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Federal Circuit Preserves Plaintiff's Choice of Forum in *Hatch-Waxman* Cases

Following the Supreme Court's decision in *Daimler AG v. Bauman* [134 S. Ct. 746 (2014)], the historical basis for asserting personal jurisdiction in *Hatch-Waxman* cases based on general jurisdiction principles became uncertain, and district courts struggled to determine the proper basis for jurisdiction under the new standard. On March 18, 2016, the Federal Circuit decided *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.* and held that planned future sales by a generic defendant of the patented product at issue is a basis for specific jurisdiction over the defendant. In doing so, the Court preserved the ability of a *Hatch-Waxman* plaintiff to choose the litigation forum. However, further litigation on this issue may be imminent, as Mylan filed a request for rehearing *en banc*. Until all appeals are exhausted, the best practice for branded pharmaceutical companies is to continue to assert both general and specific jurisdiction as a basis for personal jurisdiction over generic defendants, and to file protective suits in the defendant's state of incorporation or principal place of business.

Background and the Decisions Below

In *Daimler*, the Supreme Court appeared to limit the applicability of general jurisdiction and defined the relevant inquiry as "not whether a foreign corporation's in-forum contacts can be said to be in some sense 'continuous and systematic,' [but rather] whether that corporation's 'affiliations with the State are so 'continuous and systematic' as to render [it] essentially at home in the forum State.'" [*Daimler*, 134 S.Ct. at 761 (citations omitted).] Following *Daimler*, much of the previous jurisprudence regarding general jurisdiction in *Hatch-Waxman* cases failed, and district courts split as to (1) whether general jurisdiction is still a proper means by which to assert jurisdiction over generic companies, and (2) what factors are properly considered in a determination of specific jurisdiction.

Two Delaware cases, *AstraZeneca AB v. Mylan Pharmaceuticals* (Judge Sleet) and *Acorda Therapeutics, Inc. v. Mylan Pharm., Inc.* (Chief Judge Stark), led the jurisprudence in this area, but differed in their analysis and conclusions regarding both the general and specific jurisdiction questions. [*AstraZeneca AB v. Mylan Pharm., Inc.*, 72 F. Supp. 3d 549, 552 (D. Del. 2014), motion to certify appeal granted sub nom. *AstraZeneca AB v. Aurobindo Pharma Ltd.*, No. CV 14-664-GMS, 2014 WL 7533913 (D. Del. Dec. 17, 2014) and *aff'd sub nom. Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, No. 2015-1456, 2016 WL 1077048 (Fed. Cir. Mar. 18, 2016); *Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, 78 F. Supp. 3d 572, 576 (D. Del. 2015) aff'd, No. 2015-1456, 2016 WL 1077048 (Fed. Cir. Mar. 18, 2016).] Both cases were certified for interlocutory appeal and were heard together by the Federal Circuit.

In *AstraZeneca*, Mylan filed a motion to dismiss challenging the Court's jurisdiction. Judge Sleet held that the Court did not have general jurisdiction over Mylan because Mylan's registration to do business in Delaware and "broad network of third-party contacts within the state" did not rise to the level of activity "'comparable to domestic enterprise in [Delaware].'" [*AstraZeneca*, 72 F. Supp. at 554 (*citing Daimler*, 134 S.Ct. at 758 n.11 (alteration in original)).] However, the Court held that it had *specific jurisdiction* over Mylan because Mylan's activities, notably, its service of the requisite ANDA notice letter to AstraZeneca in Delaware, were "purposefully directed at AstraZeneca in the state of Delaware." [*Id.* at 560.]

Less than two months later, in *Acorda*, Chief Judge Stark found Mylan subject to both general and specific jurisdiction in Delaware. In deciding Mylan's motion to dismiss, the Court held that Mylan did not have operations in Delaware "of such a type and extent as to render [Mylan] 'at home'" under *Daimler* but that Mylan's registration to do business in Delaware was a sufficient basis on which to find that Mylan consented to general jurisdiction. [*Id.* at 583, 591.] Chief Judge Stark also held that the Court had *specific jurisdiction* over Mylan, though on different grounds than those relied on by Judge Sleet in *AstraZeneca*. Specifically, Chief Judge Stark held that Acorda's claims "arose out of and relate to Mylan Pharma's activities that are, and will be, directed to Delaware," including Mylan's filing of its ANDA to obtain FDA approval, sending a Paragraph IV notice letter to Acorda (a Delaware corporation), registering to do business in Delaware, registering as a pharmacy wholesaler and distributor with the Delaware Board of Pharmacy, and being a frequent litigant in Hatch-Waxman cases in the Delaware Court. [*Id.* at 593.]

