No.

IN THE

Supreme Court of the United States

NOVO NORDISK A/S,

Petitioner,

v.

SUZANNE LUKAS-WERNER AND SCOTT WERNER,

Respondents.

On Petition for Writ of Certiorari to the Circuit Court of the State of Oregon for the County of Multnomah

PETITION FOR WRIT OF CERTIORARI

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August 14, 2013

QUESTIONS PRESENTED

This lawsuit presents claims for personal injury allegedly resulting from plaintiff's consumption of Activella®, an FDA-approved prescription hormone therapy medicine. Petitioner Novo Nordisk A/S ("NN A/S") is a Danish public limited liability company which manufactures Activella® in Denmark. NN A/S does not manufacture or sell any products, own property, or employ workers in Oregon. The Circuit Court of Multnomah County, Oregon nevertheless held that NN A/S is subject to personal jurisdiction in Oregon under a "stream of commerce" theory. NN A/S's legally distinct, indirect subsidiary, Novo Nordisk Inc. ("NNI"), obtained FDA regulatory approval for and is the U.S. sponsor of Activella®. It is NNI that markets and sells Activella® in the United States, including, ultimately, the State of Oregon.

As shown more fully below, this case poses important questions regarding the stream of commerce theory of specific *in personam* jurisdiction, particularly in light of the regulatory scheme applicable to pharmaceutical products and their sponsors.

The questions presented by this case are:

1. Whether it violates due process for a court to exercise specific personal jurisdiction over a foreign manufacturer based solely upon the volume of sales of its product in the forum state, where (a) such sales were made by an indirect corporate subsidiary and not by the foreign corporation, and (b) the foreign manufacturer did nothing to avail itself of the forum state.

2. Whether it is constitutionally reasonable and consistent with due process for a court to exercise specific personal jurisdiction over a foreign manufacturer of an FDA-approved prescription medication in light of the regulatory scheme that renders the U.S. sponsor of such medication wholly liable for its design, testing, approval, manufacturing, labeling, marketing and sales, where the sponsor is a party to the action and has sufficient assets satisfy any judgment.

PARTIES TO THE PROCEEDINGS

In addition to the parties named in the caption, Novo Nordisk Inc. and Kristina Harp, M.D. are defendants below and are respondents in this Court.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Petitioner Novo Nordisk A/S ("NN A/S") is a publicly-held company. NN A/S is the indirect corporate parent of Novo Nordisk, Inc., and indirectly holds more than 10% of the stock of Novo Nordisk, Inc.

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Petitioner Novo Nordisk A/S ("NN A/S") respectfully seeks a writ of certiorari to review the the Order of the Circuit Court of the State of Oregon for the County of Multnomah, which denied NN A/S's motion to dismiss for lack of specific personal jurisdiction. Petitioner seeks review, in the alternative, of the Oregon Supreme Court's judgment in denying Petitioner's application for a writ of mandamus. (For simplicity's sake, we have omitted mention of this alternative basis from the cover of this petition.)

OPINIONS BELOW

The circuit court's ruling initially granting Petitioner's motion to dismiss for lack of personal jurisdiction is not reported and is reprinted at App. 14-17. The circuit court's subsequent order reversing itself and vacating the prior order of dismissal sets out the fundamental basis for its original ruling. It is not reported, and is reprinted at App. 1-11. The Oregon Supreme Court's order denying review is not reported and is reprinted at App. 18-19.

JURISDICTION

The Oregon Supreme Court issued its Order denying review on May 16, 2013, see App. 18-19, and therefore this petition is timely. Petitioner invokes this Court's jurisdiction under 28 U.S.C. § 1257(a). Because the Oregon Supreme Court denied review, the issue of personal jurisdiction over Petitioner consistent with the Due Process Clause of the Fourteenth Amendment to the United States Constitution is not subject to further review in the courts of the State of Oregon before final judgment. *See Cox*

Broadcasting Corp. v. Cohn, 420 U.S. 469, 485 (1975).

If this Court were to grant review and reverse the judgment, that action "would be preclusive of any further litigation on a relevant cause of action" because the Oregon courts would lack personal jurisdiction over petitioner. *Cox*, 420 U.S. at 482-83. For that reason, and because "a refusal immediately to review the state court decision might seriously erode federal policy" (*id.*), this Court has repeatedly exercised review in "cases presenting jurisdictional issues in this posture." *Calder v. Jones*, 465 U.S. 783, 788 n.8 (1984).

Additional proceedings on this issue in Oregon would be futile because the Oregon Supreme Court has already held that the Due Process Clause permits the exercise of specific *in personam* jurisdiction over a foreign manufacturer under a pure stream-of-commerce theory when there are sales of more than one of the defendant's products in the forum, even if the foreign manufacturer undertook no purposeful act to avail itself of that forum. *China Terminal & Electric Corp. v. Willemsen,* 282 P.3d 867 (Or. 2012), *cert. denied*, 2013 WL 215559 (Or. 2013). As long as *Willemsen* remains controlling precedent, any meaningful challenge to personal jurisdiction is effectively foreclosed in Oregon state courts.

Mandamus is an independent legal proceeding whose termination constitutes a "final decision" of the state courts within the meaning of 28 U.S.C. § 1257(a). *See Mt. Vernon-Woodbury Cotton Duck Co. v. Alabama Interstate Power Co.*, 240 U.S. 30, 31 (1916); Stern, Gressman, Shapiro & Geller, SUPREME COURT PRACTICE 108 (7th ed. 1993). This Court has previously addressed due process challenges to

personal jurisdiction on writ of certiorari from mandamus proceedings in the state courts. *See Burnham v. Superior Court of California*, 495 U.S. 604, 608 (1990). As a result of the Oregon Supreme Court's refusal to hear the merits, NN A/S lacks a plain, speedy, and adequate remedy in the ordinary course of the law. Interlocutory appeal is not available. Direct appeal following trial is not an adequate remedy because NN A/S would be required unnecessarily and in contravention of due process to incur the burden of defending itself in a distant, remote, and inconvenient foreign forum. Indeed, *J. McIntyre Machinery Ltd. v. Nicastro,* 131 S. Ct. 2780 (2011), and *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846 (2011), arose in roughly the same interlocutory posture (prior to trial in state courts).

CONSTITUTIONAL PROVISION INVOLVED

The Fourteenth Amendment to the United States Constitution, Section 1 provides:

> No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

U.S. Const. amend. XIV, § 1.

