

Personal Jurisdiction In Hatch-Waxman Actions In View of *Daimler*

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Prior to the Supreme Court's decision in *Daimler*,¹ concerns over personal jurisdiction in Hatch-Waxman actions were essentially non-existent. General jurisdiction commonly provided the basis to assert jurisdiction over generic drug companies ("generics").² Resort to state long-arm statutes or specific jurisdiction was rare.³ If jurisdiction were questionable in the chosen forum and dismissal was possible, a second, so-called protective suit would be filed by the patentee in a district where jurisdiction was certain, e.g., the generic's state of incorporation. This insured that a proper suit was filed within 45-days of the patentee's receipt of a generic's notice letter, a critical benefit to patentees as it prevented the FDA from approving the generic's ANDA for 30 months.⁴

Daimler drastically altered the accepted approach for establishing personal jurisdiction in Hatch-Waxman actions. In *Daimler*, the Court held that general jurisdiction existed only in those states where the defendant was "at home," i.e., the defendant's state of incorporation or its principal place of business.⁵ While the Court left open the possibility that other conduct could establish general jurisdiction, that result would be "exceptional."⁶ Apparently no court, including those adjudicating Hatch-Waxman actions, has encountered an "exceptional" case.

¹ *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014).

² See, e.g., *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 421 (D. Del. 2010).

³ Most state courts have construed the relevant long-arm statutes to the fullest extent allowed by the Constitution; therefore, these statutes have not played a significant role in the reported decisions.

⁴ 21 U.S.C. § 355(1)(5)(B)(ii).

⁵ *Daimler*, 134 S.Ct. at 760.

⁶ *Id.* at 761 n.19.

Since *Daimler*, personal jurisdiction has been found in each Hatch-Waxman action where it was challenged; thus, not one action has been dismissed.⁷ The basis of jurisdiction, however, has varied and in fact, has been somewhat inconsistent. Many courts have found that the generic defendant consented to jurisdiction by registering to do business in the forum (“consent jurisdiction”). At least one court rejected this approach, but found specific jurisdiction due to the generic’s contacts with forum. Indeed, one court found both consent and specific jurisdiction. As the scorecard indicates, both theories must be adopted by the Federal Circuit to prevent dismissals for lack of jurisdiction. For example, if the defendant is not registered to do business in the forum, a holding of specific jurisdiction is required to avoid dismissal.

JURISDICTION	ALLERGAN	ASTRA-ZENECA	ACCORDA	OTSUKA	FORREST	LILLY	SENJU
<i>General Jurisdiction</i>	Not Decided	NO	NO	NO	NO	NO	NO
<i>Consent Jurisdiction</i>	Not Discussed	NO	YES	YES	YES	Not Discussed	YES
<i>Specific Jurisdiction</i>	YES	YES	YES*	NO**	Not Discussed	YES	?***

*Discovery allowed as to Mylan Inc., which was not registered to do business in Delaware.

**Specific jurisdiction did not exist over Mylan Labs, the Indian parent of the other two Mylan defendants.

***Discovery allowed as to foreign parent.

The earliest case addressing this issue is *Allergan, Inc. v. Actavis, Inc.*⁸ There, Allergan filed a declaratory judgment action seeking a ruling that defendants had not complied with the Hatch-Waxman Act and therefore, their ANDA filings for a generic version of Allergan’s RESTASIS were ineffective. As relevant here, defendants moved to dismiss for lack of personal jurisdiction. The Texas district court, without mentioning *Daimler*, denied the motion and held that defendants had sufficient minimum contacts with the forum to establish specific jurisdiction.

⁷ This may portend the ruling of the Federal Circuit in the appeal pending before it.

⁸ 2014 WL 7336692 (E.D. Tex. 2014).

The notice letter was sent to Allergan, a Delaware Corporation, at its principal place of business in California. Thus, the notice-letter was not sent to the forum. The court nevertheless found that the harm to Allergan in Texas, where Allergan manufactured its product, established jurisdiction. This was “unavoidably connected to Defendants’ extensive efforts in Texas to sell its generic product.”⁹ In explaining its decision, the court stated:

Part and parcel of this undertaking is Defendants’ solicitation of a license to distribute prescription drugs in Texas, and Defendants’ efforts to establish contacts with Texas wholesalers, retailers and state agencies to effect drug sales, including the sale of RESTASIS.

* * *

[T]his Court concludes that Defendants’ contacts with Texas are inexplicably linked to the harm or threatened harm to Allergan in Texas ...¹⁰

In *AstraZeneca AB v. Mylan Pharmaceuticals, Inc.*¹¹ Judge Sleet, relying on *Daimler*, held that neither general jurisdiction nor consent jurisdiction existed, but specific jurisdiction did exist over Mylan. There, Astra’s U.S. subsidiary, a Delaware corporation, had received the statutory notice letter from Mylan. The subsidiary, however, was not a party to the litigation.

