June 2016

Practice Group:

Intellectual Property Litigation

ANDA Filing May Subject a Pharmaceutical Company to Personal Jurisdiction in Patent Infringement Suits Anywhere in the U.S.

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On March 18, 2016, the Federal Circuit held that filing an abbreviated new drug application ("ANDA") with the FDA for a generic drug product, and thus indicating an intention to sell that product in every state (including Delaware), subjected Mylan to specific personal jurisdiction in Delaware.[1]

Mylan had sought discretionary review of two decisions in the United States District Court for the District of Delaware that held Mylan was subject to specific personal jurisdiction in Delaware. See Acorda Therapeutics, Inc. v. Mylan Pharm. Inc., 78 F. Supp. 3d 572 (D. Del. 2015) (holding that the court had both specific jurisdiction and general jurisdiction over Mylan); AstraZeneca AB v. Mylan Pharm., Inc., 72 F. Supp. 3d 549 (D. Del. 2014) (holding that the court had specific jurisdiction, but not general jurisdiction, over Mylan).

The Federal Circuit affirmed those decisions with respect to specific personal jurisdiction only based on Mylan's ANDAs for two key reasons. First, the court held that in filing its ANDAs, Mylan sought approval to market its generic drugs throughout the United States, which undisputedly included Delaware.[2] Second, the court held that Mylan's planned marketing of the ANDA products were suit-related and had a substantial connection with Delaware because the Hatch-Waxman patent litigation will directly affect when Mylan may begin marketing those products in Delaware.[3]

Background and District Court Decisions

The Hatch-Waxman Act allows a generic pharmaceutical company to obtain expedited approval to market a generic version of a brand name drug. The Act also provides a mechanism for determining whether a generic drug infringes patents purportedly covering the brand name drug by treating an ANDA filing as an act of infringement.

In 2014, AstraZeneca AB sued Mylan in the District of Delaware over Mylan's ANDA for generic versions of two AstraZeneca diabetes drugs, ONGLYZA and KOMBIGLYZE. In 2015, Acorda Therapeutics sued Mylan in the District of Delaware over Mylan's ANDA for a generic version of Acorda's multiple sclerosis drug, AMPYRA. In both cases, Mylan moved to dismiss for lack of personal jurisdiction. Both motions were denied, but for slightly different reasons.

Mylan's theory for dismissal was rooted in Daimler AG v. Bauman, a 2014 Supreme Court decision that limited general personal jurisdiction to cases in which a company's contact with the forum state renders it essentially "at home."[4] Before Daimler, branded pharmaceutical companies typically sued generic companies under a theory of general personal jurisdiction, arguing that generic companies availed themselves of nearly every state's laws by selling

their drugs in nearly every state. Thus, they could be sued in nearly every federal district court.[5]

In AstraZeneca, however, which was decided shortly after Daimler, Judge Sleet found that Mylan was not subject to general personal jurisdiction because Mylan was not "at home" in Delaware. Judge Sleet also held that Mylan's decision to register to do business in Delaware was insufficient to constitute consent to jurisdiction in Delaware for any claim arising anywhere in the world. However, the court found Mylan was subject to specific personal jurisdiction based on Mylan's suit-related contacts with Delaware.

In Acorda, Judge Stark agreed with Judge Sleet that Mylan was not subject to general personal jurisdiction on the basis of being "at home" in Delaware, but explained that Daimler was not meant to eliminate consent as a basis for personal jurisdiction. Thus, the court concluded that Mylan was subject to general personal jurisdiction through consent when it registered to do business in Delaware. The court also found Mylan was subject to specific personal jurisdiction due to similar suit-related contacts with Delaware.

Federal Circuit Decision

The Federal Circuit chose not to address general personal jurisdiction, and instead focused on specific personal jurisdiction. The Federal Circuit first looked to Delaware's long-arm statute, which provides that the exercise of personal jurisdiction over a defendant is proper so long as it is consistent with the Fourteenth Amendment's Due Process Clause.[6] It determined that the Delaware court could exercise specific personal jurisdiction over Mylan so long as Mylan "ha[d] certain minimum contacts" that were "suit-related" and had a "substantial connection" with Delaware.[7]

The Federal Circuit noted that Mylan is incorporated in West Virginia, prepared its ANDA primarily in West Virginia, and filed its ANDA in Maryland.[8] It also noted that Mylan is registered to do business in Delaware and AstraZeneca and Acorda are incorporated in Delaware.[9] The decision, however, was not based on any of those relationships.

Rather, the Federal Circuit based specific personal jurisdiction on the ANDA filing. It held that "the minimum-contacts standard is satisfied by the particular actions Mylan has already taken—its ANDA filings—for the purpose of engaging in . . . marketing conduct in Delaware."[10] In addition, the court held that Mylan's ANDA filings "are tightly tied, in purpose and planned effect, to the deliberate making of sales in Delaware . . . and the suit is about whether that in-State activity will infringe valid patents."[11] In reaching this decision, the Federal Circuit noted that ANDA filings are "distinctive" because infringement actions based on ANDA filings focus on "whether, if a particular drug were put on the market, it would infringe the relevant patent."[12] In other words, an ANDA filing confirms a plan to engage in future sales, despite the fact that a company is not legally selling the drug yet.[13]

Finally, the court noted that considerations of fairness did not override the minimum contacts that justified exercising personal jurisdiction over Mylan.[14]

In a concurring opinion, Judge O'Malley stated that she would have found general jurisdiction based on consent because Mylan is registered to do business and licensed to distribute drugs in Delaware, as the district court in Acorda held.[15] Judge O'Malley further stated that if she reached the issue of specific jurisdiction, she would have based it on the immediate harm caused by the ANDA filings, which was expressly aimed at the plaintiffs and felt in

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Delaware, rather than Mylan's expressions of "future intent" to market a generic product.[16] Because Acorda and AstraZeneca are both Delaware corporations, she analogized the ANDA filing to the libelous statements at issue in the Supreme Court case Calder v. Jones and reasoned that specific jurisdiction is appropriate here because the focal point of both the ANDA filing and the harm suffered is Delaware.[17]

Looking Forward

This decision potentially affects all future ANDA patent infringement suits between generic and branded pharmaceutical companies and may subject an ANDA filer to specific personal jurisdiction in any district in which the ANDA filer's products are sold. On April 18, 2016, Mylan filed a petition for rehearing en banc by the Federal Circuit,[18] and Acorda filed a response on May 18.[19] K&L Gates will continue to monitor these cases.

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[1] *Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*, No. 15-1456 (Fed. Cir. Mar. 18, 2016) [hereinafter *Acorda*].
[2] *Id*. at 8–9.
[3] *Id.* at 9.
[4] *See* Corrected Brief for Appellants at 1–2, *Acorda*, *supra* note 1; see also *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014).
[5] *See id*.
[6] *Acorda, supra* note 1, at 7.
[7] *Id*. at 7–8.

[8] *Id*. at 6.
[9] *Id*.
[10] *Id*. at 8–9.
[11] *Id*. at 9.
[12] *Id*. at 10–11 (emphasis in original) (citations omitted).
[13] *See id*. (emphasis added).
[14] *Id*. at 15–16.
[15] *Acorda, supra* note 1, at 12 (O'Malley, J., concurring).
[16] *Id*. at 13–14.
[17] *Id*. at 14–18.
[18] *See* Petition for Rehearing En Banc, *Acorda, supra* note 1, ECF No. 106
[19] *See* Response to Petition for Rehearing *En Banc, Acorda*, *supra* note 1, ECF No. 124.