STATEMENT OF THE CASE

Plaintiffs-Respondents Suzanne Lukas-Werner and her husband Scott Werner asserted claims for medical malpractice against co-defendant Dr. Kristina Harp and product liability claims against Novo Nordisk Inc. ("NNI") and NN A/S. They alleged that Mrs. Lukas-Werner developed breast cancer following four years of treatment with Activella®, a prescription hormone therapy medicine manufactured in Denmark by Petitioner NN A/S and which was distributed in the United States by its indirect subsidiary, NNI. Mrs. Lukas-Werner asserted claims against NN A/S for her alleged personal injuries, and Mr. Werner asserted claims for loss of his wife's consortium. Plaintiffs' claims against NN A/S are identical to their claims against NNI.

Respondents filed their action in the Circuit Court of the State of Oregon for the County of Multnomah on September 9, 2010, and obtained service on NN A/S in Denmark via the Hague Convention under the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters. On March 30, 2011, NN A/S filed its motion to dismiss for lack of specific personal jurisdiction.

NN A/S is a Danish public limited liability company, with its headquarters in Bagsværd, Denmark. App. 2, 67. NN A/S has no employees or agents in the state of Oregon, nor does it have any physical or business presence in the state. App. 67. It is not licensed or registered to conduct business in Oregon, does not advertise or solicit business in Oregon, and does not have contracts with or sell any of its products directly to any Oregon-based vendors, retailers, distributors, or individual consumers. *Id.*

NN A/S provides Activella® to NNI, which is a Delaware corporation with its principal place of business in Princeton, New Jersey. App. 2, 68. NN A/S did not sell Activella® in Oregon to any Oregon-based distributor. *Id.*

NN A/S does not control the distribution system by which a legally separate indirect subsidiary, NNI, sells Activella® within the United States. App. 68-69, 134-35. NN A/S ships Activella® to NNI's third-party logistics provider in Indianapolis, Indiana. App. 134-35. That concludes NN A/S's involvement. At the point of sale in the U.S., Activella® belongs to NNI, and any subsequent sales transaction is between NNI and the purchaser. Indeed, even NNI does not market directly to pharmacies in Oregon, but rather it sells to wholesale distributors. *Id.* The wholesalers in turn sell to pharmacy chains and individual pharmacies in the United States, including the State of Oregon. *Id.*

NNI obtained FDA regulatory approval to market and sell Activella® in the United States. NNI, not NN A/S, is the entity that is subject to FDA regulations and state and federal law as the listed sponsor of the drug.

After permitting the plaintiffs 14 months to conduct jurisdictional discovery, the state circuit court on June 1, 2012 granted NN A/S's motion to dismiss for lack of personal jurisdiction. *See* App. 5-6, 14-17. The Court and the parties had agreed to await the decision in *J. McIntyre Machinery, Ltd. v. Nicastro,* 131 S. Ct. 2780 (2012), and the trial court's ruling granting the motion to dismiss was based upon the factors on which the plurality and the concurrence agreed in *Nicastro*. The circuit court found that the record was devoid of evidence that

NN A/S purposefully targeted the State of Oregon as to Activella®'s marketing, design, manufacture or labeling. App. 5-6, 16-17. It found no purposeful availment by NN A/S. App. 5, 16-17.

Following a decision by the Oregon Supreme Court in an unrelated product liability case, *China Terminal & Electric Corp. v. Willemsen,* 282 P.3d 867 (Or. 2012), *cert. denied*, 2013 WL 215559 (Or. 2013), the trial court in this matter *sua sponte* reconsidered (App. 12-13) and reversed itself, denying the motion to dismiss on January 30, 2013. App. 1-11.

NN A/S then applied for a writ of mandamus in the Oregon Supreme Court. Pursuant to statute, Or. Rev. Stat. § 34.250(1), original jurisdiction of the writ lay with the Oregon Supreme Court, and said writ was timely filed. The Oregon Supreme Court denied the writ without an opinion on May 16, 2013. App. 18-19.

REASONS FOR GRANTING THE PETITION

This Court's review is warranted to clarify the circumstances under which due process would permit a court to exercise specific personal jurisdiction over a foreign corporation, if ever, based solely on a subsidiary or distributor's in-state conduct. This question has produced conflicting approaches among the circuits and between the highest courts of different states, meriting this Court's review to ensure that courts are uniformly enforcing the constitutionally-mandated restrictions on the exercise of specific personal jurisdiction. Where, as here, a foreign manufacturer is not involved in distribution to or within the forum (and has engaged in no other

purposeful act in the forum state), mere sales of the product within the forum state alone is not sufficient to establish personal jurisdiction under the relevant due process standard.

The exercise of personal jurisdiction over a foreign company like NN A/S is subject to more exacting judicial scrutiny. "[L]itigation against an alien defendant creates a higher jurisdictional barrier than litigation against a sister state because important sovereignty concerns exist." *Sinatra v. National Enquirer, Inc.*, 854 F.2d 1191, 1199 (9th Cir. 1988). "Great care and reserve should be exercised when extending [U.S.] notions of personal jurisdiction into the international field." *Asahi Metal Indus. Co. v. Superior Court*, 480 U.S. 102, 115 (1987). This Court has previously recognized that foreign corporations have a legitimate interest in forming U.S.-based subsidiaries who will be responsible for compliance with U.S. laws, to avoid the undue burden and expense of defending lawsuits in a vast array of judicial systems around the world. *See Burger King v. Rudzewicz*, 471 U.S. 462, 471-72 (1985). So long as the U.S. subsidiary is capable of satisfying any judgments that may be rendered with respect to the product, courts have no legitimate interest in subjecting foreign manufacturers to personal jurisdiction in forums with which the manufacturer had no direct contact and did not directly target.

Furthermore, this Court should consider that the regulatory requirements applicable to sponsors of FDA-approved prescription medicines ought to result in a different personal jurisdiction analysis than in traditional product liability cases, because, by operation of law, the U.S. drug sponsor who seeks and

receives FDA approval for a medication is wholly liable as a matter of law for the drug, including its clinical testing, design, labeling, manufacture, marketing, post-market surveillance, and sale. *See, e.g.,* 21 CFR Part 312, 21 CFR Part 211, 21 CFR Part 314; *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 344 n.15 (2008) (listing the analogous medical device sponsor's responsibilities).

I. THE OREGON COURTS HAVE DECIDED AN IMPORTANT AND RECURRING ISSUE OF PERSONAL JURISDICTION OVER FOREIGN MANUFACTURERS GENERALLY, AND PHARMACEUTICAL MANUFACTURERS IN PARTICULAR, IN A MANNER THAT CONFLICTS WITH THIS COURT'S RULINGS AND IS OF SUBSTANTIAL IMPORTANCE TO INTERSTATE COMMERCE.

The restrictions on personal jurisdiction in the state courts "are more than a guarantee of immunity from inconvenient or distant litigation." *Hanson v. Denckla*, 357 U.S. 235, 251 (1958). Rather, "[t]hey are a consequence of territorial limitations on the power of the respective States." *Id.*; *see also World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980) (minimum contacts requirement serves the dual functions of protecting defendant against the burden of litigation and ensuring states "do not reach out beyond the limits imposed on them by their status as coequal sovereigns in our federal system").