First, the court found that Mylan was not “at home” in Delaware even though it was registered to do business there and derived substantial revenue from sales of its generic products in the state. Citing *Daimler*, the court stated: “Upholding jurisdiction on these allegations alone would permit the ‘exercise of general jurisdiction in every [s]tate,’ a result specifically precluded by the Supreme Court [in *Daimler*].”¹²

⁹ *Id.* at *6.

¹⁰ *Id.* (noting that “Defendants do not deny that they are targeting Texas for the sale of generic.”).

¹¹ 2014 WL 5778016 (D. Del. 2014).

¹² *Id.* at *3, The court also rejected Astra’s allegation that Mylan was “at home” in Delaware because it regularly appeared before the Delaware district court.

As to consent jurisdiction, Judge Sleet reasoned that since a defendant could no longer be hauled into court for merely “doing business” in a state, the mandatory requirement for “doing business,” i.e., registration, no longer confers jurisdiction. Additionally, the court held that Mylan did not consent to jurisdiction because: “Finding mere compliance with such statutes sufficient to satisfy jurisdiction would expose companies with a national presence (such as Mylan) to suit all over the country, a result specifically at odds with *Daimler*.”¹³

Addressing specific jurisdiction, the court noted that Mylan sent its notice letter to AstraZeneca in Delaware, thus triggering the distinct possibility of suit in that district. “The court is convinced 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.”¹⁴ Since minimum contacts existed, it did not offend fairness to proceed in Delaware.

Under Mylan’s theory – which excluded both general and consent jurisdiction – it was amendable to suit only in West Virginia, where it was incorporated and had its principle place of business. According to Judge Sleet, this would “substantially burden” patentees in enforcing their rights under the Hatch-Waxman Act.¹⁵ Moreover, judicial efficiency would be fostered by denying the motion because AstraZeneca had filed ten actions against different generics, all of which were pending in Delaware.¹⁶ Dismissal would result in multiple litigations with the possibility of

¹³ *Id.* at *5.

¹⁴ *Id.* at *7. This approach is inconsistent with Federal Circuit precedent holding that sending letters threatening infringement litigation to a state does not establish jurisdiction in that state. *See, e.g., Silent Drive, Inc. v Strong Industries, Inc.*, 326 F.3d 1194, 1202 (Fed. Cir. 2003); *Inamed Corp. v Kuzmak*, 249 F.3d 1356, 1361 (Fed. Cir. 2001).

¹⁵ *Id.* at *8. The court also noted that the preparation of an ANDA was irrelevant to jurisdiction as such conduct was protected by the safe harbor, 35 U.S.C. § 271(e)(1). *Id.* at *8 n.13.

¹⁶ *Id.* at *8.

inconsistent results. Judge Sleet certified his decision to the Federal Circuit for an interlocutory appeal.¹⁷ On March 23, the Federal Circuit accepted the appeal.¹⁸

In *Accorda Therapeutics, Inc. v Mylan Pharmaceuticals Inc.*¹⁹ the Delaware court again addressed personal jurisdiction in a Hatch-Waxman action. Initially, the court held that *Daimler* prevented general jurisdiction over either defendant as neither was “at home” in Delaware.²⁰ While *Daimler* did not expressly address consent jurisdiction, Judge Stark, unlike Judge Sleet, held that the decision did not alter long-standing precedent that registration to do business in Delaware was consent to jurisdiction in the state. Thus, Mylan Pharma, who was registered to do business in Delaware, was subject to suit.²¹ The court, however, rejected Accorda’s argument that Mylan Inc., the parent company, was subject to jurisdiction “by virtue of having allegedly induced Mylan Pharma, . . . to register in Delaware and to appoint an agent to accept service of process.”²² The court did permit discovery as to whether specific jurisdiction over Mylan Inc. existed.

The court also found that Mylan Pharma was subject to specific jurisdiction since it filed its ANDA and sent the Notice letter to Accorda. “[T]his lawsuit arises from Mylan Pharma’s sending the Mylan notice letter to plaintiffs, including Accorda, a Delaware corporation. . . . [under these circumstances] . . . Mylan Pharma should have reasonably anticipated being hauled into court in the District of Delaware.”²³ Significantly, the notice was not sent to Accorda in Delaware. Apparently, the notice letter need not be sent into the forum to establish jurisdiction.

¹⁷ *AstraZeneca AB v. Aurobino Pharma Ltd.*, 2014 WL 7533913 (D. Del. 2014).

¹⁸ *AstraZeneca AB v. Mylan Pharmaceuticals, Inc.*, App. No. 15-177 (3/17/15).

¹⁹ 2015 WL 186833 (D. Del. 2015).

²⁰ *Id.* at *6-*7.

²¹ *Id.* at *7-*8.

²² *Id.* at *15.

²³ *Id.* at *16. The court noted that Mylan had directed other activities to Delaware including manufacturing, distribution and sales.

