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The authors continue their examination of how the U.S. Supreme Court's *Daimler* decision affected questions of jurisdiction in pharmaceutical patent litigation. They discuss recent court rulings and provide practical tips to generic and branded companies.

### The DAIMLER Series: Five Personal, Specific Lessons Learned for Hatch-Waxman ANDA Litigants



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#### Paper II

##### I. Introduction

Our previous article discussed the viability of general personal jurisdiction in a post-*Daimler* world within the Hatch-Waxman Paragraph IV Abbreviated New Drug Application (“ANDA”) context, focusing on the District of New Jersey’s March 2015 decision in *Otsuka Pharm. Co. Ltd. v. Mylan Inc. et. al.*, No. 14-4508 (JBS/KMW), 2015 BL 79496. See “*The DAIMLER Series: District Courts analyze personal jurisdiction in ANDA cases*” (13 PLIR 958, 7/3/15).<sup>1</sup> This article dis-

<sup>1</sup> Another federal judge, Judge Mary L. Cooper, recently applied the *Otsuka* reasoning in denying Mylan Pharmaceuticals Inc.’s attempt to avoid general personal jurisdiction. *Boehringer Ingelheim Pharma GmbH & Co. KG, et. al. v. Teva*

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cusses the state of jurisdiction issues pre- and post-*Daimler* in Section II, and in Section III, the exercise of specific personal jurisdiction in ANDA litigation post-*Daimler*, *infra*, focusing on recent district court decisions that addressed jurisdiction challenges. This article also assesses the implications for foreign generic pharmaceutical companies involved in the preparation or development of an ANDA, recalling that the New Jersey district court in *Otsuka*, *supra*, declined both general and specific personal jurisdiction over Mylan Laboratories Limited (“Mylan Ltd.”), the India-based subsidiary of Mylan Inc. (a Pennsylvania corporation). In Section IV, we discuss five important practical tips for Hatch-Waxman practitioners, while in Section V, we provide a summary for the brands and then a summary for the generics.

##### II. Jurisdiction Pre- and Post-*Daimler*

Under 35 U.S.C. § 271(e)(2)(A)<sup>2</sup> of the Hatch-Waxman Act, a so-called “artificial” act of infringement

*Pharms. USA, Inc., et al.*, CA No. 14-7811 (MLC) (D. NJ, July 16, 2015). Judge Cooper held that Mylan consented to jurisdiction by registering to do business and appointing an agent for process in New Jersey, based on the language of the NJ business registration statute, as well as by actually engaging in a substantial amount of business there. *Id.* at 3.

<sup>2</sup> 35 U.S.C. § 271(e), in relevant part, states that:

creates case-or-controversy jurisdiction so a generic company can file an ANDA seeking FDA approval to market a patented drug before the relevant patent expires, “because the allegedly infringing product has not yet been marketed.” *Warner-Lambert v. Apotex*, No. 2-1073, 316 F. 3d 1348 at \*1365 (Fed. Cir. 2003); see also *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Issues of personal jurisdiction are complex in the ANDA context. While the “injury” felt by the plaintiff-patentee brand company is still hypothetical, prospective and artificial,<sup>3</sup> the analysis of specific jurisdiction involves an injury-based assessment.

In ANDA cases, pre-*Daimler*, brands filed most ANDA cases historically in New Jersey and Delaware. Plaintiffs relied on general personal jurisdiction for selecting the forum of their choosing, often based on the defendant’s license to distribute pharmaceuticals or conduct the business of making and selling drug products in the forum state. *Sandoz v. Pfizer*, 2010 BL 28093 (D. Colo., February 8, 2010) (noting that Sandoz, a Colorado corporation with its principal place of business in New Jersey, has sufficient contacts with Delaware to be subjected to personal jurisdiction because Sandoz makes and sells generic pharmaceutical products for sale throughout the U.S., including Delaware, and has a license to distribute pharmaceuticals in Delaware); see also *In re Cyclobenzaprine Hydrochloride*, 693 F. Supp. 2d 409, 421 (D. Del. 2010) (Anchen Pharmaceuticals, a California corporation with its principal place of business in California, held subject to general jurisdiction in Delaware because of its “purposeful contacts” tied to deriving “substantial revenue” from Delaware drug sales).

Post-*Daimler*, such activities, even if “continuous and systematic,” do not warrant general jurisdiction, alone; the corporation must be found to be “at home.” *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014). *Daimler* did not absolutely foreclose the ability to successfully assert general jurisdiction, but it has become more challenging to assert general personal jurisdiction over a foreign and out-of-state corporation in states that are not the corporation’s principal place of business or state of incorporation. Brand companies can argue “agency” or “alter ego” theories in asserting general jurisdiction over foreign-parent generics, based on the local activities of its subsidiaries, *Id.* at 758-760, or the “except-

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent[.]

<sup>3</sup> In the event a generic pharmaceutical company sells an allegedly infringing ANDA product in a given state, there is no need to invoke the “highly artificial” analysis for jurisdictional purposes under *Zeneca Ltd. v. Mylan Pharm., Inc.* 173 F.3d 829 (Fed. Cir. 1999) and 35 U.S.C. § 271(e)(2). The brand patent holder can assert specific personal jurisdiction over that generic in any such state based on a traditional 35 U.S.C. § 271(a) analysis: “making, using, offering to sell or selling infringing goods,” since the injury occurs at the situs of the act. See *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1570-71 (Fed. Cir. 1994) (“the situs of the injury is the location, or locations, at which the infringing activity directly impacts on the interests of the patentee, here the place of the infringing sales”); see also *North Am. Phillips Corp. v. Am. Vending Sales, Inc.*, 35 F.3d 1576, 1579 (Fed. Cir. 1994) (“the ‘tort’ of patent infringement occurs where the offending act is committed and not where the injury is felt”).

tional case,” as when generic entities’ operations are so substantial as to render it “at home” in a forum other than its principal place of business or state of incorporation. *Id.* at 761 n. 19.

