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This article is the first in a series examining how a recent U.S. Supreme Court decision affects determinations of proper venue for Hatch-Waxman cases.

The DAIMLER Series: *District Courts Analyze Personal Jurisdiction in ANDA Cases*



By Mark Fox Evens, Krishan Thakker and Dennies Varughese

I. General Jurisdiction for ANDA Defendants After *Daimler*

This is the first article in a series that analyzes how the Supreme Court's decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014) has affected Hatch-Waxman Paragraph IV abbreviated new drug application (''ANDA'') litigation, an area where district courts historically exercised general personal jurisdiction, rather than specific jurisdiction, viewing the act of filing an ANDA that gave rise to a claim under 35 U.S.C. § 271(e)(2) as a ''technical'' or ''highly artificial'' act of infringement. *Zeneca Ltd. v. Mylan Pharm., Inc.* 173 F.3d 829 (Fed. Cir. 1999) (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990)). Since such ''technical'' acts of infringement were not purposefully directed towards any particular district[1], courts applied general jurisdiction principles instead of specific jurisdiction to exercise power over the defendant generic pharmaceutical company. *See, e.g., Eli Lilly & Co. v. Sicor Pharmaceuticals, Inc.*, No. 1:06-cv-238-SEB-JMS, 2007 BL 213100 (S.D. Ind. Apr. 27, 2007) (finding general jurisdiction over generic defendants based on their ''continuous and systematic contacts'' with Indiana due to sales in-State from out-of-state wholesalers). And, litigants relied on those principles in determining the proper venues for ANDA cases.

Then came *Daimler*, which held that a defendant's place of incorporation and principal place of business in a forum state would make it ''at home.'' *Daimler* at 749-50. And, in ''exceptional'' cases, a corporation's operations in another forum ''may be so substantial and of such a nature as to render it at home in that State.'' *Id.*, n. 19. *Daimler* alters the lens through which general jurisdiction over out-of-state defendants must be analyzed. The High Court confronted a unique jurisdictional challenge: plaintiffs, a group of Argentine nation-

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[1] The Federal Circuit in *Zeneca Ltd. v. Mylan Pharm., Inc.* eliminated the possibility that Maryland (the location of the FDA and where ANDAs are filed) could exercise specific jurisdiction over ANDA filers, in order to avoid creating a ''super-court'' with jurisdiction in all cases. *AstraZeneca AB v. Mylan Pharm., Inc.*, No. 14-696-GMS, 2014 BL 312778 (D. Del. Nov. 05, 2014) at *6 (citing *Zeneca*, 173 F.3d 829 (Fed. Cir. 1999) at 832).

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als seeking damages allegedly suffered in Argentina by, in part, the acts of Mercedes-Benz Argentina, a Daimler corporate entity, during a time of political chaos and excess, sued Daimler, a German company, in California, based on the minimal California contacts of Daimler's New Jersey-based distributor, Mercedes-Benz USA. *Daimler*, 134 S. Ct. at 750-51. Reversing the Ninth Circuit's *en banc* decision, a unanimous Supreme Court found that to exercise general jurisdiction requires a corporation to be ''at-home'' in the state, which the Court explained means that the corporation must be incorporated there or the location of its principal place of business, or the presence of other extraordinary circumstances. *Id*. at 761-62.

Those who thought that *Daimler* foreclosed general jurisdiction over out-of-state Hatch-Waxman defendants should fast forward to the District of New Jersey's March 23, 2015 decision in *Otsuka Pharm. Co. v. Mylan Inc.*, No. 14-4508 (JBS/KMW), 2015 BL 79496 (D.N.J. Mar. 23, 2015). *Contra* ''*An Update On Hatch-Waxman Personal Jurisdiction Cases*,'' Law 360, New York (April 24, 2015) (''[t]he applicability of general jurisdiction came into doubt in recent years following the Supreme Court's decisions in Goodyear and Daimler'').[2] In *Otsuka*, Otsuka sued three Mylan entities: Mylan Inc., a Pennsylvania-based corporation; Mylan Pharmaceuticals, Inc., a West Virginia-based corporation; and Mylan Laboratories Limited, an India-based corporation (all three defendants collectively, ''Mylan defendants''). The Mylan defendants moved to dismiss, challenging Otsuka's assertion of general jurisdiction.

