] and of the harm suffered' is Delaware. . . . Jurisdiction over Mylan is proper in Delaware based on the 'effects' of the conduct it aimed at Delaware." Judge O'Malley concluded, "Mylan's paragraph IV certification in its ANDA filing connects it to Delaware—not just to these corporate residents—in a manner that supports a finding of specific personal jurisdiction in that forum."

### **Potential Impact**

Absent Supreme Court review, the Federal Circuit's decision in *Acorda* substantially resolves the uncertainty over personal jurisdiction in ANDA litigation that resulted from the Supreme Court's holding in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014) that general personal jurisdiction over corporations exists only where the corporation is at "home." Although the *Acorda* majority declined to address general personal jurisdiction, the decision may effectively obviate the need to address general personal jurisdiction in most ANDA cases. Specifically, under *Acorda*, branded companies will have a strong argument that specific personal jurisdiction may exist over an ANDA filer in any state where the ANDA filer intends to market the generic drug at issue.

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