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ANDA defendant Mylan Pharmaceuticals seeks rehearing en banc

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In March 2016 a panel of the Federal Circuit Court of Appeals in *Acorda Therapeutics v Mylan Pharmaceuticals* held that Mylan's filing of two abbreviated new drug applications (ANDAs) in Maryland subjected it to being sued in Delaware by two brand companies which alleged that the prospective drugs would infringe their patents. The panel reasoned that there was specific personal jurisdiction because "Mylan has taken the costly, significant step of applying to the [Food and Drug Administration] for approval to engage in future activities – including the marketing of its generic drugs – that will be purposefully directed at Delaware (and, it is undisputed, elsewhere)". Mylan has now asked the full Federal Circuit to rehear the case *en banc*.

Before the Supreme Court's 2014 landmark decision in *Daimler Ag v Bauman*, brand companies asserted personal jurisdiction against general manufacturers in ANDA patent infringement cases using the doctrine of general personal jurisdiction, which allowed a prospective generic competitor to be sued under the Hatch-Waxman Act anywhere that the generic company did 'business' (nebulously defined) or sold other products. *Daimler* drastically diminished the scope of general personal jurisdiction and sent a clear message that courts cannot claim general jurisdiction over every corporation that does business in the forum – finding such an exorbitant view of personal jurisdiction was "barred by due process constraints on the assertion of adjudicatory authority".

By limiting personal general jurisdiction to states where a corporation is "essentially at home", the Supreme Court appeared to strip Hatch-Waxman plaintiffs of their jurisdictional weapon of choice – gone were the days of suing a defendant wherever was most convenient to the plaintiff or where courts were considered friendlier to brand companies. The *Acorda Therapeutics* decision demonstrated that this was not so. The Federal Circuit effectively sidestepped the issue of general jurisdiction, finding instead that Delaware had specific personal jurisdiction over Mylan.

Mylan has asked the full Federal Circuit to rethink the decision, arguing that the Federal Circuit panel created a way around *Daimler* for Hatch-Waxman defendants. Mylan asserts that the Federal Circuit impermissibly broadened "specific jurisdiction beyond all known bounds by relying on potential 'future activities' it speculated Mylan would undertake if its ANDAs are someday approved".

As Mylan points out, the *Acorda Therapeutics* decision has significant due process implications because it bases personal jurisdiction on conduct that may hypothetically occur. The opinion presumes that:

- the ANDA applications will be approved;
- the drugs will be marketed and sold nationwide; and
- the brand companies' patents will be infringed.

Mylan wrote the following in its petition for rehearing: "This new nationwide jurisdiction – rooted in prognostication rather than a defendant's actual suit-related contacts with a forum state – deprives ANDA filers of due process protections and squarely conflicts with precedents of the Supreme Court and this Court."

The Generic Pharmaceutical Association (GPhA), a non-profit association representing nearly 100 generic drug distributors and manufacturers, has joined Mylan's petition. Together, Mylan and GphA argue that part of the due process deprivation created by the decision is the uncertainty that it creates for generic drug companies. That is, subjecting ANDA filers to nationwide jurisdiction based prospective future nationwide sales deprives generic companies of due process under *Daimler* because it denies ANDA filers a "degree of predictability... that allows [them] to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit".

The practical effect of such uncertainty undercuts one of the primary goals of the Hatch-Waxman Act – that is, to provide incentives to generic manufacturers to enter the market and make available more low cost drugs. If entering the generic market and filing an ANDA subjects the generic company to suit in the most brand friendly forum the patent-holder can find, there are significant new costs and risks associated with attempting to bring a generic drug to market. Mylan argues that this "makes litigation in the ANDA context highly unpredictable, which will chill the development of life-saving, low-cost generic drugs and undercut the goals of the Hatch-Waxman Act". Quoting the Federal Circuit's own language back to it, Mylan argues that the

decision is exactly the kind of "unnecessary and unintended punishment for filing a petition with the FDA that undermines the purpose of the Hatch-Waxman Act".

Should the Federal Circuit refuse to reconsider its ruling *en banc*, generic drug companies should not yet resign themselves to a world where filing an ANDA application subjects them to litigation nationwide. A petition for certiorari is all but inevitable.

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