Chief Judge Simandle denied Mylan Inc.'s and Mylan Pharmaceuticals, Inc.'s (''together, Mylan Inc.'') motion to dismiss Otsuka's patent infringement complaint for lack of personal jurisdiction based on a *Daimler* analysis, but granted the same motion with respect to the foreign India-based subsidiary, Mylan Laboratories Limited (''Mylan Ltd.''). *Otsuka*, 2015 BL 79496 at *1. Though the Court found that the Mylan defendants were not ''at-home'' for purposes of general jurisdiction, the Court, nevertheless, found appropriate the exercise of general jurisdiction against Mylan Inc. because those defendants consented to general jurisdiction by registering to do business and generating substantial revenues in the state. But, the Court found that Mylan Ltd. had not consented to suit in New Jersey, and granted its motion to dismiss.

The *Otsuka* Court analyzed general jurisdiction under *Daimler*, but also relied heavily on the Supreme Court's longstanding holding in *International Shoe Co. v. Washington*, 326 U.S. 110 (1945). *Otsuka* at *8-9. *Otsuka* serves as a wake-up call to ANDA litigants that the exercise of general jurisdiction remains, despite *Daimler*.

II. Overview: How District Courts Are Applying *Daimler* in the Hatch-Waxman Context

Since *Daimler*, several district courts have dealt with challenges to general jurisdiction in ANDA cases, and the differing approaches, some in the same district, are instructive. *Compare*, *e.g.*, *Otsuka* (D.N.J. March 23, 2015) (where general consent jurisdiction found over Mylan Inc. and Mylan Pharmaceuticals, Inc., but general ''at home'' jurisdiction neither asserted nor raised) *with Senju Pharm. Co., Ltd. v. Metrics, Inc.*, No. 14-3962 (JBS/KMW), 2015 BL 90802 (D.N.J. Mar. 31, 2015) (where general ''at home'' jurisdiction not found over Australian and North Carolina generics, granting limited discovery of specific jurisdiction over Australian generic's contacts with supplier in New Jersey, but finding consent jurisdiction existed over North Carolina generic through accepting service via registered agent); *compare also Novartis Pharm. Corp. v. Mylan Inc.*, No. 14-777-RGA, 2015 BL 70580 (D. Del. Mar. 16, 2015) (granting limited discovery over general specific jurisdiction over Mylan Inc., but finding consent jurisdiction over Mylan Pharmaceuticals, Inc.) *with AstraZeneca AB v. Mylan Pharm., Inc.*, No. 14-696-GMS, 2014 BL 312778 (D. Del. Nov. 05, 2014) (neither ''at home'' nor consent jurisdiction found over Mylan Pharmaceuticals, Inc., but granted personal specific jurisdiction over the same).

In this section, we will show that the *Otsuka* Court's analysis, as it pertains to the ''at home'' test for general jurisdiction, tracks with that of both Chief Judge Stark in *Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*, No. 14-935-LPS, 2015 BL 8340 (D. Del. Jan. 14, 2015), and Judge Sleet in *AstraZeneca*, *supra*, 2014 BL 312778 (D. Del. Nov. 5, 2014) (both denying *general* jurisdiction over the same defendant, Mylan Inc.). However, in determining the consent-to-be-sued test for general jurisdiction, Judge Sleet and Judge Stark arrived at diametrically opposite conclusions, with Judge Stark in agreement with *Otsuka*.

On the issue of general personal jurisdiction, Judge Sleet in *AstraZeneca* found that the defendant's compliance with Delaware's mandatory registration requirements to conduct business in the state, under 8 Del. C. §§ 371 and 376, was ***not*** sufficient to establish general jurisdiction. However, Judge Sleet ignored the Delaware Supreme Court's decision in *Sternberg v. O'Neil*, 550 A.2d 1105 (Del. 1988). In contrast, Chief Judge Stark relied on *Sternberg* for his opinion in *Acorda*. *Acorda* at *9 (''*Sternberg* held that a corporation qualified to do business in Delaware, which requires appointment of an agent to accept service of process, has consented to the general jurisdiction of the courts in the State of Delaware''); *contra AstraZeneca* at *5 (''*Stern-*

[2] Some commentators accurately forecasted that generic drug manufacturers would rely on *Daimler* and move to dismiss ANDA cases brought outside their home forums for lack of personal general jurisdiction. *See, e.g.*, ''*The Daimler Confusion And Its Impact On ANDA Litigation*'', Law360, New York (March 6, 2015) by Paul Ainsworth, Director at Sterne, Kessler, Goldstein & Fox P.L.L.C. (''[the] U.S. Supreme Court seemed to strip this weapon from a plaintiff's arsenal by narrowing the circumstances in which a defendant's unrelated contacts with the forum can give rise to personal jurisdiction.'')

