Bloomberg BNA

Pharmaceutical Law & Industry Report®

Litigation

This article, the third in our series, examines how the Supreme Court's 2014 decision in *Daimler AG v. Bauman* affects personal jurisdiction in patent cases involving pharmaceutical companies.

The DAIMLER Series: Lessons In Personal Jurisdiction for Biologic and Biosimilar Litigants




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I. Introduction

This paper represents our final effort in the DAIMLER Series focused primarily on *Daimler*'s effects on jurisdiction for Hatch-Waxman litigants in the abbreviated new drug application (ANDA) context, with Paper I exploring the effects on ''at-home'' general personal jurisdiction, primarily through the lens of the *Otsuka v. Mylan* decision,[1] while Paper II focused on specific personal jurisdiction, discussing the effects of recent district court decisions and concluding with practice-based tips for ANDA litigants. This final paper explores the possible effects of these decisions, which arose in the ANDA context, on cases that arise under the Biologics Price Competition and Innovation Act (''BPCIA'').[2]

First, we provide an introductory primer to the complex BPCIA regulatory scheme and then explore how the Federal Circuit's recent decision in *Amgen v. Sandoz* possibly affected personal jurisdiction. *Second*, we provide readers with an update from the Federal Cir-

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[1] *Otsuka Pharmaceutical Co. Ltd. v. Mylan Inc. et. al*, No. 14–4508, 2015 BL 79496 (D. N.J. March 23, 2015).

[2] We suggest to those who have not yet read Paper I and Paper II in the series, do so. The three papers, provide a full appreciation of the key issues, facts and practice-based tips. For the prior papers, see the July 3, 2015, and Sept. 11, 2015, issues of Bloomberg BNA's Pharmaceutical Law & Industry Report (13 PLIR 958, 7/3/15) (13 PLIR 1315, 9/11/15).

 ISSN 1542-9547

cuit's recent broad ANDA decision on specific personal jurisdiction and how this affects litigation strategy moving forward. *See Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals, Inc.*, No. 2015-1456; *AstraZeneca AB. v. Mylan Pharmaceuticals, Inc.*, No. 2015-1460 (Fed. Cir. Mar. 18 2016).[3] *Third*, because no court has ruled on personal jurisdiction in the BPCIA world, we explain how lessons from the post-*Daimler* ANDA cases may affect the biologics space and offer some practice-based tips to practitioners that operate in the biologic and biosimilar arenas.

II. The Ball Begins: A Brief Primer on the Biologics Price Competition and Innovation Act—Parallels to ANDA

In the BPCIA, Congress orchestrated a complex series of dance steps to provide an abbreviated pathway for regulatory approval of follow-on biological products that are similar to FDA-approved biological products. In many ways, the statute parallels the Hatch-Waxman Act for small molecule drugs, allowing follow-on competitors with a biosimilar product to benefit from clinical data obtained by the reference-product sponsor (''sponsor''). Biosimilarity depends on analytical studies that show high degrees of similarity, notwithstanding different clinically inactive components. Qualifying biologics are referred to as ''reference products.'' Applicants for a reference product submit a biologic licensing application to seek initial approval of a biologic-based treatment. ''Biosimilar'' applicants can file abbreviated biologics licensing applications (''aBLAs'') under 42 U.S.C. § 262(k), as early as four years after the FDA first approves or licenses the reference product. But, the FDA will not approve an aBLA until at least twelve years have passed from FDA licensure of the reference product. Thereafter, the first aBLA-filer typically receives market exclusivity of between one year and 42 months, depending on various contingencies laid out in the BPCIA. 42 U.S.C. § 262(k)(6).

A. The ''Patent Dance''—Important for the Jurisdictional Question

Unique to the aBLA context the statute prescribes a ''patent dance'' structure, where the aBLA applicants (''applicant'') exchange confidential information with the sponsor, including manufacturing information. 42 U.S.C. § 262 (l)(1)(B)(i), (l)(2). Later, we shall see that this section has become a battleground as sponsors and applicants struggle over conflicting interpretations. These disclosures occur no ''later than 20 days after the Secretary notifies the . . . applicant that the application has been accepted for review.'' § 262(l)(2). Within 60 days, the sponsor provides a list of patents that it believes it could assert for patent infringement against any unauthorized party that makes, uses, offers to sell, sells, or imports into the United States the biological product that is the subject of the application. § 262 (l)(3)(A)(i). The product sponsor identifies patents on the list that it would license to the applicant. § 262 (l)(3)(A)(ii).

Following receipt of the product sponsor's patent list, the applicant responds within sixty days by listing the sponsor's patents that the applicant believes the sponsor could reasonably assert against the applicant if not licensed for the biological product that is the subject of the application. § 262 (l)(3)(B). The applicant also must describe in detail, on a claim by claim basis, the factual and legal basis for the applicant's opinion that any listed patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product identified in the application or a statement that applicant does not intend to begin commercial marketing until after the patent expiration date. *Id*., at § 262 (l)(3)(B)(ii), (iii).

After the sponsor receives the applicant's response, the sponsor has sixty days to respond, detailing on a claim by claim basis the factual and legal basis that supports sponsor's opinion that the commercial marketing of the aBLA applicant's biological product infringes an identified patent. § 262 (l)(3)(C). After the completion of disclosures, the sponsor and applicant must negotiate in good faith to agree on which listed patents, if any, are subject to an action for patent infringement. § 262 (l)(4)(A). In the event the parties cannot agree, each party then lists the patents it believes should be at issue in the suit, provided that the number of patents listed by the sponsor cannot exceed the number listed by the applicant. *Id*., at § 262 (l)(5).[4] To enjoin biosimilar launch, the sponsor has thirty days to bring a patent infringement suit on the relevant patents, providing the FDA a copy of the complaint; if the sponsor does not bring suit within the first 30 days, then the sponsor can recover only royalties in any subsequent litigation (and the first aBLA filer retains its one year exclusivity).[5] *Id*., at § 262 (l)(6).

