No. 2015-1460

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ASTRAZENECA AB,

Plaintiff-Appellee,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant-Appellant.

On Appeal from the United States District Court
for the District of Delaware,
(No. 1:14-cv-00664-GMS)
(No. 1:14-cv-00696-GMS)

REPLY BRIEF FOR APPELLANT

PAUL D. CLEMENT
Counsel of Record
D. ZACHARY HUDSON
EDMUND G. LACOUR JR.
BANCROFT PLLC
500 New Jersey Avenue, NW
Seventh Floor
Washington, DC 20001
202-234-0090
pclement@bancroftpllc.com

Counsel for Defendant-Appellant

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STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, appellant states:

(a) There have been no previous appeals in this case.

(b) Other cases that may directly affect or be directly affected by this Court's decision include *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, No. 15-1456 (Fed. Cir. appeal docketed Mar. 17, 2015), and numerous pending district court cases raising issues of personal jurisdiction in ANDA litigation.

INTRODUCTION AND SUMMARY OF ARGUMENT

AstraZeneca's jurisdictional arguments are notable for their breadth. AstraZeneca contends that a corporation can be constitutionally subjected to general personal jurisdiction in a forum where it is not at home and does next to no business simply because it has complied with that forum's mandatory business registration statute. Every state has such a statute. And AstraZeneca unabashedly asserts that generic drug manufacturers can be constitutionally subjected to specific personal jurisdiction in every forum in the country simply by virtue of submitting an ANDA to the FDA in Maryland.

Fortunately for corporations and generic drug manufacturers, AstraZeneca's overbroad arguments are incompatible with controlling precedent. After *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), there should be no doubt that a corporation cannot be subjected to general personal jurisdiction in every forum in which it does business. And a state cannot condition the right to do business on mandatory registration and then deem that registration consent to all-purpose jurisdiction. Moreover, AstraZeneca's specific-jurisdiction-everywhere argument is even more problematic and a complete nonstarter under well-established due process precedent.

ARGUMENT

I. Mylan Is Not Subject To General Personal Jurisdiction In Delaware.

AstraZeneca does not contend that Mylan is "at home" in Delaware. *Daimler AG v. Bauman*, 134 S. Ct. 746, 751 (2014). "Mylan is a West Virginia corporation

with its principal place of business in that State." AstraZeneca Br. 8. And AstraZeneca does not assert that this is an "exceptional case" where Mylan's operations in Delaware are "so substantial and of such a nature as to render" Mylan subject to general personal jurisdiction in the State. *Daimler*, 134 S. Ct. at 761 n.19. As Mylan has explained, it conducts only minimal and sporadic business in Delaware. Opening Br. 5.

AstraZeneca nonetheless contends that Mylan is subject to general personal jurisdiction in Delaware on any suit arising anywhere in the world simply because Mylan complied with Delaware's mandatory requirement that any corporation conducting any business in Delaware must register and appoint an agent for service in Delaware, acts which Delaware courts have deemed sufficient to constitute consent to general personal jurisdiction. *See* Del. Code tit. 8, §371(b); *Sternberg v. O'Neil*, 550 A.2d 1105 (Del. 1988). But after *Daimler*, not even "a substantial, continuous, and systematic course of business" supports the exercise of general personal jurisdiction. 134 S. Ct. at 761. If a substantial and continuous course of business is insufficient to give rise to general jurisdiction, then engaging in the minimal business activity necessary to trigger Delaware's mandatory registration requirement—which is to say any business activity whatsoever—cannot suffice.

AstraZeneca attempts to undermine the clear import of *Daimler* by pointing out that it did not disturb the longstanding principle that a party can consent to

jurisdiction. AstraZeneca Br. 48-49. But as even AstraZeneca (intermittently) recognizes, consent to general personal jurisdiction in a forum must be "voluntary." *See, e.g.*, AstraZeneca Br. 56. And Mylan did not give "voluntary" consent to general personal jurisdiction in Delaware. The assertion of general personal jurisdiction over Mylan was based entirely on Mylan's required actions of registering and appointing a service agent. Mylan's only voluntary action was doing some minimal business in Delaware, which is what *Daimler* held to be insufficient. Simply put, AstraZeneca's assertion of general personal jurisdiction over Mylan is incompatible with *Daimler.*

A. Treating Compliance With a Mandatory Business Registration Statute as Consent to All-Purpose Jurisdiction Is Irreconcilable With *Daimler* and Controlling Consent Case Law.

Daimler made absolutely clear that a court can no longer claim general personal jurisdiction over every corporation that does business in the forum. 134 S. Ct. at 761. That "exorbitant" and "unacceptably grasping" view of jurisdiction was definitively rejected as irreconcilable with "due process constraints on the assertion of adjudicatory authority." *Id.* at 751, 761-62. *Daimler* expressly rejected the argument that a "substantial, continuous, and systematic course of business" in a forum is sufficient to subject a defendant to personal jurisdiction there on any and all claims arising anywhere in the world. *Id.* at 761.

Holding Mylan to all-purpose jurisdiction in Delaware by virtue of its compliance with Delaware's mandatory registration statute cannot be squared with *Daimler*. As the district court correctly recognized, "[i]n light of the holding in *Daimler*," mere "compliance with Delaware's registration statutes—mandatory for *doing business* within the state—cannot" serve as a basis for exercising all-purpose jurisdiction. JA11. "Finding mere compliance with such statutes sufficient to satisfy jurisdiction would expose companies with a national presence (such as Mylan) to suit all over the country, a result specifically at odds with *Daimler*." JA11.