As a result of *Daimler*, defendants increasingly are testing the boundaries of general jurisdiction jurisprudence, which is rapidly changing. This article shows that, in response to *Daimler*, some post-*Daimler* courts have based personal jurisdiction decisions on consent-based and/or specific jurisdiction theories. *Compare Allergan, Inc. v. Actavis, Inc.*, No. 2:14-CV-638, 2014 BL 361759 (E.D. Tex. Dec. 23, 2014) (finding *specific* jurisdiction over generic-defendant) *with Novartis Pharm. Corp. v. Mylan Inc.*, No. 14-777-RGA, 2015 BL 70580 (D. Del. Mar. 16, 2015) (finding no *general* ''at home'' jurisdiction, but finding consent-based jurisdiction over generic-defendant, and granting discovery over issue of specific jurisdiction). Future articles will analyze the efficacy of such challenges, and provide additional practice tips.

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berg can no longer be said to comport with federal due process.''). Chief Judge Stark concluded that *Daimler's* silence on the issue of consent meant that the Supreme Court's decision did ***not*** vitiate long-standing Delaware precedent finding consent to personal jurisdiction based on a defendant's foreign business registration.[3] *Acorda* at *7-8. Recognizing the importance of the issue and the need for further guidance, both courts certified the personal jurisdiction question for interlocutory appeal.

Nonetheless, Judge Sleet went on to recognize the practical effects presented by the filing of an ANDA, further opining that an ANDA filing might be the basis for exercising *specific* jurisdiction recognizing that regardless of how ''artificial'' the act of infringement may be, an ANDA filing is a ''real act'' with ''actual consequences,'' which would be ''suffered in Delaware,'' where AstraZeneca is incorporated. *AstraZeneca*, 2014 BL 312778 at *7. Since AstraZeneca's cause of action arose out of Mylan Inc.'s act of delivering a Paragraph IV notice letter to AstraZeneca in Delaware, the Court concluded that ''the act of filing an ANDA and the paragraph IV notification provide sufficient minimum contacts with the state of Delaware under a *specific* jurisdiction analysis.'' *Id*.

Other jurisdictions have adopted this theory of personal *specific* jurisdiction. For instance, in *Eli Lilly and Co. v. Mylan Pharmaceuticals Inc*., the Court found *specific* jurisdiction based on *mere receipt* of a Paragraph IV Notice Letter. *Id*., No. 14-389, 2015 BL 66484 (S.D. Ind. Mar. 12, 2015). The Court limited its analysis to specific jurisdiction because Eli Lilly had conceded that general jurisdiction did not apply. The Court recognized the difficulty in applying specific jurisdiction in these cases, but, after rejecting Mylan Inc.'s argument to decide the question based on where the ANDA filer conducts its development or preparation efforts, the Court focused on where the ''actual consequences [are] felt''. It found that Indiana — as home to one of the notice letter recipients — was one such place. *Id*. at *6.[4]

A recent magistrate's opinion from Delaware recommended finding consent to general jurisdiction based on the State's registration statute, thus denying the defendants' motion to dismiss for lack of personal jurisdiction. *See generally Forest Labs., Inc. v. Amneal Pharm. LLC*, No. 14-508-LPS, 2015 BL 51241, at *6 (D. Del. Feb. 26, 2015) (Judge Burke issued a 33-page Report and Recommendation, agreeing with the result in *Acorda* and expressly declining to follow the holding in *AstraZeneca*).

On March 30, 2015, Chief Judge Stark, after reviewing defendant Mylan Pharmaceuticals, Inc.'s objections to Judge Burke's report *de novo*, adopted Judge Burke's report and recommendation. Judge Stark cited his own decision in *Acorda*, and he noted similar issues regarding personal jurisdiction over Mylan currently certified for interlocutory appeal before the Federal Circuit in *AstraZeneca* and *Acorda*. *Id*., Memorandum Order at 2 (D. Del. Mar. 30, 2015) (per this Order, either party may also file such motion). As we will see, Judge Stark's recent denial of Mylan's motion to dismiss, based on Judge Burke's opinion, demonstrates a move toward Judge Simandle's reasoning in *Otsuka*, adopting a factor-based framework, where courts analyze questions of personal jurisdiction based on facts such as the State's business registration statute and a defendant's compliance with that statute, the appointment of a process agent, and whether that defendant has generated substantial revenues in that state. Judge Stark's decision also reflects a trend of moving away from Judge Sleet's line of thinking in *AstraZeneca*.