*Daimler* thus shifted the jurisdiction paradigm. As a consequence of *Daimler*, many expected that brands would file more ANDA cases where generics are “at home.” For instance, many generics are incorporated in or considered “at home” for general jurisdiction purposes in Pennsylvania (e.g. Mylan Pharmaceuticals, Inc.). However, *Daimler* did not change the test for specific jurisdiction,<sup>4</sup> and, as a consequence, the authors believe that the focus now shifts away from battling about general jurisdiction to fights about specific jurisdiction.

We will see that brands have begun to shift to a specific jurisdictional approach based on a totality of relevant factors approach that takes into account where the plaintiff brand company is located, what contacts a brand company has to a particular forum, where and to whom the Paragraph IV notice is addressed and sent, and which state(s) the generic previously has sold, and intends on selling, its ANDA products in, upon FDA approval. District courts are now conflating the “exceptional case” scenario discussed in the majority’s opinion in *Daimler* when faced with questions of specific jurisdiction in the ANDA context. *Id.* Below the authors treat recent district court decisions on specific jurisdiction in Section III, and then we propose five practice-based tips for Hatch-Waxman practitioners in Section IV.

### III. The Battleground Shifts to Specific Jurisdiction in ANDA Cases

The forum in an ANDA patent litigation can be decisive, particularly since time to disposition varies across venues.<sup>5</sup> For example, any delay in resolving a case where a generic has a strong merit-based case for patent invalidity or non-infringement means a “win” for the brand company based on the brand’s market exclusivity during the pendency of the lawsuit, the concurrent FDA 30-month stay on the generics’ ANDA-approval, and the concomitant delay of the first ANDA-filer’s 180-day exclusivity period.

<sup>4</sup> In *Daimler*, the Argentina-based plaintiffs conceded that the California district court lacked specific personal jurisdiction over *Daimler* because the plaintiffs’ claims did not arise out of *Daimler*’s purported activity in that forum. *Id.* at \*758, 765 and n.5 and 10.

<sup>5</sup> For example, patent holders continue to favor the E.D. Va, W.D. Wis., M.D. Fla., Del., and E.D. Tex. since, as of May 2015, the median time to trial for patent cases is 1.0, 1.1, 1.8, 2.0 and 2.3 years respectively, on the theory that time is money. Then couple the relative speed to trial with the higher plaintiff success rates (30%, 32%, 55%, 43% and 55%) and greater median damages awards in these jurisdictions, and ANDA litigants may realize the most attractive forums for patentees. See PwC, 2015 Patent Litigation Study, available at: [http://www.pwc.com/en\\_US/us/forensic-services/publications/assets/2015-pwc-patent-litigation-study.pdf](http://www.pwc.com/en_US/us/forensic-services/publications/assets/2015-pwc-patent-litigation-study.pdf). In contrast, the N.D. Ill. and D. Mass. have a median time to trial of 3.7 and 3.6 years, respectively, and significantly lower median damages awards. *Id.*

Additionally, the average time to trial in patent cases, between 2008 and 2014, in the E.D. Va was 514 days, whereas in contrast it was 2,026 days in the N.D. Ill. See Docket Navigator, 2014 Year in Review 24, available at: <http://home.docketnavigator.com/year-review/>.

Historically, ANDA plaintiffs relied on general jurisdiction and did not assert specific jurisdiction because typically no sales of the accused product within the forum had begun. And this was because, as previously discussed, in typical Hatch-Waxman cases, the litigation arises prior to FDA approval and launch of the accused infringing product. As a consequence, no sales have occurred on which to base specific jurisdiction.<sup>6</sup> Post-*Daimler*, brand companies found themselves reassessing where they could maintain an action, unhappy about the prospect of having to file in districts that are the generic's state of incorporation or where the generic's headquarters are located, unless some fact tied the generic to a jurisdiction that is more attractive to brand companies. *Pfizer Inc. v. Synthron Holding, B.V.*, No. 386 F. Supp. 2d 666 (M.D. N.C. 2005) (held that specific personal jurisdiction is proper in the state where the defendant and its affiliate extensively prepared and submitted the ANDA). But even if such facts miraculously appeared, brands still fretted that the case would be transferred to the generic's preferred venue. Below, we analyze four recent district court decisions that have grappled to comport with the Federal Circuit's two-prong test for specific jurisdiction: (1) the party resisting jurisdiction must be amenable to service of process under the state's long-arm statute; and (2) the exercise of personal jurisdiction must comport with the Constitution's due process limitation. *Hildebrand v. Steck Mfg. Co.*, No. 01-1087 and -1195, 279 F.3d 1351, 1354 (Fed. Cir. 2002). The Federal Circuit applies a three-prong test to determine if specific jurisdiction exists over the defendant: (1) whether the defendant purposely directed activities at residents of the forum; (2) whether the claim arises out of or relates to those activities; and (3) whether exercising personal jurisdiction is reasonable and fair. *Nuance Commc'ns Inc. v. Abbyy Software House*, 626 F.3d 1222, 1231 (Fed. Cir. 2010).

### A. Judge Sleet's AstraZeneca Decision

Our first paper discussed the decision in *AstraZeneca AB v. Mylan Pharms., Inc.*, where Judge Sleet held that no general personal jurisdiction existed over Mylan Pharmaceuticals, Inc., a wholly-owned West Virginia-based subsidiary of Mylan Inc. But, Judge Sleet found specific jurisdiction based on several factors: (1) Mylan Pharmaceuticals, Inc.'s act of filing an ANDA so it could market generic versions of two of AstraZeneca's diabetic drug products (*i.e.* Onglyza<sup>®</sup> and Kombiglyze<sup>®</sup> XR); and (2) mailing a notice letter to AstraZeneca, which is located in Delaware, that the Court found "purposefully directed at AstraZeneca in the State of Delaware." *Id.*, No. 14-696-GMS, 2014 BL 312778 at \*7-9 (D. Del. Nov. 05, 2014). The Court considered other factors, such as Mylan Pharmaceuticals, Inc.'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.* at \*9.