The due process problems that result from treating compliance with a mandatory registration statute as establishing general personal jurisdiction are identical to those posed by the California long-arm statute at issue in *Daimler*. And Delaware cannot constitutionally accomplish in two steps what the Supreme Court held California could not accomplish in one. *Daimler* conclusively prohibits a state from asserting all-purpose jurisdiction over a foreign corporation just because it has done "substantial, continuous, and systematic" business in the state. *See Daimler*, 134 S. Ct. at 760-61. But if AstraZeneca were correct, then a state could reach that proscribed result (and more) in two steps—by (1) requiring corporations that engage in "substantial, continuous, and systematic" (or less) business to register, and then (2) deeming that registration to constitute consent to all-purpose jurisdiction. If that were permissible—and it is not—then *Daimler* was merely an academic exercise

and corporations can be subject to general personal jurisdiction not just where they are at home, but in any State that forces them to register.

AstraZeneca's answer to this fatal flaw in its "exorbitant" and "grasping" view of general jurisdiction, 134 S. Ct. at 762, is that the problems posed by Delaware's regime are not the same as those at issue in *Daimler* because under California's long-arm statute it was impossible to know whether a corporation would be exposed to jurisdiction based on "doing continuous and systematic business" due to the amorphous nature of the inquiry. AstraZeneca Br. 50. When it comes to registration statutes, AstraZeneca explains, *Daimler*'s concern that corporate defendants be able to know in advance where their conduct "will and will not render them liable to suit" is not implicated because corporations can know in advance whether a forum has a statute where registration is viewed as consent. 134 S. Ct. at 762. That argument ignores the central inquiry under *Daimler* and vastly overestimates the certainty provided by registration statutes. The critical point in *Daimler* is fairness. If California made clear its intent to assert general jurisdiction over every corporation (or every corporation with more than $10,000 in sales or any corporation registered to do business in the state), the corporation would have been certain that California asserted jurisdiction, but the due process result would have been the same. Indeed, California made its interest in asserting statutory jurisdiction crystal clear. The only uncertainty was the extent to which the assertion would be consistent with due

process (which is the ultimate question under the registration statutes as well). To the extent *Daimler* was concerned about notice, having clear notice of where a corporation would be sued for certain conduct is what matters. Certainty that every state asserts jurisdiction so that the defendant could be sued in any jurisdiction is not the kind of notice and certainty that matters under *Daimler.* Instead, *Daimler* creates a predictable regime in which a defendant is subject to general jurisdiction where it is at home and specific jurisdiction where its suit-related conduct is directed. Finally, AstraZeneca overstates the certainty provided by registration statutes. Every state has a registration statute that could be construed to equate registration with consent. Not every state has opined on whether compliance with its mandatory registration statute has jurisdictional consequences. And those states that have addressed the matter and not construed registration as constituting consent may reverse course in response to *Daimler*. *See* AstraZeneca Br. 58-59 (discussing state registration statutes).

AstraZeneca's related argument that Supreme Court precedent has long permitted states to link registration and jurisdiction and states have not "rush[ed] to enact consent-by-registration statutes" is even less persuasive. AstraZeneca Br. 58. The cases on which AstraZeneca relies in claiming that "consent-by-registration statutes" are clearly constitutionally permissible have been dead letter for more than 70 years. *See* Opening Br. 21-22. Moreover, *Daimler* fundamentally changed the

jurisdictional landscape in ways that give states new incentives to assert general jurisdiction by consent. *See* N.Y.C. Bar, *Report on Legislation: A.6714 & S.4846* (2015), http://bit.ly/1qkbumh.

AstraZeneca attempts to minimize *Daimler*'s import, insisting that "it … has no bearing on the issue this case presents" because Mylan consented to all-purpose jurisdiction in Delaware. AstraZeneca Br. 47. That argument, however, suffers from two critical problems. First, *Daimler* not only has "bearing" on this case—it controls the outcome. *Daimler* makes clear that a corporation cannot be subjected to general personal jurisdiction just by voluntarily undertaking substantial business in the jurisdiction. That result does not change because the statutory basis for asserting general jurisdiction is a mandatory registration statute rather than a long-arm statute. Second, AstraZeneca's voluntary consent argument is based on an entirely false premise. Mylan gave no "voluntary" consent to all-purpose jurisdiction in Delaware. *See* Webster's Unabridged Dictionary 2131 (2d ed. 2001) (defining "voluntary" as "done, made, brought about, undertaken, etc., of one's own accord or by free choice: *a voluntary contribution*"). Mylan's only voluntary conduct in this case was its decision to do business in Delaware, which is the same voluntary conduct found insufficient in *Daimler*. Everything that followed, including the acts deemed sufficient to constitute consent, was a product of the compulsory registration regime erected by the State.

To be sure, as AstraZeneca points out, "the requirement that a court have personal jurisdiction is an 'individual right,'" and "a defendant can waive that requirement by consenting to the exercise of jurisdiction." AstraZeneca Br. 41 (quoting *Ins. Corp. of Ir. v. Compaigne des Bauxites de Guinee*, 456 U.S. 694 (1982)). But the issue here is not whether personal jurisdiction objections can be voluntarily waived; the question is whether voluntary business dealings in a state that themselves are insufficient to establish general personal jurisdiction, *see Daimler*, become sufficient because they trigger a state-law requirement to register, which is then deemed to constitute voluntary consent to all-purpose jurisdiction. They do not.