Additionally, in *Senju Pharm. Ltd. v. Metrics, supra,* 2015 BL 90802, the New Jersey Court again faced the general jurisdictional issue. One of two defendants, Metrics, a North Carolina company, was registered to do business in New Jersey and sent a Paragraph IV notice letter to plaintiffs. *Id*. at *1. That Court held that, since consent jurisdiction is firmly established in both New Jersey and Third Circuit precedent, personal jurisdiction existed over Metrics. The opinion notes that *Daimler* does not affect consent jurisdiction and that the Federal Circuit has not yet ruled on the issue.[5]

III. The Importance to ANDA Litigants of *Otsuka*'s Revelation of an Inter-District Split on Personal Jurisdiction

A. The Road to Suit in New Jersey

As stated earlier, *Otsuka* provides a factor-based framework for determining general jurisdiction in response to a motion to dismiss: (i) whether a defendant has registered to do business in the state; (ii) whether the language of the state's business registration statute requires maintenance of a registered office and appointed agent for service of process; (iii) whether defendants actually maintain an office and appointment of an

[3] Additionally, like in *Otsuka*, since Mylan Inc. was named as a defendant in *Acorda,* Judge Stark granted limited jurisdictional discovery over the specific jurisdiction issue as to Mylan Inc., but the parties agreed to a stipulated dismissal. *Id*., Dkt. 39; *see also Novartis Pharm. Corps. v. Mylan Inc., supra,* 2015 BL 70580 (D. Del. 2015).

[4] Judge Gilstrap reached a similar decision on personal *specific* jurisdiction in the Eastern District of Texas in *Allergan Inc. v. Actavis Inc*., on the fact that the ANDA filer's ''conduct will cause substantial harm to Allergan in Texas'' (where the reference listed drug is manufactured and where its nationwide distribution is coordinated). *Id*., No. 2:14-CV-638, 2014 BL 361759 (E.D. Tex. Dec. 23, 2014) at *6-7. Judge Gilstrap emphasized the generic filer's independent contacts with the state, such as: (i) its licensure to distribute prescription drugs; (ii) its establishment of wholesalers and retailers; and (iii) its intent to target the state for the sale of the proposed generic drug. *Id*.

[5] The Court allowed limited jurisdictional discovery to determine if the other defendant, Mayne Pharma (an Australian Corporation) had any contacts with its supplier in New Jersey to support a finding of personal specific jurisdiction. *Senju*, 2015 BL 90802 at *8-11. The opinion shows that Mayne Pharma manufactures and sells generic drug products around the world, and its corporate predecessors had offices in New Jersey and had filed lawsuits in New Jersey. *Id*. Ultimately, the parties entered into a stipulation whereby: (i) Plaintiffs dismissed its claims against Mayne Pharma without prejudice; (ii) Mayne Pharma agreed to be bound by any injunction rendered to Metrics; (iii) Mayne Pharma agreed to accept service of a subpoena and respond to discovery requests as if Mayne Pharma were a named defendant; and (iv) Metrics agreed to consent to jurisdiction and not challenge the same or seek a change in venue, or challenge the Court's order denying the motion to dismiss. *Id*., No. 14-3962, Dkt. 94 (entered April 17, 2015).

in-state agent; and (iv) whether a defendant derives substantial revenues from that state. As we will show, this analysis provides a more robust basis for general jurisdiction than arguing the presence of ''exceptional'' situations which *Daimler* recognized but provided no guidance on *i.e*. those circumstances necessary for general jurisdiction when the corporate defendant is not incorporated in the forum or does not have its principal place of business there.

The *Otsuka* opinion also addresses *Daimler*'s ''proportionality approach'' that may impact smaller businesses unfairly because they are more likely subject to suit in the markets they principally target, as raised in Justice Sotomayor's concurrence in *Daimler*: ''[r]ather than ascertaining the extent of a corporate defendant's forum-state contacts alone, courts will now have to identify the extent of a company's contacts in every other forum where it does business in order to compare them against the company's in-state contacts'' *Daimler* at *771-72. Smaller, ''foreign'' pharmaceutical generics that only do business in certain States may breathe a sigh of relief, if only momentarily, because *Daimler*'s ''relative''-based minimum contacts assessment means they would not be subject to general personal jurisdiction in States based on general contacts where their amount of ''in-state'' sales and business is relatively miniscule compared to their total operations. *Id.* However, as we will explore, district courts across the nation seem to be fashioning more holistic and practical approaches to the general jurisdiction question, despite *Daimler*'s test.