Another essential feature of the BPCIA requires notice of commercial marketing: The biosimilar must provide the biologic with a notice of commercial marketing 180-days prior to product launch. This notice serves as a trigger for further pre-launch litigation because after the notice, the brand company can bring a declaratory judgment action on any patents not included in the first action—*i.e*., patents that were not agreed upon during the patent dance or include methods of manufacture claims. This second ''wave'' of litigation serves an important function because biologics can seek injunctive relief in these actions to delay the biosimilar's market entry.[6]

B. No Escape from the Party for Biosimilars—''Artificial'' Acts of Infringement

The BPCIA provides that the submission of an aBLA results in an act of ''artificial'' infringement under 35

[3] The Federal Circuit addresses both the *AstraZeneca* and *Acorda* district court cases in one appellate opinion. In this paper, we refer to the consolidated appeal as *Acorda/AstraZeneca v. Mylan*, Nos. 2015-1456, -1460 (Fed. Cir. Mar. 18, 2016) (''*Acorda/AstraZeneca*'').

[4] If the parties cannot agree over the list of asserted patents, the statute permits the biologic sponsor to list the same number of patents as (or less than) the biosimilar identifies. If the biosimilar identifies no patents, the biologic still can list one patent in response.

[5] The BPCIA does not contain a 30-month FDA stay on aBLA approval, but the FDA cannot license a biosimilar for 12 years after the initial RLP sponsor's drug obtained an FDA-license.

[6] If the biologic sponsor elects not to pursue some patents during the second ''wave,'' biosimilar applicants may file for declaratory judgment at that time. *Cf.* 42 U.S.C. Section 292 (l)(8)-(9) (not explicitly preventing such declaratory judgment actions in such scenarios).

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U.S.C. § 271(e)(2)(C),[7] paralleling the Hatch-Waxman treatment of ANDA submissions. Thus, just as § 271(e)(2)(A), which provides that the mere submission of an ANDA application under the Hatch-Waxman framework creates a technical ''act of infringement'' and the requisite case or controversy, submitting an aBLA under the BPCIA with respect to a patent identified in the list of patents during the patent dance also counts as technical infringement. *See* 35 U.S.C. § 271(e)(2)(C)(i).[8] Applicants who refuse to engage in the patent dance nevertheless trigger statutory infringement, as well. 35 U.S.C. § 271 (e)(2)(C)(ii).[9]

C. The Amgen Waltz versus the Sandoz Shuffle

1. Background

The Federal Circuit's recent decision in *Amgen v. Sandoz* constitutes the first opportunity to interpret whether the BPCIA requires the patent dance set forth in 42 U.S.C. § 262 (l)(2)(A). Sandoz had filed an aBLA on Amgen's biologic Neupogen® (filgrastim), seeking to market its biosimilar Zarxio™ (filgastrim-sndz), accepted by the FDA in July 2014. *Amgen v. Sandoz,* 794 F.3d 1347, 1353 (Fed. Cir. 2015). Sandoz notified Amgen of its application, but opted not to provide its aBLA and manufacturing information identified in § 262 (l)(2)(A), noting that Amgen could bring suit pursuant to § 262 (l)(9)(C).[10]

At the district court level, Sandoz argued that the patent dance was optional, and Judge Seeborg of the District Court for the Northern District of California agreed. *Amgen Inc. v. Sandoz Inc*., No. 14-04741-RS, at *11 (N.D. Cal. Mar. 19, 2015) (holding, *inter alia*, the BPCIA's reticulated information exchange and patent resolution procedures are not mandatory for § 351(k) biosimilar applicants). Sandoz further argued that it could provide Amgen with 180-day notice of commercial marketing, as required by § 262 (l)(8)(A), *before* securing FDA approval. The District Court agreed. *Id.* at *7 (also holding, *inter alia*, that the plain language of the statute allows for the 180-day notice of commercial marketing to come well before the licensure of a § 351(k) application). Amgen promptly appealed to the Federal Circuit.

2. The Federal Circuit sides with Sandoz that the patent dance is not mandatory and sides with Amgen that the statute requires 180-day notice, which must occur after FDA licensure.

The Federal Circuit decision contains three separate opinions,[11] and Sandoz requested *en banc* rehearing. The full Federal Circuit denied Sandoz's request, leaving the Federal Circuit decision intact. For now, the case presents the position of the Federal Circuit, divided as it is, on a complicated matter of statutory construction.

First, the Federal Circuit held that the patent dance was not mandatory, finding that biosimilars could elect in or out of the dance, siding with Sandoz on this issue. The patent dance is optional—an advantage for biosimilars, given that it takes about eight months to complete, potentially delaying biosimilar approval, based on the statutory language. *Amgen v. Sandoz,* 794 F.3d 1347, 1357 (Fed. Cir. 2015). The court looked to the pertinent statutory provisions in their totality. Amgen relied on 42 U.S.C. § 262 (l)(2)(A), which requires the applicant—here, Sandoz—to provide the sponsor with a copy of the application, including information that describes the process or processes used to manufacture the biosimilar, within 20 days after the FDA notifies the applicant that it accepted the application for review. But Sandoz argued that the context of the whole statute rendered the provision optional. Amgen argued that the ''shall provide'' language in that section rendered the disclosure provision mandatory.