AstraZeneca's observations that "*Daimler* actually *confirms* that consent is an alternative basis for a court to exercise general jurisdiction over an out-of-state defendant" and that "*Daimler* expressly distinguishes between the exercise of general jurisdiction based on a defendant's contacts with a forum and the exercise of general jurisdiction based on a defendant's consent" are thus beside the point. AstraZeneca Br. 48-49. Even if a corporation could voluntarily consent to all-purpose jurisdiction, Mylan did not do so here. Mylan voluntarily engaged in business in Delaware. Delaware then imposed mandatory requirements which it deemed sufficient to require Mylan to submit to general jurisdiction. Labeling the consequences of mandatory registration "consent" does not end the due process

inquiry or create any "voluntary" consent on Mylan's part. Try as it might, neither Delaware nor AstraZeneca can force Mylan to consent voluntarily. Compelled consent remains an oxymoron.[1]

Insurance Corporation of Ireland and the precedents on which it relies amply demonstrate that forced compliance with a mandatory state registration statute cannot amount to "voluntary" consent to general personal jurisdiction. Lest there be any doubt, Mylan's mandatory registration bears no resemblance to the conduct at issue in *Insurance Corporation of Ireland* itself, where the Court based personal jurisdiction on the defendant's failure to comply with jurisdiction-related discovery orders after expressly informing the defendant that a failure to comply would result in a sanctions order finding jurisdiction. 456 U.S. at 698-99. Moreover, Mylan's compelled registration is quite unlike the other scenarios discussed in *Insurance Corporation of Ireland*: two parties expressly agreeing "'in advance to submit to the jurisdiction of a given court,'" *id.* at 703-04 (quoting *Nat'l Equip. Rental, Ltd. v. Szukhent*, 375 U.S. 311, 316 (1964)), a voluntary stipulation waiving the right to object to jurisdiction, *id.* at 704 (citing *Petrowski v. Hawkeye-Sec. Co.*, 350 U.S. 495

[1] If AstraZeneca really were correct that a state could force a company to submit to general personal jurisdiction as a price for doing any significant business in the state, it would cast such requirements into substantial constitutional doubt. Such a requirement would plainly constitute a substantial obstacle to interstate commerce. Thus, faithfully applying *Daimler* to reject AstraZeneca's theory has the additional virtue of avoiding that substantial constitutional issue.

(1956), and an agreement to arbitrate in a particular forum, *id.* (citing *Victory Transp. Inc. v. Comisaria General de Abastecimientos y Transportes*, 336 F.2d 354 (2d Cir. 1964)). All of these situations involve voluntary conduct directly related to the exercise of jurisdiction. By contrast, Mylan's only relevant voluntary action was engaging in sufficient business in Delaware to trigger the State's registration requirement. After *Daimler*, that voluntary business activity cannot itself give rise to general personal jurisdiction, and it makes no sense to conclude that complying with a *mandatory* registration requirement based on that same activity amounts to *voluntary* consent to general personal jurisdiction.

Taking a different tack, AstraZeneca suggests that "[i]f Mylan does not want to be subject to general jurisdiction in Delaware, it is free to withdraw its registration and to forgo doing business there." AstraZeneca Br. 56. That argument only underscores the incompatibility of AstraZeneca's view of the law with *Daimler* (not to mention the threat to interstate commerce posed by AstraZeneca's view). Daimler had the same option—withdrawing from doing business in California—and yet the Court found even a substantial course of business to be insufficient to support an assertion of general personal jurisdiction. In this regard, due process principles reinforce the notion that the Framers created a national market. Simply put, the price

of doing some business in a forum is not subjecting oneself to all suits arising anywhere in the world. And the option of doing business elsewhere is no answer.[2]

B. AstraZeneca's Reliance on Outdated Supreme Court Precedent Is Misplaced.

In likely recognition of its failure to explain away the dispositive impact of *Daimler*, AstraZeneca emphasizes that "only the Supreme Court has 'the prerogative of overruling its own decisions,'" AstraZeneca Br. 44-45 (quoting *De Quijas v. Shearson/Am. Express, Inc.*, 490 U.S. 477, 484 (1989)); *see id.* at 15, 49, and points to a quartet of archaic Supreme Court cases that it claims foreclose a ruling for Mylan on general personal jurisdiction absent Supreme Court action. The cases on which

[2] AstraZeneca's argument on this score highlights the unconstitutional quid pro quo exacted by Delaware's mandatory registration. As explained by the Chamber of Commerce in its *amicus* brief, "[c]onditioning a corporation's ability to transact business within a state on the corporation's waiver of its due process right not to be subject to general jurisdiction" violates the fundamental principle that "'the government 'may not deny a benefit to a person because he exercises a constitutional right.'" Chamber Br. 18 (quoting *Koontz v. St. Johns River Water Mgmt. Dist.*, 133 S. Ct. 2586, 2594 (2013)). The argument that Delaware's mandatory registration requirement violates the unconstitutional conditions doctrine is properly before this Court—it is merely a variant of the broader due process arguments that Mylan has advanced since this case's inception. *See Yee v. City of Escondido*, 503 U.S. 519, 534 (1992). This Court has not hesitated to consider arguments advanced by *amicus* that, while not the focus of the parties, are rooted in the same principles as the parties' arguments. *See, e.g., Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1005 (Fed. Cir. 2012) (expressly noting an alternative argument advanced by *amici* and adopting that argument). In all events, as the case AstraZeneca cites in support of its "forfeiture" argument notes, this Court "has discretion to consider arguments" not raised by the parties. *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 n.9 (Fed. Cir. 2006) (citing *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 800 (Fed. Cir. 1990)).