B. Procedural History

Mylan Pharmaceuticals, Inc. submitted an ANDA to the FDA, seeking approval to market a generic version of Otsuka's Abilify® product. *Otsuka* at *3. That submission included a Paragraph IV certification that the Abilify® Orange-Book patents were invalid and that the commercial manufacture, use, sale, offer for sale or importation of Mylan Inc.'s generic product would not infringe Otsuka's Abilify® patents. *Id*. Mylan Inc. notified Otsuka of its ANDA filing and certification of noninfringement and/or invalidity. *Id*.

In response, Otsuka filed a complaint in the District of New Jersey, alleging that Mylan Inc.'s proposed generic product, if approved, would infringe at least one claim of five patents that Otsuka claimed covered its Abilify® product. *Id*. Otsuka sued all three Mylan defendants, as opposed to just the ANDA-filer, alleging that the three ''operate as a single integrated business with respect to regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States,'' Complaint, *Otsuka*, 14-04508 (filed July 11, 2014), ECF Dkt No. 1 at ¶ 10. Otsuka's specific allegations against Mylan Ltd., Mylan Inc.'s Indian subsidiary, show that Otsuka deliberately included the foreign subsidiary in this action. Otsuka alleged that Mylan Ltd. manufactures and supplies low cost, high quality active pharmaceutical ingredients (''APIs'') to Mylan Inc., including Mylan Inc.'s aripiprazole API; that Mylan Ltd. is the drug master file (DMF) holder of aripiprazole; that Mylan Ltd. markets and sells generic drug products throughout the U.S.; that Mylan Ltd. wholly owns a New Jersey-based subsidiary (Mylan Laboratories, Inc.) that holds a drug wholesale distribution license in New Jersey, and that according to Mylan Inc.'s 2011 10-K Report, Mylan Inc. ''holds approximately 98% ownership and control in Mylan Laboratories Limited,'' and both share common corporate directors. *Id*., Complaint at ¶ 4, 9.

Each Mylan defendant moved to dismiss Otsuka's complaint for lack of general and specific jurisdiction, arguing that it lacked any claim-related or jurisdiction-conferring contacts with New Jersey. *Otsuka* at *2; *see also id*., Mylan's Mot. To Dismiss, ECF Dkt No. 15; Mylan's Reply at ¶¶ 1–10, ECF Dkt No. 29. Otsuka, in response, asserted three grounds for the exercise of personal jurisdiction over the Mylan defendants: (1) general jurisdiction, notwithstanding *Daimler;* (2) general jurisdiction based upon consent; and (3) specific jurisdiction. General jurisdiction requires that the defendant's contacts be ''so 'continuous and systematic' as to render them essentially at home in the forum State.'' *Otsuka* at *4. Specific jurisdiction requires that the suit ''arise out of or relate to the defendant's [specific] contacts with the forum.'' *Id*.

Specifically, Otsuka argued, in part, that the Mylan defendants': (i) compliance with New Jersey's foreign corporation licensing and registration statute constituted consent to the Court's jurisdiction; (ii) future intent to market and distribute its generic products in New Jersey suffices for specific jurisdiction; and (iii) compliance with licensing and/or registration requirements, their revenues derived from sales in New Jersey, and their related activities constituted ''continuous and systematic contacts'' with New Jersey for purposes of general jurisdiction. *Otsuka* at *1, *5-9. In support of their motions to dismiss, the Mylan defendants argued that their New Jersey contacts, coupled with their lack of corporate offices, facilities, and records in New Jersey, were not sufficient to meet the Supreme Court's *Daimler* test for general jurisdiction. *Id*. at *5, *7; *see also id*., Otsuka's Opp'n at ¶¶ 9–19, ECF Dkt No. 25 (redacted).[6]

The core issues addressed by the New Jersey Court were whether the Mylan defendants' contacts rendered them ''at home'' in the State of New Jersey, whether Mylan's registration to do business in New Jersey and appointment of an in-state agent for service of process amounted to consent to the Court's general personal jurisdiction, and whether, in submitting an ANDA for FDA approval, the Mylan defendants purposefully directed activities to this forum. *Id.* at *1-2.

C. The Mylan Defendants' Specific Contacts with New Jersey

[6] The Mylan defendants only disputed whether the quantum of connections alleged by Otsuka suffices for purposes of personal jurisdiction, in view of *Daimler*'s ''sea-change'' jurisdictional decision. The Mylan defendants did not dispute that they complied with NJ's registration requirements, that each holds a distribution license there, or that they generate revenues from sales in NJ. *See* Declaration of Robert S. Tighe, CFO-North America at Mylan Pharmaceuticals, Inc., in Support of the Mylan Defendants' Motion to Dismiss (''Tighe Dec.'') at ¶¶ 8-9, 11; Tighe Supplemental Dec. at ¶ 2, *Otsuka*, 14-04508, ECF Dkt Nos. 16 and 50, respectively. They did, however, argue neither of them maintains any corporate offices, facilities, or records in New Jersey. *See, e.g., id*., Mylan's Br. at ¶¶ 5–11, ECF Dkt No. 16; Mylan's Reply at ¶¶ 1–10, ECF Dkt No. 29.

