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# Personal Jurisdiction in Hatch-Waxman Cases Uncertain After *Daimler*

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## I. Introduction

Last year, the Supreme Court issued a ruling in which it appeared to limit the applicability of general jurisdiction. In *Daimler AG v. Bauman*, the Court held that the general jurisdiction inquiry ''is not whether a foreign corporation's in-forum contacts can be said to be in some sense 'continuous and systematic,' it is whether that corporation's 'affiliations with the State are so 'continuous and systematic' as to render [it] essentially at home in the forum State.'' 134 S.Ct. 746, 751 (2014). The effects of the Court's decision have, likely inadvertently, impacted the assertion of personal jurisdiction in Hatch-Waxman cases.

Historically, because submission of an Abbreviated New Drug Application (''ANDA'') by a generic company is a statutory act of infringement, district courts have analyzed the jurisdictional question in Hatch-Waxman cases under the rubric of general jurisdiction, relying on the generic company's continuous and systematic contacts with the forum to support jurisdiction. Under the *Daimler* standard, much of the previous jurisprudence regarding general jurisdiction in Hatch-Waxman cases fails, and district courts have split as to whether general jurisdiction is still a proper means by which to assert jurisdiction over generic companies.

Given the new limits of general jurisdiction and the uncertainty of its application, district courts have increasingly turned to specific jurisdiction as a basis for personal jurisdiction over Hatch-Waxman defendants. The courts have yet to arrive at a consistent analysis, with some courts relying on future sales and marketing of the generic drug as supporting jurisdiction and others focusing on where the generic company sends its ANDA notice letter. Generic companies have objected to the assertion of specific jurisdiction over the ''artificial'' act of infringement as a violation of due process.

Not surprisingly given that it hears more Hatch-Waxman cases than any other court, the District of Delaware has so far led the district courts in attempting to sort through the jurisdictional questions of *Daimler* as it applies to Hatch-Waxman litigation. Interestingly, the split in district courts can be seen in the opinions of different judges sitting in the same district court.

Clarity in the law may soon come. The Federal Circuit recently granted at least two petitions to hear interlocutory appeals on post-*Daimler* jurisdictional issues in Hatch-Waxman litigation.

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## II. The Supreme Court Restricts General Jurisdiction in *Daimler v. Bauman*

In *Daimler*, the Court was presented with determining the ''authority of a court in the United States to entertain a claim brought by foreign plaintiffs against *a foreign defendant* based on events occurring entirely *outside the United States*.'' *Id.* at 750 (emphasis added). The plaintiffs – a group of Argentinian residents – filed suit in federal court in the Northern District of California against a German public company, ''Daimler,'' that manufactures Mercedes-Benz vehicles. The complaint alleged that between 1976 and 1983, Daimler's subsidiary in Argentina ''collaborated with state security forces to kidnap, detain, torture and kill certain [Mercedes-Benz] Argentina workers, among them, plaintiffs or persons closely related to plaintiffs.'' *Id.* at 750-51. Plaintiffs sued under United States laws prohibiting violations of human rights. They argued that the

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Court had jurisdiction because Daimler's subsidiary and exclusive importer and distributor in the United States, Mercedes-Benz USA, LLC (''MBUSA'') – a Delaware corporation with its principal place of business in New Jersey – distributes vehicles to United States dealerships, including some located in California.

The District Court granted Daimler's motion to dismiss on its determination that Daimler's ''own affiliations with California . . . were insufficient to support the exercise of all-purpose jurisdiction over the corporation.'' *Id.* at 752. The District Court additionally concluded that a sufficient agency relationship between MBUSA and Daimler had not been established to render Daimler subject to jurisdiction in California. On appeal, and after a rehearing, the Ninth Circuit Court of Appeals ultimately held that an adequate agency relationship between MBUSA and Daimler had been shown to justify the exercise of jurisdiction over Daimler. It did not address the issue of specific jurisdiction. *Id.* at 758.

