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 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 that 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, vacating 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. The *Willemsen* court believed that *Nicastro* stands for the proposition that anything more than a single, isolated sale in the forum subjects the foreign manufacturer to personal jurisdiction, without the need for plaintiffs to prove purposeful availment.

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, 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. Some courts will clearly do their best to read, interpret, and apply this Court's recent precedents on personal jurisdiction. Others seem mired in the minutia of an unpredictable, highly fact-based analysis that provides no notice to foreign manufacturers regarding when they may be subject to personal jurisdiction. 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 concept 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. At this time, foreign corporations face substantial uncertainty regarding how to structure their corporate relationships so as to enjoy the

limited liability that should be available to them as a matter of due process.

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." *Burger 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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August 14, 2013

APPENDIX A

IN THE CIRCUIT COURT OF THE
STATE OF OREGON
FOR THE COUNTY OF MULTNOMAH

SUZANNE M. LUKAS-WERNER and **SCOTT WERNER**, wife and husband, Plaintiffs, v. **NOVO NORDISK A/S, a Denmark corporation; NOVO NORDISK PHARMACEUTICAL INDUSTRIES INC., a Delaware corporation; and KRISTINA HARP, M.D., an Oregon citizen,** Defendants.	Case No. 1009-13177 **ORDER DENYING DEFENDANT NOVO NORDISK A/S' MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION AND GRANTING NN A/S' ALTERNATIVE MOTION TO STAY MERITS DISCOVERY**

This is a medical malpractice and products liability lawsuit. Plaintiffs allege that Activella, a prescription hormone therapy medication, caused plaintiff Suzanne M. Lukas-Werner to develop breast cancer. Plaintiffs named a number of entities, including Novo Nordisk Inc., Novo Nordisk A/S, Breckenridge Pharmaceutical[1] and Kristina Harp, M.D. The operative

[1] Breckenridge, a manufacturer of a generic hormone therapy medicine, was voluntarily dismissed by plaintiffs with prejudice.

pleading is plaintiffs' Third Amended Complaint filed on January 27, 2012.

This matter initially came before the Court on June 1, 2012 on specially appearing defendant Novo Nordisk A/S's ("NN A/S") Rule 21 Motion to Dismiss for Lack of Personal Jurisdiction. Following oral argument, the Court initially granted the motion in a ruling from the bench. Before signing a written order and entering judgment, the Court, on its own motion, reconsidered its ruling at a second hearing on October 12, 2012. Plaintiffs appeared through counsel Leslie W. O'Leary, Michael L. Williams and Steven B. Seal. Defendant NN A/S appeared through counsel Patrick Lysaught, Jonathan Hoffman and Mary-Anne Rayburn. On reconsideration, and for the reasons explained below, the Court DENIES defendant NN A/S' Motion to Dismiss and GRANTS its alternative motion to stay merits discovery pending mandamus review by the Oregon Supreme Court.

I. The Court's June 1, 2012 Order

Defendant Novo Nordisk A/S ("NN A/S") filed its Motion to Dismiss for Lack of Specific Personal Jurisdiction on March 30, 2011, with a supporting brief. NN A/S is a foreign entity domiciled in Copenhagen, Denmark. NN A/S appears specially to challenge jurisdiction. Co-defendant Novo Nordisk Inc. (hereinafter "NNI") is a Delaware corporation with its principal place of business in Princeton, New Jersey, and it is a wholly owned subsidiary of NN A/S.

In their response to NN A/S' motion to dismiss, plaintiffs argued that NN A/S' motion should not be heard until they obtained discovery of jurisdictional facts. Despite NN A/S' position to the contrary, the Court concluded that under all of the circumstances, specific jurisdictional discovery as to NN A/S was appropriate.

Both parties agreed that the discovery of NN A/S should be limited to those matters relevant to the issue of this Court's exercise of personal jurisdiction over NN A/S. However, the parties disagreed about the scope of such discovery. Among other discovery, plaintiffs sought an ORCP Rule 39C(6) deposition of NN A/S. In response, NN A/S filed a Motion for a Protective Order, maintaining that the scope of discovery sought by plaintiffs was overly broad and irrelevant. The parties fully briefed the issue.

When the motion to dismiss was initially scheduled to be heard, the parties reached an agreement that determination of the scope of jurisdictional discovery should be delayed pending a decision of the United States Supreme Court in *J. McIntyre Machinery, Ltd. v. Nicastro,* 564 U.S. ___, 131 S. Ct. 2780 (2011), which the parties expected would be issued by the end of June 2011. Plaintiffs and NN A/S submitted supplemental briefing on their respective positions as to the effect of *Nicastro* on the scope of jurisdictional discovery in this matter.

The Court heard oral argument on the Motion for Protective Order on July 6, 2011. Based on its

interpretation of *Nicastro,* the Court permitted jurisdictional discovery to proceed but limited the scope of discovery to evidence that NN A/S directly targeted Activella sales to Oregon. *See* Order dated July 21, 2011.[2]

Plaintiffs took the deposition of NN A/S' ORCP 39C(6) corporate representative Anne Reker-Cordt on August 10, 2011 but maintained they were unable to complete it because NN A/S objected to certain questions on the grounds that they were beyond the scope of the Court's July 21 Order. Plaintiffs filed a motion to compel responses to approximately thirty-five (35) questions. After reviewing the parties' briefs, the Court granted plaintiffs' motion in part on January 18, 2012, and required Ms. Reker-Cordt to answer eleven (11) of the questions sought by plaintiffs. *See* Rulings on Plaintiffs' Motion for an Order Compelling Discovery on Personal Jurisdiction Issues Re: Novo Nordisk A/S (Anne Reker Cordt Deposition), dated January 18, 2012. The deposition resumed on April 26, 2012. The Court attended the deposition by phone and contemporaneously ruled on NN A/S' objections.

Meanwhile, plaintiffs also obtained discovery from NNI on facts related to personal jurisdiction as to NN A/S, as well as general discovery. The scope of

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[2] Tr. Of July 6, 2011 Hearing at 46-47. Plaintiffs chose not to pursue discovery as to NNI's ability to pay a judgment in the event that the trial of this matter resulted in a judgment in plaintiffs' favor.

these two avenues of discovery is reflected in the Court's separate Orders following hearings on March 16 and March 30, 2012.

On May 16, 2012, as provided by this Court's Order, plaintiffs filed their opposition to the Motion to Dismiss originally filed by NN A/S on March 30, 2011. NN A/S filed its Reply on May 22, 2012. The Court heard oral argument on June 1, 2012. After considering the arguments of counsel and carefully reviewing the parties' briefs and supporting evidence, the Court concluded that plaintiffs had not met their burden of establishing a factual basis under *Nicastro* to support the exercise of specific personal jurisdiction over NN A/S. The Court made the following findings of fact and conclusions of law:

1) Plaintiffs bore the burden to both plead and prove facts sufficient to meet the due process requirements under the Constitution of the United States as to the exercise of specific personal jurisdiction over NN A/S. The Court finds that plaintiffs had 14 months to conduct specific personal jurisdictional discovery and were afforded a reasonable opportunity to conduct discovery as to the factual issues concerning personal jurisdiction as to NN A/S, provided by the Court's July 21, 2011 order, and there was no just reason to delay the Court's ruling on that issue as of June 1, 2012. Under the U.S. Supreme Court's decision in *J. McIntyre Machinery, Ltd. v. Nicastro,* 564 U.S. ___, 131 S. Ct. 2780 (2011), using the most restrictive analysis (as

set forth in Justice Breyer's concurring opinion), plaintiffs must establish purposeful availment of Oregon by NN A/S directly or indirectly as to Activella, the prescription drug at issue. The record is devoid of evidence that NN A/S itself targeted Oregon, or that it intended its subsidiary NNI to target Oregon, as to the labeling, marketing, design or manufacturing of Activella. Nor have plaintiffs shown that NN A/S had actual knowledge of any such activities directed toward Oregon.

2) Plaintiffs did establish that NN A/S knew that NNI was conducting clinical studies of Activella in Oregon. Nevertheless, plaintiffs' allegations do not arise out of the clinical studies. While their claims arise from the adequacy of the studies in general, there is no contention that plaintiff was injured because of what happened or did not happen in the clinical studies in Oregon. Therefore, these studies do not provide sufficient evidence that NN A/S purposefully availed itself to this forum. Thus, NN A/S' motion to dismiss for lack of specific personal jurisdiction should be granted.

Following this Court's ruling, plaintiffs filed a motion to stay entry of the above order pending the Oregon Supreme Court's forthcoming opinion on the exercise of personal jurisdiction in *Willemsen v. Invacare Corporation,* a factually similar product liability case. NN A/S opposed plaintiffs' motion. Meanwhile, the Oregon Supreme Court published its

decision in *Willemsen* on July 19, 2012, before the Court could schedule a hearing on plaintiffs' motion to stay. *Willemsen,* 352 Or 191, 282 P3d 867 (2012). In a unanimous decision, that court held that in light of the U.S. Supreme Court's recent opinion in *J. McIntyre Machinery, Ltd. v. Nicastro,* 564 U.S. ___, 131 S Ct 2780 (2011), Oregon courts may exercise personal jurisdiction over CTE, the Taiwanese manufacturer of the defective component of the product that killed the decedent.

II. The Court's Order on Reconsideration

On July 24, 2012 the Court notified the parties by e-mail that in light of the *Willemsen* decision, it would, on its own motion, reconsider its June 1, 2012 ruling granting NN A/S' motion to dismiss for lack of personal jurisdiction. The Court directed the parties to submit simultaneous briefs, not to exceed 10 pages each, on the application of the *Willemsen* analysis to the factual record on personal jurisdiction in this case. Plaintiffs and NN A/S filed their briefs on August 9, 2012. In addition, NN A/S filed a motion to strike certain exhibits that were attached to plaintiffs' May 16, 2012 opposition to NN A/S' motion to dismiss for lack of personal jurisdiction. NN A/S argued that these documents lacked evidentiary foundation and that their contents were inadmissible for various reasons as set forth in defendant NN A/S' Motion to Strike.

On October 12, 2012, the Court heard oral argument on its motion for reconsideration and NN A/S'

motion to strike. The Court's rulings on NN A/S' motion to strike are set forth in a separate order. *See* Order Granting in Part and Denying in Part Defendant Novo Nordisk's Motion to Strike Certain Exhibits Attached to Plaintiffs' Opposition to Novo Nordisk A/S' Motion to Dismiss for Lack of Foundation.

After hearing the arguments of counsel on the application of *Willemsen* to the factual record in this case, and having carefully reviewed the parties' briefs and supporting evidence, the Court concludes as follows:

1) As to NN A/S' contention that plaintiffs' complaint fails to allege any claim or factual basis for personal jurisdiction, in light of the broad reading the Court is required to give ORCP 21, along with reasonable inferences in favor of the pleading, and any facts that can be adduced, the plaintiffs have sufficiently pled facts supporting personal jurisdiction. Even if the pleadings were insufficient, under Oregon's liberal rules for amendment, plaintiffs' oral motion to amend is allowed consistent with the facts argued in the motion, and in the opposition to NN A/S' motion to dismiss, including the evidentiary record offered by plaintiffs.

2) Applying *Willemsen's* analysis of personal jurisdiction to this case, the Court finds that plaintiffs have made a sufficient factual showing to support their allegations of personal jurisdiction against NN A/S. 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. The evidence also shows that the sales of Activella in Oregon were not fortuitous. [The analysis of attenuation is a little more difficult because], as counsel for NN A/S points out, *Willemsen* did not discuss the "attenuation" issue. However, the Court concludes that the sales of NN A/S' drug Activella were not attenuated. The fact that the Activella pills themselves arrived in Oregon through a complex distribution scheme is not a significant factor under *Willemsen.* Here, in fact, the flow of Activella sales to Oregon may be less attenuated than those in *Willemsen* because NNI, the distributor of Activella in the U.S. and in Oregon, was a wholly owned subsidiary of NN A/S, not a completely independent distributor. 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. For that reason, personal jurisdiction exists here, because there was a sufficient volume or flow of NN A/S' product into Oregon to satisfy the standard for purposeful availment.