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The Court found that Mylan Inc. is a Pennsylvania corporation having a principal place of business in Pennsylvania, that since 2006, Mylan Inc. has been authorized to transact business in New Jersey as a foreign corporation pursuant to New Jersey's registration statute, that Mylan Inc. identified a registered office in New Jersey and designated an in-state agent for service of process, and that Mylan Inc. holds a wholesale distribution license and generates more than $100 million in annual revenues in New Jersey. *Id*. at *2. The Court also noted that Mylan Inc. had litigated over 30 cases in the District of New Jersey, as both a plaintiff and defendant. *Id*. The Court further noted that despite the foregoing enumerated contacts, Mylan Inc. contends that it has no permanent, physical presence in New Jersey. *Id*.

The Court found that Mylan Pharmaceuticals, Inc., a Mylan Inc. subsidiary, is a West Virginia corporation, and has contacts with New Jersey similar to those of Mylan Inc.: it registered to do business in New Jersey, appointed an in-state agent, holds a New Jersey wholesale distribution license and generates annual revenues in excess of $50 million in New Jersey. *Id*. And, it has been an equally active litigant. *Id*.

As for Mylan Ltd., Mylan Inc.'s Indian subsidiary, the Court found that Mylan Ltd. has not registered to do business in New Jersey, nor has it appointed an agent in New Jersey for service of process. *Id*. at *3. It does, however, hold a wholesale distribution license in New Jersey, has generated some revenue attributed to New Jersey, and was involved in three cases in New Jersey. *Id*.

D. The Otsuka Court Harmonizes Daimler With International Shoe To Revive The Doctrine of General Jurisdiction

The *Otsuka* Court first analyzed whether the Mylan defendants met *Daimler*'s ''at home'' test. Appreciating that *Daimler* had expressly overruled as ''unacceptably grasping'' the longstanding test finding general jurisdiction when a corporation ''engaged in substantial and continuous business'' in the forum state, the Court applied *Daimler*'s paradigm for determining whether a corporation is ''at home'' in the forum: whether the defendant is incorporated there or the forum is its principal place of business. *Otsuka* at *5. The Court found that none of the Mylan defendants meet this test. *Otsuka* at *7. Although the Court recognized that *Daimler* had stated that in an exceptional case, the contacts may be sufficient ''to render the corporation at home in the state,'' it expressly declined to decide that Mylan Inc.'s contacts rose to that level based on the record before the Court. *Id*.

The Court then determined that it could exercise general jurisdiction over Mylan Inc. because those defendants had consented to the Court's exercise of general jurisdiction, applying the holding in *International Shoe v. Washington,* 326 U.S. 310. The Court concluded that (i) registering to do business in New Jersey, and (ii) generating substantial revenues in New Jersey, met the ''consent-by-registrant'' test. First, the Court looked at the State of New Jersey's registration statute, which requires that ''every foreign corporation authorized to transact business'' in the State of New Jersey ''continuously maintain a registered office'' and ''a registered agent having a business office identical with such registered office.'' N.J.S.A. § 14A:4–1(1). The statute, in turn, provides that ''[e]very registered agent *shall* be an agent of the corporation . . . upon whom process against the corporation may be served.'' N.J.S.A. § 14A:4–2(1).

The Court looked at cases interpreting the breadth of language, and ultimately held that the designation of an agent for the service of process under N.J.S.A. 14A:4–1 amounted to consent by defendant to be sued in the state courts of New Jersey. *Otsuka* at *9 (citing *Sadler v. Hallsmith Sysco Food Servs.*, No. 08-4423 (RBK/JS), (Dkt No. 6)., 2009 BL 85206 (D.N.J. Apr. 21, 2009) (finding that because defendant conceded that it ''registered to do business in New Jersey and ha[d] a registered agent for service of process in New Jersey . . . [that defendant] consented to being sued in New Jersey''); *Randolph Labs. v. Specialties Dev. Corp.*, 62 F. Supp. 897, 898–99 (D.N.J.1945) (finding, under the Supreme Court's decision in *Neirbo*, that defendant corporation's designation of an agent for service of process in conformity with N.J.S.A. § 14:5–3 (now, N.J.S.A. § 14A:4–2) constituted ''consent'' to be sued in a federal court in the State of New Jersey).