Paragraph (l)(9)(C), for example, addresses situations where the applicant does not fulfill its obligations under paragraph (2)(A) [initiating the patent dance], in which case, the sponsor may bring an action for declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product. And the corresponding part of 35 U.S.C. § 271(e)(2)(C)(ii), as amended by the BPCIA, provides that ''[i]t shall be an act of infringement to submit . . . if the applicant fails to provide the application and information required under § 351(l)(2)(A) [of the BPCIA], the application seeking approval of a biological product'' constitutes ''an act of infringement.''

The Federal Circuit noted that although Section 262 (1)(2)(A) when ''read in insolation,'' supported Amgen, the language could not be read in isolation, and the other parts of the statute address situations where an applicant chooses not to engage in the patent dance. *Amgen Inc. v. Sandoz Inc*., 794 F.3d 1347, 1355 (Fed. Cir. 2015). An applicant's failure to disclose results in patent infringement litigation, and ultimately the sponsor can obtain the undisclosed information at issue through discovery.

Second, the Federal Circuit also addressed the issue of when the statute required the biosimilar to file its commercial marketing notice. The Federal Circuit sided with Amgen, holding that, in the absence of the patent dance, the statutory language compelled the 180-day notice and that the notice could only be sent after FDA licensure. The Federal Circuit relied on the statutory language, finding that Congress could have used language that allowed notice during the pendency of the application, but instead referred to the product ''li-

[7] 35 U.S.C. § 271(e)(2) provides, in pertinent part, that it ''shall be an act of infringement to submit . . .'' various regulatory applications. The subsections in turn address different regulatory regimes: 271(e)(2)(A) addresses Hatch Waxman; 271(e)(2)(B) addresses animal drugs; and 271(e)(2)(C) addresses biologics and biosimilars.

[8] Section 271(e)(2)(C)(i) focuses on the patent dance: with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, . . .

[9] Section 271(e)(2)(C)(ii) provides: if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act, . . .

[10] That section provides: ''If a[n]. . . applicant fails to complete an action required under paragraph (2)(A) [initiating the patent dance] . . . [the] sponsor, but not the . . . applicant may bring an action . . . for declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.''

[11] Lourie, J. writing for majority; Newman, J. and Chen, J. dissenting-in-part.

censed'' as a biosimilar in the statute. *Id.* at 1352.[12] Amgen argued that an applicant can only give notice *after* the FDA licenses the biosimilar product, whereas Sandoz argued that it could give its 180-day notice *before* approval—that the approval simply need to be in effect on the actual commercial launch date. Sandoz claimed that requiring the biosimilar to submit its commercial marketing notice after FDA approval effectively added 180-days of exclusivity to the sponsor's term, but that submitting the notice before FDA approval allows the biosimilar to begin marketing immediately after FDA approves its aBLA. *Id*. at 1357.

Amgen v. Sandoz effectively rendered the patent dance elective since it found that the BPCIA provides the sole remedy for the failure to share information on the aBLA and manufacturing processes (*i.e*. immediate declaratory judgment infringement action by the reference product sponsor).[13] But, the decision also required full FDA licensure before the aBLA applicant can provide 180-day commercial marketing notice to the sponsor.

The Federal Circuit's decision on the notice issue benefits sponsors. This part of the decision seems to result in a *de facto* 12.5-year period of exclusivity for reference product sponsors (or, in the case where there is no longer a 12-year period in effect, a new 6-month exclusivity period). During the 180-day notice period, there is ample time for a reference product sponsor to seek and obtain an injunction against launch of a biosimilar, with the added weight of being able to argue that such an injunction would not disturb the status quo.

Sandoz has sought *certiorari* from the Supreme Court on whether the commercial marketing provision is effective if sent after FDA licensure and whether it is a ''stand alone'' provision (*i.e*. whether it is contingent upon the biosimilar invoking the patent dance). The Federal Circuit opinion leaves unclear whether biosimilars who opt-in to the patent dance process are required to provide the 180-day notice. [14]

Amgen contends that delaying the 180-day notice until after FDA approval ensures the existence of a fully crystallized controversy regarding the need for injunctive relief, as well as a defined statutory window that allows the court to assess the parties' rights before launch. Sandoz also challenged the Federal Circuit's ruling that the patent dance was optional.

III. Personal Jurisdiction: Comparing the BPCIA with the Hatch Waxman Act

The choices either to engage in the patent dance or to abstain lead to predictable results under 35 U.S.C. § 271(e)(2)(C). The sponsor can file suit either way based on the aBLA filer's act of ''artificial'' infringement within thirty days—but where the sponsor files typically is an important, strategic issue because often it can be decisive. Before and after *Daimler*, brands filed most ANDA cases in New Jersey or Delaware.[15] Brands also appreciated the trial courts' adeptness and experience with patent law, the situs of certain brand-plaintiffs and generic-defendants, as well as the lengthy time-to-trial statistics (in view of the 30-month stay). Brands relied on theories of general personal jurisdiction—often based on the defendant's license to distribute pharmaceuticals or conduct the business of making and selling drug products in those states.[16]

Daimler made asserting general jurisdiction over corporations more challenging in states that are not a particular defendant's principal place of business or state of incorporation.[17] The potential arguments for general consent-based jurisdiction, as discussed in our first DAIMLER Series paper, should apply in the biologics context, in the absence of any contrary district court decisions. *Daimler* may have diminished reliance on general personal jurisdiction, as brand companies notably have shifted their focus from asserting general jurisdiction to arguing for specific jurisdiction under the totality of relevant factors approach.[18] The case for specific jurisdiction—as detailed in our second DAIMLER series paper, which addressed the ANDA context—may be stronger over a biologics applicant engaging in the patent dance, though the effects of abstaining are less clear. And, the Federal Circuit has confirmed the viability of specific personal jurisdiction for Hatch-Waxman and BPCIA litigants alike in its recent *Acorda* (No. 15-1456) and *AstraZeneca* (15-1460) (Fed. Cir. Mar. 18, 2016) opinions, which effectively found that an ANDA-filer can be subject to jurisdiction in any state where it will market the generic drug, once approved.