3) This Court must also consider whether the exercise of personal jurisdiction over NN A/S would offend traditional notions of fair play and substantial justice, in violation of the Due Process Clause of the U.S. Constitution.

The Court is mindful that a heightened standard applies to a foreign national defendant, as was the case in *Willemsen.* The Court concludes that under the facts in this record, it would not be unfair to require NN A/S to respond to allegations against it in Oregon. There is evidence in the record that shows – as it did in *Willemsen* – that NN A/S anticipated the need to defend itself against this very sort of claim. 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. *Willemsen* does not tie foreign defendants' anticipated need to defend against this very sort of claim, wherever a sufficient volume of sales might lead to a lawsuit in the particular forum, notwithstanding Justice Breyer's italicized language in *Nicastro.* Under *Willemsen,* it is sufficient if the defendant challenging personal jurisdiction can be shown to have anticipated the need to appear wherever the flow of sales might result in a lawsuit against it. Unlike *Willemsen,* there is no Oregon-specific evidence in this case of an agreement by the foreign manufacturer to comply with all state and federal regulations. However, because there was no evidence of anything Oregon-specific in the record in *Willemsen,* the Court does not find such a showing is necessary.

4) Accordingly, on reconsideration [of its initial ruling granting the motion,] and for all of the reasons stated above, the Court DENIES defendant NN A/S' motion to dismiss for lack of personal jurisdiction.

5) However, the Court GRANTS defendant NN A/S' alternative motion to stay the merits discovery as to NN A/S pending further appellate review of the *Willemsen* case on Petition for Certiorari to the U.S. Supreme Court and of this case by the Oregon Supreme Court.

DATED this 14th day of January, 2013

/s/ Wilson
The Honorable Janice R. Wilson
Circuit Court judge

Submitted by:

/s/ Leslie W. O'Leary

Leslie W. O'Leary
WILLIAMS LOVE O'LEARY & POWERS, P.C.
12725 SW Millikan Way, Ste. 300
Beaverton, OR 97005
Phone: 503-295-2924
Fax: 503-295-3720

Dated: January 7, 2013

Of Attorneys for Plaintiffs

APPENDIX B

From: Janice.R.WILSON@ojd.state.or.us
Sent: Tuesday, July 24, 2012 12:48 PM
To: michael_williams@wdolaw.com; loleary@wdolaw.com; jhoffman@martinbischoff.com; mrayburn@martinbischoff.com; Pat Lysaught
Cc: kok@hhw.com; Janell.C.Seet@ojd.state.or.us; Erin.M.REEL@ojd.state.or.us
Subject: Lukas-Werner, et al. v. Novo Nordisk AS, et al., Case No. 100913177

Dear Counsel:

In light of the Oregon Supreme Court's recent decision in Willemsen v. Invacare, et al., this court on its own motion will reconsider its ruling on Novo Nordisk AS's motion to dismiss for lack of personal jurisdiction.

The parties should submit simultaneous briefs, not to exceed 10 pages each, on the application of the Willemsen analytic framework to the factual record on person [sic] jurisdiction in this case. Those briefs are due by 4:00 pm, Thursday, August 9, 2012.

My JA, Janell Seet, will be in touch with you to arrange a date for further oral argument.

Regards,
Janice R. Wilson

Janice R. Wilson
Circuit Judge, Multnomah County
1021 SW Fourth Ave.
Portland, OR 97204-1123
Phone: 503-988-3069
Janice.R.Wilson@ojd.state.or.us

APPENDIX C

IN THE CIRCUIT COURT OF THE
STATE OF OREGON
FOR THE COUNTY OF MULTNOMAH

SUZANNE M. LUKAS-WERNER, and SCOTT WERNER, wife and husband, Plaintiff, vs. NOVO NORDISK, A/S, a Denmark corporation, et al; NOVO NORDISK, INC.; A DELAWARE CORPORATION; BRECKENRIDGE PHARMACEUTICAL, INC., a Delaware corporation; and KRISTINA HARP, M.D., an Oregon citizen, Defendant.	No. 1009-13177 [8299-1 MSR Hearing Transcripts]

TRANSCRIPT OF PROCEEDINGS

BE IT REMEMBERED that the above-entitled matter came on regularly for Motions before the Honorable Janice R. Wilson, Judge of the Circuit Court of the County of Multnomah, State of Oregon, on June 1st, 2012.

APPEARANCES:

MS. LESLIE O'LEARY,
Attorney for Plaintiffs;

MR. PATRICK LYSAUGHT AND MS. MARY-ANNE RAYBURN, Attorneys for Defendant Novo Nordisk;

Estelle T. Keating
1021 S.W. Fourth, Room 420
Portland, Oregon 97204

* * *

[57] THE COURT: Thank you, Mr. Lysaught.

The more times I read the *Nicastro* opinions, the [58] less clear it becomes to me. I read things that I didn't see or notice or I see in a different light than I did in the earlier hearings, and then I go back and read it again.

I will tell you I am focused – I think that plaintiffs are correct in saying that the focus here really has to be on the concurring opinion, the narrowest grounds on which the decision was reached, and not the – the plurality opinion.

But, even so, the more I read Justice Breyer's concurring opinion, the more I think he doesn't even go as far as Justice O'Connor did in *Asahi.* I mean, that's kind of what surprised me the more I went through this again, is that he – his view seems to be even more restrictive than hers was with regard to the facts in *Nicastro* and the application there.

He does emphasize that he thinks you have to retain the accepted inquiry that focuses on the relationship between the defendant – the forum – and he italicizes forum – and the litigation and to look at the defendant's contacts – again italicized – with that forum.

And he points out that minimum contacts and purposeful availment are actually two separate elements that have to be met. They are not one and the same [59] element, which I tend to think if you had enough minimum contacts, you could be said to have purposefully availed. And, in fact, the further analysis, even of the plurality opinion, would tend to suggest you can get there. You get enough of this stuff, you infer purposeful availment.

That said, I think this record does show that NN A/S knew that NNI was conducting clinical studies in Oregon. But this case, as I understand the pleadings, does not arise out of the clinical studies that were conducted in Oregon. Does it arise out adequacy of the studies in general? What additional studies should have been done that weren't done and so on? Yes. But there is no contention, as I see it, that the plaintiff was injured because of what happened or didn't happen in the clinical studies in Oregon.

So, I'm focusing then on the other aspects of the plaintiff's allegations of the conduct from which she says her injuries arose and looking at – there is no question about design, really, or labeling decisions occurring in Oregon, but she alleges certainly that she was injured because of the sale of these pills in Oregon, prescribed to her in Oregon. And the question is is NN A/S sufficiently linked to that activity in Oregon to warrant sustaining jurisdiction over NN A/S? My heart is with Justice Ginsburg, Justice Sotomayor and Justice [60] Kagan, but that's not what I am required to rule upon. I am required to rule on what my analysis is here.

And I think there is an absence of a showing that NN A/S targeted Oregon, even through NNI. I think that would have been sufficient if they said, "We want you to target in each one of the 50 states." That would have been enough for me to say that's targeting, that's Oregon-specific, or maybe even that NN A/S had knowledge that these 16 or 17, or whatever, sales reps that NNI begged for the money to hire and got was so that sales rep could sell in Oregon. That probably would have gotten me there. But it's just not here.

I'm granting the motion.

MS. O'LEARY: Your Honor, I would like to – if you can enter that Judgment, we are going to seek review of it.

THE COURT: Absolutely.

MS. O'LEARY: And I would like to stay –

THE COURT: and good luck to you.

MS. O'LEARY: I would like to stay the proceedings.

Oh, I'm very hopeful about it, Judge. But I would like to stay at least some of the deadlines on that on this case, because obviously we think that if we do get a resolution in our favor, then we will obtain – we need

* * *

APPENDIX D

IN THE SUPREME COURT OF THE
STATE OF OREGON

SUZANNE M. LUKAS-WERNER and
SCOTT WERNER, wife and husband,
Plaintiffs-Adverse Parties,

v.

NOVO NORDISK AS, a Denmark corporation,
Defendant-Relator,

and

NOVO NORDISK PHARMACEUTICAL, INC;
BRECKENRIDGE PHARMACEUTICAL, INC;
KRISTINA HARP, M. D.; and
NOVO NORDISK, INC., a Delaware corporation,
Defendants.

Multnomah County Circuit Court
100913177

S061095

**ORDER DENYING PETITION
FOR WRIT OF MANDAMUS**

Upon consideration by the court.

The petition for writ of mandamus is denied.

/s/ Thomas A. Balmer 5/16/2013
7:20:00 AM

THOMAS A. BALMER
CHIEF JUSTICE, SUPREME COURT

DESIGNATION OF PREVAILING PARTY AND AWARD OF COSTS

Prevailing party: Adverse Party [X] No costs allowed

Appellate Judgment Effective Date: SUPREME COURT

c: Mary Anne S Rayburn
Linda C Love
Hon. Janice R. Wilson

kag

ORDER DENYING PETITION FOR WRIT OF MANDAMUS

REPLIES SHOULD BE DIRECTED TO: State Court Administrator, Records Section, Supreme Court Building, 1163 State Street, Salem, OR 97301-2563

APPENDIX E

Filed: July 19, 2012

IN THE SUPREME COURT
OF THE STATE OF OREGON

JEFFREY WILLEMSEN,
as Personal Representative of the
Estate of KARLENE J. WILLEMSEN,
and JAMES WILLEMSEN,

Plaintiffs-Adverse Parties,

v.

INVACARE CORPORATION,
a foreign corporation;
UNITED SEATING & MOBILITY,
a foreign limited liability company;
Motion Concepts, Inc.,
a foreign corporation;
PERPETUAL MOTION ENTERPRISES, LTD.,
a foreign corporation;
PASS & SEYMOUR, INC.,
a foreign corporation;
SIEMENS CORPORATION,
a foreign corporation;
SIEMENS INDUSTRY, INC.,
f/k/a/ Siemens Energy and Automation, Inc.,
a foreign corporation;
SUMMERS GROUP, INC., dba REXEL,
a foreign corporation; and
GAW ELECTRIC, INC.,
an Oregon corporation,

Defendants,

and

CHINA TERMINAL & ELECTRIC CORP.,
a foreign corporation;
CTE TECH CORP.,
a foreign corporation,

Defendants-Relators.

(CC 0902-01653; SC S059201)

En Banc

Original proceeding in mandamus.*

Argued and Submitted May 3, 2012, at Portland Community College, Cascade Campus, Portland.

Jonathan M. Hoffman, Martin Bischoff Templeton Langslet & Hoffman LLP, Portland, argued the cause for Defendants-Relators. Joan L. Volpert, Portland, filed the brief for Defendants-Relators. With her on the brief were Jonathan M. Hoffman and Mary-Ann S. Rayburn.

Kathryn H. Clarke, Portland, argued the cause and filed the brief for Adverse Parties. With her on the brief was Jeffrey A. Bowersox.

Gregory S. Pitcher, Williams, Kastner & Gibbs PLLC, Portland, filed the brief for *amicus curiae* Product Liability Advisory Committee, Inc.

Lisa T. Hunt, Portland, filed the brief for *amicus curiae* Oregon Trial Lawyers Association.

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* On petition for writ of mandamus from an order of Multnomah County Circuit Court, Richard C. Baldwin, Judge.

KISTLER, J.

The alternative writ of mandamus is dismissed.

Defendant CTE Tech Corp. is a Taiwanese corporation that manufactures battery chargers.[1] Defendant Invacare Corporation is an Ohio corporation that manufactures motorized wheelchairs. CTE agreed to supply Invacare with battery chargers built to Invacare's specifications, which Invacare then sold with its motorized wheelchairs in Oregon and the rest of the United States. Plaintiffs brought this action against CTE after their mother died in a fire allegedly caused by a defect in CTE's battery charger. CTE moved to dismiss plaintiffs' claims against it on the ground that Oregon lacks personal jurisdiction over it. CTE reasoned that due process would permit an Oregon court to exercise personal jurisdiction over it only if CTE had purposefully availed itself of the privilege of doing business here. In CTE's view, the fact that it sold its battery chargers to Invacare in Ohio, which sold them together with its wheelchairs in Oregon, was not sufficient to meet that standard.