"Due process protects [a defendant's] right to be subject only to lawful authority." *Nicastro*, 131 S. Ct. 2780, 2791. The crux of the personal jurisdiction inquiry is whether the defendant "reveal[ed] an intent to invoke or benefit from the protection of" the

laws of the forum state. *Id.* Absent plaintiff's proof of such intent, the forum state is "without power to adjudge the rights and liabilities" of the foreign defendant. *Id.*

The *Nicastro* plurality concluded that the true inquiry is whether the defendant's activities manifested an intention to submit to the power of a sovereign, by purposefully availing itself of the privilege of conducting activities within the forum state, and thereby invoking the benefits and protections of its laws. *Id.* at 2788. This holding is consistent with long-standing precedent of this Court, and Justices Breyer and Alito concurred that there was an absence of evidence that the defendant foreign manufacturer had purposefully availed itself of the forum state. *Id.* at 2792 (there was "no specific effort by the British Manufacturer to sell in New Jersey," including forum-directed conduct "such as special state-related design, advertising, advice, [and] marketing," leading to the concurrence's conclusion that the foreign manufacturer had not "purposefully avail[ed] itself of the privilege of conducting activities" in New Jersey).

A. VARIOUS COURTS' ATTEMPTS TO INTERPRET AND APPLY THE "STREAM OF COMMERCE" METAPHOR HAVE FAILED TO ACKNOWLEDGE THAT PURPOSEFUL AVAILMENT IS *THE* STANDARD FOR THE CONSTITUTIONAL EXERCISE OF PERSONAL JURISDICTION.

A non-resident defendant must have "purposefully availed" itself of the benefits of the forum state for jurisdiction to be exercised. *Burger King*, 471

U.S. at 472. "It is essential in each case that there be some act by which the defendant purposefully avails itself of the privilege of conducting activities within the forum state, thus invoking the benefits and protections of its laws." *Hanson*, 357 U.S. at 253.

Purposeful availment requires more than constructive knowledge that a manufacturer's products might end up being sold in a particular state. Purposeful availment means conduct which shows a purpose by the defendant to avail itself of a state's consumers. This Court has held that, to satisfy this requirement of purposeful availment, a defendant must have:

> "[D]eliberately exploited the [state's] market" – a standard akin to specific intent. *Keeton,* 465 U.S. at 781. Jurisdiction is proper, moreover, only where the "contacts proximately result from actions by the defendant *himself* that create a substantial connection with the forum State."

Burger King, 471 U.S. at 475 (quoting *McGee v. International Life Ins. Co.,* 355 U.S. 220, 223 (1957)). "[R]andom, fortuitous, or attenuated contacts" do not suffice. 471 U.S. at 480. Here, NN A/S did not have any contacts with Oregon at all.

The *Asahi* case yielded multiple opinions regarding the effect of a defendant's placement of a product in the "stream of commerce," which led the

product to be used in the forum state. In considering *Asahi*, the *Nicastro* plurality correctly noted that "stream of commerce" is simply a "metaphor" to describe the "purposeful availment" analysis in the context of the sale of goods. "[T]he stream-of-commerce metaphor cannot supersede either the mandate of the Due Process Clause or the limits on judicial authority that Clause ensures." *Nicastro* 131 S. Ct. at 2791.

The flow of products into the forum state "may bolster an affiliation" between the foreign defendant and the forum state that is germane to the jurisdictional analysis. *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846, 2855 (2011). However, there is simply no precedent supporting various lower courts' conclusions that proof that a product entered the "stream of commerce" and ended up in the forum state is alone sufficient to constitutionally exercise specific personal jurisdiction, or that it is a substitute for proof of purposeful availment by the defendant. Indeed, Justices Breyer and Scalia joined the *Nicastro* plurality in reflecting the New Jersey court's foreseeability rule as "rest[ing] jurisdiction . . . upon no more than the occurrence of a product-based accident in the forum State." *Id.* at 2793.

It is well established that the mere possibility that a product might end up in a given state cannot constitute the specific intent necessary to support personal jurisdiction. "'[F]oreseeability' alone has never been a sufficient benchmark for personal jurisdiction under the Due Process Clause." *World-Wide Volkswagen*, 444 U.S. at 295. Were it otherwise, "[e]very seller of chattels would in effect appoint the chattel his agent for service of process. His

amenability to suit would travel with the chattel." *Id.* at 296.

As this Court has explained,

> [T]he foreseeability that is critical to due process analysis is not the mere likelihood that a product will find its way into the forum State. Rather, it is that the defendant's conduct and connection with the forum State are such that he should reasonably anticipate being haled into court there.

World-Wide Volkswagen, 444 U.S. at 297. Accordingly, the "stream of commerce" metaphor invites unwarranted reliance upon hypothetical expectations and "should have knowns," rather than admissible evidence that establishes conduct by the defendant designed to take advantage of the forum state.

While the facts in *Nicastro* showed intent to serve the U.S. market generally, six Justices agreed that the plaintiff had failed to meet his burden of proof that the manufacturer purposefully and specifically targeted the New Jersey market. While *Nicastro* did not produce a majority opinion, a majority of the Court agreed that intent to serve a nationwide market is insufficient to establish purposeful availment of a specific forum, and the foreign defendant must have engaged in conduct intended to specifically avail itself of the forum state in question. Unfortunately, the Oregon courts (among others) have largely disregarded *Nicastro*, and have continued to apply a bare "stream of commerce" test that allows

the assertion of jurisdiction over a defendant that had no contact with the forum state other than the manufacture of a product that ended up there.

Just as in *Nicastro*, the undisputed evidence in this case is that NN A/S intended for Activella® to be available in the U.S. market generally, and that any contacts with Oregon were made by a legally distinct corporation, NNI. This case presents the Court the opportunity to state with clarity and finality that a plaintiff must always prove that the defendant itself had specific minimum contacts with the forum state that demonstrated a purposeful availment of that forum's market, and not merely the U.S. market as a whole.

B. OREGON COURTS HAVE ISSUED RULINGS THAT ARE IN CONFLICT WITH THIS COURT'S PRECEDENTS.

The Oregon courts rely upon Oregon Rule of Civil Procedure 4D, which purports to grant personal jurisdiction when "[p]roducts, materials, or things distributed, process, serviced, or manufactured by the defendant were used or consumed within this state in the ordinary course of trade." This is an attempted codification of the bare "stream of commerce" theory of personal jurisdiction. Apparently, Oregon courts view this basis for jurisdiction as being independent of the minimum contacts test set forth in *International Shoe Co. v. Washington*, 326 U.S. 310 (1945). As applied by the Oregon courts, the state's personal jurisdiction test is unconstrained by the Fourteenth Amendment's due process limits – a defendant manufacturer is subject to personal jurisdiction if any one of its products were "used or consumed" within the state.