A. The Federal Circuit's latest pronouncements on Specific/General Personal Jurisdiction

In Paper II, we discussed how Delaware Judges Sleet and Stark, in *AstraZeneca* and *Acorda*, *supra*, respectively, found specific jurisdiction over Mylan in the post-*Daimler* ANDA context based, *inter alia*, on the submission and receipt of a Paragraph IV notice letter (in the ANDA context).[19] Both judges disagreed on whether the court had general jurisdiction (Judge Stark held it did; Judge Sleet held it did not) and certified their jurisdictional questions to the Federal Circuit for

[12] The statute requires commercial marketing notice ''after the FDA has licensed the biosimilar product;'' the statute uses others terms like ''the biological product that is the subject of the application'' elsewhere, and ''[i]f Congress intended . . . to permit effective notice before the product [was] . . . licensed, it would have used the 'subject of' language.'' *Id.* at 1357.

[13] The Federal Circuit's decision that the patent dance is optional creates a straightforward path for marketing biosimilars for which there is no robust patent portfolio—a boon for biosimilars, because the dance can take about 8 months to complete. Nevertheless, for newer biological products with a robust patent portfolio, biosimilar applicants may choose to engage in the patent dance to limit the number of patents to litigate.

[14] 42 U.S.C. § 262 (l)(8)(B).

[15] According to the legal analytics firm Lex Machina, brands filed 41% of all ANDA suits in the District of Delaware between 2009 and 2015 and 32 % in the District of New Jersey. Many pharmaceutical companies are based in New Jersey, while many major companies are incorporated in Delaware.

[16] *See* ''*The DAIMLER Series: Five Personal, Specific Lessons Learned for Hatch Waxman ANDA Litigants*'' (13 PLIR 1315, 9/11/15) at 2.

[17] *Id.*

[18] *Id.*

[19] Judge Stark's *Acorda* decision, which declined to rely on the location of the recipient of the notice letter, adopts a more factor-based framework - such as registration to do business and prior ANDA cases in the state. He found consent-based general jurisdiction based on similar reasoning, whereas Judge Sleet did not. For a detailed discussion of Judges Sleet and Stark's opinions predicting the Federal Circuit's holding in this appeal, *see* Paper II of this series.

  PLIR ISSN 1542-9547

interlocutory review.[20] But both judges found specific jurisdiction, and the Federal Circuit recently affirmed both decisions in the consolidated appeal—ultimately making it easier for brands to choose where to sue allegedly infringing generics. [21]

The majority did not reach the issue of general jurisdiction, though it is worth noting that several specific jurisdiction arguments adopted in the opinion clearly overlap with the general jurisdiction analysis. The Federal Circuit applied a broad interpretation of specific jurisdiction, which allows brand companies to file suit wherever the generic plans to make sales, provided it is not unfair to the defendant.[22] This result will discourage preliminary personal jurisdiction challenges, especially in ANDA cases, and incentivize litigants to focus more on the merits of the case.

B. Specific Jurisdiction in the ANDA Context

Readers may recall that Mylan filed motions to dismiss in both cases, arguing that the Delaware courts could not exercise general or specific personal jurisdiction under *Daimler* consistent with the Due Process Clause of the Fourteenth Amendment because Mylan is incorporated and headquartered in West Virginia. The Federal Circuit held that, after *Daimler*, specific jurisdiction over Mylan was appropriate in Delaware given that the generic drug will ultimately be sold in the state, as well as everywhere else in the country. Judge Taranto[23] explained the constitutional requirements for specific personal jurisdiction *i.e*. ''when the defendant has certain minimum contacts with the forum such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice.'' *Id.* at 7 (citing *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)).

The court relied on two main arguments to justify Delaware exercising specific jurisdiction under the minimum-contacts analysis, namely that: (1) both the statutory language of the Hatch-Waxman Act and Congressional intent suggest that the Paragraph IV certification and the ANDA-filing itself are acts with ''sufficient close connection'' to ANDA approval and marketing; (2) Mylan's intent and ability to sell its generic products in Delaware *in the future* justify Delaware exercising personal jurisdiction over Mylan. The opinion ignored Judge Sleet's prime focus on the situs of the recipient of a Paragraph IV notice letter and adopted Judge Stark's line of reasoning.

The Federal Circuit found that, by filing an ANDA and serving a Paragraph IV notice letter, Mylan took actions that have real-world consequences that harm the patent-owner. The majority looked at the economic realities of a defendant's commitment to preparing an ANDA—ANDA filing fees, clinical studies to prove bioequivalence, and preparation of manufacturing facilities—and found a concrete plan to market in the future: a ''costly, significant step'' made ''for the purpose of engaging in . . . injury-causing and allegedly wrongful marketing . . . in Delaware.'' *Id.* at 8-9. Filing an ANDA can cost somewhere between $250,000 to $20 million. *Id.* at 11. Congress created the artificial infringement trigger in 35 U.S.C. § 271(e)(2), recognizing that ANDA's inherent purpose is to allow a generic to ''engage in the commercial manufacture, use, or sale of a drug.'' *Id.* at 9. Looking at the significant costs ANDA filers incur coupled with the statutory framework, the Federal Circuit concluded that ''Congress deemed the ANDA-filing to have a non-speculative causal connection to the ANDA filer's future infliction of real-world market injury on the patent holder,'' confirming the closeness of the connection between Mylan's ANDA filings and the marketing activities for which Mylan, by those filings, seeks approval.'' *Id.* at 12.