The trial court denied CTE's motion, and we denied CTE's petition for a writ of mandamus directing the trial court to vacate its ruling. CTE then filed a petition for certiorari with the United States Supreme Court. After the Court issued its decision in

[1] Defendant China Technical & Electric Corp. is the former business name of CTE Tech Corp. We refer to both defendants as CTE.

J. McIntyre Machinery, Ltd. v. Nicastro, 564 US ___, 131 S Ct 2780, 180 L Ed 2d 765 (2011), the Court granted CTE's petition for certiorari, vacated our order, and remanded the case to us for further consideration in light of *Nicastro. China Terminal & Elec. Corp. v. Willemsen*, ___ US ___, 132 S Ct 75, 181 L Ed 2d 1 (2011). On remand, we issued an alternative writ of mandamus to the trial court directing it to vacate its order denying CTE's motion to dismiss or show cause for not doing so. The trial court declined to vacate its order, and the parties have briefed the question whether, in light of *Nicastro*, Oregon courts may exercise personal jurisdiction over CTE. We hold that they may and accordingly dismiss the alternative writ.

Plaintiffs are Oregon residents.[2] Their mother was an Oregon resident, who purchased a motorized wheelchair manufactured by Invacare. The wheelchair came

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[2] This case arises on CTE's motion to dismiss for lack of personal jurisdiction. In considering the trial court's resolution of that issue, we take the facts from the allegations in plaintiffs' third amended complaint and the affidavits and other evidence that the parties have submitted. *See* ORCP 21 A (providing that, if a defendant moves to dismiss for lack of personal jurisdiction, a trial court is not limited to the pleadings but may consider "affidavits, declarations and other evidence" in "determin[ing] the existence or nonexistence of the facts supporting [that] defense"). We note that some of the facts necessary to determine personal jurisdiction over CTE are contained in documents filed under seal in the trial court. We also note that plaintiffs have discussed those facts, without objection, in their brief on the merits in this court. We discuss those same facts.

with a battery charger manufactured by CTE.[3] On February 1, 2008, plaintiffs' mother died in her home as a result of a fire allegedly caused by a defect in CTE's battery charger. Plaintiffs brought this action against, among other defendants, Invacare and CTE. They alleged that the battery charger that CTE had manufactured and that Invacare had sold was a defective product. Alternatively, they alleged that CTE had been negligent in failing to "adequately design, inspect, test, [and] manufacture" the battery charger.

CTE moved to dismiss plaintiffs' claims against it for lack of personal jurisdiction. On that issue, the record shows that CTE is a Taiwanese corporation with its principal place of business in that country and that Invacare is an Ohio corporation with its principal place of business in that state. In 2004, CTE entered into a "master supply agreement" with Invacare to provide Invacare with battery chargers manufactured to Invacare's specifications.[4] CTE warranted that its battery chargers would be "manufactured, packaged, labeled and stored in accordance with all applicable federal, state and local laws, ordinances,

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[3] The record is not clear whether the battery chargers are component parts of Invacare's motorized wheelchairs or sold together with the wheelchairs, in the same way that a battery charger might be sold with a cell phone.

[4] Invacare provided 3, 5, and 8 amp CTE battery chargers to customers who bought its motorized wheelchairs. Although the master supply agreement concerns only 3 amp battery chargers, the parties treat the master supply agreement as if it applied to all three types of battery chargers, and so do we.

rules and regulations * * * ." CTE also agreed to certify annually that it had current certificates of insurance for "products and general liability coverage for bodily injury, personal injury and property damage in the amount of one million dollars ($1,000,000) per occurrence." Finally, CTE promised to defend, indemnify, and hold Invacare harmless for any "claims, losses, damages, charges, [and] expenses * * * which may be made against [Invacare] or which [Invacare] may incur arising out of or concerning the [battery chargers]." In connection with that promise, CTE agreed to cooperate with Invacare "in the investigation of any actual or threatened claim, loss, damage, charge or expense."

In 2006-2007, Invacare sold 1,166 motorized wheelchairs in Oregon that Invacare made in Ohio.[5] Of those 1,166 wheelchairs, 1,102 wheelchairs came with battery chargers that CTE had manufactured and sold to Invacare.[6] CTE received approximately

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[5] It is unclear from the complaint whether Invacare itself sold its motorized wheelchairs in Oregon or whether it sold them through a distributor, United Seating & Mobility, LLC. (The complaint uses the phrase "sold and/or distributed.") As we understand CTE's argument, it does not matter whether Invacare or United Seating sold Invacare's wheelchairs and CTE's battery chargers in Oregon. In CTE's view, the dispositive facts are that *it* did not sell its battery chargers directly in Oregon and that *it* did not otherwise have any direct contacts here. We accordingly refer to Invacare's "sale" of its wheelchairs and CTE battery chargers in Oregon.

[6] CTE supplied 100 percent of the 3 and 5 amp battery chargers that Invacare provided to customers in Oregon and 73

(Continued on following page)

$30,929 from Invacare for the battery chargers that Invacare provided to Oregon purchasers. Otherwise, CTE had no contacts with Oregon. As noted, CTE's principal place business is Taiwan. It does not maintain offices in Oregon and does not directly transact business here. It does not sell its products directly in Oregon, nor does it direct advertising material to customers in Oregon or directly solicit business here.

After considering the facts set out above, the trial court denied CTE's motion to dismiss for lack of personal jurisdiction. CTE filed a petition for a writ of mandamus with this court, which we denied. As noted, after the Court issued its decision in *Nicastro*, it granted CTE's petition for certiorari, vacated our order, and remanded the case to us for further consideration in light of *Nicastro.* On remand, the parties have briefed the question whether, in light of the decision in *Nicastro*, Oregon may assert personal jurisdiction over CTE. We turn to that question.

The dispute in this case is narrow. CTE does not contend that Oregon's long-arm statute does not reach its conduct. *Cf. North Pacific v. Guarisco*, 293 Or 341, 351-52, 356, 647 P2d 920 (1982) (holding that Oregon courts lacked personal jurisdiction over out-of-state defendants to adjudicate a cause of action that did not fall within the reach of the then-applicable long-arm statute). Rather, CTE recognizes

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percent of the 8 amp battery chargers that Invacare provided to customers in Oregon.

that ORCP 4 L provides for personal jurisdiction over out-of-state defendants "in any action where prosecution of the action against [the] defendant in this state is not inconsistent with the Constitution of this state or the Constitution of the United States." CTE argues, however, that the Due Process Clause does not permit Oregon to exercise personal jurisdiction over it when it has not purposefully availed itself of the privilege of conducting business in Oregon.

Plaintiffs, for their part, do not dispute that, under the Due Process Clause, a state may require an out-of-state defendant to appear in its courts only when the state has general or specific jurisdiction over that defendant. *See Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 US ___, 131 S Ct 2846, 2851, 180 L Ed 2d 796 (2011) (discussing those bases for asserting personal jurisdiction over out-of-state defendants). Plaintiffs do not contend that Oregon has general jurisdiction over CTE; that is, plaintiffs do not contend that CTE's "affiliations with [Oregon] are so 'continuous and systematic' as to render [CTE] essentially at home in the forum State." 131 S Ct at 2851 (describing general jurisdiction); *cf. Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 US 408, 416-18, 104 S Ct 1868, 80 L Ed 2d 404 (1984) (explaining when an out-of-state corporation's "continuous and systematic general business contacts" within a state will give rise to general jurisdiction).

Plaintiffs rely instead on specific jurisdiction, which "depends on an affiliatio[n] between the forum and the underlying controversy, principally, activity

or an occurrence that takes place in the forum State and is therefore subject to the State's regulation." *See Goodyear Dunlop Tires*, 131 S Ct at 2851 (explaining specific jurisdiction) (alteration in original; internal quotation marks omitted). "In contrast to general, all-purpose jurisdiction, specific jurisdiction is confined to adjudication of issues deriving from, or connected with, the very controversy that establishes jurisdiction." *Id.* (internal quotation marks omitted). In this case, plaintiffs argue that the sale of Invacare wheelchairs and CTE battery chargers in Oregon provides sufficient minimum contacts with this state for Oregon courts to assert specific jurisdiction over CTE for injuries that its battery chargers allegedly caused here.

On that question, we note that, if CTE had sold its battery chargers directly in Oregon, there would be no dispute that Oregon could exercise personal jurisdiction over CTE for injuries that those chargers allegedly caused here. The issue in this case arises from the fact that CTE sold its battery chargers to Invacare in Ohio with the expectation that Invacare would sell its wheelchairs together with CTE's battery chargers nationwide. CTE contends that, because Invacare (and not CTE) is the one that targeted Oregon, CTE has not purposefully availed itself of the privilege of doing business in Oregon and, as a result, the Oregon courts may not assert jurisdiction over it. CTE reasons that, under *Nicastro*, the mere fact that it may have expected that its battery chargers might

end up in Oregon is not sufficient to give Oregon courts specific jurisdiction over it.

As CTE notes, the issue that this case presents is similar to the issue in *Nicastro.* In that case, a British manufacturer sold its products (metal shearing machines used in the recycling industry) to an independent United States distributor, which marketed them throughout the United States. *Nicastro*, 131 S Ct at 2786 (plurality opinion). The United States distributor sold one machine to a company in New Jersey. *Id.*[7] That machine allegedly malfunctioned and injured the plaintiff, who sued the British manufacturer in New Jersey. *Id.* In holding that the New Jersey courts could exercise personal jurisdiction over the British manufacturer, the New Jersey Supreme Court reasoned that the British manufacturer "knew or reasonably should have known 'that its products are distributed through a nationwide distribution system that might lead to those products being sold in any of the fifty states.'" *Id.* (quoting *Nicastro v. McIntyre Machinery America, Ltd.*, 987 A2d 575, 592 (NJ 2010)). That was enough, according to the New Jersey Supreme Court, to establish personal jurisdiction over the British manufacturer.

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[7] The plurality opinion noted that up to four machines may have reached New Jersey. *Nicastro*, 131 S Ct at 2786. Justice Breyer's opinion concurring in the judgment stated that only one machine had reached New Jersey. *Id.* at 2791. For the reasons explained below, Justice Breyer's opinion in *Nicastro* is controlling.

The Court allowed the British manufacturer's petition for certiorari and reversed the state court's judgment. *See Nicastro*, 131 S Ct at 2791 (plurality opinion); *id.* (Breyer, J., concurring in the judgment). The case did not produce a majority opinion for the Court. However, a majority of the members of the Court agreed that the fact that an out-of-state manufacturer sells its products through an independent nationwide distribution system is not sufficient, without more, for a state to assert personal jurisdiction over the manufacturer when only one of its products ends up in a state and causes injury there. *Id.* at 2791 (plurality opinion); *id.* at 2792 (Breyer, J., concurring in the judgment). Beyond that, the rationales advanced in the plurality opinion and the opinion concurring in the judgment differ.

Justice Kennedy, writing for the plurality, started from the premise that what matters for the purposes of determining a state court's authority over an out-of-state defendant "is the defendant's actions, not his expectations." *Id.* at 2789. In the plurality's view, the fact that it was foreseeable that a defendant's products might be distributed in one or all of the 50 states was not enough; rather, the plurality would require evidence that the out-of-state defendant had "targeted" the forum state in some way. *Id.* at 2788. As the plurality put it, the "question is whether a defendant has followed a course of conduct directed at the society or economy existing within the jurisdiction of a given sovereign, so that the sovereign has the power to subject the defendant to judgment

concerning that conduct." *Id.* at 2789. Although there was evidence that the British manufacturer had targeted the United States, there was no evidence that it had targeted New Jersey specifically. *Id.* at 2790. For that reason, the plurality would have held that New Jersey lacked personal jurisdiction over the British manufacturer. *Id.* at 2790-91.

Justice Breyer, with whom Justice Alito joined, would have decided the case on a narrower ground. He reasoned that the Court's precedents stand for the proposition that "a single sale of a product in a State does not constitute an adequate basis for asserting jurisdiction over an out-of-state defendant, even if that defendant places his goods in the stream of commerce, fully aware (and hoping) that such a sale will take place." *Id.* at 2792 (Breyer, J., concurring in the judgment). Because the evidence did not establish any connection between the British manufacturer and New Jersey other than the single sale achieved as a result of the independent distributor's efforts, Justice Breyer agreed with the plurality that, under the Due Process Clause, the British manufacturer did not have sufficient contacts with New Jersey for the courts of that state to exercise personal jurisdiction over it. *Id.* at 2791-92.