This case establishes that a brand may be able to assert specific jurisdiction against a generic on the brand's home turf, based, in large part, on receiving a Paragraph IV notice letter, which meets at least the first and second prong of the Federal Circuit's test for specific jurisdiction: the defendant purposely directed activities at a resident of the forum and that the claim

arose out of that activity. The statutory language governing notice requirements, set forth in 21 U.S.C. § 355(j)(2)(B), provides that an ANDA applicant must give notice to the: (i) patent owner, or its designated representative; and (ii) the New Drug Application (NDA) holder of the drug or a drug's use claimed in the patent, or its designated representative. The implementing regulation states that "[t]he name and address of the patent owner or its representative may be obtained from the U.S.P.T.O.," and "[t]he name and address of the application holder or its attorney, agent, or authorized official may be obtained from the Orange Book Staff." 21 C.F.R. § 314.95(a)(1)-(2). If the NDA holder does not reside or maintain a place of business in the U.S., then the generic must notify the NDA holder's attorney, agent or other authorized official. 21 C.F.R. § 314.95(a)(2). Generics have some flexibility in providing the requisite notice and should consider the better jurisdiction in determining where to send the Paragraph IV notice, if the generic has choices, as discussed further in Section IV, which discusses top practice tips.

### B. Judge Stark's Acorda Decision

Two months after Judge Sleet's *AstraZeneca* decision, Chief Judge Stark found both general and specific jurisdiction existed over defendant Mylan Pharmaceuticals, Inc. in *Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*, No. 14-935-LPS, 2015 BL 8340 (D. Del. Jan. 14, 2015). The Court based its specific jurisdiction finding on the following facts: (i) Mylan Pharmaceuticals, Inc. sent its notice letter to Acorda, a Delaware corporation, and Acorda felt the injury tangentially in Delaware even though Mylan did not send the notice to Acorda's Delaware office; (ii) Mylan Pharmaceuticals, Inc. filed an ANDA, a prerequisite to approval before selling product across the U.S., including Delaware; (iii) Acorda had begun litigation in Delaware that involved the same drug at issue; (iv) Mylan Pharmaceuticals, Inc. registered to do business in Delaware, including registering as both a pharmacy wholesaler and distributor with the Delaware Board of Pharmacy; and (v) Mylan Pharmaceuticals, Inc. is a frequent participant in Hatch-Waxman litigation. *Id.* at \*15-16.

Judge Stark concluded, based on these facts, that the assertion of specific personal jurisdiction easily met the "traditional notions of fair play and substantial justice" standard discussed in opinions from *Int'l Shoe* through *Daimler*, in view of the: (i) minimal burden on Mylan Pharmaceuticals, Inc. to litigate in Delaware; (ii) 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; and (iii) Acorda's interest in obtaining convenient and effective relief. *Id.* at \*16-17.

### C. Judge Gilstrap's Allergan Decision

Judge Gilstrap of the Eastern District of Texas applied Judge Stark's reasoning in *Allergan v. Actavis*, No. 2:14-cv-638, 2014 BL 361759 (E.D. Tex. Dec. 23, 2014). Here, defendants Actavis and Watson moved to dismiss Allergan's (a Delaware entity with its principal place of business in California) complaint, filed over the defendants' ANDA filing over Restasis<sup>®</sup>. *Id.* Judge Gilstrap focused on specific personal jurisdiction, ignoring any general personal jurisdiction issues. *Id.* at \*6-7.

The Court found specific jurisdiction based on the facts that the defendants' conduct would erode Aller-

<sup>6</sup> *Supra* n.3

gan's sales, manufacture and distribution of the drug in Texas, that the ANDA filing caused "substantial harm to Allergan in Texas," as Allergan produces its Restasis® drug in Texas, that Allergan coordinates nationwide distribution of the drug in Texas, and that Allergan sells the drug in Texas, especially within the Eastern District. *Id.* Judge Gilstrap emphasized Watson's and Actavis' independent contacts with Texas, such as: (i) their potential license to distribute prescription drugs in Texas; (ii) their efforts to establish contacts with wholesalers and retailers for distribution; and (iii) their intent to target Texas for the sale of Restasis®, holding that these factors supported the conclusion that "the harm to Allergan in this case is unavoidably connected to Defendants' extensive efforts in Texas to sell a generic version of Restasis."<sup>7</sup> *Id.* at \*8. The Court further noted that Allergan had filed declaratory judgment claims in the jurisdiction, further stating 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." *Id.* at \*9 (emphases added) (internal citation omitted).

#### D. Judge Barker's Eli Lilly Decision

Although Judge Barker found no general jurisdiction existed over Mylan Pharmaceuticals, Inc., because neither it nor any of the other Mylan-entity defendants were "at home" under *Daimler (Eli Lilly & Co. v. Mylan Pharms., Inc.*, No. 14-389, 2015 BL 66484 (S.D. Ind. Mar. 12, 2015) at \*6-7), he found that specific jurisdiction existed, like in *AstraZeneca*, since Mylan Pharmaceuticals, Inc. purposefully directed its activities at Indiana by sending its ANDA notice letter to Eli Lilly in Indiana. *Id.* at \*8-9. Judge Barker, like Judge Stark in *Acorda*, also considered "traditional notions of fair play and substantial justice," and held that such considerations comported with the assertion of personal specific jurisdiction over Mylan Pharmaceuticals, Inc. *Id.* The Court rejected Mylan's invitation to decide the question based on where the ANDA filer conducts its development or preparation efforts, and focused instead on where the "actual consequences [are] felt," finding that Indiana—as home to one of the notice letter recipients—was one such place. *Id.*; see also *Eli Lilly & Co. et. al. v. Nang Kuang Pharm. Co., Ltd. et. al.*, 1:14-cv-01647 (S.D. Ind. Aug. 24, 2015) at 4 (denying motion to dismiss for lack of personal jurisdiction, holding that "what is relevant is the fact that Defendants sent the Notice Letter to Plaintiffs in Indiana . . . Because [plaintiffs'] state of incorporation is Indiana, the Court considers Indiana to be the place of the injury that Plaintiffs allege arose by the filing of the ANDA"). The Court also looked to Mylan's intent to sell its ANDA product in Indiana in the future, in addition to nationwide sales.<sup>8</sup> *Id.* at \*4, 9 n.11. Judge Barker held that My-

