No. 2015-1456

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ACORDA THERAPEUTICS INC. and
ALKERMES PHARMA IRELAND LIMITED,

Plaintiffs-Appellees,

v.

MYLAN PHARMACEUTICALS INC. and MYLAN INC.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Delaware,
(No. 1:14-cv-00935-LPS)

REPLY BRIEF FOR APPELLANTS

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STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, appellants state:

(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 *AstraZeneca AB v. Mylan Pharmaceuticals Inc.*, No. 15-1460 (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

Acorda's brief is long on purported contacts that it and Mylan independently have with Delaware. But what due process requires, and what are notoriously absent in Acorda's brief, are suit-related contacts between Mylan and Delaware.

Facing this glaring absence of jurisdictionally-relevant contacts, Acorda submits that Mylan is nonetheless subject to personal jurisdiction in Delaware because (1) Mylan consented to general jurisdiction by complying with the State's mandatory registration requirements; (2) Mylan presently intends to engage in "future infringing sales" in Delaware; and (3) Mylan should have known that Acorda would file suit in that forum. These arguments, however, are unavailing. After *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), there should be no doubt that a state cannot condition the right to do business on mandatory registration and then deem that registration consent to all-purpose jurisdiction. And Acorda's arguments that the prospect of future sales or the possibility that Mylan could have anticipated suit in Delaware fall well short of justifying the district court's ill-founded specific jurisdiction analysis.

ARGUMENT

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

Acorda concedes, as it must, that Mylan is not "at home" in Delaware. *Daimler AG v. Bauman*, 134 S. Ct. 746, 751 (2014). "Mylan is a West Virginia company with its principal place of business in Morgantown, West Virginia."

Acorda Br. 7. And Acorda does not contend 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. 5-6.

Acorda 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. *See* Acorda Br. 28 (*Daimler* "makes clear that the mere fact that a foreign corporation regularly conducts business in the forum is not sufficient to establish general personal jurisdiction over the corporation.").

Acorda attempts to sidestep this glaring problem by arguing that *Daimler* did not disturb the longstanding principle that a party can consent to jurisdiction. Acorda Br. 26. But, as Acorda itself concedes, when it comes to "consent" to jurisdiction in a forum "all that matters for constitutional purposes" is whether the purported consent was "knowing and voluntary." *Id.* at 24 (citing *Wellness Int'l Network v. Sharif*, 135 S. Ct. 1932, 1948 n.13 (2015)). And Mylan never gave "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, Acorda'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 explained in Mylan's opening brief, 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*. Opening Br. 18-20. 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 Acorda 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.

But *Daimler* is Supreme Court precedent to be faithfully applied, not an obstacle to be evaded by a clever two-step. And while the district court at least acknowledged that its view of general personal jurisdiction was in considerable "tension" with *Daimler*, Acorda breezily contends that *Daimler* "has no bearing" on this case because Mylan gave "knowing and voluntary consent … to general personal jurisdiction in the courts of Delaware." Acorda Br. 2, 26; *see id.* at 33 n.7. 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, Acorda'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.

Citing to and excerpting the Supreme Court's decision in *Insurance Corp. of Ireland v. Compaigne des Bauxites de Guinee*, 456 U.S. 694 (1982), Acorda repeatedly notes that "[p]ersonal jurisdiction is 'an individual right' that 'can, like other such rights, be waived' through knowing and voluntary consent." Acorda Br. 11; *see id.* 15, 16, 23. Mylan has never suggested otherwise. Opening Br. 17. 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.

Thus, Acorda's contention that *Daimler* and "other leading opinions on general personal jurisdiction" have not done away with voluntary consent as a permissible basis for all-purpose jurisdiction is entirely beside the point. Acorda Br. 12; 20. 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 Acorda 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 (1956), and an agreement to arbitrate in a particular forum, *id.* (citing *Victory Transp.*

[1] If Acorda 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 Acorda's theory has the additional virtue of avoiding that substantial constitutional issue.