The Supreme Court granted certiorari and reversed the Ninth Circuit. In its decision, the Court emphasized that none of the alleged acts giving rise to the plaintiffs' complaint occurred in California or any part of the United States. In fact, the Court noted the ''absence of any California connection to the atrocities, perpetrators, or victims described in the complaint.'' *Id.* at 751. The Court held that even if MBUSA were deemed to be ''at home in California'' and even if its contacts were ''imputable to Daimler'' there would still be ''no basis'' to exercise general jurisdiction over Daimler because it had ''slim contacts'' with the state. *Id.* at 760. To hold otherwise would require exercising general jurisdiction ''in every State in which a corporation 'engaged in substantial, continuous, and systematic course of business' '' which would be ''unacceptably grasping.'' *Id.* at 760-61. The ''transnational'' nature of the acts giving rise to the complaint further supported the Court's determination that ''subjecting Daimler to the general jurisdiction of courts in California would not accord with the 'fair and substantial justice' due process demands.' '' *Id.* at 763 (citing *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (quoting *Milliken v. Meyer*, 311 U.S. 457, 463 (1940)).

Consequently, ''substantial, continuous and systematic course of business'' in a forum cannot by itself subject a defendant to general jurisdiction. *Id.* at 749, 761. Pursuant to *Daimler*, jurisdiction may be established ''only when the corporation's affiliations with the [s]tate in which suit is brought are so constant and pervasive 'as to render [it] essentially at home' in the forum State.'' *Id.* at 751 (citing *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S.Ct. 2846, 2851(2011)).

## III. District Courts Analyze Personal Jurisdiction in Hatch-Waxman Cases

Historically, courts have relied on principles of general jurisdiction as the basis for personal jurisdiction over generic defendants in Hatch-Waxman cases. *See e.g.*, *Forest Labs. Inc. v. Cobalt Labs. Inc.*, No. 08-21-GMS-LPS, 2009 WL 605745, at *6 (D. Del. Mar. 9, 2009) (analyzing jurisdiction under Delaware's long arm statute and considerations of due process); *In re Cyclobenzaprine Hydrochloride*, 693 F. Supp. 2d 409, 421 (D. Del. 2010) (concluding that general jurisdiction exist[ed] because the ''submission of the ANDA constitute[d] an act of infringement'' and defendant derive[d] ''substantial revenue'' from drug sales in Delaware exemplifying its ''purposeful contacts with Delaware''). *Daimler* calls into question the application of general jurisdiction in such circumstances. The facts of *Daimler*, however, are significantly different than facts ordinarily present in a Hatch-Waxman case.

A strict reading of *Daimler* could severely limit general jurisdiction to the state (or states) in which the generic company is a registered corporation and/or is domiciled – that is, ''at home'' under *Daimler* – thereby significantly restricting a patentee's choice of forum. Because Hatch-Waxman cases often include many unrelated defendants who seek to market a copy of the same branded drug and are accused of infringing the same patents, such a strict interpretation of *Daimler* could force patentees to litigate multiple suits in multiple forums. Such a result—one not considered in the context of *Daimler*—appears to unnecessarily restrict the prevailing jurisdictional standard as it has been applied in Hatch-Waxman cases for the past three decades.

District courts have been unable to define a clear application of this new general jurisdiction standard to Hatch-Waxman litigation. For example, even within the Delaware district court judges are split as to whether ''registration to do business'' in Delaware is a sufficient basis for general jurisdiction.

Moreover, not only has *Daimler* forced district courts to reconsider the role of general jurisdiction in Hatch-Waxman cases, but it has also led them to consider specific jurisdiction as a basis to hear such cases. Because in Hatch-Waxman cases the ''artificial'' act of infringement (filing of an ANDA) occurs before a generic drug is marketed, the specific jurisdiction question is not always straightforward. The courts have not consistently applied the specific jurisdiction analysis.