AstraZeneca relies, however—*Ex Parte Schollenberger*, 96 U.S. (6 Otto) 369 (1878), *Pa. Fire Ins. Co. v. Gold Issue Mining & Milling Co.*, 243 U.S. 93 (1917), *Robert Mitchell Furniture Co. v. Selden Breck Constr. Co.*, 257 U.S. 213, 216 (1921), and *Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165 (1939)—come nowhere close to calling the district court's general personal jurisdiction holding into question. AstraZeneca Br. 41-47.

As the district court recognized, these cases were all "decided in the era dominated by *Pennoyer*'s territorial thinking," *Daimler*, 134 S. Ct. at 761, and no longer provide "a viable path to finding jurisdiction." JA9; *see* Opening Br. 21-22. Whatever was true when *Pennoyer* held sway, in 2015, every assertion of jurisdiction over a nonresident "must be evaluated according to the standards set forth in *International Shoe* and its progeny." *Shaffer v. Heitner*, 433 U.S. 186, 212 (1977). That is true whether the theory of jurisdiction is rooted in minimum contacts or consent—modern due process doctrine "places all suits against absent nonresidents on the same constitutional footing." *Burnham v. Superior Court*, 495 U.S. 604, 621 (1990) (opinion of Scalia, J.). Case law speaking to consent that predates *International Shoe* is of no moment if it cannot be reconciled with "*International Shoe* and its progeny." *Shaffer*, 433 U.S. at 212. Indeed, the Supreme Court has unequivocally stated that "[t]o the extent that prior decisions are inconsistent with" *International Shoe*, they have been "overruled." *Id.* at 212 n.39.

The primary authority on which AstraZeneca relies—*Pennsylvania Fire*—did not survive *International Shoe*. *See* Opening Br. 19-22. Thoroughly infected by *Pennoyer* and the unworkable fictions on which it was based, the *Pennsylvania Fire* Court focused on whether an in-forum agent was properly authorized to accept service in the forum on a cause of action unrelated to the forum. *See* 243 U.S. at 95-96. That focus was necessitated by the fact that, under *Pennoyer*, a tribunal's personal jurisdiction "reache[d] no farther than the geographic bounds of the forum." *Daimler*, 134 S. Ct. at 753. That discarded fiction necessitated the inquiry there and put pressure on courts to find innovative ways to expand jurisdiction. *International Shoe* ended all that in favor of a more straightforward approach. *Pennsylvania Fire* was clearly a product of *Pennoyer*'s "strict territorial approach" to jurisdictional questions and is thus in the heartland of cases that "are inconsistent with" *International Shoe* and its progeny and that have been "overruled." *Shaffer*, 433 U.S. at 212 n.39.

Pennsylvania Fire was by no means resurrected through the Supreme Court's citation to it in a string cite in a footnote in the "post-*International Shoe* general-jurisdiction case" *Perkins v. Benguet Consolidated Mining Co.*, 342 U.S. 437 (1952). AstraZeneca Br. 46 (citing *Perkins*, 342 U.S. at 446 n.6). To the contrary—*Perkins* further highlights *Pennsylvania Fire*'s incompatibility with current controlling precedent. The *Perkins* Court cited *Pennsylvania Fire* following its statement that

the Court had, on occasions, deemed "continuous corporate operations within a state" sufficient to warrant the exercise of general personal jurisdiction. 342 U.S. at 446. After *Daimler*, the argument that "continuous corporate operations within a state" in and of itself is sufficient to give rise to all-purpose jurisdiction is a constitutional nonstarter.

Moreover, while *Schollenberger*, *Neirbo*, and *Robert Mitchell* are equally suspect post-*International Shoe*, none of those cases supports AstraZeneca's arguments. Both *Schollenberger* and *Nierbo* focused on venue, not jurisdiction. *See Schollenberger*, 96 U.S. (6 Otto) at 377; *Neirbo*, 308 U.S. at 166-68. And *Robert Mitchell*'s relevance is cabined to its reminder that courts should not needlessly construe registration requirements as creating all-purpose jurisdiction, a caution the Delaware Supreme Court might have heeded in *Sternberg*. Opening Br. 17 n.5.

II. Mylan Is Not Subject To Specific Jurisdiction In Delaware.

AstraZeneca's arguments in support of the district court's specific personal jurisdiction analysis fare no better. Indeed, AstraZeneca's specific personal jurisdiction arguments only underscore the unsupportable breadth of its view of jurisdiction as a whole. According to AstraZeneca, in addition to being potentially subject to general jurisdiction in any state on any cause of action arising anywhere in the world, Mylan is also subject to specific jurisdiction in ANDA cases in every forum in the United States. Not so.

AstraZeneca's need to argue for nationwide ANDA jurisdiction simply highlights Mylan's utter lack of suit-related contacts with Delaware. AstraZeneca repeatedly emphasizes *its* contacts with Delaware (and every other state), but the Supreme Court's recent decision in *Walden* makes absolutely clear that Mylan's contacts with the forum—not AstraZeneca's—are all that matters. Moreover, AstraZeneca's contention that Mylan is subject to specific jurisdiction everywhere because it might (or might not) one day sell a generic version of AstraZeneca's product nationwide is baseless. Nothing in the precedents of this Court or the Supreme Court supports that limitless view of jurisdiction, which is unsurprising given its fundamental incompatibility with due process. And, while this Court need not address the matter, it would be patently unfair and unreasonable to subject Mylan to specific jurisdiction in Delaware in this case.