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.[2] 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. As one court put it: "Consent requires more than legislatively mandated compliance with state laws." *Leonard v. USA Petroleum Corp.*, 829 F. Supp. 882, 891 (S.D. Tex. 1993). Despite Acorda's suggestion to the contrary, "[e]xtorted actual consent and equally unwilling implied consent are not the stuff of due process." *Id*. at 889.

It makes no difference that Delaware had construed its mandatory registration requirement as giving rise to consent to all-purpose jurisdiction in advance of Mylan's registration. *See* Acorda Br. 15. Acorda wrongly conflates knowledge with volition. No matter how clearly Delaware indicates that the consequence of doing

[2] Moreover, all of these situations involve consent to jurisdiction over a particular dispute or against a particular party. No party to a forum selection agreement voluntarily agrees to litigate any dispute involving any party arising anywhere in the world in a particular forum. Only a state law could even purport to compel such an extraordinary result, and that compulsion bears no resemblance to the truly voluntary undertakings addressed in *Insurance Corporation of Ireland.*

business in the State is that Delaware will assert general jurisdiction over the defendant, that assertion of jurisdiction must comport with due process. Indeed, if Delaware's business registration statute itself indicated expressly that registration constitutes consent to all-purpose jurisdiction, it would not make the assertion of general jurisdiction any more constitutional or consistent with *Daimler.* By the same token, the result in *Daimler* would not have changed if California had made crystal clear that its courts could exercise general personal jurisdiction over any corporation doing substantial and continuous business in the state.

Acorda wrongly asserts that Mylan's "consent" to general personal jurisdiction in Delaware may be "implied from its actions in registering to do business and appointing an agent" for service there. Acorda Br. 23. But mandatory actions, such as registration and the appointment of an agent, are an even less promising basis for inferring "voluntary" consent than the voluntary actions that trigger those mandatory requirements. Compelled consent is an oxymoron, and inferring voluntary consent from actions compelled by the state as a condition for undertaking business is just as nonsensical. In all events, as Acorda itself recognizes elsewhere, Acorda Br. 2, 26; *see id.* at 33 n.7, implied, inferred or deemed consent

is not enough; voluntary relinquishment of a known constitutional right is what is required, and that has simply not happened here.[3]

Acorda's effort to limit its undermining of *Daimler* by painting Delaware as something of an outlier is unavailing. Acorda reports that while "every State has a foreign corporation registration statute," "no more than a dozen States" currently have a statute that—either on its face or as interpreted by a state court—equates mandatory registration with consent to all-purpose jurisdiction. Acorda Br. 31. But *Daimler* limited general personal jurisdiction to states in which a corporate defendant was at home. Opening up corporate defendants to their home jurisdiction and a dozen more is hardly consistent with *Daimler.* More fundamentally, Acorda ignores the reality that, as countless state long-arm statutes attest, states have not been shy about extending their jurisdiction to the full extent the Constitution permits. It is thus not surprising states are already considering recapturing territory lost in *Daimler* via the registration-as-consent two-step. *See* N.Y.C. Bar, *Report on Legislation: A.6714 & S.4846* (2015), http://bit.ly/1qkbumh. There is thus a very real danger that, moving forward, states' claims to general personal jurisdiction will

[3] None of Acorda's authorities is to the contrary. In *Adam v. Saenger*, 303 U.S. 59, 67-68 (1932), for instance, the Supreme Court merely recognized that when a party voluntarily invokes the judicial machinery of a particular forum it cannot later complain that a cross-claim lodged in that forum in the same case violates due process.

be even more "exorbitant" and "unacceptably grasping" than ever before. *Daimler*, 134 S. Ct. at 761-62.

Taking a different tack, Acorda suggests that if Mylan is unhappy with being exposed to suit in Delaware on any and all causes of action arising anywhere in the world it can "withdraw its registration." Acorda Br. 22 (citing Del. Code tit. 8, §381 (a corporation "may surrender its authority to do business in this State" by certifying that it is no longer authorized to conduct business and will "withdraw" from the State)). That is so, the argument goes, because "[c]orporations are not *required* to do business in Delaware" and so Mylan can cease doing business in the forum and obviate the need for registration. *Id.* That argument only underscores the incompatibility of Acorda's view of the law with *Daimler* (not to mention the threat to interstate commerce posed by Acorda'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.[4]