Finally, Justice Ginsburg, with whom Justices Sotomayor and Kagan joined, dissented. Justice Ginsburg reasoned that, when the British manufacturer "dealt with the United States as a single market" and sought to have its products distributed throughout the nation, due process did not prevent

the state where the injury had occurred from holding the manufacturer accountable. *Id.* at 2801 (Ginsburg, J., dissenting). In her view, the fact that only one of the British manufacturer's machines had been sold in New Jersey was no bar to exercising jurisdiction over the manufacturer, when that machine was the one that gave rise to the plaintiff's claim. *Id.* at 2804.

When, as in this case, "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 judgmen[t] on the narrowest grounds. . . ." *Marks v. United States*, 430 US 188, 193, 97 S Ct 990, 51 L Ed 2d 260 (1977) (internal quotation marks omitted) (ellipsis in original); *accord Panetti v. Quarterman*, 551 US 930, 949, 127 S Ct 2842, 168 L Ed 2d 662 (2007) (following *Marks*). Applying that rule, we look to Justice Breyer's opinion concurring in the judgment for the "holding" in *Nicastro* that guides our resolution of this case; that is, Justice Breyer's rationale was narrower than the plurality's and, as a result, controls our resolution of this case on remand. We accordingly discuss the rationale in Justice Breyer's opinion in greater detail.

In explaining why the record was not sufficient to establish personal jurisdiction over the British manufacturer, Justice Breyer reasoned:

> "Here, the relevant facts found by the New Jersey Supreme Court show no 'regular . . .

> flow' or 'regular course' of sales in New Jersey; and there is no 'something more,' such as special state-related design, advertising, advice, marketing, or anything else. Mr. Nicastro, who here bears the burden of proving jurisdiction, has shown no specific effort by the British Manufacturer to sell in New Jersey. He has introduced no list of potential New Jersey customers who might, for example, have regularly attended trade shows [in other states at which the British Manufacturer had appeared and solicited sales]. And he has not otherwise shown that the British Manufacturer 'purposefully avail[ed] itself of the privilege of conducting activities' within New Jersey, or that it delivered its goods in the stream of commerce 'with the expectation that they will be purchased' by New Jersey users. *World-Wide Volkswagen* [*Corp. v. Woodson*, 444 US 286, 297-98, 100 S Ct 559, 62 L Ed 2d 490 (1980)]."

Nicastro, 131 S Ct at 2792 (Breyer, J., concurring in the judgment) (ellipsis and second alteration in original).[8] Without evidence of a "'regular . . . flow' or

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[8] The phrases "'regular . . . flow' or 'regular course' of sales" are taken respectively from Justice Brennan's and Justice Stevens' separate opinions in *Asahi Metal Industry Co. v. Superior Court of California*, 480 U.S. 102, 117, 122, 107 S Ct 1026, 94 L Ed 2d 92 (1987). Justice Breyer previously had quoted those phrases in parentheticals describing Justice Brennan's and Justice Stevens' opinions in *Asahi*. *Nicastro*, 131 S Ct at 2792 (Breyer, J., concurring in the judgment).

'regular course' of sales" in New Jersey (or, in the absence of that evidence, evidence of "'something more,' such as special state-related design, advertising, advice, [or] marketing"), Justice Breyer concluded that the record in *Nicastro* was insufficient to establish personal jurisdiction over the out-of-state defendant. *Id.* (ellipsis in original).

Having reached that conclusion, Justice Breyer noted that he "d[id] not agree with the plurality's seemingly strict no-jurisdiction rule" or the "absolute approach adopted by the New Jersey Supreme Court" – *i.e.*, that a state could assert jurisdiction over an out-of-state manufacturer as long as the manufacturer knows or should know that its products "'are distributed through a nationwide distribution system that *might* lead to those products being sold in any of the fifty states.'" *Id.* at 2793 (quoting the New Jersey Supreme Court's decision) (emphasis supplied by the opinion concurring in the judgment).

Justice Breyer explained that the New Jersey Supreme Court's rule was problematic for two reasons. First, it did not focus on the defendant's relationship with the forum, leading to the possibility that jurisdiction would rest "upon no more than the occurrence of a product-based accident in the forum State." *Id.* Second, New Jersey's rule would result in jurisdiction over all out-of-state manufacturers who distribute goods nationally without regard to the fairness of making them appear and defend. *Id.* at 2793-94. He explained that, although that rule might seem fair with regard to a large manufacturer that had the

ability to appear and defend wherever its products caused injury (or to hedge against that possibility by buying insurance), New Jersey's rule did not seem as fair when applied to a small manufacturer selling its products through a national or international distributor. *Id.* Not only would it impose potentially undue burdens on small manufacturers selling only a few products in a state, but it also would require those manufacturers to anticipate and comply with the laws of the 50 states. *Id.* at 2794. For those reasons, Justice Breyer declined to follow either of the broad approaches advanced by the plurality or the New Jersey Supreme Court.

With that understanding of *Nicastro* in mind, we turn to the facts of this case.[9] The trial court reasonably could have found that CTE understood that Invacare would sell its wheelchairs and CTE's battery

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[9] Plaintiffs argue that we should look to this court's decision in *State ex rel. Hydraulic Servocontrols v. Dale*, 294 Or 381, 657 P2d 211 (1982), to determine whether Oregon courts may assert specific jurisdiction over CTE. This court decided *Hydraulic Servocontrols* shortly after the Court decided *World-Wide Volkswagen*. Since then, the Court has attempted to define, first in *Asahi* and more recently in *Nicastro*, when a state court may assert specific jurisdiction over an out-of-state manufacturer that sells its product to another company, which then sells or distributes the product nationwide. Not only do the terms of the Court's remand direct us to consider this case further in light of *Nicastro*, but we would be remiss if we did not look initially to the more recent decisions in *Nicastro* and *Asahi* for guidance in deciding CTE's due process claim. As explained below, we need look no further than *Nicastro* to conclude that Oregon courts may exercise specific jurisdiction over CTE.

chargers throughout the United States.[10] CTE agreed to manufacture the battery chargers to Invacare's specifications and in compliance with federal, state, and local requirements. To be sure, nationwide distribution of a foreign manufacturer's products is not sufficient to establish jurisdiction over the manufacturer when that effort results in only a single sale in the forum state. *See Nicastro*, 131 S Ct at 2791 (Breyer, J., concurring in the judgment). In this case, however, the record shows that, over a two-year period, Invacare sold 1,102 motorized wheelchairs with CTE battery chargers in Oregon. In our view, the sale of over 1,100 CTE battery chargers within Oregon over a two-year period shows a "'regular . . . flow' or 'regular course' of sales" in Oregon. *See id.* at 2972 (Breyer, J., concurring in the judgment) (ellipsis in original).[11] The sale of the CTE battery charger in Oregon that led to the death of plaintiffs' mother was not an isolated or fortuitous occurrence.

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[10] As noted, ORCP 21 A authorizes Oregon trial courts to consider "affidavits, declarations and other evidence" in "determin[ing] the existence or nonexistence of the facts supporting" the defense of a lack of personal jurisdiction. It thus authorizes a state trial court to determine the facts and draw reasonable inferences from undisputed facts in the course of deciding whether it has personal jurisdiction over an out-of-state defendant. As a matter of state law, when a trial court has engaged in that enterprise, we construe the facts and draw all reasonable inferences consistently with the trial court's ruling.

[11] By contrast, over a 15-year period, only one British metal shearing machine was sold in New Jersey. *See Nicastro*, 987 A2d at 579 (noting that the British manufacturer's marketing efforts in the United States lasted from 1990 to 2005).

In arguing for a different conclusion, CTE relies primarily on the reasoning in the plurality opinion in *Nicastro.* If that opinion were controlling, it might be difficult for plaintiff to show that, on this record, CTE's contacts with Oregon were sufficient to establish jurisdiction over it. As explained above, however, the rule that the Court announced in *Marks* for construing splintered decisions leads us to conclude that the rationale expressed in Justice Breyer's opinion concurring in the judgment controls our resolution of this case. Following his opinion, we hold that the volume of sales in this case was sufficient to show a "regular course of sales" and thus establish sufficient minimum contacts for an Oregon court to exercise specific jurisdiction over CTE. *Cf. Nicastro*, 131 S Ct at 2792 (Breyer, J., concurring in the judgment) (internal quotation marks omitted).

CTE argues alternatively that "Invacare's sales figures in Oregon were a min[i]scule fraction – both in sheer numbers, as well as the proportion of end product manufacturer's total sales in the forum – compared to what the United States Supreme Court unanimously found to be insufficient in *Asahi* [*Metal Industry Co. v. Superior Court of California*, 480 US 102, 107 S Ct 1026, 94 L Ed 2d 92 (1987)]." We read both the holding and the record in *Asahi* differently. In that case, a Japanese manufacturer (Asahi) sold valve assemblies to a Chinese tire tube manufacturer (Cheng Shin), which incorporated both Asahi's valve assemblies and valve assemblies from other manufacturers into its tire tubes, which it sold worldwide. *Id.*

at 106. Cheng Shin alleged that 20 percent of the tire tubes that it sold in the United States were sold in California. *Id.* Beyond that, the decision in *Asahi* does not identify the total number of Cheng Shin tire tubes sold in either the United States or California, nor does it identify either the number of Cheng Shin tire tubes sold in the United States or California that incorporated Asahi's valve assemblies. *See id.* Apparently, the only evidence in the record on that issue consisted of an "informal examination" of a single store in California, which revealed that Cheng Shin had manufactured 53 of the 115 tire tubes offered for sale in that store and that only 12 of the 53 Cheng Shin tire tubes contained Asahi valve assemblies. *Id.* at 107.

When one of Cheng Shin's tire tubes failed, the person injured as a result of that failure brought suit in a California state court against Cheng Shin, which filed an indemnification claim against Asahi. *Id.* at 105-06. All the parties settled except for Cheng Shin and Asahi, which defended against Cheng Shin's indemnification claim on the ground that the California state courts lacked personal jurisdiction over it. As we read the various opinions in *Asahi*, a majority of the Court did not agree whether the evidence of Cheng Shin's sales of tire tubes containing Asahi valves established sufficient minimum contacts between Asahi and California for California to assert jurisdiction over it.

Justice O'Connor, writing for four Justices in *Asahi*, would have required evidence that Asahi

purposefully had availed itself of the privilege of doing business in California; in her view, the fact that Asahi was "awar[e] that some of the valves sold to Cheng Shin would be incorporated into tire tubes sold in California" was not sufficient to satisfy due process. *Id.* at 112 (opinion of O'Connor, J.). Justice Brennan, writing for four Justices, would have held that the sale of Asahi's valve assemblies in California established a "regular and anticipated flow of products from manufacture to distribution to retail sale," which was sufficient to establish the minimum contacts with California necessary for that state to assert personal jurisdiction over Asahi. *Id.* at 117, 121 (Brennan, J., concurring in part and concurring in the judgment). Finally, Justice Stevens found it unnecessary to decide whether minimum contacts existed. *Id.* at 121 (Stevens, J., concurring in part and concurring in the judgment). He reasoned that, even if they did, "this case fits within the rule that 'minimum requirements inherent in the concept of "fair play and substantial justice" may defeat the reasonableness of jurisdiction even if the defendant has purposefully engaged in forum activities.'" *Id.* at 121-22 (Stevens, J., concurring in part and concurring in the judgment) (quoting *Burger King Corp. v. Rudzewicz*, 471 US 462, 477-78, 105 S Ct 2174, 85 L Ed 2d 528 (1985)).

The Court agreed on only one point in *Asahi.* After Justice O'Connor expressed her view that Asahi's contacts with California were not sufficient to give the California courts jurisdiction over it, she

reasoned alternatively that, even if those contacts were sufficient, exercising jurisdiction in the circumstances of that case would offend "traditional notions of fair play and substantial justice." *Id.* at 113 (internal quotation marks omitted). That part of her opinion rested primarily on the unique circumstance that, after all the other parties had settled, the only issue left to be adjudicated in California was an indemnification claim by one foreign company against another involving a transaction (Asahi's sale of valve assemblies to Cheng Shin) that had no connection to either California or the United States. *Id.* at 114-15.