A. Mylan Lacks the Necessary Suit-Related Contacts With Delaware to Support the Exercise of Specific Jurisdiction There.

As Mylan explained in its opening brief, the exercise of specific jurisdiction is appropriate only when a defendant (1) "purposefully direct[s] its activities at … the forum state, (2) the claim arises out of or relates to" those activities, "and (3) assertion of personal jurisdiction is reasonable and fair." *Grober v. Mako Prods.*, 686 F.3d 1335, 1346 (Fed. Cir. 2012); *see* Opening Br. 22-23. In other words, for a state to exercise specific personal jurisdiction over a defendant, due process requires that "the defendant's suit-related conduct … create a substantial connection with the

forum." *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). The palpable absence of a substantial connection based on *suit-related contacts* between Mylan and Delaware in this case requires reversal of the judgment below.

The lynchpin of the district court's specific jurisdiction finding was that Mylan sent "its paragraph IV certification to AstraZeneca U.S. in Delaware." JA15. The sending of that letter comes nowhere close to creating the necessary suit-related contacts to support specific personal jurisdiction, *see* Opening Br. 30-42, which may be why AstraZeneca barely even defends that aspect of the district court's reasoning. *See, e.g.*, AstraZeneca Br. 35. But what little AstraZeneca does have to say on the issue in no way salvages the district court's analysis.

AstraZeneca contends that, for purposes of establishing minimum contacts, Mylan's notice letters are equivalent to infringement letters that patentees send to alleged infringers. AstraZeneca Br. 34 (citing *Avocent Huntsville Co. v. Aten Int'l Co.*, 552 F.3d 1324, 1333 (Fed. Cir. 2008)). While AstraZeneca quibbles with this Court's reasons for so holding, none of the infringement letter cases cited by AstraZeneca resulted in a finding of specific jurisdiction. In all events, as *Avocent* recognized in conducting its minimum contacts analysis, threat letters "relate in some material way," *Avocent*, 552 F.3d at 1336, to a declaratory judgment action because they "are 'purposefully directed' at the forum and the declaratory judgment action 'arises out of' the letters," *id.* at 1333 (quoting *Silent Drive, Inc. v. Strong*

Indus., Inc., 326 F.3d 1194, 1202 (Fed. Cir. 2003)). In *Silent Drive*, for example, where the defendant sent a letter that explicitly threatened the plaintiff with substantial fines and jail time, the declaratory judgment action arose from the letter. 326 F.3d at 1199, 1202. The same cannot be said of Mylan's statutorily-required notice letters. Any suit plainly arises out of the ANDA itself, not the subsequently mailed notice letters.

Anticipating this critical flaw in its argument, AstraZeneca declares that the notice letters are nonetheless sufficient minimum contacts because they "'relate to' the claim in *some* way." AstraZeneca Br. 34 (emphasis added). But it is not enough to show merely *some* relation between the contact and the claim. *Walden* makes clear that the connection must be "substantial." *Walden*, 134 S. Ct. at 1121. And even before *Walden*, this Court held that "contacts material to the specific jurisdiction analysis … are not just any [related] activities"—they must "relate in some *material* way" to the underlying action. *Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1019-20 (Fed. Cir. 2009) (emphasis added). Applying this standard to a declaratory judgment claim for non-infringement, this Court held that even the defendant's sales of goods covered by the challenged patent do not sufficiently "relate in any material way to the patent right that is at the center of" the case. *Avocent*, 552 F.3d at 1336. Mylan's after-the-fact notice letters fail the

materiality test, *a fortiori*. The significant act is the filing of the ANDA, not the ministerial and statutorily-mandated act of sending a notice letter.

Zeneca further underscores that Mylan's statutorily-mandated notice letters do not establish the required suit-related contacts. *See* Opening Br. 32-36. AstraZeneca attempts to distinguish that important decision on the ground that neither opinion in the case addressed notice letters. But ANDA notice letters are statutorily-required companions to the ANDA filing, which "clearly falls within the First Amendment right to petition." *Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829, 832-33 (Fed. Cir. 1999) (opinion of Gajarsa, J.). Requiring Mylan to submit to specific jurisdiction merely because it complied with the statute's requirements would premise specific jurisdiction on involuntary actions and similarly burden Mylan's First Amendment petition right. *Id.* It would be akin to exercising personal jurisdiction based on sending a notice copy of a brief. In reality, the notice letter is "not actually [a contact] with the state of [Delaware] at all." *Id.* at 835 (opinion of Rader, J.).

Implicitly acknowledging that the purported contact on which the district court focused is insufficient, AstraZeneca points to its "corporate interests" in Delaware and contends that it will suffer harm there. AstraZeneca Br. 19, 27. But this plaintiff-centric approach to jurisdiction was resoundingly rejected by *Walden*, which could not have been clearer that "[t]he proper question is not where the

plaintiff experienced a particular injury or effect but whether the defendant's conduct connects him to the forum in a meaningful way." *Walden*, 134 S. Ct. at 1125.