[4] Acorda'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

B. Acorda's Reliance on Outdated Supreme Court Precedent is Misplaced.

Acorda follows the district court's lead and focuses its attention on a trio of Supreme Court decisions that predate *International Shoe Co. v. Washington*, 326 U.S. 310 (1945): *Pennsylvania Fire Insurance 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). *See* Acorda Br. 17-19, 21-22, 34-35. But these discredited cases are no basis for ignoring *Daimler*. As *Daimler* explained, these cases were "decided in the era dominated by *Pennoyer*'s territorial thinking" and "should not attract heavy reliance today." *Daimler*, 134 S. Ct. at 761 n.18; *see also* Opening Br. 23-30.

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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, 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).

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; *see McGee v. Int'l Life Ins. Co.*, 355 U.S. 220, 222 (1957). Thus, contrary to Acorda's suggestion, this Court is not being asked to *anticipate* the overruling of these old precedents; to the extent they are inconsistent with *International Shoe*, the Supreme Court itself has already overruled them in *International Shoe*.

The primary authority on which Acorda relies—*Pennsylvania Fire*—plainly did not survive *International Shoe*. *See* Opening Br. 23-30. 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. Notably, Acorda does not cite a single post-*International Shoe* Supreme Court precedent embracing and applying the logic of *Pennsylvania Fire.*

Moreover, while both *Neirbo* and *Robert Mitchell* are equally suspect post-*International Shoe*, neither case squarely supports plaintiffs' arguments. *Nierbo* focused on venue, not jurisdiction. *See* 308 U.S. at 167-68. 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. 14 n.6.

Acorda's confusion about the continuing vitality of these *Pennoyer*-era precedents might have been understandable before *Daimler*. Courts struggled with the question of whether, when, and how a state can compel consent through registration requirements. *See* Opening Br. 28-29 & nn.11-12; JA19 (noting the

fractured opinions on the permissibility "of treating registration to do business in a state as consent to the jurisdiction of the courts in that state"); *AstraZeneca AB v. Mylan Pharm.*, No. 14-696, 2014 WL 5778016, at *555 (D. Del Nov. 5, 2014) ("[T]here is a circuit split as to whether this type of 'statutory consent' is an adequate basis on which to ground a finding of personal jurisdiction."). But after *Daimler*, it should be beyond dispute that conditioning the right to do business on mandatory registration and then construing that compulsory act as voluntary consent to all-purpose jurisdiction is incompatible with due process.

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

Acorda's arguments in support of the district court's specific personal jurisdiction analysis fare no better. Acorda repeatedly emphasizes *its* contacts with Delaware, but the Supreme Court's recent decision in *Walden* makes absolutely clear that Mylan's contacts with the forum—not Acorda's—are all that matters. Moreover, Acorda's contention that Mylan is subject to specific jurisdiction in Delaware because its ANDA filing will result in "future infringing sales," *see, e.g.*, Acorda Br. 1, 4, 13, 40, has no basis in law or fact. Future sales may give rise to personal jurisdiction in the future, but for now the filing of an ANDA in Maryland and the mailing of a mandatory notice letter to New York hardly provide a basis for specific jurisdiction in Delaware. Finally, while this Court need not reach the issue,

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. 33. 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 should have resulted in a judgment for Mylan.

The district court's error was largely based on its view that at the time Mylan sent its statutorily-required notice letters to New York and Ireland, Acorda had already filed an ANDA suit in Delaware related to the patent referenced in the letters. JA32. This "chronology of events" made it "particularly evident" that Delaware would be a fair venue for Mylan, JA33-34, because Mylan "knew or should have known" that Acorda would sue Mylan in Delaware too, JA32. But the predictability of a plaintiff suing a defendant in the wrong forum can hardly alter the constitutional

analysis. No matter how clearly the plaintiffs in *Walden* indicated that they would sue in Nevada, Nevada was still the wrong forum. And, more broadly, all the factors that made it predictable that Acorda would file in Delaware have everything to do with Acorda, and nothing to do with Mylan. But *Walden* could not have been clearer that the relationship between a defendant's suit-related conduct and the forum state "must arise out of contacts that the 'defendant *himself*' creates with the forum State." 134 S. Ct. at 1122 (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475 (1985)). "Put simply, however significant the plaintiff's contacts with the forum may be, those contacts cannot be 'decisive in determining whether the defendant's due process rights are violated.'" *Id.* (quoting *Rush v. Savchuk*, 444 U.S. 320, 332 (1980)).