All the Court joined that part of Justice O'Connor's opinion. *See id.* at 116 (Brennan, J., concurring in part and concurring in the judgment); *id.* at 121 (Stevens, J., concurring in part and concurring in the judgment). As we read *Asahi*, its holding is limited to the alternative ground stated in Part II-B of Justice O'Connor's opinion; that is, the Court decided the case on an alternative ground that either assumed, in Justice O'Connor's opinion, or found, in Justice Brennan's opinion, sufficient minimum contacts.

Contrary to CTE's argument in this case, a unanimous Court did not find in *Asahi* that Asahi's contacts were not sufficient to establish personal jurisdiction over it.[12] Beyond that, we think that CTE

[12] Not only would four Justices have found that Asahi's contacts were sufficient for California to exercise jurisdiction

(Continued on following page)

misperceives the significance of the facts regarding the sales in *Asahi*. As CTE correctly notes, the decision recites that Asahi sold 100,000 to 500,000 valve assemblies to Cheng Shin annually. *See id.* at 106. However, the decision also explained that "Cheng Shin purchases valve assemblies from other suppliers as well, and sells finished tubes throughout the world." *Id.* As noted, the decision does not identify the annual sales figures in California (or the United States) of Cheng Shin's tubes containing Asahi's valve assemblies. It does not even identify how many tire tubes Cheng Shin sold annually in California (or the United States), with or without Asahi's valve assemblies. *See id.* at 106-07. Without that information, it is difficult to make much of the annual sales from Asahi to Cheng Shin, not only because Asahi was not the only manufacturer that supplied valve assemblies to Cheng Shin but also because Cheng Shin sold its tire tubes throughout the world and could have sold its tire tubes with Asahi valves primarily in countries other than the United States. *Cf. Goodyear Dunlop Tires*, 131 S Ct at 2852 (noting that Goodyear's European subsidiaries marketed their tires for use primarily in European countries and that only a small percentage of those tires reached the forum state).

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over it, *Asahi*, 480 US at 121 (Brennan, J., concurring in part and concurring in the judgment), but Justice Stevens observed that, if he were to reach the issue, he would be inclined to conclude that the evidence was sufficient, *id.* at 122 (Stevens, J., concurring in part and concurring in the judgment).

In our view, the decision in *Asahi* provides little assistance to CTE. However, to the extent that the annual number of battery chargers that CTE sold to Invacare matters, we note that the trial court reasonably could have found that, in 2006-2007, CTE sold roughly 76,000 battery chargers to Invacare in Ohio, which Invacare then sold with its wheelchairs throughout the United States.[13] In any event, in 2006-2007, 1,102 Invacare wheelchairs equipped with CTE battery chargers were sold in Oregon. CTE has provided no valid reason to say that the sale of 1,102 CTE battery chargers in Oregon over a two-year period does not constitute a "regular course of sales" in this state. *See Nicastro*, 131 S Ct at 2792 (Breyer, J., concurring in the judgment) (internal quotation marks omitted). Put differently, the pattern of sales of CTE's battery chargers in Oregon establishes a "relationship between 'the defendant, the *forum*, and the litigation,' [such that] it is fair, in light of the defendant's contacts *with* [*this*] *forum*, to subject the defendant to suit [h]ere.'" *Id.* (Breyer, J., concurring

[13] We say "roughly" because the record is not precise. It discloses only the "total accounts payable" from Invacare's manufacturing facility in Ohio to CTE. Using the figures that CTE's representative used to determine the weighted average cost of the battery chargers that Invacare sold in Oregon and the "total accounts payable" to CTE, the trial court could have found that the total sales from CTE to Invacare exceeded 76,000. We note that that calculation assumes that the weighted average cost was the same both in Oregon and nationally. It also assumes that the total amount payable to CTE reflected only the cost of battery chargers that CTE had sold to Invacare.

in the judgment) (quoting *Shaffer v. Heitner*, 433 US 186, 204, 97 S Ct 2569, 53 L Ed 2d 683 (1977)) (emphasis added by the opinion concurring in the judgment).

One other issue remains. As *Asahi* makes clear, even if the sale of CTE's battery chargers in Oregon provides sufficient minimum contacts for Oregon courts to assert personal jurisdiction over CTE, the remaining question is whether exercising jurisdiction would "offend traditional notions of fair play and substantial justice" and thus be inconsistent with due process. *See Asahi*, 480 US at 113 (internal quotation marks omitted). On that issue, we note that this is not a case, as in *Asahi*, where the only question that remains to be adjudicated is a claim for indemnification between two out-of-state defendants. Rather, in this case, Oregon residents seek to vindicate their claims for the death of their mother in the state where the death occurred, allegedly as a result of a defect in CTE's battery charger. Oregon has a strong interest in providing a forum for its residents who are injured in this state to recover for their injuries. *Cf. Asahi*, 480 US at 114-16 (noting that the calculus would be different if California had an interest in determining the plaintiff's claim).

Moreover, this case does not raise the concerns about exercising jurisdiction over small manufacturers that distribute only a few products in a state as a result of a national distribution system, which Justice Breyer noted in *Nicastro*. *See* 131 S Ct at 2794 (Breyer, J., concurring in the judgment). As an

initial matter, the trial court reasonably could have found that CTE is not a small manufacturer. Rather, over a two-year period, CTE's revenues (or at least the amounts payable) from Invacare alone exceeded $2,150,000. As noted, the trial court also reasonably could have found that, over that period, Invacare purchased approximately 76,000 battery chargers from CTE for distribution in this country. Additionally, in the master supply agreement between CTE and Invacare, CTE promised that its battery chargers would comply with all federal, state, and local laws. CTE thus voluntarily undertook to bring its battery chargers into compliance with the laws of the various states in which Invacare sold them. Finally, as part of the master supply agreement, CTE agreed that it would "continuously have on file with [Invacare] a current Certificate of Insurance showing evidence of products and general liability coverage for bodily injury, personal injury and property damage in the amount of one million dollars ($1,000,000) per occurrence." In selling its battery chargers to Invacare, CTE anticipated the need to defend against the very sort of claim that plaintiffs have brought here, and it agreed to obtain insurance as a hedge against the cost of doing so.

Requiring CTE to appear in Oregon does not offend traditional notions of fair play and substantial justice and thus does not preclude the trial court from exercising jurisdiction over CTE as a result of its contacts with this forum. The trial court could, consistently with due process, require CTE to appear in

an Oregon court and respond to plaintiffs' claims that a defect in its battery charger caused their mother's death.

The alternative writ of mandamus is dismissed.

APPENDIX F

IN THE CIRCUIT COURT OF THE
STATE OF OREGON

FOR THE COUNTY OF MULTNOMAH

SUZANNE M. LUKAS-WERNER, and SCOTT WERNER, wife and husband, Plaintiffs, v. NOVO NORDISK A/S, a Denmark corporation, et al.; NOVO NORDISK INC.; a Delaware corporation; BRECKENRIDGE PHARMACEUTICAL, INC., a Delaware corporation; and KRISTINA HARP, M.D., an Oregon citizen, Defendants.	Case No.: 1009-13177 SPECIALLY APPEARING DEFENDANT NOVO NORDISK A/S'S MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION **ORAL ARGUMENT REQUESTED** Prayer: Over $1 Million Fees: First Appearance $527 and Motion Fee $50

UTCR 5.050 NOTICE

Pursuant to UTCR 5.050, oral argument is, requested. It is estimated the hearing will take 30 minutes. Motion Praecipe will be filed after Judge Wilson sets a hearing date.

UTCR 5.010 CERTIFICATION OF COMPLIANCE

Counsel for Specially Appearing Defendant Novo Nordisk A/S certifies that she conferred in good faith with counsel for Plaintiffs before filing this motion but was unable to resolve the issues in dispute satisfactorily.

MOTION TO DISMISS

Novo Nordisk A/S ("NN A/S"), pursuant to ORCP 21, hereby moves to dismiss Plaintiffs' claims against it on the grounds that this Court lacks personal jurisdiction over NN A/S because NN A/S does not have sufficient contacts with the state of Oregon to support the exercise of personal jurisdiction. NN A/S did nothing more than place Activella® in the stream of commerce, has no offices and no employees within the state, and does not sell or market Activella® within the state of Oregon. NN A/S makes a special appearance to contest the Court's exercise of personal jurisdiction over this Defendant.

INTRODUCTION

This is a product liability action in which Plaintiffs allege that Plaintiff Suzanne Lukas-Werner contracted breast cancer as a result of exposure to a prescribed hormone replacement therapy medication Activella®. Plaintiffs have sued multiple Defendants who they believe were potentially involved in the

design, manufacture, production, testing, study, labeling, marketing, sale, and distribution of Activella®.

NN A/S is a Danish public limited liability company, with its headquarters in Bagsvaerd, Denmark. ***See***, Declaration of Anne Reker Cordt, Exhibit A, at ¶ 4 (Original will be filed upon receipt). NN A/S manufactures and sells medications, including Activella®. *Id.* at ¶ 5. NN A/S manufactures Activella® in Denmark. *Id.* at ¶¶ 10-11.

NN A/S does not have any employees or agents in the state of Oregon. ***See***, Declaration of Ms. Reker Cordt at ¶ 9. NN A/S has no physical or business presence in the State of Oregon. The company 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.* at ¶¶ 7-12, 16-17.

NN A/S sells Activella® to an indirect subsidiary, Novo Nordisk Inc., which is a Delaware corporation with its principle place of business in Princeton, New Jersey. ***See***, Declaration of Ms. Reker Cordt at ¶¶ 13-14. NN A/S ships Activella® to Novo Nordisk Inc.'s third-party logistics provider in Indianapolis, Indiana. *Id.* at ¶ 13.

Plaintiffs cannot satisfy their burden of proving the facts necessary to support this Court's exercise of personal jurisdiction over NN A/S. NN A/S lacks the requisite minimum contacts with the state of Oregon,

and the assertion of personal jurisdiction over this Defendant would be constitutionally unreasonable.

POINTS AND AUTHORITIES.

I. Plaintiffs Cannot Satisfy the Constitutional Requirements for the Exercise of Personal Jurisdiction Over Non-Resident Novo Nordisk A/S.

Plaintiffs bear the burden of establishing personal jurisdiction over a non-resident defendant. *White v. Mac Air Corp.*, 147 Or App 714, 720, 938 P2d 241, 244 (1997). Plaintiffs' claims against NN A/S must be dismissed unless Plaintiffs can both plead and prove specific jurisdictional facts, not mere conclusory allegations, that demonstrate that the Court's jurisdiction over the non-resident Defendant is proper. *Showalter v. Edwards and Associates, Inc.*, 112 Or App 472, 476, 831 P2d 58, 60 (1992).

In determining whether personal jurisdiction exists, the Court must determine whether the facts of the case or the nature of the defendant fit within one of the specific enumerations of jurisdiction under ORCP 4. ***See***, *e.g.*, *State ex rel. Circus Circus Reno, Inc. v. Pope*, 317 Or 151, 153, 854 P2d 461, 46 2 (1993). Moreover, personal jurisdiction under the rule cannot exceed the bounds of the Due Process Clause of the United States Constitution. *Circus Circus*, 317 Or at 156, 854 P2d at 463-64; *Portland Trailer & Equipment, Inc. v. A-1 Freeman Moving & Storage, Inc.*, 166 Or App 651, 654, 5 P3d 604, 607 (2000).

Even if the facts of a case fall within the express terms of ORCP 4, the exercise of personal jurisdiction must always comport with the due process requirement that a defendant have "minimum contacts" with Oregon. ***See***, *Biggs By and Through Biggs v. Robert Thomas, O.D., Inc.*, 133 Or App 621, 626, 893 P2d 545, 547 (1995); *Nike, Inc. v. Spencer*, 75 Or App 362, 373, 707 P2d 589, 596 (1985); *Gray & Co. v. Firstenberg Machinery Co., Inc.*, 913 F2d 758, 760 n.1 (9th Cir. 1990).