AstraZeneca endeavors to rewrite *Walden* and argues that that case "merely reiterated the familiar precept that a defendant's fortuitous contacts with a plaintiff *outside the plaintiff's home State* are insufficient" when they form the only link between the defendant and the forum. AstraZeneca Br. 32. Thus, even under *Walden*, jurisdiction is proper in Delaware because "Mylan took express aim at AstraZeneca's interests in Delaware, and AstraZeneca suffered the effects of that conduct there." *Id*. at 33. But AstraZeneca is simply parroting the same arguments that were rejected in *Walden*. The Ninth Circuit had held that because Officer Walden "'*expressly aimed*' his submission of the allegedly false affidavit at Nevada by submitting the affidavit with knowledge that it would affect persons with a 'significant connection' to Nevada," jurisdiction was proper in Nevada. 134 S. Ct. at 1120 (quoting *Fiore v. Walden*, 688 F.3d 558, 581 (9th Cir. 2012)) (emphasis added). The Supreme Court rejected that improper effort to "shift[] the analytical focus from petitioner's contacts with the forum to his contacts with respondents." *Id.* at 1124.

As if cribbing from the *Walden* plaintiffs, AstraZeneca argues that jurisdiction is proper because "Mylan intended to injure AstraZeneca in Delaware" and "targeted AstraZeneca's corporate interests in Delaware." *Compare* AstraZeneca Br. 19, 27,

with Walden, 134 S. Ct. at 1125 ("respondents emphasize that they suffered the 'injury' caused by petitioner's allegedly tortious conduct … while they were residing in the forum"). But even if AstraZeneca or its "corporate interests" are injured in Delaware, the location of this harm says nothing about "the relationship among the defendant, the forum, and the litigation." *Walden*, 134 S. Ct. at 1126 (quoting *Calder v. Jones*, 465 U.S. 783, 788 (1984)). As explained, the only even arguable suit-related contact between Mylan and Delaware is the courtesy copy of the statutorily-required notice letter that Mylan sent to AstraZeneca's marketing subsidiary, and that letter cannot support the exercise of specific jurisdiction.

Despite the fact that *Walden* clearly controls here and clearly cabined *Calder*, AstraZeneca bizarrely (and repeatedly) invokes *Calder* in support of jurisdiction here. *See, e.g.*, AstraZeneca Br. 20. That argument is strange in light of *Walden*, which explained that the connection between the tort and the "effects" in *Calder* "was largely a function of the nature of the libel tort," which requires a third-party response. *Walden*, 134 S. Ct. at 1124. "The crux of *Calder* was that the reputation-based 'effects' of the alleged libel connected the defendants to California, not just to the plaintiff." *Id.* at 1123-24. This is because libelous literature "can lead to a loss of reputation only if communicated to (and read and understood by) third persons." *Id.* at 1124. "Indeed, because publication to third persons is a necessary element of libel, the defendants' intentional tort actually occurred *in* California." *Id.*

The "effects" of Mylan's ANDA filings lack any comparable relation to Delaware. AstraZeneca's harm, if any, was immediately suffered when Mylan submitted its ANDA to the FDA in Maryland. The Hatch-Waxman Act provides plaintiffs with an immediate cause of action once a defendant files an ANDA by treating that filing as a "highly artificial" act of patent infringement. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). That act of infringement, and its effects upon the plaintiff, are not contingent on third-party conduct in Delaware. And just like the *Walden* plaintiffs, AstraZeneca would have suffered the effects of that infringement "in California, Mississippi, or wherever else [it] might have [located its business]." *Walden*, 134 S. Ct. at 1125.

In short, while it is doubtful that Mylan could have ever been subjected to specific personal jurisdiction in Delaware in this action, under *Walden* there is no doubt that the purported contacts identified by AstraZeneca are insufficient.

B. The Prospect of Future Distribution or Sales—Which May Never Occur—Does Not Create Specific Personal Jurisdiction Over Mylan Now.

In tacit recognition of the fact that it cannot identify any current suit-related contacts Mylan actually has with Delaware, AstraZeneca attempts to draw on far-from-certain future suit-related contacts that Mylan might one day have with the forum. In so doing, AstraZeneca goes far beyond the district court's flawed but comparably modest effort to expand specific jurisdiction and contends that an

ANDA filer is subject to specific personal jurisdiction in every forum across the country simply because it filed a paragraph IV certification. That is because Mylan might (or might not) one day at some point in the distant future distribute and sell the ANDA-related drugs nationwide.[3]

Nothing in controlling precedent or commonsense supports AstraZeneca's efforts to create a new specific jurisdiction doctrine. At most, future production and sales would support jurisdiction in the future if, when, and where they occur. But they certainly do not support personal jurisdiction *now* in Delaware or in any and every jurisdiction AstraZeneca may hypothesize that they will occur. That much is clear from *Walden*. *Walden* underscored that "an injury is jurisdictionally relevant only insofar as it shows that the defendant has *formed* a contact with the forum State" based on its "suit-related conduct." 134 S. Ct. at 1125, 1121 (emphasis added). While Mylan might one day form such a contact, it has not done so yet. And that now-hypothetical contact might never materialize, which is why actual, existing, suit-related contacts are required. *See also Fastpath, Inc. v. Arbela Techs. Corp.*,

[3] That the district court did not adopt AstraZeneca's potential-future-distribution-or-sales argument is unsurprising—that argument was not advanced below. *See* JA51-JA63 (complaint); Doc. 17 (opposition to motion to dismiss). Indeed, when arguing that the district court could exercise specific personal jurisdiction over Mylan, AstraZeneca argued without qualification that Mylan's "sales (or lack thereof) are irrelevant to jurisdiction in ANDA litigation." *Id*. at 9. *See Gant v. United States*, 417 F.3d 1328, 1332 (Fed. Cir. 2005) ("Arguments not made in the court or tribunal whose order is under review are normally considered waived.").