### A. *AstraZeneca v. Mylan Pharmaceuticals*

In November 2014, the Delaware District Court, in *AstraZeneca AB v. Mylan Pharmaceuticals*, was the first court to examine the effects on Hatch-Waxman litigation resulting from the post-*Daimler* ''shift'' in the general jurisdiction standard. *AstraZeneca AB v. Mylan Pharm., Inc.*, No. CV 14-696-GMS, 2014 BL 312778 (D. Del. Nov. 5, 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).

Mylan filed two ANDAs for approval to market generic versions of two of AstraZeneca's drug products. In connection with these applications, AstraZeneca, a Swedish company with its principal place of business in Sweden, filed the complaint at issue in the District of Delaware alleging patent infringement. AstraZeneca's subsidiary in the United States is a limited partnership incorporated and having its principal place of business in Delaware.

In its complaint, AstraZeneca relied on Mylan's ''actions . . . directed toward Delaware and because Mylan has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware'' as the bases for the Court's jurisdiction. *Id.* at *1. Specifically, AstraZeneca pointed to Mylan's regular and continuous business transactions in Delaware, including Mylan's sales of pharmaceutical products in Delaware and the fact that Mylan had previously been sued in Delaware without objection to the Court's exercise of personal jurisdic-

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tion. Mylan filed a motion to dismiss challenging the court's jurisdiction, citing primarily to the ''two ANDAs at issue [being] prepared in West Virginia and filed in Maryland with the FDA,'' and Mylan's lack of property, employees and ''direct sales'' in Delaware. *Id.* at *2.

Judge Sleet considered Mylan's motion to dismiss in view of *Daimler*. Finding that the Supreme Court restricted general jurisdiction to ''a narrow set of circumstances'' in *Daimler*, Judge Sleet held that the Court did not have general jurisdiction over Mylan. The Court held that 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].' '' *Id.* at *4 (citing *Daimler*, 134 S.Ct. at 758 n.11 (alteration in original)). Contrary to the approach taken by courts pre-*Daimler*, the court in *AstraZeneca* noted that Mylan's ''extensive litigation history'' in Delaware was insufficient to ''render [Mylan] at home [], as envisioned by *Daimler*.'' *Id.* Importantly, Judge Sleet held that Mylan's registration to do business cannot constitute consent to jurisdiction under *Daimler*: ''In holding that 'continuous and systematic contacts' alone are insufficient to establish general jurisdiction, the Supreme Court rejected the idea that a company could be haled into court merely for 'doing business' in a state.'' *Id.* at *6 (citing *Daimler*, 134 S. Ct. at 761-62).

Though the Court held that there was not sufficient basis to establish general jurisdiction, it nonetheless found that it had *specific* jurisdiction over Mylan. In particular, the court reasoned that Mylan was appropriately subject to specific jurisdiction in Delaware because Mylan's activities—notably, its service of the requisite ANDA notice letter—were ''purposefully directed at AstraZeneca in the state of Delaware.'' *Id.* at *9. The court also considered several equitable factors which it determined to weigh in favor of finding the jurisdictional standard satisfied. These factors included Mylan's litigation history in Delaware and the burden AstraZeneca would otherwise endure if it were required to pursue lawsuits in the respective home states of each ANDA filer. *Id.* The Court denied Mylan's motion to dismiss because it had specific jurisdiction over Mylan.

Judge Sleet recognized that post-*Daimler* jurisdiction in Hatch-Waxman cases is a ''controlling (and novel) question of law for which there is substantial ground for difference of opinion.'' *AstraZeneca AB v. Aurobindo Pharma Ltd.*, No. CV 14-664-GMS, 2014 WL 7533913, at *1, n.1 (D. Del. Dec. 17, 2014). Noting the importance of the decision to Hatch-Waxman litigation generally, and to the Delaware district court in particular given the large volume of cases, the court subsequently granted Mylan's request to file an interlocutory appeal. *Id.* Mylan filed its Petition for Permission to Appeal Pursuant to 28 U.S.C. § 1292(b) with the Federal Circuit on December 30, 2014. *See AstraZeneca AB v. Mylan Pharm., Inc.*, No. 15-117 (Fed. Cir. filed Dec. 30, 2014). On March 17, 2015, the Federal Circuit agreed to hear the appeal.