The court then addressed the practical consequences of Mylan's actions, noting that Mylan's distribution channels *combined with* its ANDA filings establish that Mylan plans to sell its drug in the entire U.S. market, and it does some business indirectly or directly in every state. *Id.* at 15. The court recognized that Mylan intended to do business in Delaware—pointing to its business registration in the state and appointment of an in-state registered agent for service of process: Mylan's ''certificate of registration notes that it intends to engage in pharmaceutical manufacturing, distribution, and sales in Delaware.'' *Id*. Further, Mylan registered ''with the Delaware Board of Pharmacy as a licensed Pharmacy-Wholesale and a Distributor/Manufacturer CSR [controlled substances registration].'' *Id.* Even if Mylan did not sell directly in Delaware, ''it has a network of independent wholesalers and distributors with which it contracts to market the drugs in Delaware.'' *Id.* The court found this type of sales activity significant, and that it constituted sufficient minimum-contacts to meet the specific-jurisdiction test. *Id.* The Court added that ''the marketing in Delaware that Mylan plans is suit-related: the suits over patent validity and coverage will directly affect when the ANDA can be approved to allow Mylan's Delaware marketing and when such marketing can lawfully take place.'' *Id*. at 9-10.

After finding that Mylan had the requisite minimum contacts with Delaware, the Court noted that Mylan still could defeat specific personal jurisdiction if it ''sufficiently demonstrate[ed] that other considerations render jurisdiction unreasonable.'' *Id.* at 16. But the Court quickly closed that escape-path, finding that any burden on Mylan by virtue of a suit in Delaware was ''at most modest,'' as Mylan is a large generic manufacturer that has litigated many ANDA lawsuits in Delaware already, ''including some that it initiated.'' *Id.* The Court concluded that it could reasonably exercise specific jurisdiction over Mylan because Delaware had an interest in providing a forum to resolve disputes that ''involve the pricing and sale of products in Delaware and harm to firms doing business in Delaware,'' and the judicial system has an interest in efficiently resolving the mul-

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[20] *Compare Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, 78 F. Supp. 3d 572, 583–92 (D. Del. 2015) (Judge Stark holding that, ''*Daimler* does not eliminate consent as a basis for a state to establish general jurisdiction over a corporation which has appointed an agent for service of process in that state, as is required as part of registering to do business in that state''), *with AstraZeneca AB v. Mylan Pharm., Inc.*, 72 F. Supp. 3d 549, 555–58 (D. Del. 2014) (Judge Sleet holding that, ''[i]n light of the holding in *Daimler*, the court finds that Mylan's compliance with Delaware's registration statutes—mandatory for doing business within the state— cannot constitute consent to jurisdiction, and the Delaware Supreme Court's decision in *Sternberg* can no longer be said to comport with federal due process'').

[21] *Acorda/AstraZeneca*.

[22] Judge O'Malley, however, in her concurring opinion, held that she would affirm the lower court's decision but on grounds of both specific and general jurisdiction. *Id.*, Concurring Op. at 12.

[23] Judge Newman joined the majority.

tiple lawsuits pending in Delaware against other generic defendants based on the same patents.[24]

C. The Concurrence—General Consent-Based and Specific Jurisdiction

The concurrence serves as a cautionary tale for anyone who believes that general jurisdiction is a dead theory. *See also* Paper I, DAIMLER Series. Judge O'Malley's concurring opinion employed an ''effects'' test for specific jurisdiction[25] because Mylan's ANDA filing and Paragraph IV certification had the ''effect'' in Delaware of questioning the validity of and value of property rights of two Delaware corporations (Acorda and AstraZeneca's subsidiary). While similar to Judge Sleet's opinion in *AstraZeneca*, Judge O'Malley argues that the case could more easily have been decided on a less fact-intensive analysis, under general consent-based jurisdiction grounds, since Mylan complied with Delaware's statute that required it to register to operate in Delaware and to provide a local agent for service of process in the state.[26] *Id*., Concurring Op. at 6-7, 11. Judge O'Malley—like Judge Stark in *Acorda* and Judge Simandle in *Otsuka*—acknowledged that *Daimler* confirms that consent to jurisdiction is an alternative to the minimum contacts analysis. *Id*. at 6, 12. Judge O'Malley cited a long line of Supreme Court case law, including ''key'' case *Pennsylvania Fire Insurance Co. v. Gold Issue Mining & Miling Co.*, 243 U.S. 93 (1917) (held that appointment of an agent by a foreign corporation for service of process could subject the corporation to general jurisdiction).[27]

D. Practical Tips: Specific Jurisdiction in the Biosimilars Context

In the absence of Federal Circuit or district court guidance, but based on the five personal jurisdiction lessons we set forth in our prior paper, it seems the presence or absence of specific personal jurisdiction turns on whether the biosimilar has chosen to dance with the sponsor. *See ''The DAIMLER Series: Five Personal, Specific Lessons Learned for Hatch Waxman ANDA Litigants''* (13 PLIR 1315, 9/11/15). We explore each eventuality.

1. Specific Jurisdiction based on the Biosimilars that Dance

If filing of an ANDA and sending the Paragraph IV notice letter can form the basis for specific jurisdiction in the Hatch-Waxman context, then filing an aBLA and beginning the ''patent dance'' in the biologics context should provide the basis for specific jurisdiction. The aBLA requires bioequivalence data similar to the data that an ANDA demands. By filing an aBLA, the biosimilar expresses the same, if not more, monetary commitment to bring a product to market than does an ANDA applicant. By engaging in the patent dance, the biosimilar exhibits the same level of planning and commitment to marketing a biosimilar as does the sending of a Paragraph IV notice letter.

The notice letter and ANDA-filing constitute the first part of the Federal Circuit's analysis for specific personal jurisdiction for Hatch-Waxman litigants. The second part of the jurisdictional analysis considers distribution channels and business registration. A biologic may establish personal jurisdiction over a biosimilar in a state where the biosimilar is registered to do business, has an appointed agent for service of process, has a national distribution chain, and has previously engaged with wholesalers and pharmacies over other types of drugs in the jurisdiction at issue.

