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ALERT

GPhA *Amicus* Brief Filed in *Acorda v. Mylan*

May 5, 2016

Wiley Rein has filed an *amicus* brief on behalf of The Generic Pharmaceutical Association (GPhA) urging the U.S. Court of Appeals for the Federal Circuit to rehear *en banc* two important cases involving the scope of personal jurisdiction in Hatch-Waxman Act litigation: *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, No. 2015-1456, and *AstraZeneca AB v. Mylan Pharmaceuticals Inc.*, No. 2015-1460 (*Acorda*).

Historically, Hatch-Waxman Act plaintiffs have filed suit against generic defendants wherever they pleased under a liberal interpretation of the scope of general personal jurisdiction. But in the recent *Daimler* case, the Supreme Court of the United States dramatically cut back on the availability of general personal jurisdiction, describing the assertion of nationwide jurisdiction in that case as "exorbitant" and "unacceptably grasping" because it did not "permit out-of-state defendants to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit." *Daimler A.G. v. Bauman*, 134 S. Ct. 746, 761–62 (2014).

In *Acorda*, a Panel of the Federal Circuit held that, notwithstanding *Daimler*, Mylan (a West Virginia company) is subject to *specific* personal jurisdiction in Delaware based on a mistaken assumption that the filing of an Abbreviated New Drug Application (ANDA) shows that Mylan "intends to direct sales of its drugs into Delaware." *Acorda* Slip Op. at 6. The Panel's opinion set forth a new standard for specific jurisdiction based on "planned, non-speculative harmful conduct," *i.e.*, infringing future sales. *Id.* at 13.

Wiley Rein's brief points out that the Panel's reasoning overlooks a key point about Hatch-Waxman Act litigation: "The Hatch-Waxman Act's carefully balanced framework, chosen by Congress, ensures that

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in the vast majority of cases there will never be an infringing sale." The Hatch-Waxman Act provides for a 30-month stay of U.S. Food and Drug Administration (FDA) approval while the patent infringement case is litigated, which ensures that the most likely outcome in ANDA litigation will be either an adjudication of non-infringement or invalidity prior to any sales or an injunction against sales.

Moreover, as the *amicus* brief points out, "the Panel's decision, in effect, subjects every ANDA filer to nationwide jurisdiction for Hatch-Waxman Act litigation"—exactly the result the Supreme Court found unacceptable in *Daimler*. The brief also shows that the Panel's opinion conflicts with other prior opinions of both the Supreme Court and the Federal Circuit.