The exercise of personal jurisdiction over a foreign company like NN A/S is subject to even higher scrutiny. "[L]itigation against an alien defendant creates a higher jurisdictional barrier than litigation against a citizen from a sister state because important sovereignty concerns exist." *Sinatra v. National Enquirer, Inc.*, 854 F2d 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 US 102, 115 (1987).

A. Oregon Cannot Exercise "General Jurisdiction" Over NN A/S Pursuant to ORCP 4A(4).

ORCP 4A(4) enumerates the circumstances in which a court may exercise "general" personal jurisdiction over a non-resident defendant. The rule states that a non-resident defendant is subject to personal jurisdiction if the defendant "[i]s engaged in substantial

and not isolated activities within the state, whether such activities are wholly interstate, intrastate, or otherwise . . . ." General jurisdiction requires that the defendant have engaged in "continuous and systematic" activities within the forum. ***See***, *Helicopteros Nacionales de Columbia v. Hall*, 466 US 408, 414 (1984).

The constitutional Due Process standard for general jurisdiction is a very high bar. "[T]he Supreme Court has upheld general jurisdiction only once," and the Ninth Circuit has "regularly declined to find general jurisdiction even where the contacts were quite extensive." *Amoco Egypt Oil Co. v. Leonis Navigation Co.*, 1 F3d 848, 851 (9th Cir 1993). General jurisdiction requires that foreign corporations consent to jurisdiction or actually be present within the state. *Circus Circus*, 317 Or at 155 n.1, 854 P2d at 463 n.1.

Plaintiffs do not allege and cannot prove that NN A/S has "continuous and systematic" contacts or a physical presence in the state of Oregon. NN A/S has no offices, manufacturing facilities, or employees in Oregon. ***See***, Declaration of Ms. Reker Cordt, ¶¶ 8-11. NN A/S owns no real property or bank accounts within the state. *Id.* at ¶ 8. NN A/S is not licensed to do business in Oregon, does not make sales to the state, and does not advertise within the state. *Id.* at ¶¶ 8-12. The stringent requirements for general jurisdiction are not met.

B. NN A/S Is Not Subject to Contact-Based Specific Jurisdiction Under ORCP 4 Because It Did Nothing More Than Place a Medication into the Stream of Commerce.

Specific jurisdiction under sections C through K of ORCP 4 requires the foreign defendant to engage in particular, enumerated conduct within the state and requires that the plaintiff's claims arise out of such conduct. *Circus Circus*, 317 Or at 155 n.1, 854 P2d at 463 n.1. Plaintiffs' Complaint is entirely devoid of allegations that any specific provision of ORCP 4 is satisfied as to NN A/S because Plaintiffs cannot identify conduct by NN A/S within the state of Oregon that gives rise to their claims.

When a defendant raises the issue of lack of personal jurisdiction in a motion to dismiss, the burden shifts to the plaintiff to make a prima facie showing that the trial court has personal jurisdiction by demonstrating: (1) that the action arose out of an activity covered by the long-arm jurisdiction provisions of ORCP 4 ***and*** (2) that defendant had sufficient minimum contacts with the forum state to satisfy due process. *Circus Circus*, 317 Or at 156, 854 P2d 463-64. Plaintiff bears the burden of proving that ***both*** jurisdictional tests are met for the Court to exercise personal jurisdiction over each of the non-resident defendants. *Id.*

The minimum contacts test is satisfied for due process purposes when a non-resident defendant

"purposefully directed" its activities at residents of the forum state, and the litigation results from alleged injuries that "arise out of or relate to" those activities. *Burger King Corp. v. Rudzewicz*, 471 US 462, 472 (1985) (emphasis added). For the Court to exercise jurisdiction under the specific jurisdiction provisions of ORCP 4C-K, it is not sufficient that the non-resident defendant have some contact with Oregon. The defendant must have purposefully directed the contact by choosing to engage in conduct in Oregon, and the case must actually arise out of the specific contact the defendant had with the state.

In construing the Fourteenth Amendment's Due Process requirements with respect to personal jurisdiction, the United States Supreme Court in *Kulko v. Superior Court of California*, 436 US 84 (1978) rejected a state court's conclusion that due process is satisfied where a nonresident defendant simply causes "an effect" in the state by an act or omission outside the state. This is because the non-resident defendant must have "purposefully availed" itself of the benefits of the forum state for jurisdiction to be exercised. *Burger King*, 471 US at 472. Accordingly, it is not constitutionally sufficient for Plaintiffs merely to allege that NN A/S manufactured a medication in Denmark that allegedly caused injuries in Oregon.

Asahi Metal Industry Co. v. Superior Court of California, 480 US 102 (1987) is the most recent Supreme Court guidance regarding the constitutional Due Process limitations on personal jurisdiction over foreign corporations. In the *Asahi Metal* case, a

Japanese manufacturer sold component parts to a Taiwanese distributor, knowing that some of those parts would likely be sold in the United States (including the forum state of California). Personal injury plaintiffs sued the distributor in California, who in turn filed an indemnification claim against the manufacturer. Ultimately, the injured plaintiffs' claim was settled and dismissed, and the procedural posture of *Asahi Metal* involved the Japanese manufacturer's motion to dismiss the indemnification claim by the Taiwanese distributor, the only claim remaining in the California case.

The *Asahi Metal* court found that there was no basis to exercise personal jurisdiction over the Japanese company because Asahi had no offices or agents in California, did not advertise or solicit business in the state, and "did not create, control, or employ the distribution system that brought its valves" there. 480 US at 112-13.

Under a test articulated by Justice O'Connor, subsequently referred to as the "stream of commerce plus" test, the actions of a defendant must be "purposefully directed toward the forum State" for a court of that state to exercise personal jurisdiction. 480 US at 112. "The placement of a product into the stream of commerce, ***without more***, is not an act of the defendant purposefully directed toward the forum State." *Id.* (emphasis added). The stream-of-commerce plus test requires that the defendant engage in "[a]dditional conduct . . . indicat[ing] an intent or purpose to serve the market in the forum State." *Id.*

That "additional conduct" could include "designing the product for the market in the forum State, advertising in the forum State, establishing channels for providing regular advice to customers in the forum State, or marketing the product." *Id.* Under the "stream of commerce plus" test, however, it is not enough that the defendant knows or has reason to believe that the product will be "swept by the stream of commerce" into the forum state. Instead, the defendant must have actively engaged in conduct designed to market or sell the product in the state.

The Oregon federal courts apply the "stream of commerce plus" test from *Asahi Metal*, requiring some conduct by the manufacturer that is directed at the forum state beyond simply placing the product in the stream of commerce with the knowledge that it might end up in the forum state. ***See***, *Adidas America, Inc. v. Topline Corp.*, 2009 WL 1270256, *7 (D Or May 5, 2009). The Oregon Court of Appeals has adopted the "stream of commerce plus" test of *Asahi Metals.* ***See***, *Johnson v. Peacock Lumber Co., Inc.*, 95 Or App 710, 714, 770 P2d 960, 962 (1989) ("The placement of a product into the stream of commerce, without more, is not an act of the defendant purposefully directed toward the forum State.").

NN A/S notes that the Oregon Supreme Court last considered this issue in *State ex rel. Hydraulic Servocontrols Corp. v. Dale*, 294 Or 381, 657 P2d 211 (1982). This case was decided five years before *Asahi.* While the *Hyrdaulic Servocontrols* court reached a conclusion contrary to that which was later reached

in *Asahi*, the Oregon Supreme Court agreed that ORCP 4's jurisdictional reach is limited by the Due Process Clause of the U.S. Constitution. 294 Or at 385, 657 P2d at 213. The U.S. Supreme Court established limits on the exercise of personal jurisdiction over a non-resident product manufacturer in *Asahi*, and that determination is binding upon this Court. The Oregon Supreme Court simply is not in a position to disagree with the U.S. Supreme Court regarding the requirements of constitutional due process, and there is no indication that the Oregon Supreme Court would purport to deviate from *Asahi.* As noted above, the Oregon Court of Appeals has recognized that it is bound by *Asahi. Peacock Lumber Co.*, 95 Or App at 714, 770 P2d at 962.

Applying *Asahi's* "stream of commerce" theory, the Ninth Circuit Court of Appeals and U.S. District Court of Oregon have consistently held that a foreign product manufacturer's/distributor's placement of a product into the stream of commerce, without some additional affirmative act directed at the forum state, is insufficient to support personal jurisdiction. ***See*** *e.g.*, *Holland America Line, Inc.*, 485 F3d 450, 459 (9th Cir. 2007); *Doe v. American Nat'l Red Cross*, 112 F3d 1048, 1051 (9th Cir 1997); *Omeluk v. Langsten Slip and Batbyggeri A/S*, 52 F3d 267, 271 (9th Cir 1995); *Adidas America, Inc, v. Topline Corporation*, 2009 WL 1270256 (D Or May 5, 2009); *Espinoza v. Blitz*, 2004 WL 2165358 (D Or Sept. 24, 2004); *Sunset Fuel v. Zanjani*, 1997 WL 118440 (D Or February 26, 1997).

While ORCP 4D purports to provide for 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," it is well-established that the provision must be interpreted and applied in a manner consistent with the outer limits of federal due process as set forth in the *Asahi Metal* decision. ***See*** *Biggs*, 133 Or App at 626, 893 P2d at 547; *Gray & Co. v. Firstenberg Machinery Co., Inc.*, 913 F2d at 760 n.1. It is therefore insufficient for Plaintiffs merely to allege or prove that NN A/S placed a product into the stream of commerce that ultimately was used and caused injury in Oregon. *Asahi Metal* requires that NN A/S have done something more to avail itself of the forum.

Purposeful availment requires more than constructive knowledge that products might end up in a particular state. Purposeful availment means a ***purpose*** by the defendant to avail itself of a state's consumers. The U.S. Supreme Court has explained that, to satisfy this requirement of purposeful availment, a defendant must have ddeliberately exploited the [state's] market" – a standard akin to specific intent. *Keeton v. Hustler Magazine, Inc.*, 465 US 770, 781 (1984). 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 US at 475 (quoting *McGee v. International Life Ins. Co.*, 355 US 220, 223 (1957)). "[R]andom,

fortuitous, or attenuated contacts" do not suffice. *Burger King*, 471 US at 480.

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 US 286, 295 (1980). 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.

Plaintiffs do not allege, and cannot prove, that NN A/S engaged in the "something more" that is required for the constitutional exercise of personal jurisdiction in this case. As in *Asahi Metal*, NN A/S has no offices or manufacturing facilities in Oregon, has no employees stationed in Oregon, and does not control the distribution system by which a legally separate, indirect subsidiary, Novo Nordisk Inc., markets Activella® within the United States. ***See***, Declaration of Ms. Reker Cordt, ¶¶ 7-14. NN A/S did not design Activella® for the Oregon market and did not advertise or market the product in Oregon. *Id.* at ¶¶ 10-12. NN A/S did not sell Activella® in Oregon or to any Oregon-based distributor. *Id.* at ¶¶ 13, 16-17. NN A/S has no direct commercial relationship with Oregon or any of its residents. NN A/S did nothing more than the foreign manufacturer in *Asahi Metal* did when it sold its product to a distributor, which then sold the product in the forum state.

C. This Court's Exercise of Personal Jurisdiction Would "Offend Traditional Notions of Fair Play and Substantial Justice."

The due process clause of the Fourteenth Amendment acts as a limitation upon the power of a court to exercise personal jurisdiction over a non-resident defendant. The Due Process Clause requires that a defendant have certain minimum contacts with the forum ~~s~~state such that maintenance of the suit "does not offend traditional notions of fair play and substantial justice." *International Shoe Co. v. Washington*, 326 US 310, 316 (1945).

In *Asahi Metal*, the Supreme Court found that, if the "stream of commerce plus" test is not satisfied, then the exercise of jurisdiction over the non-resident defendant is, as a matter of law, not consistent with "fair play and substantial justice." 480 US at 116. The Ninth Circuit's test for contact-based specific personal jurisdiction likewise turns upon the "fair play and substantial justice" standard. ***See***, *Omulek v. Langsten Slip & Batbyggeri A/S*, 52 F3d 267, 270 (9th Cir 1995).