Chief Judge Simandle concluded that consent-by-registration for purposes of general jurisdiction provided a valid basis for asserting personal general jurisdiction in light of *International Shoe*, even after *Daimler*, rejecting the Mylan defendants' argument that the post-*International Shoe* world could not be squared with *Daimler*. *Otsuka* at *8-9. Judge Simandle differentiated *Otsuka* from *Daimler*, finding that ''each Mylan Defendant has specific, undisputed contacts with this forum and an intention to market generic aripiprazole throughout the United States, *including in this forum*; and, at the time Mylan provided Otsuka with notice of its ANDA submission, Mylan had already filed related Abilify® ANDA litigation in this District. In that regard, this litigation concerns primarily domestic corporations and their domestic patent dispute, including Mylan's ANDA application to market a generic version of Otsuka's Abilify®, *a factual predicate far more related to domestic and forum interests and activities than that addressed by the Supreme Court in Daimler*.'' *Otsuka* at * 7. (Emphases added.) The Court explained that *Daimler* reflects the U.S. Supreme Court's jurisprudence on general jurisdiction, where there has been ''no consent to be sued'' or no appointment of an agent for service of process. *Id*. at *9 (citing *Int'l Shoe Co*., 326 U.S. at 317).

The Court then cited cases that upheld the exercise of personal jurisdiction based on the appointment of an agent for service of process, explaining that even though those decisions predated *International Shoe*, those cases remained good law. *See, e.g.*, *Neirbo Co. v. Bethlehem Shipbuilding Corp.,* 308 U.S. 165 (1939) (finding that the defendant corporation waived its right to contest venue in federal court in New York, by complying with a New York State statute that required it to designate an agent for service of process); *Pa. Fire Ins. Co. of Phila. v. Gold Issue Mining & Milling Co.,* 243 U.S. 93, 95 (1917) (finding that a corporation consented to personal jurisdiction in Missouri by appointing an agent for service under a Missouri statute). Accordingly, the Court found that Mylan Inc. consented to personal jurisdiction in New Jersey based on those defendants' compliance with New Jersey's registration statute and their engaging in a substantial amount of business in New Jersey. Mylan Inc. has not appealed

the *Otsuka* Court's decision, and in any event, can no longer do so.

Though *Acorda* and *AstraZeneca* reveal a split in Delaware jurisprudence on whether registering to do business in Delaware, or any U.S. State for that matter, remains a viable basis for finding personal jurisdiction, *Otsuka* may provide clarity and guidance on this issue while the interlocutory appeals are pending, based on consent-based personal jurisdiction sanctioned in *International Shoe*. *Otsuka* at *10. Judge Simandle reasoned, *in dictum*, that the majority of circuit courts that have considered the issue have concluded that compliance with registration statutes *may* constitute consent to personal general jurisdiction. *Id.* Thus, *Otsuka*'s rationale is more closely tied with Judge Stark's opinion in *Acorda*, but contrary to that of Judge Sleets' opinion in *AstraZeneca*.

E. Unanswered Jurisdictional Questions over Foreign Generics: Mylan Ltd.

The *Otsuka* Court reached a different result regarding Mylan Ltd., finding that it could not exercise general jurisdiction over Mylan Ltd. because it was not ''at home'' in New Jersey and it had not complied with New Jersey's registration statute. Thus, Mylan Ltd. had not consented to general jurisdiction. *Otsuka* at *12. The Court also found it also lacked specific jurisdiction over Mylan Ltd. because it appeared Mylan Ltd. has ''no appreciable connection to the alleged infringement issues''. *Id*. Otsuka had not identified any specific activities or ''relevant claims-based contact'' directed at New Jersey by Mylan Ltd. that related to Otsuka's infringement claims. *Id*. The Court found no general jurisdiction despite the fact that: (i) Mylan Ltd. manufactures and supplies the aripiprazole API to Mylan Inc., which Mylan Ltd. is the DMF holder of; (ii) Mylan Inc. owns a majority stake in Mylan Ltd. and shares common corporate directors; and (iii) Mylan Ltd. 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, however, the Court held that Otsuka did not plead any basis to ''impute the alleged jurisdictional contacts of [Mylan Ltd.]'s subsidiaries to Mylan Ltd. 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 Ltd. escaped jurisdiction potentially due to Otsuka's nature of its written pleadings.

