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in the news

Hatch-Waxman Litigation

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Recent Developments in Exercising Personal Jurisdiction in Hatch-Waxman Cases

In this Issue:

Once a seemingly settled issue, personal jurisdiction has become a significant issue in Hatch-Waxman cases. New drug application sponsors typically do business throughout the country. Consequently, district courts usually exercised personal jurisdiction over Hatch-Waxman litigants under the theory of general jurisdiction. Notwithstanding a few holding companies or foreign-based sponsors, for most Hatch-Waxman litigants, this was the end of the story.

In the past few years, however, the Supreme Court has reined in the application of general jurisdiction that had begun to wander from its traditional foundation. See *Goodyear Dunlop Tires Operations, S.A. v. Brown, 564* U.S. - - -, 131 S. Ct. 2846 (2011) and *Daimler AG v. Bauman*, 571 U.S. - - -, 134 S. Ct. 746 (2014). Even domestic Hatch-Waxman litigants may now have colorable arguments that they are not subject to personal jurisdiction in some of the popular forums for these cases.

I. Traditional Use of General Jurisdiction in Hatch-Waxman Cases.

The first post-*Daimler* decisions suggest district courts will rely on new theories of general and specific jurisdiction to exercise personal jurisdiction in Hatch-Waxman cases. Traditionally, district courts exercised personal jurisdiction in Hatch-Waxman cases based on theories of general jurisdiction because there was no "real" act of infringement in any district (infringement under 35 U.S.C. § 271(e)(2) being so-called "imaginary"). Tending to find that such "acts" of infringement did not really "occur" anywhere, Courts instead relied on general jurisdiction to exercise power over a party. *See, e.g., Eli Lilly v. Sicor Pharmaceuticals, Inc.*, No. 06-cv-238, 2007 WL 1245882 (S.D. Ind. Apr. 27, 2007).

II. Amenability to General Jurisdiction May Be Waning.

The applicability of general jurisdiction came into doubt in recent years following the Supreme Court's decisions in *Goodyear* and *Daimler*, which held that general jurisdiction requires contact with a state that is so pervasive it makes the defendant "essentially at home" or "comparable to a domestic enterprise." Although many Hatch-Waxman litigants may do business throughout the country, they are not subject to general jurisdiction wherever they have substantial sales. To hold otherwise would be to essentially subject them to jurisdiction everywhere, a conclusion the majority in *Daimler* found "unacceptably grasping."

III. Freedom from Jurisdiction Could Be An Advantage.

A measure of control over where one may have to defend a Hatch-Waxman case may be a valuable commodity that could provide a strategic and tactical advantage in litigation. For example, litigants may disfavor particular jurisdictions for their local rules or practices, or they want to avoid consolidation with related co-pending cases, or they may seek to avoid litigating before a court that issued an unfavorable decision in an earlier related matter. In cases that may involve a launch at-risk, for which damages may be sought, the potential makeup of a jury could also be a significant factor. And if a brand declines to file a safety-suit when jurisdiction is arguable, a generic defendant may find an opening into a dismissal that could end the 30-month stay on approval, changing the landscape of the litigation.

IV. Early District Court Decisions Push Back.

A. Judge Sleet & Judge Gilstrap Find Specific Jurisdiction Based on Notice Letter.

The initial reactions from district courts, however, suggest that not much will change from the business as usual. First, in *AstraZeneca AB v. Mylan Pharmaceuticals, Inc.*, No. 14-696-GMS, dkt. # 26 (D. Del. Nov. 5, 2014), Judge Sleet found filing an abbreviated new drug application could be the basis for exercising specific jurisdiction. Regardless how artificial the act of infringement may be, the filing of an ANDA is a "real act" with "actual consequences," which in that case would be "suffered in Delaware," where AstraZeneca is incorporated. Judge Sleet found that AstraZeneca's cause of action arose out of Mylan's delivery of a paragraph IV notice letter to AstraZeneca in Delaware. Thus, he concluded that "the act of filing an ANDA and the paragraph IV notification provide sufficient minimum contacts with the state of Delaware under a specific jurisdiction analysis."

Judge Gilstrap reached a similar decision in the Eastern District of Texas in *Allergan, Inc. v. Actavis, Inc.*, No. 2:14-cv-638, dkt. # 97 (E.D. Tex. Dec. 23, 2014), in large part on the fact that the applicant's "conduct will cause substantial harm to Allergan in Texas," which is where the reference listed drug is manufactured and from where its nationwide distribution is coordinated. He also emphasized the applicant's independent contacts with the state, such as its licensure to distribute prescription drugs, its establishment of wholesalers and retailers, and its intent to target the state for the sale of the proposed generic drug.

B. Judge Stark Revives General Jurisdiction and Expands Specific Jurisdiction.

Most recently, in *Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals Inc.*, Case No. 14-935-LPS (Dist. Del. Jan. 14, 2015), Judge Stark not only found specific jurisdiction based on the sending of a notice letter, but also by finding general jurisdiction under a consent theory based on the ANDA-filer's registration to do business in Delaware and by its appointment of a registered agent to accept service of process in Delaware. In addition to reviving general

jurisdiction as an option in Hatch-Waxman cases, Judge Stark's decisions also expands the use of specific jurisdiction premised on the sending of a notice letter. In *Allergan* and *AstraZeneca*, the brands had principal places of business in Texas and Delaware, respectively. In contrast, the brand in *Acorda* had a principal place of business in another state—New York—and was merely incorporated under the laws of Delaware.

A notable distinction between the factual circumstances in this case as opposed to *Allergan* or *AstraZeneca* is that the applicant did not mail its notice letter into the state of Delaware. Although the drug sponsor is incorporated in Delaware, the applicant sent its notice letter to the sponsor's principal place of business in New York and to the patent-owner's principal place of business in Ireland. Judge Stark opined that while "mailing a paragraph IV certification ***into*** Delaware is an additional activity directed at Delaware that should be considered . . . . [i]t does not follow . . . that the absence of a mailing into Delaware eliminates the possibility of exercise of specific jurisdiction." (Emphasis original).

Judge Stark's order also serves as a warning for parent companies that file ANDAs through wholly-owned subsidiaries. Although Judge Stark only found general jurisdiction and specific jurisdiction over the subsidiary ANDA-filer in *Acorda*, he granted jurisdictional discovery into the parent company's relationship with the subsidiary to determine whether jurisdiction could be exercised based on an agency theory. Such discovery can be an unwelcome event for Hatch-Waxman defendants as it is a costly and invasive detour from the substantive merits of the litigation.

V. Evolving Area of the Law.

Despite these earlier decisions, there is still no controlling authority, but that may change. In December, Judge Sleet certified his decision in *AstraZeneca* for interlocutory appeal. Mylan's petition for leave to appeal pursuant to 28 U.S.C. § 1292(b) is pending before the Federal Circuit in Case No. 15-117, and it has attracted the attention of the Generic Pharmaceutical Association in the form of an amicus brief. On January 30th, Judge Stark also certified his decision in *Accorda*.

Continuing developments in this area may be of interest for stakeholders on all sides of Hatch-Waxman litigation. Polsinelli attorneys will continue to monitor the changing Hatch-Waxman litigation landscape. For questions on how the topics covered in this discussion may impact your business, please contact the authors or your Polsinelli attorney.

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* Law360, March 2014

** *The American Lawyer* 2013 and 2014 reports

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