There is no evidence that NN A/S specifically targeted the Oregon market for sales of Activella®, and, in fact, there can be no such evidence as NN A/S did not specifically target the Oregon market. Therefore, the exercise of personal jurisdiction in this case is based on nothing more than NN A/S's conduct in placing Activella® into the stream of commerce by

selling it to Novo Nordisk Inc. outside of the state of Oregon. The medication allegedly consumed by Plaintiff was not destined for Oregon at the time of its manufacture or original sale but apparently reached an Oregon consumer through indirect distribution channels after passing through at least one independent company, Novo Nordisk Inc.

1. NN A/S Is Not Liable for the Conduct of Novo Nordisk Inc.

Plaintiffs allege that NN A/S is vicariously liable for any tortious conduct of Novo Nordisk Inc. ***See***, First Amended Complaint, ¶ 2. As a corporate entity distinct from NN A/S, Novo Nordisk Inc.'s separate corporate existence will be disregarded only in the most extraordinary circumstances, which have not been alleged and do not exist in this case.

Piercing the corporate veil "is an extraordinary remedy which exists as a last resort, where there is no other adequate and available remedy to repair plaintiff's injury." *State ex rel. Neidig v. Superior Nat. Ins. Co.*, 343 Or 434, 445, 173 P3d 123, 131 (2007).

> We need not pause to consider the vague distinction between the instrumentality or alter ego test and the identity test for disregarding the corporate entity of a wholly-owned subsidiary. Whichever test is used, it is necessary for the complainant to prove that the conduct of the parent corporation prejudiced the rights of the creditor and resulted in the perpetration of a fraud or injustice. This court

> has uniformly held that the corporate entity of a subsidiary corporation should be disregarded only to prevent fraud or injustice and to protect persons whose rights have been jeopardized by the conduct of the parent corporation:

Schlecht v. Equitable Builders, 272 Or 92, 96, 535 P2d 86, 88 (1975).

A plaintiff seeking to pierce the corporate veil must both plead and prove that another entity actually controlled the corporation, that the other entity used its control over the corporation to engage in improper conduct, and that, as a result of the improper conduct, the plaintiff was harmed. *Neidig*, 343 Or at 455, 173 P3d at 136. Where actual exercise of control is shown to exist, use of that control to accomplish improper conduct must also be demonstrated. *Amfac Foods, Inc. v. International Systems & Controls Corp.*, 294 Or 94, 107, 654 P2d 1092, 1101 (1982).

There must be more than merely shared financial interests and corporate ownership for a court to treat a subsidiary as the ***alter ego*** of the parent and make the parent liable for the subsidiary's tort. The "fiction" of the subsidiary's corporate existence must have been established by the parent corporation for the purpose of engaging in activities that are contrary to public policy. ***See***, *Amfac*, 294 Or at 107, 654 P2d at 1100-01.

Plaintiffs have not pled, and cannot prove, that Novo Nordisk Inc. is a "corporate fiction" that exists solely to permit NN A/S to engage in wrongful conduct. NN A/S and Novo Nordisk Inc. have in the past observed and continue to observe the legal requirements necessary for the separate and distinct corporate existence of each company. ***See***, Declaration of Ms. Reker Cordt, ¶ 15. Accordingly, Plaintiffs could not prevail upon any theory that NN A/S is liable for alleged tortious conduct by its legally separate and distinct subsidiary, Novo Nordisk Inc.

2. Novo Nordisk Inc.'s Contacts with Oregon Do Not Support the Court's Exercise of Personal Jurisdiction Over Foreign Corporation NN A/S.

Moreover, although Novo Nordisk Inc. 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 Novo Nordisk Inc. had with Oregon cannot legally be attributed to NN A/S. ***See***, Declaration of Ms. Reker Cordt, ¶¶ 14-15. "It is well settled that the existence of a relationship between a parent company and its subsidiaries is not sufficient to establish personal jurisdiction over the parent on the basis of the subsidiaries' minimum contacts with the forum." *U.S. Vestor, LLC v. Biodata Information Tech. AG*, 290 F Supp 2d 1057, 1064 (ND Cal 2003). 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 Metal*, 480 US at 109.

Generally, a foreign parent corporation is not subject to the jurisdiction of a forum state simply because its subsidiary is present or doing business there. The existence of a parent-subsidiary relationship, without more, is insufficient to establish personal jurisdiction over a nonresident corporation. *Overby v. Oregonian Pub.*, 882 F Supp 964, 966 (D Or 1995). When a subsidiary and its parent maintain separate and distinct corporate entities, the contacts of one cannot be imputed to the other for purposes of jurisdiction. A parent company's interactions with its subsidiary are insufficient to establish personal jurisdiction over the parent "unless those interactions are sufficient to meet the alter ego or general agency tests for jurisdiction; otherwise, a nonresident parent would be subject to jurisdiction in every state where it has a subsidiary, which is not now and never has been the case." *Cai v. DaimlerChrysler AG*, 480 F Supp 2d 1245, 1252 (D Or 2007).

3. <u>The Court's Exercise of Jurisdiction Would Impose an Unreasonable Burden Upon NN A/S.</u>

Furthermore, the Court must consider the burden of defending the action in a forum with which NN A/S has had no minimum contacts. *World-Wide Volkswagen Corp. v. Woodson*, 444 US at 292. Where, as here, a plaintiff seeks to assert jurisdiction over a

foreign company, the interests of other nations, "as 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 Metal*, 480 US at 115.

It is permissible 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 US, at 471-72. The due process substantial justice analysis turns on whether a foreign defendant had notice that it could expect to be sued in the forum state. Where, as here, the foreign defendant had no direct contact with the forum, it is unreasonable for the defendant to be sued, particularly where the plaintiff has already named U.S.-resident defendants who ***do*** have the requisite minimum contacts with the state of Oregon.

Accordingly, this Court's exercise of personal jurisdiction over NN A/S would offend traditional notions of fair play and substantial justice as there is no evidence that NN A/S did anything more than place Activella® into the stream of commerce outside the state of Oregon, and the sale of Activella® in Oregon resulted from the unilateral actions of a third party, not NN A/S's own purposeful conduct.

D. If the Court is in Doubt Regarding the Effect of *Asahi* Upon Oregon Law, the Court Should Defer Ruling on this Motion Pending an Imminent Decision by the U.S. Supreme Court.

Based on existing case law, this Court should grant Defendant's motion and dismiss Plaintiffs' Complaint against NN A/S. However, any doubt regarding the application of *Asahi* is expected to be resolved by another case presently pending in the U.S. Supreme Court. *Nicastro v. McIntyre Machinery America, Ltd.*, 201 NJ 48, 987 A2d 575 (2010), *cert. granted*, ___US ___, 131 S Ct 62, 177 LEd2d 1151 (2010), which was argued before the U.S. Supreme Court on January 11, 2011, raises the very issue this Court is asked to consider.[1] If there is any doubt about the effect of *Asahi* on existing Oregon case law, NN A/S moves this Court for an order deferring its decision pending a ruling by the U.S. Supreme Court in *Nicastro.*

CONCLUSION

For the reasons above and those set forth in Novo Nordisk A/S's motion, Novo Nordisk A/S asks that this Court dismiss Plaintiffs' action against it for lack of personal jurisdiction.

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[1] The transcript of oral argument is available online at http://www.supremecourt.gov/oral.arguments/argument.transcripts/09-1343.pdf.

DATED: March 30, 2011.

MARTIN, BISCHOFF, TEMPLETON,
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[EXHIBIT A]

DECLARATION OF ANNE REKER CORDT

Bagsvaerd) SS.
Denmark)

1. I, Anne Reker Cordt, hereby declare the following, under penalty of perjury:

2. I am over the age of 18, have personal knowledge of the facts recited herein, and would and could competently testify to the same.

3. I am a Vice President in Biopharmaceuticals Product Supply with Novo Nordisk A/S ("NN A/S"). Until February 1, 2011, my responsibilities included

the oversight of business project development and logistics. My current responsibilities include oversight of new production establishment. I have been employed by NN A/S since September of 2007.

4. NN A/S is a Danish public limited liability company, with its headquarters in Bagsvaerd, Denmark.

5. NN A/S is in the business of manufacturing and selling prescription pharmaceutical medications.

6. NN A/S was served in this action in Denmark, via means which sought to comply with The Hague Service Convention.

7. NN A/S does not maintain a registered agent for service in Oregon.

8. NN A/S does not do business in the state of Oregon, and does not maintain a place of business or an office in Oregon. NN A/S does not own any real properly within the state of Oregon and has no bank accounts within the state.

9. NN A/S has no employees or agents who are located within the state of Oregon.

10. NN A/S has no manufacturing plants in the United States. NN A/S manufactures Activella in Denmark.

11. All aspects of the manufacture of Activella by NN A/S occur in Denmark.

12. NN A/S does not advertise or solicit business in the state of Oregon.

13. NN A/S sells Activella to Novo Nordisk Inc., an American corporation that is organized under the laws of the state of Delaware, with its principal place of business in Princeton, New Jersey. NN A/S ships Activella to Novo Nordisk Inc.'s third-party logistics provider, MD Logistics, in Indianapolis, Indiana.

14. Novo Nordisk Inc. is an indirect subsidiary of NN A/S. NN A/S is the parent company of a number of global subsidiaries, including Novo Nordisk U.S. Holdings, Inc., a Delaware corporation, which is a holding company that owns Novo Nordisk Inc., among other entities.

15. NN A/S and Novo Nordisk Inc. have in the past and do continue to strictly observe the legal requirements necessary for the separate and distinct corporate existence of each company.

16. Activela was first marketed in the United States in the year 2000. NN A/S does not sell Activella to any person or company in the United States other than to Novo Nordisk Inc. NN A/S began selling Activella to Novo Nordisk Inc. in 2003. Between 2000 and 2003, NN A/S's only sales of Activella in the United States were to Pharmacia Upjohn, in Kalamazoo, Michigan.

17. NN NS does not have contracts with or sell any of its prescription mediums or any other products

directly to any Oregon-based vendors, retailers, distributors, or individual consumers.

18. Further declarant sayeth not.

I HEREBY DECLARE THAT THE ABOVE STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF, AND THAT I UNDERSTAND IT IS MADE FOR USE AS EVIDENCE IN COURT AND IS SUBJECT TO PENALTY FOR PERJURY.

29-3-2011 /s/ Anne Reker Cordt
Anne Reker Cordt

Executed on this ___ day of March 2011.

[Certificate Of Service Omitted In Printing]

APPENDIX G

IN THE CIRCUIT COURT
OF THE STATE OF OREGON

FOR THE COUNTY OF MULTNOMAH

SUZANNE M. LUKAS-WERNER and **SCOTT WERNER**, wife and husband, Plaintiffs, v. **NOVO NORDISK A/S**, a Denmark corporation; **NOVO NORDISK PHARMACEUTICAL INDUSTRIES INC.**, a Delaware corporation; and **KRISTINA HARP, M.D.**, an Oregon citizen, Defendants.	Case No. 1009-13177 **PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANT NOVO NORDISK A/S'S MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION**

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[1] I. INTRODUCTION

Although NN A/S insists it has no connection to Oregon or the U.S. market that would warrant the exercise of personal jurisdiction in this case, discovery and corporate witnesses produced by NNI tell a different story. Plaintiffs finally obtained unredacted documents from NNI two weeks ago. We are only beginning to scratch the surface, but from what we have reviewed so far, it is undeniable that NN A/S was pervasively involved in – and directed – NNI's Activella-related marketing and sales activities. Those activities directly or indirectly targeted Oregon. Virtually every Supreme Court precedent holds that a fact pattern like the record in this case establishes sufficient minimum contacts to satisfy Due Process concerns.[1] The Court has personal jurisdiction over NN A/S. Accordingly, NN A/S must be held legally accountable for its complicity with NNI in marketing an unreasonably dangerous and defective drug.

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[1] Plaintiffs do not argue that general jurisdiction or corporate veil piercing principles apply. Rather, personal jurisdiction is the correct analysis in this case.