760 F.3d 816, 822 (8th Cir. 2014) (potential "future development" "is not relevant in" personal jurisdiction analysis); *Eli Lilly & Co. v. Nang Kuang Pharm. Co.*, No. 14-1647, 2015 WL 3744557, at *1 (S.D. Ind. June 15, 2015) ("personal jurisdiction cannot be based on future contacts, even if such contacts are allegedly 'inevitable'").

The "artificial" nature of ANDA infringement does not justify AstraZeneca's effort to rely on potential future injuries or otherwise create a new jurisdictional doctrine. *Eli Lilly*, 496 U.S. at 678. To the contrary, the statutory creation of the artificial act of infringement embodied by the ANDA filing itself—and not future sales that may or may not occur—was necessitated by the lack of any current injury. The ANDA filing is "itself an act of infringement," *Caraco Pharm. Labs. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012)—a "purposefully committed … federal tort in Maryland," *Zeneca*, 173 F.3d at 833 (opinion of Gajarsa, J.). That tort "gives the brand an immediate right to sue," *Caraco*, 132 S. Ct. at 1677, and AstraZeneca's infringement claim based on that tort is equally valid (or invalid) whether or not Mylan ever makes, packages, distributes, or sells a single pill or tablet.

AstraZeneca responds that because ANDA litigation "requires a hypothetical and prospective inquiry into" whether a drug would infringe, it does not matter that "Mylan has not yet begun to sell infringing products in Delaware." AstraZeneca Br. 23-24. But "[a] plaintiff may not create personal jurisdiction over one claim by arguing that jurisdiction might be proper over a different, hypothetical claim not

before the court." *Picot v. Weston*, 780 F.3d 1206, 1215 n.3 (9th Cir. 2015); *see Fastpath*, 760 F.3d at 822 (potential "future development" "is not relevant in" personal jurisdiction analysis). As with any other claim, specific jurisdiction turns on the defendant's *actual* suit-related contacts, not on those imagined by the plaintiff.

Moreover, if the prospect of future distribution or sales were sufficient to create jurisdiction, there would have been no need for Congress to make an ANDA filing into an artificial act of infringement by enacting 35 U.S.C. §271(e)(2)(A). Plaintiffs could simply have brought suit under §271(a)-(c) on the theory that the ANDA would lead to future distribution and sales. *But see Eli Lilly*, 496 U.S. at 678 (explaining that §271(e)(2)(A) was necessary "to enable the judicial adjudication" of the challenged patents' validity).

Little ink need be wasted on AstraZeneca's limited efforts to root its potential-future-distribution-and-sales arguments in this Court's precedent. AstraZeneca's invocation of *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558 (1994), is unavailing. *See* AstraZeneca Br. 22-23, 25, 29, 40. That case provides no support for the contention that potential future distribution or sales in a forum can justify the exercise of specific jurisdiction in the forum. In *Beverly Hills*, this Court addressed jurisdiction in a case where a defendant was already selling allegedly infringing ceilings fans in Virginia. 21 F.3d at 1560. The Court had no occasion to address whether potential future distribution or sales were sufficient to create specific

jurisdiction because the relevant sales were already occurring. AstraZeneca quotes this Court out of context in discussing the "situs" of the injury and nature of patent rights. AstraZeneca Br. 22. Those comments were made in the course of interpreting and applying Virginia's long-arm statute, and do nothing to advance AstraZeneca's novel arguments.

Sunovion Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., 731 F.3d 1271 (2013), is—if anything—less apposite. *See* AstraZeneca Br. 24-25. That case is silent on jurisdiction and stands for no more than the uncontroversial proposition that when assessing the merits of an ANDA-related infringement claim courts must evaluate the product that the "ANDA applicant is asking the FDA to approve for sale." 731 F.3d at 1278.

The fatal problems with AstraZeneca's jurisdiction-everywhere-based-on-potential-future-distribution-and-sales argument do not end there. Most glaringly, that argument would mean that the ANDA filer could be sued in any jurisdiction where future sales are a possibility. The notion of *specific* personal jurisdiction in *every* forum in the nation is odd enough. But since the whole point of the Hatch-Waxman Act is to encourage generic competition across the country, using the possibility of future generic competition as a basis for allowing a current suit anywhere in the country is perverse and contrary to "'traditional notions of fair play and substantial justice.'" *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)

(quoting *Milliken v. Meyer*, 311 U.S. 457, 463 (1940)). Indeed, AstraZeneca's jurisdiction-everywhere argument is exactly the sort of "unnecessary and unintended punishment for filing a petition with the FDA" that "undermines the purpose of the Hatch-Waxman Act." *Zeneca*, 173 F.3d at 833 (opinion of Gajarsa, J.). If AstraZeneca's view is endorsed, and filing an ANDA creates specific personal jurisdiction in every forum in the country, that will undoubtedly have a substantial chilling effect on desirable generic activity.