In *Otsuka Pharmaceutical Co., Ltd. v. Mylan, Inc.*²⁴ the court held that by registering to do business in New Jersey, defendants Mylan Inc. and Mylan Pharma had consented to jurisdiction.²⁵ The court, however, held that Mylan’s integrated nature, the international scope of Mylan Labs operations, and the in-state activities of its independent subsidiaries did not provide specific jurisdiction over the defendants’ Indian patent, Mylan Labs.²⁶

In *Forest Labs, Inc. v. Amreal Pharmaceuticals, Inc.*²⁷ Magistrate Judge Burke of the Delaware court held that defendant Mylan had consented to jurisdiction by registering to do business in the state. After a detailed discussion, he concluded that *Daimler* did not affect consent jurisdiction.²⁸ The court found that Mylan’s best argument was that it had registered to do business in 21 states and thus could be considered “at home” in each. Nevertheless, the court ruled that even though Mylan was “at home” in only West Virginia, it could still consent to personal jurisdiction in other states.²⁹ In sum, Magistrate Judge Burke agreed with Judge Stark’s decision in *Accorda*, not Judge Sleet’s decision in *AstraZeneca*.

In *Eli Lilly and Co. v. Mylan Pharmaceuticals, Inc.*³⁰ the court held that specific jurisdiction existed over Mylan Pharma, Mylan, Inc. and Mylan Labs as the three Mylan defendants had not differentiated their conduct from one another in pursuing their motion to dismiss. Jurisdiction was found because the “Mylan Defendants purposefully directed their activities at

²⁴ 2015 WL 1305764, *8-*9 (D.N.J. 2015).

²⁵ The court cited two pre-*Daimler* Supreme Court decisions where appointment of an agent was consent to jurisdiction. *Id.* at *9. Again, the notice letter was not sent into the forum, but this did not factor into the decision.

²⁶ *Id.* at *12.

²⁷ 2015 WL 880599 (D. Del. 2015).

²⁸ *Id.* at *12-*14.

²⁹ *Id.* at *14.

³⁰ 2015 WL 1125032 (S.D. Ind. 2015).

Indiana by sending a paragraph IV certification notice letter to Lilly in Indiana, which they knew would trigger the forty-five day period within which Plaintiffs were empowered to file suit under the Hatch-Waxman framework.”³¹ Having found minimum contacts, it was not unreasonable for Mylan to defend itself in Indiana. Once again, a court noted that it would significantly burden patentees if they were forced to sue each defendant in its “home” jurisdiction. Indeed, resolving the controversy in one forum would promote judicial efficiency and avoid the possibility of inconsistent judgments.³²

In *Senju Pharmaceuticals, Ltd. v. Metrics*³³ the New Jersey court again faced the jurisdictional issue. Defendant Metrics, a North Carolina company, was registered to do business in New Jersey and sent the notice letter to plaintiffs. Defendant Mayne Pharma is an Austrian corporation that manufactures and sells generic drug products around the world. Its corporate predecessors had offices in New Jersey and had filed lawsuits there. Moreover, its supplier of active ingredients was based in New Jersey.

Once again, a court held that *Daimler* did not affect consent jurisdiction³⁴ and noted that the Federal Circuit had not ruled on the issue.³⁵ Since consent jurisdiction was firmly established in New Jersey and in the Third Circuit precedent, the court found that personal jurisdiction existed over Metrics.³⁶ The court did allow discovery to determine if Mayne’s contacts, if any, with its supplier in New Jersey supported specific jurisdiction.

³¹ *Id.* at *6 (footnote omitted).

³² *Id.* at *7.

³³ 2015 WL 1472123 (D.N.J. 2015).

³⁴ *Id.* at *6.

³⁵ *Id.* at *7.

³⁶ *Id.* at *8.

All courts but one (*AstraZeneca*) that have addressed consent jurisdiction in Hatch-Waxman cases have found jurisdiction. It would appear that *Daimler* has not affected this type of jurisdiction. Specific jurisdiction would seem more problematic. Where the notice letter is sent to the plaintiff in the eventual forum, a direct contact with the forum from which the Hatch-Waxman claim emanates exists (*AstraZeneca, Eli Lilly*). Assuming the generic had other contacts with the forum, albeit minor, this single contact would seem to satisfy due process. But when the notice letter is sent to the patentee in a state where the action is not filed, specific jurisdiction could become more problematic but still exists (*Allergan, Accordia*). In these instances, the defendant's conduct/future conduct in the forum becomes more significant. Indeed, such decisions highlight the plaintiffs' contacts with the forum, even though these contacts are of questionable relevance to jurisdiction over the defendant.

Policy considerations regarding the proper enforcement of the Hatch-Waxman Act and judicial efficiency were discussed in many decisions and were seemingly influential in their outcomes. These considerations may be more important where the notice letter is not sent into the forum. It will be interesting to see how the Federal Circuit accommodates these policy considerations with due process concerns in addressing both consent and specific jurisdiction in the pending appeal.