### B. *Acorda Therapeutics v. Mylan*

Two months after the *AstraZeneca* decision, Judge Stark in *Acorda Therapeutics, Inc. v. Mylan Pharm., Inc.* found Mylan to be subject to general *and* specific jurisdiction in Delaware. *See Acorda Therapeutics, Inc. v. Mylan Pharm., Inc.*, No. CV 14-935-LPS, 2015 BL 8340 (D. Del. Jan. 14, 2015). Acorda, a corporation organized under the laws of Delaware with its principal place of business in New York, researches, develops and sells biotech and pharmaceutical products. Mylan gave notice to Acorda of its ANDA filing for a drug relating to five patents owned by Acorda. Acorda filed a patent infringement suit against Mylan Inc., a Pennsylvania corporation with its principal place of business in Pennsylvania, and its subsidiary Mylan Pharmaceuticals, Inc., the same West Virginian entity subject to the *AstraZeneca* suit. *Id.* at *2.

Analyzing the motion under *Daimler*, the Court noted that neither Mylan entity is a Delaware corporation or has its principal place of business in Delaware. Consistent with *AstraZeneca*, the Court held there was not sufficient basis to find that Mylan had operations in Delaware ''of such a type and extent as to render [Mylan] 'at home.' '' *Id.* at *8. The Court specifically noted that both Mylan entities' frequent litigation in Delaware and numerous Mylan Inc. subsidiaries being incorporated in Delaware were together ''inadequate for purposes of general jurisdiction'' and therefore did not represent the type of ''exceptional case'' contemplated by *Daimler* in which a corporation may be deemed ''at home.'' *Id.*

However, in contrast to *AstraZeneca*, the Court held that Mylan Pharmaceuticals' registration to do business in Delaware was a sufficient basis to find that Mylan consented to general jurisdiction in Delaware.[1] The Court in *Acorda* distinguished the ''problem identified'' in *Daimler* as existing when ''continuous and systematic contacts are used to assess whether a corporation is 'at home' in a forum state.'' *Id.* at *15. In contrast, ''voluntary compliance with a state's registration statute'' is an adequate basis for jurisdiction because it leaves ''no uncertainty [for a corporation] as to the jurisdictional consequences of its actions.'' *Id.* The Court stated: ''the undersigned judge does not believe that *Daimler* meant, *sub silentio*, to eliminate consent as a basis for jurisdiction. Such a holding would threaten to fundamentally alter the personal jurisdiction defense from a waivable to a non-waivable right . . . .'' *Id.* at *16. Noting the difficult issues raised by *Daimler* and the difference between the holdings in *AstraZeneca* and *Acorda*, Judge Stark acknowledged that ''Judge Sleet's rejection of consent as a basis for general jurisdiction [in *AstraZeneca*] over Mylan Pharma [was] well-reasoned and may well be the correct view.'' *Id.*

Notwithstanding the different bases on which Judge Sleet and Judge Stark decided the respective motions to dismiss on general jurisdiction, both *Acorda* and *AstraZeneca* found that the court had *specific jurisdiction* over Mylan, though on different grounds. Specifically, the *Acorda* Court 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 ''in order to sell

[1] The Court held that it lacked general jurisdiction over the second Mylan defendant—parent company Mylan Inc.—because unlike Mylan Pharma, Mylan Inc. is ''neither 'at home' nor registered to do business in Delaware.'' *Id.* at *1. However, because Acorda alleged but had not proven ''a non-frivolous claim that Mylan Inc. used Mylan Pharma as its agent in connection with the ANDA filing giving rise to this litigation,'' it held that Acorda may take ''jurisdictional discovery of Mylan Inc.'s relationship with Mylan Pharma and with the ANDA filing at issue in th[e] case.'' *Id.* at *1-*2. On February 10, 2015, Mylan Inc. was dismissed from the action without prejudice.