However, Otsuka may still have some form of recourse against Mylan Ltd. in the litigation, particularly since it has been alleged to have helped develop and prepare Mylan Inc.'s ANDA. For instance, Otsuka could seek third party discovery of Mylan Ltd.'s documents and personnel through Mylan Ltd.'s U.S. subsidiary, Mylan Inc., based on the fact that Mylan Ltd. is the DMF holder and API manufacturer of aripiprazole. Also, when applying for an injunction against Mylan Inc., Otsuka may be able to argue that the scope of any such order would also sufficiently protect Otsuka's interests by prohibiting Mylan Ltd. from launching the Mylan defendants' generic Abilify® product in the U.S. However, since this topic is beyond the scope of this article, we will address additional strategy for both brand and generic pharmaceutical companies facing ANDA litigation, that involve foreign companies, in our next article in this series.

Daimler and *Otsuka* teach that foreign ANDA-filers might be subject to personal jurisdiction in the United States, and potentially even subject to jurisdiction in the plaintiff's forum. *See Zeneca*; *AstraZeneca* (Judge Sleet found specific jurisdiction to exist in Delaware over Mylan Inc., where brand company-patentee was organized, where Paragraph IV certification letter was sent, and where Mylan Inc. had been sued before). This post-*Daimler* view inexorably leads generics back to pre-Daimler jurisdictional problems, based on Fed. R. Civ. P. 4(k)(2). That Rule provides that if a defendant sued for a claim arising under federal law, such as a foreign ANDA-filer, 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 is consistent with the United States Constitution and laws.[7]

This issue was not raised in *Otsuka*. 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. A foreign generic can set up an office in its preferred jurisdiction and conduct activities there such that it can argue that it chose to be subject to personal jurisdiction in that particular state. The generic can also set up a 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, the generic should be able to select a preferred jurisdiction without materially altering its business operations. Again, since this is an area outside the focus of this article, we will address such practical implications of foreign entities for ANDA litigants in our next article in this series.

IV. Closing Remarks

A foreign corporation that is (i) registered to do business in a State pursuant to the State's registration statute, assuming it contains similar language to that of New Jersey, and that (ii) intentionally actually conducts substantial business in that State, likely will be deemed to have consented to personal (and general) jurisdiction in that State. It remains to be seen whether other district courts or the Federal Circuit will follow Chief Judge Simandle's reasoning and opinion, based on individual state business registration statutes and the interpretation of language contained in the same. As we await the outcome of the certified questions sent to the CAFC *via* interlocutory appeal from Judges Sleet and Stark[8], in light of the intra-Delaware as well as inter-district split on this issue, it is likely that generic com-

[7] 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.''

[8] Appellant Mylan's principal brief was filed in the *AstraZeneca* appeal on May 18, and on May 26, the Generic Pharmaceutical Association (supporting Mylan) and U.S. Chamber of Commerce (in support of neither party) filed their Amicus Briefs. Mylan is expected to also file its brief shortly in the *Acorda* case. *See* Case No. 15-1460, Dkt. 16-17 (Fed. Cir. 2015), and Case No. 15-124, Dkt. 21 (Fed. Cir. 2015), respec-

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panies will continue to file motions to dismiss for lack of personal jurisdiction until the courts come to a consensus regarding the effect of *Daimler* on jurisdictional issues in Hatch-Waxman litigation.

Regardless, the authors of this article believe that in light of *International Shoe*, *Daimler* did not limit the circumstances in which a defendant's unrelated contacts with a forum can give rise to personal general jurisdiction. Indeed, if anything, *Otsuka* makes apparent that we should not ignore the former Hatch-Waxman jurisdictional framework even after *Daimler*. When faced with questions of general jurisdiction over a foreign out-of-state defendant, we should closely examine a defendant's compliance with State registration statutes, defendant's appointment of a process agent, as well as that defendant's sales and revenue figures in the applicable State.

Our next article in this series will assess the implications surrounding the *Otsuka* Court's decision not to extend both specific and general jurisdiction over Mylan Ltd., Mylan Inc.'s Indian subsidiary, which left many questions unanswered. We will also discuss some practice-focused strategic tips for both U.S.-based brand pharmaceutical and non-U.S. based generic pharmaceutical entities (that partake in preparing or developing ANDAs abroad, and/or filing ANDAs in the U.S.) facing personal jurisdictional questions during Hatch-Waxman Act litigation in district courts.

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tively. Appellee AstraZeneca's brief is due July 2, 2015. *Ceteris paribus,* the Court could hear argument early this Fall.