In reversing itself and vacating its prior ruling dismissing NN A/S for lack of personal jurisdiction, the trial court relied upon Rule 4D and the Oregon Supreme Court's decision in *Willemsen,* 282 P.3d 867. The trial court found that there was sufficient volume or flow of Activella® into the state of Oregon to satisfy the purposeful availment standard and that the actor who actually conducted the sales, marketing, and distribution was irrelevant to the personal jurisdiction analysis under *Willemsen*.

This Court has previously taken up *Willemsen*, 132 S. Ct. 75 (2011), granting certiorari, vacating the judgment, and remanding the case to the Oregon Supreme Court for further consideration of the case in light of its decision in *Nicastro*. Following remand by this court, the Oregon Supreme Court persisted in its prior finding of personal jurisdiction over the defendant in *Willemsen*, a Chinese supplier of battery chargers that were incorporated into wheelchairs, approximately one thousand of which were distributed in Oregon by the U.S. manufacturer or its distributor. The Oregon Supreme Court interpreted this Court's ruling in *Nicastro* to mean that anything more than a single sale of a product in the forum state by a manufacturer or distributor of the finished product was sufficient to permit exercise of personal jurisdiction over the foreign entity that manufactured the product under a bare "stream of commerce" theory. App. 29 n.7.

The Oregon Supreme Court in *Willemsen* erroneously laser focused on the notion that personal jurisdiction was found lacking in *Nicastro* solely because only a single sale had occurred in the forum state. App. 29 n.7, 32. The Oregon Supreme Court overlooked that Justice Breyer's concurrence was

critical of plaintiffs for failing to develop a sufficient evidentiary record before the trial court. 131 S. Ct. at 2791 ("respondent Robert Nicastro failed to meet his burden"). Justice Breyer most certainly did ***not*** hold or even remotely suggest that anything more than a single sale was sufficient to support personal jurisdiction.

The essential foundation for the Oregon courts' decisions in this case and in *Willemsen* is a "singular sale" theory of due process, which is based (in both instances) on a fundamental misunderstanding of the legal effect of the evidentiary record before the Supreme Court in *Nicastro*. In interpreting *Nicastro*, the Oregon Supreme Court cited the "*Marks* Doctrine" for the proposition that, "[w]hen a fragmented Court decides a case and no single rationale explaining the result enjoys the assent of five Justices, the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds." *Marks v. United States*, 430 U.S. 188, 193 (1977). The *Willemsen* court, in its fact-bound analysis, mistakenly concluded that the "narrowest grounds" for those justices joining Justice Breyer's concurrence (Breyer and Justice Alito) was that only a single sale had occurred within the forum. App. 29 n.7, 32. But the plurality did not find that there was only a singular sale – it found that four sales had occurred. 131 S. Ct. at 2790. Moreover, the *Marks* Doctrine applies to the narrowest *legal grounds* upon which the plurality and concurrence(s) agreed, not the narrowest interpretation of the facts. Justice Breyer did not "join" the plurality on the grounds of the number of sales; he *disagreed* with the plurality's

consideration of evidence that was not before the trial court. 131 S. Ct. at 2794.

Instead of the "singular sale" rationale cited by the *Willemsen* court, on which this Court formed no genuine consensus, the narrowest holding upon which Justices Breyer and Alito actually agreed with the four-member plurality was that the plaintiff bore the burden of proving purposeful availment by the defendant itself. *Nicastro*, 131 S. Ct. at 2792. Indeed, six Justices concurred that the constitutional exercise of due process required proof that the defendant had purposefully availed itself of the forum state, and this was the narrowest legal ground on which a majority of Justices agreed.

The constitutional standard for the exercise of personal jurisdiction cannot be, as the Oregon courts contend, anything more than a single sale of a product in the forum state. In *Asahi*, it appeared that thousands of units of the foreign manufacturer's product made it into the forum state of California. This volume of sales alone was insufficient for the *Asahi* court to find personal jurisdiction over the foreign manufacturer, because sales volume alone is not the end of the constitutional inquiry.

Some justices in *Asahi* concluded that there was an absence of minimum contacts, despite the sales volume, and others found that the unreasonableness of the exercise of personal jurisdiction prevailed over minimum contacts. *Asahi*, 480 U.S. at 116 (Brennan, J., concurring in part and concurring in the judgment, joined by White, Marshall, and Blackmun, JJ.) (finding minimum contacts but personal jurisdiction was unreasonable); *Asahi*, 480 U.S. at 121–22 (Stevens, J., concurring in part and concurring in the judgment, joined by White and

Blackmun, JJ.) (finding that minimum contacts need not even be addressed because of lack of reasonableness); *see also Burger King*, 471 U.S. at 477-78.

This case presents a unique opportunity for the Court to clarify that multiple sales, even thousands of sales, is not the standard for assessing a foreign manufacturer defendant's due process rights with respect to specific personal jurisdiction, when it did nothing to purposefully avail itself of that forum. The lower courts have become fixated upon the quantification of the number of sales occurring in a forum state through a distribution channel as if this is the sole relevant criteria for evaluating personal jurisdiction, when purposeful availment, targeting the forum and reasonableness are, in fact, the constitutional touchstones of the inquiry.

C. LOWER COURTS HAVE BEEN AND REMAIN IN CONFLICT AS TO THEIR INTERPRETATION OF THE RELEVANT CONSTITUTIONAL STANDARDS.

1. Pre-*Nicastro* Confusion.

Before *Nicastro* was decided, courts expressed widely divergent views of how to apply due process considerations to the assessment of the constitutional exercise of specific personal jurisdiction over a foreign defendant. Based on *Asahi*, certain courts concluded that bare stream of commerce was not enough, seemingly moving to the "stream of commerce plus" test set out by Justice O'Connor in that case. *See Kernan v. Kurz-Hastings, Inc.*, 175 F.3d 236, 243-44 (2d Cir. 1999); *Pennzoil Products Co. v. Colelli & Associates, Inc.*, 149 F.3d 197, 203-05 (3d

Cir. 1998); *Vermeulen v. Renault, U.S.A., Inc.*, 985 F.2d 1534, 1548 (11th Cir. 1993), *cert. den.*, 508 U.S. 907 (1993); *Ruckstuhl v. Owens Corning Fiberglas Corp.*, 731 So.2d 881, 889-90 (La. 1999), *cert. den.,* 528 U.S. 1019 (1999); *Juelich v. Yamazaki Mazak Optonics Corp.*, 682 N.W.2d 565, 572 (Minn. 2004); *CMMC v. Salinas*, 929 S.W.2d 435, 439-40 (Tex. 1996).

