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LITIGATION

Attorneys from Sterne Kessler examine a recent Federal Circuit decision on where abbreviated new drug application (ANDA) cases can be heard. They say that, for the time being, ANDA plaintiffs can rest easy on their choice of forum. In the meantime, ANDA defendants should prepare to face litigation anywhere in the United States.

Acorda Therapeutics v. Mylan Pharmaceuticals: A New Kind of Jurisdiction for ANDA Cases

BY PAUL A. AINSWORTH AND JOSHUA I. MILLER

The Supreme Court's decision in Daimler AG v. Bauman[1] looked as if it had stripped the Hatch-Waxman plaintiff's favored jurisdictional weapon from its armament: the doctrine of general personal jurisdiction. Daimler was written broadly enough that at least one court read it to vitiate the question of consent to general jurisdiction. Another court in the same jurisdiction came to the opposite conclusion—in a case against the same defendant.

That defendant—Mylan—appealed both district court rulings to the Federal Circuit, and the Federal Circuit has clarified the relevance of Daimler to abbreviated new drug application (ANDA) cases—in a rather unexpected way. The Federal Circuit majority, like both district court judges, determined that specific personal jurisdiction attached due to Mylan's activities in Delaware [2]. This was expected.

The sweeping scope of the Federal Circuit's decision, however, was not expected. The majority's reasoning is hardly limited to the facts of the Mylan cases; in fact, much of the Court's analysis revolves around Mylan's

[1] 134 S. Ct. 746 (2014).

Paul A. Ainsworth is a Director at Sterne, Kessler, Goldstein & Fox P.L.L.C. He focuses his practice on representing patent owners in enforcement proceedings and in representing pharmaceutical industry clients in patent litigation arising under the Hatch-Waxman Act. Joshua I. Miller is an Associate at the firm whose work involves complex intellectual property disputes in the U.S. District Courts and in the ITC.

[2] *Acorda Therapeutics, Inc. v. Mylan Pharm., Inc.*, 2016 BL 83256 (Fed. Cir., Mar. 18, 2016).

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(or any ANDA filer's) obligations under federal law. As we explain below, the result is effectively national jurisdiction over any ANDA filer.

The District Court Decisions

In two ANDA cases over different patents filed against Mylan Pharmaceuticals in Delaware, Judge Sleet and Chief Judge Stark addressed three potential grounds for personal jurisdiction.[3] The judges decided these issues—(1) general jurisdiction, (2) consent to jurisdiction, and (3) specific jurisdiction—in different ways, but the result was the same: Delaware had personal jurisdiction over Mylan. The two judges largely agreed on the questions of general and specific jurisdiction: they each found that Daimler prohibited the exercise of general jurisdiction on the facts of their cases, but found that Mylan's actions gave rise to specific jurisdiction in Delaware.

The judges disagreed on whether Daimler left untouched the question of consent to jurisdiction. The key fact on consent, in both decisions, was that Mylan was registered to do business in Delaware. Under Delaware law that predated Daimler, registering to do business in the state equates to consent to jurisdiction. In Judge Sleet's estimation, through Daimler's broad language regarding jurisdiction, the Supreme Court had vitiated the doctrine of consent— and therefore Mylan had not consented to jurisdiction in Delaware. Chief Judge Stark, on the other hand, observed that Daimler was not about consent. In his view, a party could still consent to jurisdiction—and Mylan had done so.

The Majority Decision

Mylan filed interlocutory appeals on both decisions. The majority decision, penned by Judge Taranto, sidestepped the consent issue—it only addressed the question of specific jurisdiction and found that Mylan was subject to specific jurisdiction in Delaware. Judge O'Malley, in concurrence, agreed that Delaware had specific jurisdiction but argued that the question of consent was the simpler analysis. In her view, Daimler did not change the law of consent and Mylan had consented to jurisdiction in Delaware.

The curious part of the majority opinion is not that it found specific jurisdiction. Rather, it is how the majority arrived at that conclusion. Most of the analysis is dedicated not to the facts of the case but to generally applicable ANDA filing requirements. For example, the majority highlighted: the fact that Mylan had filed an ANDA; the fee for filing an ANDA; the potential costs for bioequivalence studies to satisfy the FDA's requirements; and the fact that an ANDA filer seeks approval to market a generic drug throughout the nation. Every ANDA filer does these things.

The majority did discuss some of the case-specific facts as well. For example, it emphasized that Mylan has distribution channels that will either directly or indirectly lead to sales in Delaware. It also noted that Mylan has litigated ANDA cases before in Delaware, and that Mylan is registered to do business in Delaware. Again, nearly every ANDA filer will mirror these facts, with the possible exception of registration to do business in Delaware.