<sup>7</sup> Judge Gilstrap reasoned that, "[A] manufacturer who 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." *Id.*

<sup>8</sup> In *Acorda*, Judge Stark also addressed the issue of future impact while hesitant to base specific jurisdiction over Mylan Pharmaceuticals, Inc., solely on where the infringing acts would occur in the future. Judge Stark, nevertheless, found that the injury also would be "felt" in Delaware, the place of both *Acorda's* and numerous Mylan Inc. subsidiaries' incorpo-

ration, among other factors. *Acorda*, *supra* at \*8, 17-20; see also *Novartis Pharms. Corp. et. al. v. Zydus Noveltch Inc. et. al.*, No. 1:14-cv-01104, Dkt. No. 61, at 10-15 (D. Del. Aug. 7, 2015) (declining specific jurisdiction over defendant, despite its future plans to sell generic dementia-treatment patches in Delaware).

## IV. Five Top Practice Tips for ANDA Litigants Based on These Recent Cases

### A. Tip No. 1: Future Sales and Marketing Activities Are Important Factors in Determining Specific Jurisdiction in Certain States

According to the cases discussed above, courts will assess both the brands' and the generics' contacts with the particular forum. In selecting a forum, brand companies should assess whether they can establish that the generic company will conduct *future activities* with the challenged new drug in the forum (*i.e.* where the generic is expected to make sales and/or conduct marketing), based on past sales and marketing activities in the jurisdiction, given that the Hatch-Waxman Act, per 35 U.S.C. § 271(e)(2)(A), creates a "highly artificial" cause of action wherein infringement is analyzed based on what ANDA product the generic is expected to sell.

Conversely, generics will benefit from trying to limit the case that there is a future expectation of contacts in any particular forum, especially in view of the Federal Rule of Civil Procedure's long-arm jurisdictional reach under Rule 4(k)(2) (as discussed in our prior article, "*The DAIMLER Series: District Courts analyze personal jurisdiction in ANDA cases*"). For example, generics can limit such contacts by not developing business or marketing plans for any specific jurisdiction or by using third-party marketing representatives to enter specific jurisdictions so that the generic is not deemed to be active in any particular jurisdiction. Foreign-based generics may want to consider directing their contacts into a single jurisdiction *e.g.*, preparing the ANDA in one state,<sup>10</sup> in order to have the best chance of limiting lawsuits against them to that particular jurisdiction. See

<sup>9</sup> In contrast, the courts in *Acorda* and *Novartis Pharms. Corp. v. Mylan Inc.*, No. 14-777-RGA, 2015 BL 70580 (D. Del. Mar. 16, 2015) allowed limited discovery into the issue of specific jurisdiction over Mylan Inc., the parent of Mylan Pharmaceuticals, Inc. The brands had asserted that Mylan Inc. used Mylan Pharmaceuticals, Inc. as its "agent" or "alter ego" regarding the filing of its ANDA.

<sup>10</sup> Mylan Pharmaceuticals, Inc. argued this position in its opening brief at the Federal Circuit, during the interlocutory appeal from Judge Sleet in *AstraZeneca*, *supra*. Pending the Federal Circuit's ruling, brand companies should consider arguing that adopting such a rule would unfairly force patent owners to litigate in the generic-defendant's home forum, leading to prejudicial delays and inconsistent rulings particularly where "multiple generic manufacturers file ANDAs concerning the same patented drug" (as *AstraZeneca* has argued in its response brief, and Teva, various industry groups, and law professors have argued in amicus briefs).

Fed. R. Civ. P. 4(k)(2).<sup>11</sup> And, special attention should be given during the analysis of the foreign generics' subsidiary or affiliate contacts, so as to avoid any potential "alter ego" or "agency" veil-piercing type theories of jurisdiction by the brand company.<sup>12</sup> For example, the district court in *Pfizer Inc. v. Synthon Holding, B.V.*, 386 F. Supp. 2d 666, 677 (M.D.N.C. 2005), addressed this question and found that it had specific jurisdiction over Synthon Labs, a Virginia-based entity, because two North Carolina entities, Synthon Holding and Synthon Pharma, had created Synthon Labs solely to file the ANDA "in an effort to manipulate jurisdiction." The district court further found that the two North Carolina companies "completely dominate and controlled" the finances, policies and business practices of Synthon Labs (citing *Minnesota Mining and Mfg. Co. v. Eco Chem, Inc.*, 757 F.2d 1256, 1265 (Fed. Cir. 1985) (noting that "a court which has jurisdiction over a corporation has jurisdiction over its alter egos").