Still other courts applied Justice Brennan's "foreseeability" test in *Asahi* to establish specific personal jurisdiction, *See Barone v. Rich Bros. Interstate Display Fireworks Co.*, 25 F.3d 610, 615 (8th Cir. 1994), *cert. den.,* 513 U.S. 948 (1994); *Ruston Gas Turbines, Inc. v. Donaldson Co., Inc.*, 9 F.3d 415, 418-420 (5th Cir. 1993); *Ex Parte Lagrone v. Norco Industries, Inc.*, 839 So.2d 620, 627-628 (Ala. 2002); *A. Uberti and C. v. Leonardo*, 892 P.2d 1354, 1362-64 (Ariz. 1995); *Grange Ins. Assoc. v. State*, 757 P.2d 933, 938 (Wash. 1988), *cert. den.*, 490 U.S. 1004 (1989); *Hill v. Showa Denko, K.K.*, 425 S.E.2d 609, 616 (W. Va. 1992), *cert. den.,* 508 U.S. 908 (1993); *Kopke v. A. Hartrodt S.R.L.*, 629 N.W.2d 662, 674 (Wis. 2001), *cert. den.,* 534 U.S. 1079 (2002).

Further, still other Courts, notably including the Third Circuit, applied both tests proposed by Justices O'Connor and Brennan in *Asahi. See*, *e.g., Pennzoil Prods.*, 149 F.3d at 205-207 n. 11.

This fractured state of decisions resulted in unpredictable results and conflicting holdings in substantially similar circumstances. The need for clarification was beyond question.

2. *Nicastro* Did Not Abate the Confusion.

Lower courts continue to struggle with the meaning of the "stream of commerce metaphor" and how it guides the analysis of personal jurisdiction. These courts find that *Asahi* and *Nicastro* "provided no clear guidance regarding the scope and application of the theory, leaving little uniformity among the many different federal and state courts decisions," and therefore simply disregard these cases and attempt to formulate their own understanding of "stream of commerce." *Sproul v. Rob & Charlies, Inc.*, --- P.3d ---, 2012 WL 6662638, *6 (N.M. App. Aug. 15, 2012); *see also, e.g., Surefire, LLC v. Casual Home Worldwide, Inc.*, 2012 WL 2417313, *4 (S.D. Cal. June 26, 2012); *Original Creations, Inc. v. Ready Am., Inc.*, 836 F. Supp. 2d 711, 716-17 (N.D. Ill. 2011). The federal circuit has adopted an *ad hoc* approach, concluding that each case should be decided on its own merits, which offers no meaningful guidance. *See AFTG-TG, LLC v. Nuvoton Tech. Corp.*, 689 F.3d 1358, 1362 (Fed. Cir. 2012).

The lower courts' confusion in applying *Nicastro* is well illustrated by the fates of two cases in which this Court entered orders granting certiorari, vacting the judgment of the lower courts, and directing them to reconsider their decisions on personal jurisdiction upon remand in light of *Nicastro*. *See Dow Chemical Canada ULC v. Fandino,* 131 S. Ct. 3088 (2011); *Willemsen*, 132 S. Ct. 75. Despite closely analogous fact patterns to these cases, however, the results were dramatically different. In *Dow Chemical Canada*, the California court, upon reconsideration, found that the Canadian manufacturer of fuel tanks that were incorporated into personal

water craft sold in the state of California was not subject to specific personal jurisdiction in the state. 202 Cal. App. 4th 170, 134 Cal. Rptr. 3d 597. As discussed more fully *supra*, the Oregon Supreme Court reached the opposite conclusion in *Willemsen* with respect to the foreign manufacturer of a wheelchair component.

Post-*Nicastro,* the largest group of courts, including the First, Fourth and Tenth Circuit Courts of Appeals, have seemingly adopted the "stream of commerce plus test" espoused by Justice O'Connor in *Asahi*. *See, e.g., Adelson v. Hannanel,* 652 F.3d 75, 82 (1st Cir. 2011); *ESABGrp, Inc. v. Zurich Ins. PLC*, 685 F.3d 376, 392 (4th Cir. 2012); *Monge v. RG Petro Machinery (Group) Co. Ltd.*, 701 F.3d 598, 613-20 (10th Cir. 2012).

Other courts, including the Fifth Circuit, appear to have adopted the foreseeability test, rejected by both the plurality and concurrence in *Nicastro*. *See Ainsworth v. Moffett Eng.'g Ltd.*, 716 F.3d 174, 179 (5th Cir. 2013); *Russell v. SNFA*, 987 N.E.2d 778 (Ill. 2013); *Willemsen*, 282 P.2d at 876-77. The Federal Circuit has adopted an *ad hoc* approach, concluding that each case should be decided on its own merits, which clearly offers no meaningful guidance. *See AFTG-TG, LLC v. Nuvoton Tech. Corp.,* 689 F.3d 1358, 1363 (Fed. Cir. 2012).

Concluding that *Nicastro*'s precedential effect, if any, is limited to closely analogous facts, numerous courts have attempted to define the boundaries of "stream of commerce jurisdiction" by the number of sales that occur within the forum state. *See, e.g., Askue v. Aurora Corp. of Am.*, 2012 WL 843939, at *6-7 (N.D. Ga. March 12, 2012); *Oticon, Inc. v. Powell v. Profile Design LLC*, No. 4:10–cv–2644, 2012 WL

149518, at *8 (S.D. Tex. Jan. 18, 2012); *Ainsworth v. Cargotec USA, Inc.*, 2011 WL 6291812, *2 (S.D. Miss. Dec. 15, 2011); *Dejana v. Marine Tech., Inc.*, No. 10–CV–4029, 2011 WL 4530012, at *6 (E.D.N.Y. Sept. 26, 2011); *Sebotek Hearing Sys., LLC*, No. 08–5489, 2011 WL 3702423, at *10 (D.N.J. Aug. 22, 2011); *N. Ins. Co. of N.Y. v. Constr. Navale Bordeaux*, No. 11–60462–CV, 2011 WL 2682950, at *5 (S.D. Fla. July 11, 2011). This approach, as is true of the *ad hoc* approach, does not provide a clear standard by which a defendant may predict whether it will be subject to specific jurisdiction, because the inquiry is so fact- and product-specific.