Mylan's Generic Product in the United States, including in Delaware'' and Mylan's mailing of its Paragraph IV notice letter to Acorda, a Delaware corporation. *Id.* at *17. The Court emphasized that Mylan directed additional activities at Delaware, including 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 *17 - *18. The Court additionally noted that a generic company's business model is ''expressly dependent on the certainty of its participation'' in Hatch-Waxman litigation. *Id.* at *18.

The Court explained that its assertion of specific jurisdiction was consistent with ''traditional notions of fair play and substantial justice,'' as set forth in Supreme Court decisions from *International Shoe* through *Daimler*. *Id.* For example, considering the *Burger King* factors, the Court noted that its decision was ''reasonable and fair'' because of the minimal burden on Mylan to litigate in Delaware; the state's interest in adjudicating the dispute, particularly given Acorda's status as a Delaware corporation and its ongoing related litigation pending in the same court; Acorda's interest in obtaining convenient and effective relief; and not burdening other districts when the same issues are already before the court, *i.e.*, the ''interstate judicial system's interest in efficient resolution of controversies.'' *Id.* at *19 (relying on *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 477 (1985)). The Court further held that because Acorda is a Delaware corporation, its injury as a result of Mylan's ANDA filing will be suffered in Delaware. *Id.* at *19-*20. Therefore, the Court held that it had specific jurisdiction over Mylan, an additional basis for its denial of Mylan's motion to dismiss.

Two weeks after Judge Stark's decision, he granted Mylan's Motion for Interlocutory Appeal certifying the following questions of law for review: ''(1) Does Mylan Pharmaceuticals' compliance with Delaware's registration statutes . . . constitute consent to general personal jurisdiction in Delaware? [and] (2) Does the U.S. Constitution permit Delaware to exercise specific personal jurisdiction over Mylan Pharmaceuticals in this ANDA suit?'' Order Granting Certification for Interlocutory Appeal, *Acorda*, Dkt. No. 36 (D. Del. Jan. 30, 2015). Mylan filed a Petition for Permission to Appeal with the Federal Circuit on February 11, 2015. *See Acorda Therapeutics, Inc. v. Mylan Pharm., Inc.*, No. 15-124 (Fed. Cir. filed Feb. 11, 2015). On March 17, 2015, the Federal Circuit agreed to hear the appeal.

### C. *Novartis Corp. v. Mylan*

A third case filed in the District of Delaware, *Novartis Pharm. Corp. v. Mylan, Inc.*, No. 1:14-cv-00777-RGA (D. Del. filed June 19, 2014) highlights another issue arising from the applicability of *Daimler* to Hatch-Waxman cases. Patentees in Hatch-Waxman cases often file a second, identical ''protective suit'' in another forum so that if the first-filed forum dismisses the action for lack of jurisdiction, the patentee will still have filed suit within the 45-day statutory period and enjoy the benefit of the 30 month stay of approval of the generic's ANDA. Here, the District of Delaware was the first-filed forum, and Novartis filed a protective suit in the Northern District of West Virginia, where Mylan is domiciled. *Novartis Pharm. Corp. v. Mylan, Inc.*, No. 1:14-cv-00111-IMK (N.D. W.Va. filed June 26, 2014). Mylan filed a motion to dismiss in the Delaware action, alleging lack of personal jurisdiction.