### **B. Tip No. 2: Notice Letters May Prove Sufficient to Establish Jurisdiction**

In *AstraZeneca*, Judge Sleet held that when an ANDA filer directs its activities into the patentee brand companies' forum, and towards the patentee brand company, the brand company feels the harm in its home forum. *Id.* at \*9. The Court viewed the ANDA filing as a "tortious act" with real consequences; otherwise, the result would be the "untenable position that [defendants'] conduct is not directed to any jurisdiction." *Id.* at \*7. The choice of notifying NDA holders, patent owners and their agents can affect specific personal jurisdiction, as noted in our discussion of *AstraZeneca*. Recently, Judge Andrews of the District of Delaware also adopted this reasoning in *Novartis Pharms. Corp. et. al. v. Zydus Noveltech Inc. et. al.*, No. 1:14-cv-01104, Dkt. No. 61 (D. Del. Aug. 7, 2015). Judge Andrews held that because the notice letter was directed to Novartis' office in New Jersey, the case originated there despite the fact that Novartis is incorporated in Delaware, and regardless of Zydus' future sales of generic Exelon® rivastigmine patch system, used to treat mild to moderate dementia, in Delaware ("[i]t is beyond dispute that the ANDA process triggered an injury, and that the submission of the ANDA letter triggered an injury against plaintiff."). *Id.* at 10-15; see also *Eli Lilly & Co. v. Mylan Pharms., Inc.*, *supra*, at \*6-9; *Eli Lilly & Co. et. al. v. Nang Kuang Pharm. Co., Ltd. et. al.*, *supra* at 4. As discussed earlier, the critical statutory section for providing notice, § 21 USC 355(j)(2)(B), is ambiguous.

For that reason, brand companies may try to maneuver competing generics to provide the requisite notice letters in the brand's favored forum by "designating" a representative to receive the generic's notice letters in its favored forum. On the other hand, a generic will

seek ways to provide the requisite notice in a forum more favorable to generics. The generic may simply choose to ignore the designation by the brand and send its notice letter directly to the NDA holder and patent owner, asserting a strict reading of the statutory provision. If a representative of the brand is located in a generic's favored forum, that generic may decide to send its notice letter to that representative, rather than to the patent owner or NDA holder.

To take advantage of this "notice" factor, generics should modify their current behavior. Often, generics resort to the USPTO's website in trying to ascertain the true patent owner or assignee, and recognizing that such information is not always correct, generics frequently serve notice letters on every possible patent owner/assignee, and their respective offices, sometimes on a global scale. In trying to assert specific jurisdiction, this broad-brush approach will prove counterproductive. Generics need to perform a competent analysis calculated to obtain the most favorable forum before serving ANDA notices.

### **C. Tip No. 3: Brands' "Protective Suits" Can Counter Generics' "Actions for Certainty" and Guarantee FDA's 30-Month Stay**

Brands can file in the forum where a notice letter is sent to intentionally provoke a battle over jurisdiction. That battle may increase the delay in resolving the case while resolving this issue. But generics can turn the brand's attempt to gain a tactical advantage back on the brand by arguing that the brand's attempt to benefit from delay is not appropriate, arguing that the FDA 30-month stay on ANDA approval is not triggered by a suit where jurisdiction is challenged. The generic can argue further that this situation affects the 45-day statutory suit-filing requirement (over patents that are Orange Book listed at the time of the initial ANDA submission), because arguably the brand filed suit in a forum without proper jurisdiction. Accordingly, without jurisdiction, such a lawsuit should be considered as not having been filed. As a consequence, the generic can file "an action for certainty" declaratory judgment complaint in its home forum. The generic must be open with the court about its tactics, particularly to avoid the first-filed doctrine, which the brand surely will file to challenge the generic's action.

In response to generics' "actions for certainty," brand companies usually file actions known as "protective cases," so that if the first-filed forum dismisses the action for lack of personal jurisdiction, the patentee will still have filed suit within the 45-day statutory window, and enjoy the benefit of the 30-month FDA stay of approval over the generics' ANDA. See also *Pfizer Inc. et. al. v. Mylan Pharms. Inc.*, No. 1:15-cv-13 (Keeley, J.), Dkt. No. 46, Order Granting Plaintiffs' Motion to Stay Second-Filed Suit (N.D. W. Va, July 24, 2015) (staying a second-filed suit in West Virginia pending Mylan's CAFC interlocutory appeal from the District of Delaware's denial of Mylan's motions to dismiss in *Acorda, supra* and *AstraZeneca, supra*). And brand companies often attempt to stay the second-filed suit if the first case is proceeding on course, with the option to lift the stay on the second suit if the first suit is dismissed for jurisdictional issues. *Id.*; see also *Noven Pharms., Inc. et. al. v. Mylan Techns., Inc., et. al.*, No. 1-15-cv-00069 (N.D. W. Va. Aug. 25, 2015) at 8 (granting plaintiffs' motion to stay second-filed "protective" ANDA case

<sup>11</sup> Federal Rule of Civil Procedure 4(k)(2) provides that a defendant sued for a claim arising under federal law, such as a foreign ANDA-filer, that is not subject to personal jurisdiction in any specific state court, nevertheless, will be subject to personal jurisdiction in every state court if exercise of such jurisdiction is consistent with the United States' Constitution and laws.

<sup>12</sup> *Daimler* allows brand companies to argue an agency test to assert general jurisdiction over a foreign parent corporation, based on local activities of a subsidiary, although it left open what that test should look like. *Id.* at 758-760.

pending jurisdictional dispute in first-filed case, since “first-to-file rule squarely applies . . . [A]lthough [the District of Delaware] has not yet ruled on [defendant’s] motion to dismiss, [it] has expressed [its] desire to move the case forward into discovery”).