In the wake of *Nicastro*, a single defendant in the course of a single week was subjected to different jurisdictional rulings from two courts. *See Lindsey v. Cargotec USA, Inc.*, No. 4:09CV-00071-JHM, 2011 WL 4587583 (W.D. Ken. Sept. 30, 2011); *Ainsworth v. Cargotec USA, Inc.*, 2011 WL 4443626 (S.D. Miss. Sept. 23, 2011), *aff'd, Ainsworth v. Moffet Eng'g Ltd.,* 716 F.3d 174, 179 (5th Cir. 2013). In both cases, at the trial court the same Irish manufacturer of forklifts had sold its products to a legally distinct U.S.-based corporation that distributed the products. The Kentucky court held that it did not have jurisdiction over the foreign defendant, while the Mississippi court held that it did.

Inconsistent holdings will no doubt continue to bedevil international companies whose products are sold within the various states, absent a clarifying decision by this Court. The plethora of conflicting results speaks to the essential need for this Court to speak with clarity and finality regarding the requisite due process factors to be satisfied before courts

may exercise specific personal jurisdiction over foreign manufacturers.

D. CLARIFICATION OF THE STANDARDS FOR THE EXERCISE OF *IN PERSONAM* JURISDICTION OVER FOREIGN DEFENDANTS AND THE MEANING OF THE "STREAM OF COMMERCE" METAPHOR IS OF UTMOST IMPORTANCE TO THE NATIONAL ECONOMY.

Foreign defendants that do business in the United States face an unfair and unpredictable application of what should be simple but universal constitutional due process principles, resulting in an inability to tailor their business operations so as to avoid unnecessary exposure to litigation in the U.S. The conflict amongst the various courts that have attempted to apply their versions of a "stream of commerce" test for personal jurisdiction imposes substantial economic costs upon international businesses that target the U.S. market as a whole.

It is lawful and appropriate for a foreign corporation to structure its corporate affairs so as to avoid the burden and expense of defending foreign lawsuits. *See Burger King*, 471 U.S. at 471-72. Companies operating in the global marketplace utilize a wide variety of corporate structures and business arrangements to design, manufacture, and distribute their products. Companies may establish subsidiaries or affiliates to serve different countries or regions or may sell their products to independent distributors in a country. These arrangements are not nefarious schemes; they are legitimate forms of conducting beneficial international and interstate commerce. They bring significant benefits to the

U.S. economy in the form of direct foreign investment.

Here, the Oregon trial court found jurisdiction over NN A/S based on the actions of NNI, an indirect subsidiary of NN A/S that distributed Activella® for ultimate sale in various states, including Oregon. Under the Oregon Supreme Court's rule, any foreign manufacturer could potentially be subject to jurisdiction in Oregon and other states solely because it has a U.S. subsidiary or unrelated distributor that sells products in the U.S. market. This is true despite the fact that the foreign manufacturer did nothing itself to target or avail itself of any particular state.

The U.S. subsidiaries of foreign companies provide significant benefits to the U.S. economy. U.S. subsidiaries of foreign companies provide jobs to 5.6 million Americans and support an annual payroll of over $408 billion. OFII, *Insourcing Facts*, available at http://www.ofii.org/resources/insourcing-facts.html (last visited July 24, 2013) ("*Insourcing Facts*"). These subsidiaries support an additional 4.6 million jobs because they purchase 80 percent of their inputs from U.S. businesses. U.S. Dep't of Treasury, *Fact Sheet: An Open Economy Is Vital to United States Prosperity* (May 10, 2007), available at http://www.treas.gov/press/releases/hp395.htm. These U.S. subsidiaries also make significant investment expenditures here, spending more than $41 billion on research and development and $149 billion on plant construction and new equipment. *See Insourcing Facts*.

Furthermore, approximately $2.3 trillion worth of foreign-manufactured goods were sold in the U.S. in 2012. App. 137-40. Transactions just like the one at issue in this case occur literally thousands

of times each day. In fact, $16.5 billion of foreign-manufactured goods were sold in Oregon alone in 2012. App. 141-43.

Foreign companies considering investment in the United States must be able to objectively assess the potential exposure to litigation based upon their lawful establishment of legally distinct U.S.-based subsidiaries. A foreign manufacturer's susceptibility to personal jurisdiction is a recurrent, critical concern that will persist in the lower courts. The current fractured approach to personal jurisdiction engenders tremendous uncertainty for those companies, and jeopardizes their continued investments in the U.S. economy.

Oregon's "pure stream of commerce" rule, wherein anything more than a "single sale" justifies the exercise of personal jurisdiction, discourages both foreign and interstate commercial activity. If another entity's distribution of a foreign corporation's products in a state subjects that foreign corporation to personal jurisdiction, "then the defense of personal jurisdiction, in the sense that a State has a geographically limited judicial power, would no longer exist. The [corporation] . . . would be subject to personal jurisdiction in every State." *ALS Scan, Inc. v. Digital Serv. Consult., Inc.*, 293 F.3d 707, 713 (4th Cir. 2002). As "an instrument of interstate federalism," *World-Wide Volkswagen*, 444 U.S. at 294, the Due Process Clause prohibits this obliteration of the defense of personal jurisdiction. Here, the Oregon Supreme Court's decision negates the protection intended by the Due Process Clause.

Justice Breyer, in his *Nicastro* concurrence, correctly observed that the "stream of commerce" metaphor threatens to overwhelm entirely the con-

cept of constitutional due process. 131 S. Ct. at 2793 (Breyer, J., concurring in the judgment). Indeed, under the test adopted by the Oregon courts and various other jurisdictions, any foreign manufacturer that sells a product that may, through a distribution system controlled by an entity legally distinct from the defendant, be subject to jurisdiction anywhere its products may land.

It is important for all corporations, both foreign and domestic, to operate within an identifiable framework of clear, predictable, and uniformly applied jurisdictional rules that permit "defendants to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit." *Burger King*, 471 U.S. at 472. The current uncertainty as to what conduct is sufficient to subject a foreign manufacturer to personal jurisdiction, particularly where there is a fully-responsible U.S. subsidiary already present in the action, has a chilling effect upon international business and corporations' attempts to lawfully structure their affairs so as to achieve a fair and predictable result.

The conflicting interpretation of how application of varying versions of the "stream of commerce" metaphor determines the personal jurisdiction analysis encourages the proliferation of product liability litigation in particular jurisdictions, such as Oregon, that have the lowest standards to assess constitutional due process requirements. It encourages forum-shopping by plaintiffs. This burdens judicial resources and the financial resources of the population located in these states while putting an unfair burden on foreign companies who have structured their corporate affairs consistent with legal

requirements necessary to maintain separate corporate identities.