Turning a blind eye to *Walden*, Acorda picks up where the district court left off. Acorda contends that jurisdiction over Mylan is proper in Delaware because the notice letters "were sent to Plaintiffs, one of which is a Delaware corporation, *after* Plaintiffs had already initiated ANDA litigation in Delaware regarding the *same* patents that were the subject of Mylan's notice letters." Acorda Br. 44. Thus, "Mylan should have anticipated being sued by Plaintiffs in Delaware." *Id.* at 45.

But neither Acorda's status as a Delaware corporation nor its preference for Delaware courts say anything about whether *Mylan's* action formed a substantial connection with the State. Moreover, the mere sending of the notice letters to New

York and Ireland comes nowhere close to creating the necessary suit-related contacts with Delaware. *See* Opening Br. 34-46. Acorda contends that, for purposes of establishing minimum contacts, Mylan's notice letters are equivalent to infringement letters that patentees send to alleged infringers. Acorda Br. 42 (citing *Red Wing Shoe Co. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1360 (Fed. Cir. 1998)). They are not. While Acorda quibbles with this Court's reasons for so holding, none of the infringement-letter cases cited by Acorda resulted in a finding of specific jurisdiction. In all events, as this Court has recognized in conducting its minimum contacts analysis, threat letters "relate in some material way," *Avocent Huntsville Corp. v. Aten Int'l Co.*, 552 F.3d 1324, 1336 (Fed. Cir. 2008), 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. And to the extent the notice letters were directed anywhere, they were directed at New York and Ireland, *not* Delaware.

Zeneca further underscores that Mylan's statutorily-mandated notice letters do not establish the required suit-related contacts. *See* Opening Br. 42-45. Acorda attempts to distinguish that important decision on the ground that neither opinion in the case addressed notice letters. But that only underscores the notice-letters' jurisdictional irrelevance. *Zeneca* addressed the main event, 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 [New York, let alone Delaware,] at all." *Id.* at 835 (opinion of Rader, J.).

Acorda tries to distinguish *Zeneca* by noting that the *Zeneca* plaintiff "sought to premise jurisdiction on transmission of its ANDA to a particular State," while this case involves a letter sent to a Delaware corporation. Acorda Br. 44. But this fact cuts sharply *against* Acorda. If actually sending an ANDA to Maryland was not sufficient for Maryland to properly exercise jurisdiction, then *a fortiori* sending mere notice about an ANDA to a Delaware corporation in New York is wholly irrelevant to whether Delaware can properly exercise jurisdiction. Again, it is the defendant's

connections to the forum state, not plaintiff's, that matters. That Acorda is "at home" in Delaware for general jurisdiction purposes does not somehow create personal jurisdiction over Mylan, even if Mylan sends Acorda a statutorily-mandated letter.

Despite the fact that *Walden* clearly controls here and clearly cabined *Calder*, Acorda bizarrely invokes *Calder* as supporting jurisdiction here. Acorda Br. 39-40. 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. Acorda'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, Acorda 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 Acorda 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, Acorda attempts to draw on far-from-certain future suit-related contacts that Mylan might one day have with the forum. According to Acorda, because Mylan's ANDA "filing was purposefully directed toward making future infringing sales in Delaware," specific jurisdiction is proper in that forum. Acorda Br. 40. While those future sales could potentially generate jurisdiction in the future (if they, in fact, materialize), they are plainly insufficient to support jurisdiction now.

Nothing in controlling precedent or commonsense supports Acorda's "future infringing sales" argument, which—as Acorda begrudgingly recognizes—would mean that is Mylan is subject to specific jurisdiction not just in Delaware, but in

every forum across the country. *Id.* at 41. At most, "future infringing 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 any and every jurisdiction Acorda 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.*, 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 Acorda'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 Acorda'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 in Delaware or anywhere else.