The equitable doctrine known as “first-to-file” rule “favors the forum of the first-filed action . . .” *Genentech, Inc. v. Eli Lilly and Co.*, 998 F.2d 931, 937-38 (Fed. Cir. 1993) (but listing the absence of jurisdiction as a “sound reason that would make it unjust or inefficient to continue the first-filed action.”), *abrogated on other grounds*; *Wilton v. Seven Falls Co.*, 515 U.S. 277, 115 S.Ct. 2137 (1995). When two courts have concurrent jurisdiction in substantially identical cases, the court hearing the second-filed action generally defers to the court hearing the first-filed action. *See Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1299 (Fed. Cir. 2012). However, jurisdiction in the first-filed case has been held to be just one factor to consider. *See, e.g., Cadle Co. v. Whataburger of Alice, Inc.*, 174 F.3d 599, 605 (5th Cir. 1999) (“[w]hile the likelihood of a jurisdictional dispute in the first-filed court may be a factor to consider in applying the rule, resolving the dispute in favor of that court’s jurisdiction is never a condition precedent to applying it.”) Courts usually consider three factors to determine whether the first-to-file rule applies, including: (i) chronology, (ii) identity of parties, and (iii) similarity of issues. *Intersearch Worldwide, Ltd. v. Intersearch Group, Inc.*, 544 F. Supp.2d 949, 957 (N.D. Cal. 2008).

Indeed, in *Novartis, supra*, the brand initially filed suit in Delaware, and then subsequently in the Northern District of West Virginia, where Mylan Inc. is domiciled. *See Novartis Pharms. Corp. v. Mylan, Inc.*, Nos. 1:14-cv-00111-IMK and 1:14-cv-106, Dkt No. 1. Mylan Inc. subsequently filed a motion to dismiss in Delaware for lack of personal jurisdiction. While the Delaware motion to dismiss was pending, Novartis moved the West Virginia Court to stay the case pending resolution of the Delaware motion, but the Court denied the motion, relying on judicial economy being served in “moving forward with the suit,” the absence of any significant hardship on the parties, and the uncertainty surrounding when the Delaware Court would decide the pending jurisdictional motion to dismiss. *Id.*, Nos. 1:14-cv-106, Dkt. No. 47, and No. 1:14-cv-00111-IMK, Dkt. No. 38 at 14 (finding that the first-to-file rule did not apply due to a vigorous jurisdictional dispute); *see Orthmann v. Apple River Campground, Inc.*, 765 F.2d 119, 121 (8th Cir. 1985) (dismissing first-filed action where jurisdiction was “vigorously dispute[d],” to allow second-filed action to progress). The West Virginia Court, however, welcomed Novartis to file a second motion to stay or transfer, assuming the Delaware Court decided the personal jurisdiction question in Novartis’ favor. *Id.* at 15.

Subsequently, the Delaware *Novartis* Court denied Mylan Inc.’s motion to dismiss, following *Acorda*, holding it has consent-based personal jurisdiction over Mylan Pharmaceuticals, Inc., based on the latter’s business registration license in Delaware, but granted limited discovery into specific jurisdiction over Mylan Inc. *Id.*, No. 14-777-RGA, 2015 BL 70580 (D. Del. Mar. 16, 2015) at \*3. *Novartis* consequently was successful in renewing its motion to stay the West Virginia action, based on the Delaware Court’s decision to proceed. *Id.*, No. 1:14-cv-00111-IMK, Dkt No. 63. However, the West Virginia Court ordered the parties to “inform the Court on a

timely basis of any developments regarding the outcome of Mylans’ interlocutory appeal or otherwise affecting its jurisdictional status in the District of Delaware.” *Id.*, Dkt. No. 75<sup>13</sup>; *see also Purdue Pharma LP et. al v. Collegium Pharm., Inc.*, No. 1-15-00260 (D. Del. Aug. 6, 2015) (granting defendants’ motion to dismiss for lack of personal jurisdiction, as well as partially granting defendants’ transfer motion and sending case to D. Mass., the situs of patentee’s “protective case,” defendant’s HQ and other drug development activities).

#### **D. Tip No. 4: Corporate Strategy and Re-structuring Can Affect Jurisdiction**

The cases discussed under section III teach that foreign ANDA-filers can be subject to personal jurisdiction in the United States, and potentially even subject to jurisdiction in the plaintiff’s forum. *See Zeneca Ltd. v. Mylan Pharms., Inc.* 173 F.3d 829 (Fed. Cir. 1999); *AstraZeneca, supra* (Judge Sleet found specific jurisdiction exists in Delaware over Mylan Inc., because brand company-patentee was organized there, Paragraph IV certification letter was sent there, and Mylan Inc. previously had been sued there); *see also Eli Lilly v. Nang Kuang, supra*, at 4. And, Fed. R. Civ. P. 4(k)(2) provides that if a defendant that is sued for a claim arising under federal law, such as a foreign ANDA-filer, and is not subject to personal jurisdiction in any specific state court, it nevertheless will be subject to personal jurisdiction in every state court if exercise of such jurisdiction comports with constitutional due process.<sup>14</sup> Therefore, a foreign generic, in planning its corporate strategy, may decide to include a home forum in the United States to avoid subjecting itself to possible Rule 4 jurisdiction in every state.

To take advantage of the forum debate, a foreign generic should set up an office in its preferred jurisdiction and conduct activities there. It then can argue that it chose to be subject to personal jurisdiction in that particular state. The generic may also decide to set up a

<sup>13</sup> The briefing from the *AstraZeneca* CAFC appeal suggests that AstraZeneca has focused more on specific jurisdiction arguments, requesting the Court to affirm J. Sleet’s ruling based on the Paragraph IV notice letter Mylan sent AstraZeneca’s Delaware office, which notified it of planned generic diabetes drugs. AstraZeneca also argues that *Daimler* has no relevance to the issue since it did not address the “highly artificial” act of infringement presupposed in Hatch-Waxman Paragraph IV cases, and that Mylan consented to general jurisdiction when it voluntarily registered to do business in Delaware.

Teva Pharmaceuticals Inc., Pharmaceutical Research and Manufacturers of America, Biotechnology Industry Organization and a group of law professors filed amicus briefs on July 23, urging the CAFC to affirm the *AstraZeneca* court’s denial of Mylan Pharma Inc.’s motion to dismiss, which subjects Mylan to specific jurisdiction in Delaware based on its anticipated future sales of the ANDA product there.