II. ACTIVITIES OF A SUBSIDIARY ARE INSUFFICIENT TO ESTABLISH THE "MINIMUM CONTACTS" REQUIRED TO SUPPORT JURISDICTION.

The trial court, when applying *Nicastro*, found that NN A/S had not purposefully availed itself of the forums state of Oregon. App. 14-17. The trial court only reversed itself when forced to apply the Oregon Supreme Court's ruling in *Willemsen* following remand of that case by this Court. App 1-11. "The record shows not merely an isolated single sale in Oregon – which the *Willemsen* decision concludes was pivotal to Justice Breyer's controlling opinion in *Nicastro* – but rather, a significant volume of sales in Oregon of Activella pills manufactured by NN A/S." *Id.* The trial court also found that these sales in Oregon were not "attenuated" contacts because NNI was a subsidiary of NN A/S and not an independent distributor. *Id.* "Given the facts found by this Court and the holding in *Willemsen*, the flow of the product into the state amounts to, perhaps, for some, in a metaphysical sense, purposeful availment." App. 9.

That actions "perhaps", "for some", may "in a metaphorical sense" "amount[] to" purposeful availment is not the constitutional standard for the exercise of personal jurisdiction. Plaintiffs had the burden of proving that NN A/S had purposefully availed itself of the forum state of Oregon by engaging in conduct that evidenced a specific intent to target the Oregon market. They did not. The record is entirely devoid of such evidence, and the trial court's purported exercise of personal jurisdiction

over foreign defendant NN A/S deprives it of its due process rights under the Fourteenth Amendment.

The evidence did not establish that NN A/S had the constitutionally-required minimum direct contacts with Oregon necessary to support personal jurisdiction in this matter. Indeed, it has none. NN A/S has no offices or manufacturing facilities in Oregon, has no employees permanently stationed in Oregon, and does not control the distribution system by which its legally separate indirect subsidiary, NNI, markets Activella® within the United States. NN A/S did not design Activella® for the Oregon market, and did not advertise or market the product in Oregon. NN A/S did not sell Activella® in Oregon or to any Oregon-based distributor. NN A/S has no direct commercial relationship with Oregon or any of its residents related in any way to Activella®. At the point of sale in the U.S., Activella® belongs to NNI, and any subsequent sales transaction is between NNI and the purchaser.

Both *Burger King* and *World-Wide Volkswagen* hold that jurisdiction must rest on the *defendant's* purposeful actions, and not the actions of third parties. *See* 471 U.S. at 475; 444 U.S. at 295-98. "The 'substantial connection' between the defendant and the forum State necessary for a finding of minimum contacts must come about by an action of the defendant purposefully directed toward the forum State." *Asahi*, 480 U.S. at 112.

It has long been held by this Court that the actions of third parties are insufficient to establish personal jurisdiction over a foreign defendant. *See, e.g., Rush v. Savchuk*, 444 U.S. 320, 332 (1980); *Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770, 781 n. 13 (1984); *Calder*, 465 U.S. at 790. The only

conduct relevant to the minimum contacts inquiry is the defendant's conduct – and whether that conduct is purposefully directed at the forum.

The "respect for corporate distinctions" is a "bedrock principle" of law "deeply ingrained in our economic and legal systems." *United States v. Bestfoods*, 524 U.S. 51, 61-62 (1998); *Anderson v. Abbott*, 321 U.S. 349, 362 (1944) ("Limited liability is the rule, not the exception; and on that assumption large undertakings are rested, vast enterprises launched, and huge sums of capital attracted."). This fundamental legal principle provides that "a corporation will not be held liable for the acts of its subsidiaries or other affiliated corporations." 1 William Meade Fletcher, Fletcher Cyclopedia of the Law of Corporations § 43 (2007); *see Cannon Mfg. Co. v. Cudahay Co.*, 267 U.S. 333 (1925) (holding that a Maine based manufacturer was not subject to specific personal jurisdiction in North Carolina based on the acts of its Alabama based subsidiary in North Carolina, since the subsidiary was a distinct corporate entity which did not act as its agent).

In this case, NN A/S's acts are limited to manufacturing the medication Activella® in Denmark, and providing that medication to its U.S. distributor. Just as in *Nicastro*, Petitioner here provided its medication to NNI with the knowledge that, when resold, it would ultimately come to rest *somewhere* in the United States. This was not enough to support personal jurisdiction in *Nicastro*, and is not enough to support personal jurisdiction here.

The "constitutional touchstone" of whether personal jurisdiction comports with due process "remains whether the defendant purposefully established minimum contacts in the forum State." *Burg-*

er King, 471 U.S. at 474; *Asahi*, 480 U.S. at 108-09. "This Court's precedents make clear that it is the defendant's actions, not his expectations, that empower a state's court to subject him to judgment." *Nicastro*, 131 S. Ct. at 2789. Likewise, it is not the acts of a third party, whether an indirect subsidiary or independent distributor. The "pure stream of commerce" rule, utilized in Oregon and elsewhere, that the sale of a product in the form by whatever route or means is an act of purposeful availment by the product manufacturer who is otherwise a stranger to the forum is inconsistent with the well-established precedent of this Court.

Although NNI is an indirect subsidiary of NN A/S, it is and was at all times an independent U.S. corporation, such that any contacts that NNI had with Oregon cannot legally be attributed to NN A/S. Plaintiffs did not pursue an "alter ego" theory in response to NN A/S's motion to dismiss. App. 74. Indeed, this Court recognized in *Goodyear*, 131 S. Ct. at 2857, that to consider the acts of legally distinct but related corporate entities would require a piercing of the corporate veil analysis. This is the very analysis and claim that plaintiffs below made clear they were not pursuing.

Exercise of specific personal jurisdiction is inconsistent with fair play and substantial justice unless it is based upon "actions by the defendant himself that create a 'substantial connection' with the forum State." *Asahi*, 480 U.S. at 109. The activities of legally-distinct corporate affiliate NNI cannot be and are not a basis for the assertion of jurisdiction over NN A/S, which did not have the constitutionally-requisite minimum contacts with Oregon.

III. IN LIGHT OF EXTENSIVE REGULATIONS PERTAINING TO THE LIABILITY OF SPONSORS OF MEDICATIONS, EXERCISE OF JUSRISDICTION OVER AN AFFILIATED FOREIGN CORPORATION IS UNREASONABLE AND, THUS, INCONSISTENT WITH DUE PROCESS REQUIREMENTS.

Even where a defendant does have minimum contacts with a forum, due process still requires that the exercise of jurisdiction over the defendant be "reasonable." *Asahi*, 480 U.S. at 116, 121-22; *Burger King*, 471 U.S. at 477-78. The determination of the reasonableness of the exercise of jurisdiction in each case will depend on several factors, including the burden on the defendant, the interests of the forum State, the plaintiff's interest in obtaining relief, the interstate judicial system's interest in obtaining the most efficient resolution of controversies, and the shared interest of the several States in furthering fundamental substantive social policies. *Asahi*, 480 U.S. at 113.