Acorda responds that because the merits of ANDA litigation "focus[] on what the ANDA applicant will likely market if its application is approved," the jurisdictional analysis should focus on where the applicant intends to market its drug. Acorda Br. 37-38. But the ANDA litigation is just as likely to turn on the validity of the plaintiff's patent, wholly independent of what the defendant intends to market. And the litigation is exceedingly unlikely to focus on where that marketing might actually take place. But in all events, suppositions about the focus of the litigation are beside the point. What matters is that Mylan's tort was complete—and Acorda's suit was ripe—when Mylan filed its ANDA. And personal jurisdiction needs to be present at the outset; it cannot develop as the nature of the litigation comes into focus. *See Walden*, 134 S. Ct. at 1125.

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 Acorda's limited efforts to root its "future infringing sales" arguments in this Court's precedent. In *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997), for example, the Court's sole focus was on the technical question of whether "the manufacture, use, or sale of the" the generic's drug would infringe the brand's patent. *Id.* at 1569. The Court's "focus on what the ANDA applicant will likely *market*," Acorda Br. 37 (quoting *Glaxo*, 110 F.3d at 1569) (emphasis added), is no more relevant to the question of jurisdiction than if the Court had focused on what the applicant would *manufacture* or *use*. The other cases from this Court on which Acorda relies in advancing its "future infringing sales" argument are similarly inapposite.

Acorda asserts that "principles of fairness" favor allowing patentees to file ANDA suits wherever they please because the ANDA filer "has provided formal notice of its intent to begin infringing sales upon receiving approval from the FDA." Acorda Br. 43. But Acorda's flawed reasoning assumes an outcome of the litigation that is contrary to its own allegations and ignores how ANDA litigation works. First, in a paragraph IV certification, the generic manufacturer declares its view that the

NDA's "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. §355(j)(2)(A)(vii)(IV). Thus, contrary to Acorda's premise, the ANDA does not declare an "intent to infringe," but alleges the exact opposite.

While Acorda's complaint alleges that the generic product infringes its valid patent, if those allegations are sustained, the likelihood that any "infringing sales" will actually occur is vanishingly small. If Acorda prevails, there will be no sales at all until its patents expire. *See Caraco*, 132 S. Ct. at 1676 ("the FDA cannot authorize a generic drug that would infringe a patent").[5] Thus, Acorda is attempting to premise current jurisdiction on future infringing sales that will never occur if Acorda proves its allegations. And, of course, if Mylan prevails, the sales will be non-infringing and the public's "paramount interest in seeing that patent monopolies … are kept within their legitimate scope" will be vindicated. *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 851 (2014). But either way, the future infringing sales on which Acorda would premise jurisdiction are exceedingly unlikely to occur.

The fatal problems with Acorda's "future infringing sales" argument do not end there. Most glaringly, that argument would mean that the ANDA filer could be

[5] If litigation continues beyond the term of the 30-month stay, the district court has discretion to extend the length the stay. *See* 21 U.S.C. §355(j)(5)(B)(iii).

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*, 326 U.S. at 316 (quoting *Milliken v. Meyer*, 311 U.S. 457, 463 (1940)). Indeed, Acorda'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.). As this Court has noted, one of the primary aims of the Hatch-Waxman Act was "to make available more low cost generic drugs …." *Glaxo*, 110 F.3d at 1568 (quoting H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984)). If Acorda'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 Acorda really were correct that the uncertain prospect of future sales 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 traditionally been disfavored by courts as a basis for finding personal jurisdiction in an ANDA case."

JA38. If Acorda's view of the law were correct, specific personal jurisdiction would have been the rule—not the exception. Put differently, if Acorda 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. 45-46, 52. *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).

Acorda attempts to distinguish these controlling precedents by suggesting that a patentee's attempt to suppress competition in pursuit of additional profit is somehow more meritorious than a competitor's attempt to challenge a potentially invalid patent pursuant to a congressionally authorized scheme. Acorda Br. 43. But, as the Supreme Court has recognized, "[i]t 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). 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 this respect, essentially 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. 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." *Id.*

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.

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,

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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 6,999 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).

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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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