In contrast, Mylan argues that while the *AstraZeneca* court’s holding that it could not exercise general personal jurisdiction over Mylan in this case under *Daimler* was correct, the court’s ruling on specific jurisdiction was wrong.

<sup>14</sup> Fed. R. Civ. P. 4(k)(2) provides, in pertinent part: “[f]or a claim that arises under federal law, serving a summons or filing a waiver of service establishes personal jurisdiction over a defendant if: (A) the defendant is not subject to jurisdiction in any state’s courts of general jurisdiction; and (B) exercising jurisdiction is consistent with the United States Constitution and laws.”

subsidiary in a preferred jurisdiction and use that subsidiary to prepare, develop and submit ANDAs. Because activities outside of the United States should not affect a jurisdictional analysis, as we witnessed with Mylan Laboratories Limited, the India-based subsidiary, escaping the New Jersey Court's jurisdictional reach in *Otsuka, supra*, the generic company should be able to select a favorable jurisdiction without materially altering its business operations. But, to avoid jurisdictional reach via "alter ego"-type theories, foreign generic parent companies should be cognizant of the way they govern, document and structure their domestic subsidiary's corporate formalities and financial arrangements, any inter-corporate transactions, sharing of high level inter-company personnel, board of director and other management committee meetings, employment decisions, and corporate policymaking. See, e.g., *Pfizer Inc. v. Synthon Holding, B.V.*, *supra* at 677 (specific jurisdiction over Virginia entity created solely to file ANDA, in view of two North Carolina entities' complete domination and control over Virginia entity's finances, policies and business practices).

Lessons can be learned from the *Otsuka* decision: the Court declined to exercise general jurisdiction over Mylan Laboratories Limited because it was not "at home" in New Jersey and it had not complied with New Jersey's registration statute; nor did it find specific jurisdiction over the same, because it appeared the Indian entity had "no appreciable connection to the alleged infringement issues." *Otsuka* at \*12. Further, *Otsuka* had not identified any specific activities or "relevant claims-based contact" directed at New Jersey by Mylan Laboratories Limited that related to *Otsuka*'s infringement claims. *Id.* The Court found no general or specific jurisdiction existed, despite the fact that: (i) Mylan Laboratories Limited manufactures and supplies the aripiprazole API to Mylan Inc., which Mylan Laboratories Limited is the Drug Master File holder of; (ii) Mylan Inc. owns a majority stake in Mylan Laboratories Limited and shares common corporate directors; and (iii) Mylan Laboratories Limited owns a New Jersey-based subsidiary which also holds a drug wholesale distribution license in New Jersey. See *Otsuka*, Complaint at ¶ 9. Regarding the third factor, the Court held that *Otsuka* did not plead any basis to "impute the alleged jurisdictional contacts of [Mylan Laboratories Limited]'s subsidiaries to Mylan Laboratories Limited itself for purposes of specific jurisdiction." *Id.* No limited discovery was taken by *Otsuka* on the personal jurisdiction question, nor was any appeal lodged by *Otsuka*. It is all too easy to infer that Mylan Laboratories Limited escaped jurisdiction potentially due to *Otsuka*'s nature of its written pleadings.

The key take-away for brands faced with litigation involving competing generic ANDA-filers with a complex corporate structure: plead Rule 4(k)(2) long-arm jurisdiction over any out-of-state entities in the Complaint, as well as both specific and general personal jurisdiction theories, including an "alter ego" type theory, if possible.<sup>15</sup> For foreign generics, the key take-away is

<sup>15</sup> Brands may consider taking some pre-action discovery into the inter-corporate relationship between a foreign generic parent and its U.S. subsidiary for jurisdictional purposes, especially if there is a risk of "a failure or delay in justice." Fed. R. Civ. P. 27(a)(3); see also *Acorda, supra*, and *Novartis Pharms. Corp. v. Mylan Inc.*, No. 14-777-RGA, 2015 BL 70580 (D. Del.

don't engage in filing the ANDA with the FDA (leave it to the U.S. subsidiary or affiliated company), handle any development, preparation or research relating to a possible ANDA abroad, and avoid registering to do business or obtaining distribution or wholesale licenses in U.S. states which are not preferred for generics *i.e.* New York, New Jersey and Delaware. And, at the same time, ANDA entities (or filers) need to independently structure the domestic subsidiary in a way to minimize the risk of jurisdictional reach via any "alter ego"-type theory piercing the corporate veil. See *Forest Labs. Inc. v. Cobalt Labs. Inc.*, No. 08-21-GMS-LPS, 2009 BL 47521, at \*11 (D. Del. Mar. 9, 2009) report and recommendation adopted, No. CA 08-21-GMS-LPS, 2009 BL 183180 (D. Del. Aug. 27, 2009) (in granting ANDA generic-defendants' motion to dismiss Orchid India, an India-based entity, Orchid Pharma, a shell-Delaware entity, and Orgenus, a New Jersey entity, but transferring case to New Jersey, Court held that for alter ego theory, plaintiffs failed to show "fraud or inequity" in Orchid India's use of Orchid Pharma; for agency theory, even assuming Orchid India exercises control over Orchid Pharma and Orgenus, these subsidiaries have insufficient contacts with Delaware); but see *Pfizer Inc. v. Synthon Holding, B.V.*, *supra*, 386 F. Supp. 2d at 677 (specific jurisdiction over Virginia entity created solely to file ANDA, in view of two North Carolina entities' complete domination and control over Virginia entity's finances, policies and business practices).

### **E. Tip No. 5: The Best Way to Shape MDL Practice**

Generic pharmaceutical companies should file their motions to dismiss for lack of personal jurisdiction early in the patent infringement action, even if the generic company also files a declaratory judgment "action for certainty" in its separate, "home" forum, based on lack of suit within the 45-day period (over patents that were Orange Book listed at the time of the ANDA submission) by the brand company in that forum. Should such motions to dismiss on personal jurisdiction grounds result in a multiplicity of suits in the generics' home states, then the authors predict the emergence of Multi-District Litigation ("MDL") practice in the Hatch-Waxman litigation context, involving multiple ANDA filers reasonably proximate in time in their FDA submissions and Paragraph IV certifications.

