PAUL HASTINGS
STAY CURRENT
A CLIENT ALERT FROM PAUL HASTINGS

November 2014

District of Delaware Finds Specific Jurisdiction Exists Over an ANDA Filer in the Context of a Hatch-Waxman Case

BY JOSEPH O'MALLEY, MELANIE RUPERT & JENNIFER NGUYEN

On November 5, 2014, the District of Delaware denied a motion to dismiss for lack of personal jurisdiction that had been filed by a defendant in a Hatch-Waxman case. *See generally* *AstraZeneca AB v. Mylan Pharmaceuticals*, Civ. No. 1:14 cv-00696, Doc. 26 (D. Del. Nov. 5, 2014) ("Slip. Op."). In the accompanying decision, Judge Sleet held that Delaware could exercise specific jurisdiction over the defendant ANDA filer. Importantly, this decision is the first opinion by a district court to address personal jurisdiction in the Hatch-Waxman context following the Supreme Court's landmark decision in *Daimler AG v. Bauman,* 134 S. Ct. 746 (2014).

By way of background, Plaintiff AstraZeneca filed a complaint in the District of Delaware against Defendant Mylan, alleging that Mylan's filing of two ANDAs for generic versions of AstraZeneca's Onglyza® (saxaglitptin hydrochloride tablets) and Kombiglyze® (saxaglitptin hydrochloride and metformin hydrochloride extended-release tablets) gave rise to the "highly artificial" act of patent infringement under 35 U.S.C. § 271(e)(2)(A). Slip. Op. at 2, 12-14. AstraZeneca U.S. is incorporated in Delaware and has its principal place of business there, while Mylan is incorporated and has its principal place of business in West Virginia. *Id.* at 2-3. In lieu of an answer, Mylan filed a motion to dismiss for lack of personal jurisdiction under Rule 12(b)(2), Fed. R. Civ. P., alleging that the District of Delaware lacked both general jurisdiction and specific jurisdiction over Mylan. *Id.*

The district court denied Mylan's motion of dismiss, holding that "Mylan is subject to specific jurisdiction in Delaware."[1] *Id.* at 12. In framing its analysis, the court described the unique challenges that arise with respect to evaluating personal jurisdiction in the Hatch-Waxman context, especially in a post-*Daimler* world:

> "ANDA litigation is unlike other patent infringement litigation: The injury is abstract, making it difficult to point to a location out of which the injury arises for jurisdictional purposes. At the same time, defending against an infringement lawsuit is an inherent and expected part of the ANDA filer's business. To put it simply: a lawsuit is often inevitable, but it is not clear where it should be held. This challenge is compounded by *Daimler*'s narrowing of the doctrine of general jurisdiction."

Id. at 14. In the context of these unique considerations, the district court found that, with respect to Mylan's ANDA filing in this case, the "consequences are suffered in Delaware." *Id.* While Mylan argued that "its activities are not purposefully directed at the state of Delaware, where AstraZeneca U.S. is organized," the court rejected Mylan's argument as "creat[ing] the untenable position that its conduct is not directed to any jurisdiction." *Id.* The court noted that the Federal Circuit, in its prior decision in the *Zeneca* case,[2] "eliminated the possibility that Maryland (the location of the FDA and where ANDAs are filed) could exercise specific jurisdiction over ANDA filers, in order to avoid creating a supercourt with jurisdiction in all cases."[3] *Id.* As a result, "the only possible alternative forum is the state of residence for the patent holder." *Id.* at 15. In further support of its finding, the court also noted that "Mylan's contact with Delaware is not illusory," in view of the fact that Mylan's Paragraph IV certification was sent to AstraZeneca U.S. in Delaware. *Id.* Accordingly, the court found that Mylan "cannot plausibly argue that it could not reasonably anticipate being haled [*sic*] into court in Delaware when patent litigation is an integral part of a generic drug company's business." *Id.*

In further support of its decision, the district court also included a significant discussion of the policy concerns surrounding "traditional notions of fair play and substantial justice" in the unique context of Hatch-Waxman cases. The court observed that the Hatch-Waxman Act "attempted to strike a balance" between generic drug companies and branded or pioneer drug companies, rather than "burden patent holders or reduce the patent protection afforded in ANDA cases." *Id.* at 13, 17. Specifically, generic drug companies were given greater protection when developing their drugs (*e.g.*, benefiting from an exemption from infringement for pre-ANDA development activities), and in turn, branded drug companies were given the right to initiate a patent infringement lawsuit before the generic companies entered the U.S. market with their ANDA products. *Id.* at 13. In light of these policy considerations, the court found that limiting AstraZeneca's choice of forum to Mylan's home state of West Virginia was not the kind of "adequate protection" for patent holders that the Hatch-Waxman Act was intended to provide and would be "inconsistent with the balance that Congress sought to create." *Id.* at 16-17. Instead, AstraZeneca would be "substantially burdened if forced to bring lawsuits against each ANDA filer in the defendants' home states." *Id.* at 16. The district court also noted that Mylan is "no stranger to ANDA litigation in Delaware," and there would be "no meaningful burden on Mylan in defending in Delaware." *Id.* at 16.

The district court also made clear that judicial efficiency weighed in favor of the exercise of specific jurisdiction over defendants in Hatch-Waxman cases with multiple ANDA filers. The court noted that, "in this case, which is by no means unique in the ANDA litigation sphere," AstraZeneca had filed suit against "no fewer than ten generic defendant groups." *Id.* at 17. Accordingly, the court found that resolving these cases in a single district "would promote judicial economy and avoid the possibility of inconsistent outcomes." *Id.*

As the first post-*Daimler* case to decide a motion to dismiss for lack of personal jurisdiction in the context of a Hatch-Waxman action, this decision by the District of Delaware provides plaintiffs with valuable guidance in arguing that specific jurisdiction may be exercised over defendant ANDA filers in certain circumstances. Notably, the policy considerations underlying this decision are broadly applicable and should be helpful tools for branded drug companies faced with a motion to dismiss for lack of personal jurisdiction by a generic drug company, especially where multiple defendant groups are involved.

✧ ✧ ✧

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

Joseph O'Malley
212.318.6090
josephomalley@paulhastings.com

Melanie Rupert
212.318.6846
melanierupert@paulhastings.com

---

[1] With respect to general jurisdiction, the district court found that "contacts sufficient to render [Mylan] at home in Delaware, in light of *Daimler*" had not been alleged. Slip. Op. at 6. The court thus declined to exercise general jurisdiction over Mylan.

[2] *See Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829 (Fed. Cir. 1999).

[3] Unless otherwise indicated, all internal citations and quotations have been omitted, and all emphasis has been added.