While the motion to dismiss was pending in Delaware, Novartis moved the West Virginia Court stay the case pending resolution of the motion to dismiss Mylan filed in Delaware. Noting the ambiguity surrounding general jurisdiction in ANDA cases post-*Daimler*, the West Virginia Court emphasized that various circuits have ''listed the lack of jurisdiction, or a dispute over jurisdiction, as sound reasons for refusing to stay or transfer the second-filed case.'' Order Denying Plaintiffs' Motion to Stay Pending Resolution of Jurisdictional Challenge to the First-Filed Delaware Case, *Novartis*, Dkt. No. 39 (N.D. W. Va. Jan. 29, 2015). The Court denied the motion to stay, relying primarily on judicial economy being served in ''moving forward with the suit,'' the absence of any significant hardship on the parties, and the uncertainty in when the Delaware court would decide the pending jurisdictional motion to dismiss. *Id.* at 14. The Court noted that Novartis ''is free to file a second motion to stay, or a motion to transfer, should the District of Delaware resolve the jurisdictional dispute in its favor.'' *Id.* at 15. Thus, while the motion to dismiss was pending in Delaware, the second-filed case is proceeding in West Virginia.

On March 16, 2015, Judge Andrews of Delaware decided Mylan's motion to dismiss. *Novartis Pharm. Corp. v. Mylan Inc.*, No. 1:14-cv-00777-RGA, 2015 BL 70580 (D. Del. Mar. 16, 2015). Following the reasoning in *Acorda*, Judge Andrews held that the Court has personal jurisdiction over Mylan Pharmaceutical, Inc. (''Mylan Pharma'') because Mylan Pharma was registered to do business in Delaware. *Id.* at *3. The decision distinguished *Daimler* on its facts, noting that *Daimler* involved a claim by foreign plaintiffs, brought against foreign defendants, for acts occurring entirely outside of the United States. *Id.* The Court also noted that *Daimler* had not overruled consent as a basis for jurisdiction. Moreover, the Court stated: ''*Daimler* does not necessarily mean that domestic corporations with national business operations cannot sue their similarly-situated competitors, consistent with due process, in all fifty states for activities that the competitor wants to occur in all fifty states, and which are part and parcel of their nationwide competition.'' *Id.* at *4. Having decided that the Court had general jurisdiction over Mylan Pharma, the Court declined to consider whether it also had specific jurisdiction.[2]

Judge Andrews stated that he considered the issue an important one for the Court of Appeals to consider, as the current uncertainty in the law would cause wasteful and duplicative litigation. He suggested that although other cases had already been filed in the Federal Circuit, multiple appeals on the same issue might sway the appeals court in exercising its discretion to hear the issue. He further indicated that he would proceed with the case while any interlocutory appeal is pending.

Following Judge Andrews' decision, Novartis renewed its motion to stay in the West Virginia action. Briefing for the motion was completed in April.

[2] With respect to co-defendant Mylan, Inc., the Court followed the *Acorda* Court in holding that it did not have general jurisdiction over Mylan, Inc. and allowing discovery regarding the question of specific jurisdiction.

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### D. Cases in Other Jurisdictions

The District of Delaware is not the only court to consider post-*Daimler* challenges to jurisdiction in Hatch-Waxman cases, nor is Mylan the only generic pharmaceutical company to challenge jurisdiction. For example, Actavis and Watson moved for dismissal of a Hatch-Waxman complaint filed by Allergan (a Delaware corporation with its principal place of business in California) in the Eastern District of Texas alleging patent infringement based defendants' filing of its ANDA to make and sell a generic version of Restasis®. *See Allergan, Inc. v. Actavis, Inc. et al.*, No. 2:14-cv-638, 2014 BL 361759 (E.D. Tex. Dec. 23, 2014). The Court sidestepped an analysis of general jurisdiction under *Daimler*, instead holding that it need not consider the question of general jurisdiction because it had specific jurisdiction over defendants in the forum. *Id.* at *10.

In its specific jurisdiction analysis, the Court found that the filing of defendants' ANDAs will cause substantial harm to Allergan in Texas because, *inter alia*, Allergan produces its Restasis® drug in Texas, coordinates nationwide distribution of the drug in Texas, and sells its drug in Texas (and the Eastern District), and defendants' conduct would erode Allergan's sales, manufacture and distribution of the drug in Texas. *Id.* at *7-*10. The Court further held that the generics' obtaining a license to distribute prescription drugs in Texas and efforts to establish contacts with wholesalers and others for distribution of their drugs was further support that ''the harm to Allergan in this case is unavoidably connected to Defendants' extensive efforts in Texas to sell a generic version of Restatsis.'' *Id.* at *8.