Brands should then seek Section 1407 MDL centralization of cases venued in disparate forums that involve common issues of patent validity. See 28 U.S.C. § 1407. Commentators expect the centralization of MDL in ANDA Paragraph IV cases in New Jersey, New York and Delaware, as these forums are brand pharmaceuti-

Mar. 16, 2015) (allowing limited discovery into the issue of specific jurisdiction over Mylan Inc., Mylan Pharmaceuticals, Inc.'s parent, given Novartis' assertion that Mylan Inc. used Mylan Pharmaceuticals, Inc. as its "agent"/"alter ego" regarding the ANDA filing).

The current Federal Rules of Civil Procedure limit pre-suit discovery to perpetuate testimony of an individual who may not be available to testify after suit has commenced, or to preserve evidence which may not be available for inspection at trial. Fed. R. Civ. P. 27 ("Depositions before Action or Pending Appeal," provides for the perpetuation of testimony prior to filing a formal complaint). Rule 27 permits a party to seek an order from the court to take a deposition of "any expected adverse party."

cal company “favorites,” and also have well-established jurisprudence in the Hatch-Waxman spectrum.

## V. Conclusion

Due to the early and significant nature of jurisdictional disputes in Hatch Waxman litigation, such issues are decisive in resolving Hatch Waxman Paragraph IV cases and often affect which side is ultimately successful. Below, we sum up our five top tips for both brand and generic-side Hatch-Waxman practitioners who are frequently involved in advising on, and implementing, jurisdictional litigation strategy:

- **Patentee-brand** companies can maximize their chances of succeeding against a defendant-generic’s jurisdictional challenges by:

(1) pleading Rule 4(k)(2) long-arm jurisdiction over any out-of-state entities, as well as general, consent-based and specific jurisdiction and any agency, “alter-ego” or corporate veil-piercing theories, if possible (brands should consider taking limited pre-suit discovery into jurisdictional issues under FRCP 27, such as into inter-corporate formalities and relationships);

(2) suing in a state where **general personal jurisdiction** exists because the generic:

- (a) is incorporated in the forum; or
- (b) has its principal place of business in that forum; and/or
- (c) has a registered office, statutory business license or an appointed process server in the forum; or

(3) suing in a state where **specific personal jurisdiction** exists because:

- (a) the generic committed prior allegedly infringing acts in the forum and, arguably, can be expected to commit such acts once the FDA approves the ANDA product subject to Paragraph IV litigation and all legal challenges end;
- (b) in a new ANDA case, the brand patent/NDA holder resides in the forum and the generic has directed its Paragraph IV notice letter to the brands’ “designated representative” in that forum (*i.e.* consider only designating such agents in brand-preferred forums);
- (c) in an ANDA case, there is evidence of the generic’s future sales and marketing activities occurring in that forum; or
- (d) in a declaratory judgment action, the generic has directed purposeful enforcement actions towards the forum’s residents;

(4) filing a “protective suit” in an alternative-preferred forum, so that if the first-filed forum dismisses the action for lack of personal jurisdiction, the brand will still have filed suit within the 45 day statutory window, and reap advantages of the 30-month FDA stay of approval over the generics’ ANDA; and

(5) seeking § 1407 MDL centralization in brand-preferred forums (*i.e.* New Jersey, New York or Delaware) if the brand is suing multiple generics over the same patents covering the same drug product on similar theories, and assuming the generics’ motions to dismiss are successful, causing

the brand to otherwise litigate in several different states.

- **Defendant-generic** companies can maximize their chances of success during jurisdictional challenges by:

(1) arguing a lack of specific jurisdiction, and distinguishing *Daimler* as it did not affect the test for specific personal jurisdiction;

(2) in ANDA cases, sending the Paragraph IV notice letter only to the brand patentee/NDA holder’s designated representative in the forum(s) preferred by the generic;

(3) if the facts warrant, arguing that the generic:

- (a) is not incorporated in the forum;
- (b) does not have its principal place of business in the forum;
- (c) does not have a registered office, statutory business license or an appointed process server in the forum; and/or
- (d) is not developing any ANDA preparation, business or marketing plans in the forum, and/or is not using third-party marketing representatives there;

(4) filing a DJ “action for certainty” against the brand in a generic-preferred forum, claiming that the brand’s initial suit within the 45 day statutory window of receiving a Paragraph IV notice does not trigger the FDA’s 30-month stay over the generic’s ANDA approval because the brand filed in a forum where jurisdiction is defective; and

(5) setting up an office and/or a subsidiary only in the generic’s preferred jurisdictions and conducting drug development activities there, using the subsidiary to prepare, develop and submit ANDAs; *and for foreign-based generic parent entities:*

(a) refrain from engaging in filing the ANDA (leave it to a U.S. subsidiary or affiliated company), and handle any development, preparation or research relating to an ANDA overseas; and

(b) avoid registering to do business or obtaining distribution or wholesale licenses in U.S. states which are not typically “generic-friendly” (*i.e.* statistically, New York, New Jersey and Delaware); *but*

(c) to minimize the risk of jurisdictional reach via “alter ego”-type theories piercing the corporate veil:

(i) independently structure any U.S. subsidiary’s corporate formalities (*e.g.* articles, by-laws), banking, tax and other financial arrangements, as well as employment and other corporate policymaking;

(ii) ensure that the U.S. entity is adequately capitalized and solvent;

(iii) minimize high-level use of inter-company personnel, and regularly hold separate board of director and other management committee meetings; and

(iv) ensure any inter-company transactions, particularly involving majority shareholders of the U.S. subsidiary, are well-documented.