In any event, the majority's analysis is notable for its focus on the actions of the defendant and the relationship of those actions to the litigation, rather than specifically on the harm to the plaintiff. The distinction is a fine one, but important for the reasons discussed below.

As a final point, the majority recognized that a defendant may defeat specific jurisdiction by showing that other considerations render jurisdiction unreasonable. These factors include the burden on the defendant, the forum state's interest in adjudicating the dispute, the plaintiff's interest in obtaining convenient and effective relief, and the interstate judicial system's interest in obtaining the most efficient resolution of controversies.

These considerations are given short shrift in the majority opinion, and the analysis is once again quite broad. For example, the majority observed that Delaware has an interest in adjudicating the case because it involves the pricing and sales of drugs that will wind up in Delaware and because it involves harm to firms doing business in Delaware. The nature of ANDA litigation makes these statements true in any state, not just Delaware. The majority also noted that judicial efficiency is furthered because other cases over the same patents had already been filed in Delaware. But under the majority's analysis, a brand company could just as easily bring suit against multiple defendants in Tennessee, shifting the improved efficiency to that forum. These considerations, like the factors considered in the initial jurisdictional inquiry, are generally true across the board.

Practical Takeaways

There is really only one practical takeaway from this case: ANDA plaintiffs' lives are much easier. The majority opinion focuses its analysis on the defendant's actions outside the State, and expected actions within the State that. But, as explained above, each of these ''actions'' is national in scope. An ANDA seeks approval to market a generic drug *nationally*. Every ANDA filer must pay the filing fee and satisfy the bioequivalence requirement. Most, if not all, ANDA filers will have distribution channels that reach every state. These actions have a national reach and, under the Federal Circuit's analysis, they give rise to specific jurisdiction in every state. The corollary is that generic manufacturers are now at risk of being haled into federal court in virtually every jurisdiction in the country.

Is en banc or certiorari coming?

At this time, no petition for *en banc* rehearing or *certiorari* has been filed, but the sheer scope of this decision opens the door for both. Even if these appeals are not taken further, ANDA defendants in particular should be aware of these issues in their own cases.

First, the majority opinion creates a special kind of jurisdiction that is (for now) specific to ANDA patent cases. As explained above, the Federal Circuit's analysis centered on the defendant's actions, not the harm to the plaintiff. And many of the actions the majority relied upon are national in scope: an ANDA filer seeks *national* approval, and many generics will distribute their drugs throughout the country. The logical result is a prospective nationwide jurisdiction over any ANDA filer. This national jurisdiction is unique to ANDA litigants. This unique rule runs contrary to the Supreme Court's recent emphasis that the Federal Circuit should not deviate from the general body of law to create spe-

[3] *See AstraZeneca AB v. Mylan Pharms. Inc.* (D. Del. Nov. 5, 2015) (Sleet, J.); *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.* (D. Del. Jan. 14, 2015).

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cialized rules for patent cases. The Court has rejected patent-specific rules in cases like eBay[4] and Teva[5], and it may do so again here. Like the injunctions and standards of review addressed in those cases, jurisdiction is a fundamental legal principle that applies to all cases, not just patent litigations.

Second, the opinion effectively shifts the burdens in the specific jurisdiction inquiry. Until Acorda, the plaintiff had the burden of proving jurisdiction.[6] Upon adequate showing, the burden shifted to the defendant to show that other considerations defeat jurisdiction. But here, based strictly on the legal requirements attendant to an ANDA filing, an ANDA plaintiff may establish jurisdiction. Thus, the ''old'' *prima facie* showing is gone and the burden falls immediately upon the defendant to show other considerations. Given that the Daimer decision—the case that precipitated the Federal Circuit's ruling here—was intended to narrow the scope of jurisdiction, it seems likely that the Supreme Court may also curtail this unprecedented expansion of specific jurisdiction.

Final Thoughts

The Mylan decision, as it stands, creates a new type of personal jurisdiction—one that will be very hard for ANDA defendants to defeat. For the time being, ANDA plaintiffs can rest easy on their choice of forum. In the meantime, ANDA defendants should prepare to face litigation anywhere in the United States. They may also consider challenging personal jurisdiction in order to bring these issues before the full Federal Circuit or even the Supreme Court.

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[4] *eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006).

[5] *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015).

[6] *See, e.g., Grayson v. Anderson*, —- F.3d —— (4th Cir. Mar. 7, 2016); *IMO Indus., Inc. v. Kiekert AG*, 155 F.3d 254 (3d Cir. 1998); *Northern Laminate Sales, Inc. v. Davis*, 403 F.3d 14 (1st Cir. 2005); *Grober v. Mako Products, Inc.*, 686 F.3d 1335 (Fed. Cir. 2012).