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[24] Three district courts have cited the Federal Circuit's decision in *Acorda/AstraZeneca*. *See Pfizer v. Mylan*, No. 15-26-SLR-SRF (D. Del. Apr. 4, 2016); *Helsinn Healthcare v. Hospira, Inc.*, No. 15-2077 (D.N.J. Apr. 5, 2016); *Allergan v. Teva*, No. 2:15-cv-1445-WCB (E.D. Tex. Apr. 19, 2016). In *Helsinn*, Judge Cooper cited *Acorda/AstraZeneca* to subject Hospira to specific personal jurisdiction in New Jersey: Hospira, although not incorporated in New Jersey, had litigated cases in the district. *Id.* at 12. And ''[u]nder the rationale set forth in *Acorda*, the Court [found] that Hospira's marketing of generic Aloxi® will, at least in some part, take place in new Jersey.'' *Id.* at 13. The court found that ''these facts establish sufficient minimum contacts to find specific jurisdiction over both Hospira and Worldwide with respect to the pending ANDA.'' *Id.*

In *Pfizer,* Magistrate Judge Fallon found specific jurisdiction with respect to Agila, a Mylan subsidiary, because it filed the ANDA and planned to market its product throughout the United States. Judge Fallon applied a consent-based theory: MPI had registered to do business in Delaware, and the court found that, ''[i]n accordance with Chief Judge Stark's decision and Judge O'Malley's concurrence in *Acorda*, and consistent with the Supreme Court's decision in *Daimler*. . . MPI's registration to do business in Delaware amounts to its consent to the personal jurisdiction of Delaware.'' *Pfizer v. Mylan*, No. 15-26-SLR-SRF, at 21. The court recommended limited discovery ''regarding the existence of an agency relationship between Agila and Mylan regarding the filing of the ANDA.'' *Id.* at 22-23.

And in *Allergan*, Judge Bryson, sitting by designation in the Eastern District of Texas, requested the parties submit supplemental briefing specifically addressing the *Acorda/AstraZeneca* decision, as the Federal Circuit issued *Acorda/AstraZeneca* after the motion to dismiss was fully briefed in *Allergan*. *Allergan v. Teva*, No. 2:15-cv-1445-WCB at 5. There were two defendants in this case challenging personal jurisdiction—Teva and Mylan. *Id.* Teva admitted that it planned to market its generic product in Texas, and Judge Bryson found that fact sufficient to exercise personal jurisdiction after *Acorda/AstraZeneca*. *Id.* Mylan, however, argued that the *Acorda/AstraZeneca* decision did not affect the pending motion to dismiss because it may be overturned on appeal. *Id.* Judge Bryson, however, found that Mylan's filing of the ANDA and intent to market nationwide—including presumably Texas—was sufficient for the court to exercise personal jurisdiction. *Id.* at 6-7.

[25] According to Judge O'Malley:''[T]he targeted nature of an ANDA filing – which is intended to challenge a particular patent owned by a known party with a known location'' sufficiently establishes specific jurisdiction because ''the harm is targeted only to these Delaware companies, occurs only in Delaware, and is only triggered by the filing of the ANDA.'' *Id*., Concurring Op. at 17.

[26] Del. Code Ann. tit. 8, § 371(b)(2)(i).

[27] On April 18, 2016, Mylan filed its petition for rehearing *en banc* in the *Acorda/AstraZeneca* appeals. Mylan argued that the decision is contrary to both Supreme Court and Federal Circuit precedent—namely, *Daimler*, *International Shoe*, and *Zeneca Ltd. v. Mylan Pharm., Inc*., 173 F.3d 829 (Fed. Cir. 1999) (mere filing an ANDA in Maryland does not establish jurisdiction over generic in Maryland). Pet. for Rehearing En Banc at 1, *Acorda/AstraZeneca*, No. 15-1456 (Fed. Cir. Apr. 18, 2016). Further, Mylan argued that the Court should resolve whether: (1) filing an ANDA supports specific personal jurisdiction over that party anywhere in the country; and (2) whether a party's compliance with mandatory business-registration statutes in a state constitutes consent to general personal jurisdiction. *Id.*

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2. Specific Jurisdiction based on Biosimilars that Reject the Dance—Biologics Beware

When the aBLA filer elects out of the patent dance mechanism, we might expect the filing of an aBLA and existence of national sales and distribution chains poised to sell in the state will result in a finding of specific jurisdiction. Absent the patent dance communications, the mandatory 180-day notice of commercial marketing may also invoke specific personal jurisdiction.[28] But that result is not foreordained because important distinctions exist between an ANDA-filer's Paragraph IV notice letter and the 180-day notice of commercial marketing in an aBLA case.

Because Paragraph IV notice letters are sent before litigation, courts evaluate the recipient of notice letters for purposes of establishing personal jurisdiction contacts. On the other hand, a biosimilar applicant only provides a notice of commercial marketing after the FDA licenses the biosimilar. This event could take place before the litigation begins, but it could also occur later in litigation—even after responsive pleadings because BPCIA litigation can commence either upon a biosimilar's refusal to engage in the dance (by virtue of the biologic immediately being able to bring a declaratory judgment claim) or if the biosimilar engages in the dance. Issues of personal jurisdiction must be resolved quickly in litigation, and if not raised early on, are waived per Fed. R. Civ. P. 12(h)(1). An aBLA notice of commercial marketing filed after suit begins likely will not affect personal jurisdiction if it occurs *after* the defendant-biosimilar answers the complaint.