"[E]ven apart from the question of the placement of goods in the stream of commerce," the unreasonableness of the assertion of personal jurisdiction will require dismissal of a foreign manufacturer. *Id.* at 114. Unreasonableness will defeat the exercise of personal jurisdiction even where the defendant has purposefully engaged in forum activities. *Burger King*, 471 U.S. at 477-78.

In assessing the reasonableness of exercising personal jurisdiction over NN A/S, the trial court found:

> NN A/S is clearly a very large, global company. The

> size of the defendant seems to be a significant factor in terms of fairness and the ability to appear and respond here. Thus, it would not be an undue hardship for NN A/S to appear and respond here.

App. 10. The state court opinion under review in *Asahi* similarly found that "Asahi obviously does business on an international scale. It is not unreasonable that they defend claims of defect in their product on an international scale." 480 U.S. at 107.

But this Court, in *Asahi*, expressly reversed the trial court's opinion that "doing business on an international scale" made it constitutionally reasonable to subject a foreign manufacturer to personal jurisdiction in a state court. Likewise, the trial court's ruling in this matter should be reversed, because the mere size and global reach of a defendant does not justify the unreasonable exercise of personal jurisdiction. It is per se unreasonable to use suspect criteria such as the presumed size and wealth of a defendant to impose jurisdiction on one party where under virtually identical factual circumstances a smaller, less wealthy defendant would not be subject to jurisdiction. *See State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 427-28 (2003); *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 585 (1996) (discussing wealth as an improper factor in evaluating punitive damage awards).

A. THE EXERCISE OF PERSONAL JURISDICTION OVER FOREIGN CORPORATIONS IS SUBJECT TO EXACTING JUDICIAL SCRUTINY, AND REQUIRES "GREAT CARE AND RESERVE."

Where, as here, plaintiff seeks to assert jurisdiction over a foreign company, the interests of other nations,

> [A]s well as the Federal interest in its foreign relations policies, will be best served by a careful inquiry into the reasonableness of the assertion of personal jurisdiction in the particular case, and of an unwillingness to find the serious burdens on an alien defendant outweighed by minimal interests on the part of the plaintiff or the Forum state.

Asahi, 480 U.S. at 115. Here, where NNI is fully responsible for Activella® in the U.S. and has more than sufficient assets to satisfy any reasonable judgment, it is hard to imagine that the forum has any legitimate interest in haling NN A/S into state court to defend the very same claims based on the very same evidence.

Indeed, in his concurrence in *Nicastro*, Justice Breyer concluded that the New Jersey court's finding of jurisdiction based upon the foreseeability that a product placed in the stream of commerce would reach the forum state was particularly troubling in a case involving a foreign manufacturer. *Nicastro*, 113

S. Ct. at 2793-29 ("the fact that the defendant is a foreign, rather than a domestic, manufacturer makes the basic fairness of an absolute rule yet more uncertain. I am again less certain than is the New Jersey Supreme Court that the nature of international commerce has changed so significantly as to require a new approach to personal jurisdiction").

The exercise of personal jurisdiction over foreign corporations has profound implications for both foreign and domestic corporations, as well as for international relations. "Great care and reserve should be exercised when extending our notions of personal jurisdiction into the international field." *Asahi*, 480 U.S. at 115.

There is a substantial legal and financial burden in subjecting foreign corporations to U.S. laws and the discovery process in state courts, particularly given the very different legal systems, regulatory schemes, and privacy law requirements that govern in other nations, including Denmark and the E.U. "The unique burdens placed upon one who must defend oneself in a foreign legal system should have significant weight in assessing the reasonableness of stretching the long arm of personal jurisdiction over national borders." *Asahi*, 480 U.S. at 114.

Oregon's interest in subjecting NN A/S to personal jurisdiction, in light of the presence of NNI, the FDA sponsor of Activella® who is, as a matter of law, wholly liable for the medication, is gossamer at best, and runs counter to the interests of Denmark, the European Union and its member nations. *See Asahi*, 480 U.S. at 115. In this case, Oregon has no substantial interest in subjecting NN A/S to jurisdiction, and the burdens placed upon NN A/S greatly outweigh whatever token interest Oregon may have in

demonstrating its sovereign power by subjecting an additional defendant to jurisdiction over claims that are fully answerable factually, legally and economically by existing defendant NNI, the U.S. sponsor of Activella®.

B. PERSONAL JURISDICTION OVER FOREIGN PHARMACEUTICAL MANUFACTURERS SHOULD BE MORE CIRCUMSCRIBED IN LIGHT OF THE COMPLETE LIABILITY IMPOSED UPON U.S. DRUG SPONSORS.

Further, unlike in traditional product liability suits in less heavily-regulated industries, actions against pharmaceutical companies should be subject to a more exacting personal jurisdiction analysis, due to the highly-regulated nature of the industry and the mandatory presence of a U.S.-based drug or device sponsor. NN A/S's indirect subsidiary, NNI, is the U.S. sponsor of Activella®, and is a named defendant in the *Lukas-Werner* case.

NNI sought and obtained FDA approval to market and sell Activella® in the U.S. NNI, not NN A/S, is responsible for assuring the safety and efficacy of Activella® in the U.S. from clinical development, approval, manufacturing, labeling, and post-approval safety monitoring. *See, e.g.,* 21 CFR Part 312, 21 CFR Part 211, 21 CFR Part 314; *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 344 n.15 (2008) (listing the analogous medical device sponsor's responsibilities). Indeed, there was undisputed evidence before the trial court that NNI has more than sufficient assets to satisfy any reasonable judgment in plaintiffs' favor. *See* App. 130.

Any substantive, legally-cognizable claims that a plaintiff could assert against a foreign pharmaceutical manufacturer like NN A/S could be (and in this case, in fact have been) equally directed to and asserted against the U.S.-based sponsor, NNI. NNI is a defendant already joined in this lawsuit, as to whom there is no question as to the proper exercise of personal jurisdiction.

For legal and regulatory reasons, a U.S. drug sponsor is different from an ordinary product manufacturer. The drug sponsor is wholly responsible for the approval, design, testing, manufacture, labeling, marketing, and sales of the drug for which it has sought and received FDA approval. The presence of the U.S. sponsor for a drug should, as a matter of law, preclude the joinder of foreign affiliates who, as here, undertook no purposeful acts in the forum state. Under such circumstances, there is no compelling state interest in haling into court the foreign manufacturer NN A/S. Simply put, it is *per se* unreasonable to do so.

CONCLUSION

In light of the significant conflict that has permeated judicial decisions since this Court decided *Nicastro*, this case presents an ideal vehicle to clarify the requisite bases for exercising specific personal jurisdiction over a foreign manufacturer consistent with the Due Process Clause of the Fourteenth Amendment of the Constitution of the United States. For the foregoing reasons, certiorari should be granted.

Respectfully submitted,

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