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Federal Circuit Issues Sprawling Opinion Certain to Continue Big Pharma Forum Shopping in ANDA Litigation

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In an opinion handed down Friday that will continue the trend of forum shopping, the Federal Circuit in *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals, Inc.*, 2015-1456, (Fed. Cir. 2016) held that the filing of an abbreviated new drug application (ANDA) opens the door to specific personal jurisdiction in any state where the generic company will market the drug. This effectively means that Hatch-Waxman defendants may be forced to defend litigation in any forum chosen by brand drug companies.

The Federal Circuit reached its decision after considering two unrelated Hatch-Waxman suits against generic drug manufacturer Mylan, *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, No. 2015-1456, and *AstraZeneca AB v. Mylan Pharms. Inc.*, No. 2015-1460, that presented identical questions of whether Mylan, by seeking FDA approval to market an ANDA product throughout the United States, including in Delaware, subjected itself to specific personal jurisdiction in Delaware. In both cases, Mylan, as a West Virginia corporation with its principal place of business in West Virginia, unsuccessfully moved to dismiss for lack of personal jurisdiction in Delaware. The Federal Circuit affirmed, finding Delaware had specific personal jurisdiction over Mylan.

Explaining its decision, the Federal Circuit, citing *Calder v. Jones*, 465 U.S. 783 (1984) and *Walden v. Fiore*, 134 S. Ct. 1115 (2014) indicated that an ANDA application would cause harmful "effects" on the Plaintiffs in Delaware (and possibly every state in the country). (Opinion at 15). The court found that Delaware had specific personal jurisdiction over Mylan, reasoning that "Mylan has taken the costly, significant step of applying to the FDA 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)." (Opinion at 8). The court emphasized "the close connection between an ANDA filing and the real-world acts that approval of the ANDA will allow and that will harm patent-owning brand-name manufacturers." (Opinion at 9).

As such, generic drug manufacturers and ANDA filers find themselves (at least for now) in a world where filing an ANDA may subject them to litigation nationwide. As counsel for Mylan wrote in its opening brief, the decision "effectively declare[s] that all ANDA plaintiffs can claim personal jurisdiction in their own home states over all ANDA defendants…" and "deprive[s] ANDA defendants of the protection that the personal jurisdiction requirement is intended to provide against 'the burdens of litigating in a distant or inconvenient forum.'"

This is likely not the end of the story for two reasons. First, given the top flight Supreme Court seasoned lawyers retained by the parties, including Paul Clement for Mylan, a petition for certiorari is all but inevitable. Second, even if the Supreme Court declines to take the issue up, a legislative correction may be forthcoming. On Tuesday, the U.S. Senate introduced a bill that would place new restrictions on where patent suits can be filed. The "Venue Equity and Non-Uniformity Elimination Act of 2016" would restrict patent suits to district courts where the parties are incorporated or where they have physical facilities tied to either the development of the technology-at-issue or alleged infringement.

For more information on how this issue may affect your business or related matters, contact any member of the Firm's Intellectual Property Group.