The Federal Circuit Addresses Jurisdiction

The Federal Circuit jointly decided the *AstraZeneca* and *Acorda* appeals in *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.* [No. 2015-1456, 2015-1460, 2016 WL 1077048 (Fed. Cir. Mar. 18, 2016) ("*Acorda II*")]. The Federal Circuit affirmed the assertion of specific jurisdiction in both cases but did not consider the general jurisdiction question. In her concurring opinion, Judge O'Malley explained that the Court should have addressed the question of general jurisdiction, in part because specific jurisdiction raises more "complexity," as evidenced by her opinion that she "would find specific jurisdiction over Mylan in these cases under a different legal theory than employed by the majority." [*Acorda II*, 2016 WL 1077048, at *8 (O'Malley, J., concurring).] In discussing the general jurisdiction question, she noted that Mylan "voluntarily elected to do business in Delaware and to register and elect an agent for service of process in that state" and should therefore be subject to general jurisdiction. [*Id.* at *9.] In particular, the Court held that the filing of an ANDA with a Paragraph IV Certification (21 U.S.C. §355(j)(2)(A)(vii)(IV)) is sufficient to confer specific jurisdiction in a forum where the "minimum contacts" standard set forth by the Supreme Court has been met.

In its decision, the Court noted the unique features of the Hatch-Waxman Act relevant to the jurisdictional question, including the filing of a Paragraph IV Certification, and relied on its Article III precedent in holding that Mylan's ANDA filings and intent to market the drugs in Delaware were not speculative. [*Acorda II*, 2016 WL 1077048, at *4,*6.] The Court held that Mylan's ANDA filings and Paragraph IV Certifications, and its taking "the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at Delaware (and, it is undisputed, elsewhere)," were sufficient bases for finding that Mylan had minimum contacts with the state. [*Id.* at *3.] The Court explained that "it suffices for Delaware to meet the minimum-contacts requirement in the present cases that Mylan's ANDA filings and its distribution channels establish that Mylan plans to market its proposed drugs in Delaware and the lawsuit is about patent constraints on such in-State marketing." [*Id.* at *6.]

Notably, the Court also held that district courts must consider other due process factors set forth by the Supreme Court in determining jurisdiction, including burden on the defendant, the plaintiff's interest in obtaining convenient and effective relief, and the forum state's interest in adjudicating the matter. [*Id.* at *7 (citing *World–Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980)).] Here, however, the Court held that the "burden on Mylan will be at most modest, as Mylan, a large generic manufacturer, has litigated many ANDA lawsuits in Delaware, including some that it initiated." [*Id.* at *7.] The Court further held that upholding jurisdiction would serve plaintiffs' interests because "multiple lawsuits against other generic manufacturers on the same patents are pending in Delaware." [*Id.*]

Litigation after *Acorda*

The Federal Circuit's decision in *Acorda II* preserves the Hatch-Waxman plaintiff's choice of forum. Notably, in side-stepping the general jurisdiction question to focus on specific jurisdiction, the Court shifted the historical basis of jurisdiction in these cases from general jurisdiction to specific jurisdiction.

The decision provides some certainty to litigants in determining where they can sue and be sued under the Hatch-Waxman Act, and appears to preserve the pre-*Daimler* considerations of forum selection. Caution is warranted, however, because of the lack of appellate guidance on the general jurisdiction question and because assertion of specific jurisdiction in such cases is still in its relative infancy. Moreover, further litigation on this issue may be forthcoming. Mylan filed a request for rehearing *en banc* on April 18, 2016, and the Court invited responses from appellees. Thus, pending the outcome of the motion for rehearing *en banc* and potential appeals, the best practice for branded pharmaceutical companies in bringing Hatch-Waxman suits is to assert both general and specific jurisdiction as a basis for jurisdiction and to file protective suits as necessary in the state of incorporation or principal place of business of the defendant.

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