It also bears emphasis that if AstraZeneca really were correct that the uncertain prospect of future sales and distribution creates specific jurisdiction in every forum across the country, then courts have been missing the obvious for decades. While jurisdiction has oft been litigated in ANDA disputes, "specific jurisdiction has historically been disfavored by courts as a basis to exercise jurisdiction over generic drug company defendants in ANDA cases." JA12. If AstraZeneca's view of the law were correct, specific personal jurisdiction would have been the rule—not the exception. Put differently, if AstraZeneca is correct then cases such as *Zeneca* were much ado about nothing. There was no need for Judge Gajarsa and Judge Rader to debate whether it was the government contacts exception or due process principles that precluded the exercise of personal jurisdiction over Mylan in Maryland because specific personal jurisdiction could have been exercised

over Mylan in Maryland—and everywhere else—based on the prospect of future distribution and sales.

C. Holding Mylan to Specific Jurisdiction in Delaware Would Not Be Fair and Reasonable.

In the unlikely event that this Court concludes that Mylan has a substantial suit-related connection to Delaware, it should still reverse. Even where there is an ample amount of suit-related activity, the exercise of jurisdiction must be fair and reasonable and it would not be in this case.

This Court's precedents involving infringement letters prove the point. *See* Opening Br. 46-49. *Avocent*, *Silent Drive*, and *Red Wing Shoe*, all stand for the proposition that exercising specific jurisdiction over a party that mails a letter into a forum is not fair and reasonable. Here, there are no "'other activities' directed at the forum *and related to the cause of action*" that would justify departing from these precedents. *Avocent*, 552 F.3d at 1333 (quoting *Silent Drive*, 326 F.3d at 1202).

AstraZeneca attempts to distinguish these controlling precedents on the ground that the "policy concerns" related to infringement and notice letters are different because "Mylan is the alleged infringer, not the patentee." AstraZeneca Br. 34; *see id.* at 37. AstraZeneca, however, offers no reason why this distinction should make a difference, and no such reason exists. The policy considerations informing the Court's infringement letter analysis center on the concern "that a patentee be free to inform a party who happens to be located in a particular forum of suspected

infringement without the risk of being subjected to a law suit in that forum." *Hildebrand v. Steck Mfg. Co.*, 279 F.3d 1351, 1356 (Fed. Cir. 2002). ANDA notice letters are, in many respects, merely a mirror image of infringement letters; a party that believes it is not infringing (or that the relevant patent is invalid) informs the patentee of that fact. "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *Lear, Inc. v. Adkins*, 395 U.S. 653, 663-64 (1969). Thus, the ANDA filer should "be free to inform a party who happens to be located in a particular forum of suspected [non-]infringement without the risk of being subjected to a law suit in that forum." *Hildebrand*, 279 F.3d at 1356.

That the ANDA notice letters, unlike infringement letters, are government-mandated and central to the Hatch-Waxman Act only reinforces the unfairness and unreasonableness of using them as a basis for jurisdiction. The Hatch-Waxman Act is designed to encourage the development and manufacture of generic drugs, *see, e.g.*, *Caraco*, 132 S. Ct. at 1676, which requires testing allegedly invalid patents. The notice letter is a key part of that process, and the ANDA filer has a legal right (and obligation) to send the notice letter just as a patentholder has a legal right to send its infringement letter. *Cf. Avocent*, 552 F.3d at 1333.

The efficiency arguments that AstraZeneca proffers in support of its efforts to circumvent *Walden* and to manufacture jurisdiction everywhere based on uncertain

future distribution and sales do not impact the analysis. Those arguments ignore the fundamental principle that "[d]ue process limits on the State's adjudicative authority principally protect the liberty of the nonresident defendant—not the convenience of plaintiffs." *Walden*, 134 S. Ct. at 1122. They also fail to account for the fact that "due process is not intended to promote efficiency," but to protect individual liberty. *Fuentes v. Shevin*, 407 U.S. 67, 90 n.22 (1972). "[T]he Constitution recognizes higher values than speed and efficiency." *Id.*

That said, there is no need to create a new doctrine of personal jurisdiction where every forum in the country has jurisdiction over an ANDA filer in order to promote efficiency. There are tools that can be employed short of ignoring due process to achieve the sort of efficiency that AstraZeneca envisions. *See* Amicus brief for the Generic Pharmaceutical Association 10 (discussing the use of multidistrict litigation).

CONCLUSION

For the reasons set forth above and in Mylan's opening brief, this Court should reverse the decision below and order the case dismissed for lack of personal jurisdiction.

Respectfully submitted,

s/Paul D. Clement
PAUL D. CLEMENT
Counsel of Record
D. ZACHARY HUDSON
EDMUND G. LACOUR JR.
BANCROFT PLLC
500 New Jersey Avenue, NW
Seventh Floor
Washington, DC 20001
202-234-0090
pclement@bancroftpllc.com

Counsel for Defendant-Appellant

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CERTIFICATE OF COMPLIANCE

1. This Brief complies with the type-volume limitation of Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure because, according to the "word count" function of Microsoft Word 2013, the Brief contains 6,994 words, excluding the parts of the Brief exempted from the word count by Rule 32(a)(7)(B)(iii) of the Federal Rules of Appellate Procedure and Fed. Cir. R. 32(b).

2. This Brief complies with the typeface requirements of Rule 32(a)(5) and the typestyle requirements of Rule 32(a)(6) of the Federal Rules of Appellate Procedure because the Brief has been prepared in a proportionally spaced typeface using Microsoft Word 2013 in 14-point Times New Roman font.

Dated: August 10, 2015

s/Paul D. Clement
Paul D. Clement

CERTIFICATE OF SERVICE

I hereby certify that on August 10, 2015, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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Paul D. Clement