As a practical matter, because of the personal jurisdiction implications of the patent-dance mechanism, biosimilar applicants have an incentive to opt-out of the dance, particularly since timing of commercial marketing notices is not entirely clear given uncertainties with FDA licensure. When the biosimilar opts out of the patent dance, the biologic company brings the suit for infringement, and a biologics company may rely on the commercial marketing notice to establish specific jurisdiction or business registration to establish consent-by-registration jurisdiction. But since the biosimilar may not send commercial marketing notices to biologics until after litigation begins (given delays with FDA licensure), it may avoid the basis for determining personal jurisdiction at the time the complaint is filed. Thus, biosimilars might be able to ''game'' the system.

For instance, biosimilars may strategically abstain from the patent dance and only send the 180-day marketing notice *after* FDA licensure – creating, over many foreign-based biosimilars with no presence in the U.S., a (specific) jurisdictional ''black hole'' up until the point of submission of the marketing notice letter. Of course, this strategy assumes the absence of general jurisdiction arguments. Since personal jurisdiction challenges are waived if not raised early in the proceedings, biosimilars may now have a way to legitimately contest specific personal jurisdiction under this strategy.

The situation gets even more complex for foreign-based biosimilars that are not registered to do business anywhere in the U.S. In such cases, a biologic needs to argue that long arm jurisdiction anywhere in the United States applies pursuant to Fed. R. Civ. P. 4(k)(2), in the absence of any forum with personal jurisdiction as long as exercise of jurisdiction is reasonable and fair. By refusing to engage in the patent dance, a biosimilar can limit the ways a biologic can argue for personal jurisdiction. This effect increases the likelihood that the suit will be dismissed and/or settled.

In the absence of such clarity, it makes sense that biosimilar-defendants should focus on challenges to specific personal jurisdiction, arguing, if possible, the absence of evidence about any future sales and marketing activities directed at the state, lack of a business registration license or appointed process server in-state, as well as lack of alleged infringing acts and residence in such state.

E. Personal Jurisdiction over the Preliminary-Injunction Action

A further complication arises in the context of the *second* ''wave'' in BPCIA litigation: When a patentee opts into the patent dance, the first ''stage'' of litigation includes only patents that the parties agreed on via the patent dance. After the 180-day notice of commercial marketing expires, the biologics company can bring a declaratory judgment action to enforce other patents it believes the biosimilar infringes.[29] The brand can seek a preliminary injunction to prevent the allegedly infringing biosimilar from reaching the market after the 180-day commercial notice.

If the notice is held to be a standalone provision, *i.e.* not contingent on the biosimilar's invocation of the dance, then if the brand applicant brings suit over the ''second wave'' of patents, the brand can argue that the biosimilar is not ''burdened'' by personal jurisdiction in the jurisdiction where it first filed suit.[30] This possibility puts the burden on the biosimilar to challenge personal jurisdiction before the second wave occurs to avoid the possibility of a crippling injunction.

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In Paper II, we provided practice-based tips for ANDA litigants based on post-*Daimler* jurisprudence. This paper has explained how that analysis translates into the BPCIA context. Future sales and marketing activities are just as important for determining specific jurisdiction in the BPCIA space as in ANDA cases. And the Federal Circuit's *Acorda*/*AstraZeneca* decisions show that marketing and distribution channels are essential to the specific-jurisdiction analysis, as well. As mentioned above, Paragraph IV notice letters in the

[28] *Amgen v. Sandoz* left open the question whether the commercial marketing notice was necessary for biosimilars who engage in the patent dance. At least one case has found the 180-day commercial notice is mandatory. Judge Cohn of the Southern District of Florida found the 180-day commercial marketing notice is mandatory when an applicant engages in the patent dance. *Amgen v. Apotex*, No. 0:15-cv-61631-JIC (S.D. Fla. Dec. 9, 2015) (order granting preliminary injunction). Sandoz has petitioned for certiorari review to gain clarity on whether the provision is mandatory for all litigants. Petition for Writ of Certiorari at ii, *Sandoz, Inc. v. Amgen, Inc.*, No. 15A672 (Feb. 16, 2016).

[29] In *Amgen v. Sandoz*, the Federal Circuit suggested in a footnote that method-of-manufacture claims could be the first phase of litigation: *Amgen v. Sandoz*, 794 F.3d. at n.3.

[30] *See Acorda*/*AstraZeneca* (finding Mylan's burden on being sued in Delaware to be modest, ''as Mylan, a large generic manufacturer, has litigated many ANDA lawsuits in Delaware, including some that it initiated.'').

ANDA context seem equivalent to the ''patent dance'', and, potentially, the 180-day notice of commercial marketing in BPCIA cases likely may be a powerful tool for establishing specific jurisdiction.

Corporate restructuring can affect the analysis: Foreign biosimilars can set up offices in their preferred jurisdictions and conduct domestic U.S. drug development and manufacturing activities from there. Such biosimilars can also set up subsidiaries in other preferred jurisdictions, and use them as bases from which to submit aBLA applications and ''patent dance'' communications. But, of course, the decision over where to sue depends not only on personal jurisdiction, but considerations of venue as well.[31]

F. BPCIA & General Consent-based Personal Jurisdiction

Paper I discussed how the District of New Jersey married the *Daimler* standard with *International Shoe* in *Otsuka Pharm. Co. v. Mylan Inc.*. No. 14-4508 (D.N.J. Mar. 23, 2015). In *Otsuka*, the court evaluated general jurisdiction in the ANDA context after *Daimler*, using a factor-based framework: (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 against for service of process; (iii) whether the defendants actually maintain an office and appointment of an in-state agent; and (iv) whether a defendant derives substantial revenues from that state.

