

## The Daimler Confusion And Its Impact On ANDA Litigation

*Law360, New York (March 06, 2015, 8:12 AM ET) --*

Hatch-Waxman plaintiffs have long relied upon allegations of general jurisdiction to obtain personal jurisdiction over generic drug manufacturers in patent-friendly forums. And, until recently, courts did not hesitate to find personal jurisdiction where a defendant allegedly distributed drugs throughout the United States.[1] But in *Daimler AG v. Bauman*,[2] the U.S. Supreme Court seemed to strip this weapon from a plaintiff's arsenal by narrowing the circumstances in which a defendant's unrelated contacts with the forum can give rise to personal jurisdiction.

In *Daimler*, a group of Argentinian plaintiffs filed suit in California against a German defendant for activities that occurred in Argentina based on allegations that the German defendant had systematic and continuous contacts with California through significant but unrelated commercial activities of its subsidiary. The *Daimler* court held, however, that the doctrine of general jurisdiction is limited to those circumstances where the defendant's contacts are such that it is "at home" in the forum — i.e. the forums where it is incorporated or where it has its principal place of business — in all but "exceptional" situations.

A pair of recent Delaware decisions highlight the issues that the *Daimler* decision creates for Hatch-Waxman litigants.[3] These decisions make clear that the "old" Hatch-Waxman jurisdictional tack will not work after *Daimler*, but they also set out a framework for establishing personal jurisdiction over a foreign defendant.

### The Delaware Decisions

The decisions — issued by Chief Judge Leonard P. Stark and Judge Gregory Sleet — are particularly interesting because they involve the same corporate defendant, Mylan Pharmaceuticals, and largely the same set of operative jurisdictional facts. For this article's purposes, the most relevant facts are that Mylan is a West Virginia corporation with a principal place of business in Morgantown, West Virginia. Under *Daimler*, Mylan is plainly "at home" in West Virginia. However, Mylan is also registered to do business as a foreign entity in Delaware.

Both Delaware decisions addressed three possible grounds for the exercise of personal jurisdiction: (1) general jurisdiction; (2) consent to general jurisdiction; and (3) specific jurisdiction. It comes as no



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surprise that both judges rejected general jurisdiction under Daimler. However, the Delaware courts' analyses of the other two personal jurisdiction theories are more noteworthy.

The plaintiffs alleged in both cases that the Delaware court had personal jurisdiction over Mylan because it had registered to do business in the state of Delaware. Under longstanding Delaware precedent established in *Sternberg v. O'Neil*,<sup>[4]</sup> this should have constituted consent to general jurisdiction. But in *AstraZeneca*, Judge Sleet held that "the Delaware Supreme Court's decision in *Sternberg* can no longer be said to comport with federal due process."<sup>[5]</sup> As a consequence, the fact that a defendant has complied with Delaware's mandatory registration requirements in order to conduct business in the state is no longer sufficient to establish general jurisdiction. However, the court also recognized that reasonable legal minds could differ on whether *Daimler* should be taken that far as he certified the personal jurisdiction question for interlocutory appeal.

In contrast, Chief Judge Stark came to the opposite conclusion on the ongoing vitality of *Sternberg* in his decision in *Acorda*. The court concluded that *Daimler*'s silence on the issue of consent meant that the Supreme Court's decision did not vitiate long-standing Delaware precedent for finding consent to personal jurisdiction based on a defendant's foreign business registration.<sup>[6]</sup> The *Acorda* and *AstraZeneca* decisions reveal an intra-district split on whether registering to do business in Delaware remains a viable basis for finding personal jurisdiction. Like Judge Sleet, Chief Judge Stark certified the personal jurisdiction question for interlocutory appeal.

While Chief Judge Stark and Judge Sleet reached different conclusions on the issue of consent, both courts nonetheless found specific jurisdiction present — a theory that has, at least until *Daimler*, been less preferred by ANDA litigants. Judge Sleet justified the court's exercise of personal jurisdiction over Mylan by reasoning that the "highly artificial" harm of filing an ANDA must be directed somewhere. Since that somewhere cannot be where ANDAs are filed,<sup>[7]</sup> Judge Sleet determined that this artificial harm occurred in Delaware because that is where the patentee is located and where Mylan sent its statutorily-mandated Paragraph IV certification.

