

The Effect of *Daimler AG v. Bauman* on Personal Jurisdiction in Hatch-Waxman Lawsuits

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In early 2014, the Supreme Court limited a plaintiff's ability to sue a defendant under general jurisdiction. In order to subject a defendant to personal jurisdiction in a forum where the defendant is not present, the defendant must have enough contacts with the forum that maintaining the lawsuit does not "offend traditional notions of fair play and substantial justice." *International Shoe Co. v. State of Washington, Office of Unemployment Compensation & Placement*, 326 U.S. 310, 316 (1945). Personal jurisdiction is divided into two categories – specific and general jurisdiction. General jurisdiction exists when a defendant's contacts with a forum "are so continuous and systematic as to render it essentially at home in the forum State." *Daimler AG v. Bauman*, 134 S.Ct. 746, 761 (2014) (quoting *Goodyear Dunlop Tires Operations, S.A. v. Brown* 131 S.Ct. 2846, 2851 (2011)). Specific jurisdiction exists in a forum when a defendant has purposefully directed its activities to residents of the forum, and the litigation results from alleged injuries that arise out of or relate to those activities.

In *Daimler AG v. Bauman*, the Supreme Court curtailed general jurisdiction, explaining that a corporation is "at home" for purposes of general jurisdiction in only a narrow set of circumstances – for example, a corporation's place of incorporation and the corporation's principal place of business. The Court explained that while this list is not exhaustive, general jurisdiction is intended to be afforded in only limited circumstances. The Court also explained that a substantial, continuous, and systematic course of business alone is not sufficient to create general jurisdiction, rejecting the exercise of general jurisdiction in every State in which a corporation engages in a substantial, continuous, and systematic course of business as unacceptably grasping.

In Hatch-Waxman litigation, general jurisdiction traditionally provided the basis to assert jurisdiction over generic drug company defendants. Thus, the Hatch-Waxman community has been considering whether the *Daimler* decision could provide a route for generic drug companies to contest personal jurisdiction in ANDA cases. Using *Daimler* as a basis, generic drug company Mylan Pharmaceuticals, Inc. has filed motions to dismiss for lack of personal jurisdiction in several newly filed ANDA cases.

A decision on one of Mylan's motions to dismiss issued in November 2014 in the U.S. District Court for the District of Delaware.¹ *AstraZeneca AB v. Mylan Pharmaceuticals, Inc.*, 1:14-cv-696, D.I. 26, 27. In that case, AstraZeneca sued Mylan alleging patent infringement under 35 U.S.C. §271(e)(2) for Mylan's filing of ANDAs for generic versions of AstraZeneca's drugs Onglyza® (saxagliptin hydrochloride tablets) and Kombiglyze® (saxagliptin hydrochloride and metformin hydrochloride extended-release tablets). District Court Judge Sleet agreed with Mylan on the issue of general jurisdiction – finding that there was no general jurisdiction over Mylan in Delaware in light of the Supreme Court's decision in *Daimler*. In doing so, Judge Sleet held that *Daimler* abrogated the Third Circuit's precedent holding that statutory registration in the State of Delaware was sufficient to confer general jurisdiction. Judge Sleet nonetheless denied Mylan's motion to dismiss based on

¹ Mylan is incorporated in West Virginia and has its principal place of business in West Virginia. Mylan is registered to do business in Delaware.

specific jurisdiction. Judge Sleet found that the Court had specific jurisdiction because Mylan “purposefully directed” its ANDA filing at AstraZeneca, which is incorporated in Delaware.

Although Mylan was unsuccessful in its jurisdiction challenge², Judge Sleet’s decision could form the basis for personal jurisdiction challenges in ANDA lawsuits in the future. Specifically, according to the Court’s decision, personal jurisdiction will likely exist over an ANDA filer in forums: (i) where the ANDA filer is incorporated; (ii) that are the ANDA filer’s principal place of business; or (iii) that are the home state of the plaintiff. If other courts follow suit on this issue, Brand companies may be forced to file ANDA lawsuits against Generics (particularly in multi-defendant cases where there is no common home state for all generics) in only the state in which the Brand companies are incorporated or have a principal place of business if they hope to keep all parties together in a single suit.

If you have any questions or wish to discuss how the revised guidelines will impact your business, please contact an attorney in the [Biotechnology & Pharmaceutical group](#) at Brinks Gilson & Lione.

2 Judge Sleet’s decision is currently under interlocutory appeal.

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