Although the Mylan defendants in *Otsuka* failed the *Daimler* ''at home'' test for general jurisdiction, the *Otsuka* court found that the Mylan defendants nevertheless had consented to suit in New Jersey. The court found that by registering to do business in New Jersey[32] and generating substantial revenues there, the defendants met the ''consent-by-registration'' test, which provides a valid basis for general jurisdiction under *International Shoe*.

The ANDA context shows that BPCIA litigants, when faced with questions whether general jurisdiction applies to foreign out-of-state entities, should closely examine the biosimilar's compliance with state registration statutes, appointments of process agents, and sales and revenue figures in-state. Evaluation of compliance with registration formalities, and its relevant business revenues, will form the basis of arguments both for and against courts exercising personal jurisdiction.[33]

IV. Concluding Remarks—The Journey Ahead for BPCIA and ANDA Litigants

Consent-based general personal jurisdiction and specific personal jurisdiction issues in the post-*Daimler* world are as present in the BPCIA framework as they are in the Hatch-Waxman context. Conveniently, many of the same practice prescriptions likely will apply to aBLA filers, and a close analysis of ANDA-*Daimler* case law should serve BPCIA litigants as a reliable roadmap. The Federal Circuit's *Acorda*/*AstraZeneca* opinions show that specific jurisdiction is a good path for BPCIA and Hatch-Waxman litigants alike to establish personal jurisdiction over biosimilars and generics in cases for future infringement—and the act of filing an aBLA coupled with a market strategy may be enough for personal jurisdiction in the future. Brand pharmaceutical and biologic companies may file suits in places like the Eastern District of Texas, and continue to file suit in New Jersey and Delaware as their preferred choice-of-forum, absent any unfairness or burden on defendants. Indeed, the *Acorda*/*AstraZeneca* opinions may shut down future efforts by generics and biosimilars to challenge jurisdiction. In this respect, biosimilar and generic defendants are well-advised to carefully study (or re-structure, to the extent possible) their marketing plans when submitting their FDA applications, analyze prior sales of pharmaceutical products and relevant state substitution statutes regarding AB- or AT-rated drugs, and review existing drug distribution and wholesale agreements or licenses.[34]

How a court might determine specific jurisdiction in the BPCIA context based on the notice letter remains, at present, an open-question with very little guidance where the aBLA filer elects to proceed without the patent dance. Practitioners should keep in mind that, while the Federal Circuit's *Acorda*/*AstraZeneca* opinions will affect ANDA litigants directly[35], its holding will simi-

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[31] Currently, venue is proper wherever there is personal jurisdiction. The Federal Circuit recently affirmed this status quo in *In re: TC Heartland LLC, Order on Petition for Writ of Mandamus*, No. 2016-105 (Fed. Cir. Apr. 29, 2016) (permitting courts to continue to rely on the more expansive venue provisions of 28 U.S.C. § 1391(b) rather than the more limited scope under 28 U.S.C. § 1400(b)). Thus, unless TC Heartland files a petition for writ of certiorari with the Supreme Court, Congress is now the last hope for a more limited patent venue proposal (*infra* note 34).

[32] New Jersey's registration statute requires all foreign corporations maintain a registered office and agent, and provides that every registered agent shall be an agent of the corporation, against whom the corporation may be served. N.J.S.A. § 14A:4-1(1).

[33] Certain district courts in the ANDA context get around *Daimler*'s ''at home'' jurisdiction requirement with theories like consent-based general jurisdiction. *See, Otsuka v. Mylan*, *supra* and *Acorda*. Further, the concurrence in the *Acorda*/*AstraZeneca* Federal Circuit opinion agreed that Mylan had properly been sued in Delaware, though would have adapted a simpler theory of general jurisdiction, based on Mylan's registering to do business in Delaware. *Acorda*/*AstraZeneca.*(Fed. Cir. Mar. 2016), Concurring Op. at 12.

[34] Many practitioners believe that most brands will continue to file ANDA suits in Delaware and New Jersey after *Acorda*/*AstraZeneca*, rather than in the state of incorporation or principal place of business of the particular generic manufacturers, given these jurisdictions' familiarity and experience with ANDA patent law issues. Even if this holds true in the ANDA context, the authors believe it is too early to tell for the BPCIA context.

Moreover, a Senate bill (Venue Equity and Non-Uniformity Elimination Act of 2016, S. 2733), introduced March 17, 2016, seems to be in tension with the Federal Circuit's recent *Acorda*/*AstraZeneca* and *TC Heartland* (*supra* note 31) decisions as it would place new restrictions on where patent suits can be filed, including limiting them to courts where parties are incorporated, where the defendant has its principal place of business, or where defendants have physical facilities tied to the development of the technology or alleged infringement, and hence not just facilities that exist ''primarily for the purpose of creating venue.'' But as written, it does not prevent parties from consenting to allow suit in certain districts. The passage of the bill remains to be seen.

[35] Paper II discussed the possibility of generics filing ''declaratory judgment actions for certainty'' given defective jurisdiction in brand-preferred forums, and in response, brands being able to file secondary ''protective suits'' in generic-preferred forums in order to retain the 30-month FDA stay (as

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larly apply in the BPCIA space as well, with the exception of perhaps specific personal jurisdiction based on receipt of the aBLA filer's 180-day notice of commercial marketing (contingent on the Supreme Court's decision to accept or reject Sandoz's petition for certiorari in *Amgen v. Sandoz*, given the disparate timing of such notice from the ANDA context).

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it is an open question as to whether a brand company would be entitled to the stay if its suit was dismissed on jurisdictional grounds). The Federal Circuit's decision likely will eliminate the need for such a belt-and-suspenders approach.

Paper II also provided tips for brands to seek § 1407 MDL centralization in their preferred-forums when suing multiple defendants over the same patents covering the same product.

We expect the Federal Circuit's ruling to encourage brands to coordinate suits in one jurisdiction.