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March 2016

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Federal Circuit Issues Expansive Ruling in Upholding Jurisdiction over Mylan in Delaware

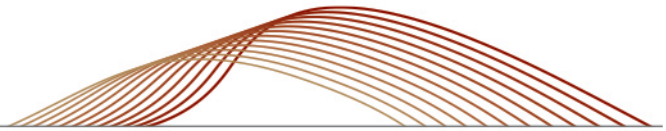
By Bruce Wexler, Eric Dittmann, Melanie Rupert, & Nicholas Tymoczko

In two closely watched cases, *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, No. 2015-1456, and *AstraZeneca AB v. Mylan Pharms. Inc.*, No. 2015-1460, the Federal Circuit today affirmed that Mylan is subject to specific personal jurisdiction in these Hatch-Waxman cases pending in Delaware. The Federal Circuit, in a decision by Judge Taranto, concluded that because Mylan would ultimately market its ANDA product in Delaware, Mylan had sufficient minimum contacts with the state such that it would not offend due process to exercise specific personal jurisdiction over Mylan, and that Delaware was a reasonable forum in which to hear these cases. Judge O'Malley concurred in the judgment and would have found general jurisdiction based on registering to do business or specific jurisdiction in view of the fact that Plaintiffs had a relationship to Delaware.

The two cases on appeal raised the issues of (1) whether Mylan had consented to general personal jurisdiction in Delaware based on its compliance with Delaware's requirement that foreign corporations register to do business and appoint an agent for service of process there, or (2) whether Mylan was subject to specific jurisdiction in Delaware based on certain facts relating to Mylan seeking FDA approval to market an ANDA product throughout the United States, including in Delaware. In both cases, Mylan, as a West Virginia corporation with its principal place of business in West Virginia, had moved to dismiss for lack of personal jurisdiction in Delaware. Chief Judge Stark and Judge Sleet had denied Mylan's motions and certified their decisions for interlocutory review.

On appeal, the Federal Circuit, in its majority decision, did not reach the issue of general personal jurisdiction. Instead, the Court reasoned 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)." (Op. at 8, emphasis added.) Accordingly, the Federal Circuit concluded that "the minimum-contacts standard is satisfied by the particular actions Mylan has already taken – its ANDA filings – for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in Delaware." (Op. at 8-9.) In reaching this decision, the Federal Circuit 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." (Op. at 9.) The Federal Circuit thus concluded that Mylan had not shown that the "planned future conduct in the State" could not support exercise of personal jurisdiction by the Delaware district court. (Op. at 13.)

Finally, the Federal Circuit noted Delaware was a reasonable forum for suit against Mylan because, among other reasons, litigating in Delaware would place an "at most modest" burden on Mylan and Delaware had an interest in providing a forum to resolve disputes that "involve the pricing and sale of products in Delaware and harms to firms doing business in Delaware." (Op. at 16.) The Court also noted that "upholding personal jurisdiction will serve the interests of the plaintiffs and the judicial



system in efficient resolution of litigation, because multiple lawsuits against other generic manufacturers on the same patents are pending in Delaware." (*Id.*)

Judge O'Malley concurred in the result, but would have found both general personal jurisdiction based on consent as a result of Mylan's compliance with Delaware's corporate registration statute (Concurring Op. at 12) and specific jurisdiction "under the Supreme Court's precedent in *Calder v. Jones*, 465 U.S. 783 (1984), and not predicate the exercise of jurisdiction primarily on Mylan's expressions of *future* intent." (Concurring Op. at 14.) Judge O'Malley reasoned that because "[b]oth Acorda and AstraZeneca are corporations organized under the laws of the State of Delaware," they "clearly experienced legally cognizable injuries in Delaware upon the filing of the ANDA applications by Mylan," which were specifically "targeted only to these Delaware companies." (*Id.* at 16-17.)

Mylan still has the right to file a petition for rehearing, and it is unclear if it will do so. Assuming this decision is maintained, it will give innovator pharmaceutical companies more flexibility in their choice of where to file suit and reduce wasteful jurisdictional disputes, and may serve to stem the tide of protective suits filed in other jurisdictions as a hedge against jurisdictional challenges.

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

Bruce Wexler
1.212.318.6020
brucewexler@paulhastings.com

Eric Dittmann
1.212.318.6689
ericdittmann@paulhastings.com

Melanie Rupert
1.212.318.6846
melanierupert@paulhastings.com