Judge Sleet also noted that *AstraZeneca* had filed "no fewer than ten" suits in Delaware against generic defendant groups, which presumably placed Mylan on notice that it similarly faced potential litigation in Delaware. Further, Judge Sleet reasoned that moving forward with litigation in Delaware placed "no meaningful burden on Mylan," and, therefore, the court found that the efficient resolution of the related actions weighed in favor of the exercise of jurisdiction.<sup>[8]</sup>

Chief Judge Stark's analysis was similar. He noted that Mylan's ANDA filing harmed *Acorda* in Delaware. He also highlighted the efficiency of coordinated litigation in a single district. Doubling back on his consent analysis, Chief Judge Stark also found that Mylan's registration "to do the business of 'pharmaceutical manufacturing, distribution and sales,'" and its appointment of an agent to accept process in Delaware further supported the exercise of specific jurisdiction.<sup>[9]</sup> Chief Judge Stark also noted that ANDA litigation had already commenced in Delaware when Mylan filed its ANDA. *Id.*

The premise of both decisions is that ANDA filings necessarily carry with them a harm — even if it is "artificial" — that should give rise to jurisdiction somewhere other than just the filer's home forum. They both rely on similar ideas to conclude that this harm is most likely those forums where the patent holder is "at home." And because that harm is the direct and necessary result of the intentional act of filing an ANDA, the patent holder's "home" forum will often be the appropriate location for the exercise of specific jurisdiction.

On its face, this outcome appears at odds with the Federal Circuit's holding in *Zeneca* that Maryland is not the proper venue for a Hatch-Waxman suit simply because that is where an ANDA is filed and also with the Supreme Court's consistent rejection of arguments that a plaintiff's contacts with the forum are relevant to personal jurisdiction analysis.<sup>[10]</sup> But both judges sidestep these concerns by explaining that their decision rest in part on the location of the harm caused by Mylan and not the location of plaintiff's business. Nevertheless, the result is the same and it means that generic pharmaceutical companies continue to face the risk of litigation in a foreign forum even if their only contact with that forum is the result of complying with the Hatch-Waxman Act's notice requirements.

Until the Federal Circuit resolves the issues raised in the *AstraZeneca* and *Acorda* interlocutory appeals, Hatch-Waxman plaintiffs should take care to ensure that their jurisdictional allegations encompass both consent and specific jurisdictional theories. And for Hatch-Waxman defendants, until the Federal Circuit addresses the interlocutor appeals in *AstraZeneca* and *Acorda*, there remains a continuing risk of facing patent litigation in a foreign forum.

### **A Few Key Takeaways**

The *AstraZeneca* and *Acorda* decision offer some very important insights for both Hatch-Waxman plaintiffs and defendants.

- Allegations of specific jurisdiction remain the surest way to obtain personal jurisdiction over a foreign defendant. To ensure the best result, allegations of specific jurisdiction over a Hatch-Waxman defendant may be strengthened by alleging close ties between the plaintiff and the forum.
- Allegations of consent remain a viable basis for personal jurisdiction over a foreign defendant.
- Hatch-Waxman defendants should consider more carefully where they register to do business if they wish to reduce the risk of facing suit in a foreign jurisdiction.
- Plaintiffs should include allegations concerning the existence of related litigation in the forum as courts have given this factor some weight in evaluating whether the assertion of personal jurisdiction comports with due process.

### **Conclusion**

Daimler's general jurisdiction analysis has altered the way jurisdiction is analyzed in Hatch-Waxman litigation. These recent decisions from Delaware may provide roadmaps for Hatch-Waxman litigations as to how to best assert or avoid personal jurisdiction in a foreign forum.

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[1] See AstraZeneca v. Mylan Pharms. Inc., --- F.Supp.3d ----, (D. Del. Nov. 5, 2014).

[2] 134 S. Ct. 746 (2014).

[3] See AstraZeneca; Acorda Therapeutics Inc. v. Mylan Pharms. Inc. (D. Del. Jan. 14, 2015).

[4] 550 A.2d 1105 (Del. 1988).

[5] AstraZeneca.

[6] Acorda.

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

[8] AstraZeneca, (citing World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 292 (1980)).

[9] Acorda.

[10] See Walden v. Fiore, --- U.S. ----, 134 S.Ct. 1115, 1122 (2014).

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