In response to defendants' ''inevitable complaint'' that the Court's decision would subject it to jurisdiction in every state, the Court stated: ''[A] manufacturer who (successfully) targets a nationwide consumer base is fundamentally distinct from an individual defendant who is connected to a forum state only by the fact that the injured plaintiff resides there.'' The Court further held that plaintiffs had filed declaratory judgment claims and that ''[w]hile a 'purely subjective or speculative fear of future harm' cannot constitute a case or controversy, it remains a 'bedrock rule' that a 'real and immediate injury *or threat of future injury*' is sufficient to grant to the courts subject matter jurisdiction.'' *Id.* at *9 (emphasis in original) (citations omitted). The Court, therefore, denied defendants' motions to dismiss because it had specific jurisdiction.

In *Eli Lilly & Co. v. Mylan Pharm., Inc.*, No. 1:14-cv-00389-SEB-TAB, 2015 BL 66484 (S.D. Ind. Mar. 12, 2015), the Southern District of Indiana held that it did not have general jurisdiction over Mylan because the Mylan defendants were not ''at home'' in Indiana under *Daimler*.[3] *Id.* at *6-*7. Turning to the question of specific jurisdiction, the Court followed *AstraZeneca* in holding that Mylan purposefully directed its activities at Indiana by sending its ANDA notice letter to Lilly in Indiana. *Id.* at *8-*9. As the *Acorda* Court did, the Indiana Court considered ''traditional notions of fair play and substantial justice'' and held that the such considerations comported with its assertion of jurisdiction over Mylan.[4] Like the Delaware Courts, the Court noted that this was an important issue of first impression, hinting that it was appropriate for interlocutory appeal.

It is likely that generic companies will continue to file motions to dismiss for lack of personal jurisdiction until the courts come to a consensus regarding the effect and analysis of *Daimler* on jurisdictional issues in Hatch-Waxman litigation.

## IV. Federal Circuit To Consider Jurisdictional Issues in Hatch-Waxman Litigation

The cases discussed here highlight the jurisdictional issues raised in post-*Daimler* Hatch-Waxman litigation, and provide the framework for an analysis of the questions, arguments and potential resolutions to the personal jurisdiction question. Notably, despite the different approaches taken by different judges, all seem to agree that *Daimler*, while it may have limited the reach of general jurisdiction, did not impact the court's ability to assert personal jurisdiction over generic defendants on the basis of specific jurisdiction, an issue not widely considered in Hatch-Waxman cases prior to *Daimler*. Moreover, the split on the issue of whether consent to jurisdiction survives *Daimler* may have implications beyond Hatch-Waxman litigation.

The Federal Circuit will likely soon clarify many of the issues surrounding the application of *Daimler* to Hatch-Waxman jurisdiction – it has granted petitions to hear interlocutory appeals of *AstraZeneca* and *Acorda*. *See* Case No. 15-1460, Dkt. 1-2 (Fed. Cir. 2015), Case No. 15-124, Dkt. 21 (Fed. Cir. 2015). The issues raised in the Federal Circuit will include, at least, whether compliance with a state's business registration statutes constitutes consent to general jurisdiction and whether the Constitution permits the assertion of specific jurisdiction over a generic defendant in Hatch-Waxman litigation.

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[3] The Court did not address the issue of consent, which was not an issue raised by plaintiffs.

[4] Notably, unlike *Acorda* and *Novartis*, the Court held that Mylan Pharmaceutical Inc.'s activities could be attributed to Mylan, Inc. and Mylan Labs, and therefore, the Court had jurisdiction over those companies as well.