II. STATEMENT OF FACTS

A. NN A/S's Global Reach

Defendant Novo Nordisk A/S ("NN A/S") is a global manufacturer and seller of prescription drugs. Its corporate headquarters are in Copenhagen, Denmark. NN A/S employs more than 32,000 people worldwide in 75 countries[2] and operates through 81 wholly owned subsidiaries.[3] The primary activity for the vast majority of these subsidiaries is "sales and marketing" of NN A/S's drugs.[4] NN A/S's wholly owned subsidiary in the United States is Novo-Nordisk, Inc. ("NNI"). NN A/S sells its products in more than 190 countries.[5]

[2] B. NN A/S's Contacts with the United States Drug Market

NN A/S actively trades its stock in the United States. NNI does not. NN A/S is listed on the New York Stock Exchange under the tag NVO. NN A/S boasts that it operates research and development centers, production facilities, and headquarters and corporate hubs in the U.S.[6] North America alone accounts for the largest share of NN A/S's annual sales

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[2] Ex. 01, Novo-Nordisk Annual Report to Shareholders, at 10, 28 (2011).

[3] *Id.* at 89-90.

[4] *Id.* (see last four columns).

[5] *Id.* at 18.

[6] Ex. 01, NN A/S Annual Report 2011, at 28.

(40.1%),[7] more than 90% of which derive from sales to consumers in the U.S.[8] As NN A/S notes, "Less than 1% of the total sales is realized in Denmark. Sales to external customers attributed to the US are collectively the most material to the company. The US is the only country where sales contribute more than 10% of total sales." Thus, the U.S. is NN A/S's primary source of revenues.

NN A/S maintains a global drug surveillance system to monitor the safety of its products in "full compliance . . . with all regulatory requirements including standard operating procedures, quality audits, quality improvement plans and systematic senior management reviews."[9] In its most recent Annual Report to Shareholders, NN A/S acknowledged it has been sued in the U.S. by the Department of Justice and the Department of Health and Human Services in two separate claims of improper marketing.[10] In 2011, NN A/S settled the civil suit with the DOJ for $25 million.[11] Indeed, NN A/S has admitted to shareholders that it expects to be sued in any country where its drugs are sold:

> Novo Nordisk operates in a complex global legal and regulatory environment with diverse

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[7] Ex. 01, NN A/S Annual Report 2011, at 28.

[8] Ex. 01, NN A/S Annual Report 2011, at 67.

[9] Ex. 01, NN A/S Annual Report 2011, at 23.

[10] *Id.* at 24.

[11] *Id.*

> national, regional and international [3] legislation. Legal issues may arise relating to product liability claims, company practices and government investigations.[12]

Among these product liability claims are Activella lawsuits. NN A/S informs its shareholders that one of them (Ms. Lukas-Werner's suit) is set for trial in 2012.[13] However, NN A/S assures shareholders that it does not expect this or other claims "to have a material impact on Novo Nordisk's financial position, operating profit or cash flow."[14] NN A/S regularly uses the U.S. court system to pursue its own legal claims against competitors for drug patent infringements[15]

C. NN A/S's Direction and Oversight of Activella

NN A/S is the designer and manufacturer of Activella, the postmenopausal hormone replacement therapy drug prescribed and sold to plaintiff Suzanne Lukas-Werner in Oregon. She alleges that Activella caused her breast cancer. Activella is a single-pill combination of 1 mg. estradiol ("E2"), an estrogen, and .5 mg. norethindrone acetate ("NETA"), a synthetic

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[12] Ex. 01, NN A/S Annual Report 2011, at 24.

[13] Ex. 01, NN A/S Annual Report 2011, at 87.

[14] Ex. 01, NN A/S Annual Report 2011, at 87. It is notable that in its discussion of pending HRT litigation, NN A/S did not separately identify NNI as a defendant.

[15] Ex. 02, NN A/S Annual Report 2005, at 50; Ex. 01, NN A/S Annual Report 2011, at 87.

progestin.[16] Activella remains one of NN A/S's most popular hormone replacement therapy drugs, owing to its "35 years of experience with hormone treatment for menopausal symptoms."[17] By 2006, NN A/S recognized that the U.S. market in particular was a significant source of Activella sales.[18] North America, and the U.S. in particular was the fastest growing segment of NN A/S's HRT sales.[19] Accordingly, NN A/S focused its Activella marketing efforts there.

[4] NNI's internal documents and the testimony of its corporate witnesses confirm that NN A/S directly controlled the design, development, regulatory approval process, marketing and labeling of Activella in the United States, including in Oregon.

1. Studies

For many years, NN A/S marketed a higher dose of this combination drug in Europe under the brand name Kliogest.[20] NN A/S later marketed a lower dose of estradiol/NETA in Europe under the trade name Activelle.[21] Before it could market this drug in the U.S., NN A/S had to obtain FDA approval under the NDA process. Activella was approved by the FDA in

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[16] Ex. 03, Activella®Label for 2007.

[17] Ex. 01, NN A/S Annual Report 2011, at 39.

[18] Ex. 04, NNAPUR081855-93, at 081885.

[19] *Id.* at NNAPUR081863.

[20] Ex. 05, NDA 20-907, 1998 FDA Activella approval

[21] Ex. 05.

1998 for the treatment of symptoms of menopause.[22] Although NNI is listed in the FDA's approval papers as the sponsor of Activella,[23], [sic] NN A/S and its affiliates supervised the design and implementation of the preclinical and clinical studies necessary to obtain FDA approval for Activella.[24] NN A/S manufactures the Activella pills for NNI at its plant in Bagsvaerd, Denmark.[25] NN A/S also prepares the Activella product label distributed in Oregon and the rest of the U.S.[26]

Dr. Diane Petrovich is NNI's Vice President of Medical Operations and Clinical, Medical and Regulatory Affairs. As she explained, all preclinical work (*i.e.*, animal studies) on Activella was either conducted by NN A/S or "under the purview of NN A/S."[27] Many of the clinical trials on women submitted by NNI to the FDA to obtain FDA approval for Activella consisted of [5] studies conducted by NN A/S on Kliogest (the original higher dose version of Activella sold in Europe).[28] Several of these clinical trials were also conducted in the United States.[29]

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[22] Ex. 05.

[23] Ex. 05

[24] Ex. 06, Diane Petrovich Dep. at 16, 21-22, 48-50, 79-80, 83 (Mar. 27, 2012).

[25] Ex. 07, NNALH003889 at 003890.

[26] *Id.* at 3889.

[27] Ex. 06, Petrovich Dep. at 16:6-16:11; 16:24-17:10.

[28] Ex. 06, Petrovich Dep. at 18:6-20:16 (Mar. 27, 2012).

[29] Ex. 06, Petrovich Dep. at 21:13-23:6; 68:11-69:9.

NN A/S even controls the extent of NNI's investigation of Activella's breast cancer risk. Although no such investigation was ever done, if NNI wanted to conduct an observational study on Activella risks (such as breast cancer), it would have to get approval from NN A/S in Denmark.[30]

2. Global Safety Surveillance

NN A/S monitors and advises its affiliates globally regarding adverse event reporting for Activella, including breast cancer. Pursuant to NN A/S protocols, NNI employees from the Product Safety Group collect information regarding adverse events reported by consumers, healthcare professionals[31] and clinical trials.[32] NNI then enters it into a global database and transmits the information to NN A/S.[33] The International Product Safety Group (IPSG) in Denmark maintains the global database for all adverse reaction reports.[34] The information entered into the database is sent electronically to IPSG, which reviews, evaluates and assesses how to handle the event.[35] NNI's Product Safety Group has daily contact with the

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[30] Ex. 06, Petrovich Dep. at 41:9-44:13.

[31] Ex. 08, Irene Schubert Dep. at 10:10-15 (July 19, 2007) MDL deposition 30(b)(6) re: Adverse Event Reporting for both Clinical Trials and Postmarketing.

[32] *Id.* at 31:20-32:19.

[33] *Id.* at 11:15-20.

[34] *Id.* at 12:4-7.

[35] *Id.* at 17:10-17.

IPSG.[36] For example, if there were an adverse report of breast cancer, the IPSG would be responsible for conducting a literature review, not the affiliate (*e.g.*, NNI).[37] The IPSG would then issue a report [6] to the affiliates (including NNI), and the affiliates would determine whether it needed to be submitted to the health authorities of that country.[38] Affiliates may provide their opinions, and they might be taken into consideration. However, IPSG ultimately decides, based on its own assessment and evaluation, whether the adverse report is "medically significant."[39]

3. Labeling

NN A/S also has the final word on the content of the Activella label regarding safety issues such as breast cancer risk.[40] In addition, NN A/S develops training programs for its subsidiaries "to address emerging trends, such as changes in the regulatory environment,"[41] and 97% of its subsidiary employees participated in these training activities.[42] Among these programs were sessions concerning how to respond to

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[36] *Id.* at 17:24-18:5.

[37] *Id.* at 18:10-19:1.

[38] *Id.* at 19:16-19:22.

[39] *Id.* at 29:19-30:8.

[40] Ex. 09, Mary Ann McElligott Dep. at 40:4-42:19 (Mar. 27, 2012).

[41] Ex. 01, NN A/S Annual Report 2011, at 11.

[42] Ex. 01, NN A/S Annual Report 2011, at 17

publicity surrounding studies on breast cancer. For example, following the publication of reports from the WHI study and the Million Women Study, each of which found that HRT pills containing the combination of estrogen and the synthetic progestin medroxyprogesterone acetate (MPA) increased the risk of breast cancer, NN A/S developed Powerpoint slide decks for NNI to use for regulatory and marketing purposes to downplay these studies' findings, and to argue that Activella had a better safety and efficacy profile than Prempro.[43]

4. Sales and Marketing

NN A/S's policy is to recruit and groom a mobile global workforce to implement the company's marketing directives. That way, its employees "can operate seamlessly across national borders as well as functional areas."[44] NN A/S's goal in mobilizing its work force is to [7] bring more uniformity in marketing strategies. It also allows NN A/S to move employees fluidly to fill vacant positions in subsidiary locations and to transfer personnel wherever in the world NN A/S needs them, based on their qualifications.[45] NN A/S transferred a number of employees from Europe to the U.S. to make sure that NNI properly implemented NN A/S's global marketing strategies for

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[43] Ex. 10, NNROGU078571-078628.

[44] Ex. 02, NN A/S Annual Report 2005, at 28.

[45] Ex. 02, NN A/S Annual Report 2005, at 28-29

Activella.[46] Some employees, like Klaus Davidsen, bounced back and forth between NN A/S and NNI in managerial positions after going through management training in Copenhagen.[47]

NN A/S supervised the training of NNI's Activella sales reps, including the Oregon sales rep who called on Dr. Harp, while plaintiff Suzanne Lukas-Werner was being prescribed Activella. In fact, NNI required permission and funds from NN A/S to increase its budget so that NNI could hire more sales staff – including in Oregon – to promote Activella.[48] Exs. 4,

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[46] Ex. 11, Jakob Riis, Senior VP Novo Nordisk A/S webpage http://www.zoominfo.com/#!search/profile/person?personId=1166866577&targetid=profile, last visited May 15, 2012. Ex. 12 Robert Gut, VP Clinicl [sic] Development & Medical Affairs, BioPharmaceuticals at Novo Nordisk Inc. Liinkedin [sic] page. www.linkedin.com/profile/view?id=14768186&authType=NAME_SEARCH&authToken=PyPx&locale=en . . . , last visited May 15, 2012.

[47] Ex. 13 Klaus Davidsen, Corporate VP, Product Supply Global Investments and Finance at Novo Nordisk A/S. Linkedin page http://www.linkedin.com/ . . . _*1_*51_*1_*51_true_*2_*2_*2_*2_*2_*2_*2_*2_*2_*2_*2_*2_*2_*2_*2_*2-*2_*2_*2_*2_*2_*2&pvs=ps&trk=pp_profile_name_link. Last visited May 8, 2012.

[48] *See*, *e.g.*, Ex.14, NNROGU019655-56 (Email chain between Pablo de Mora and Klaus Bulow Davidson dated Nov. 28-29, 2006). Ex.04, NNAPUR081855-93 (Powerpoint attachment to Pablo de Mora email chain dated Nov. 28-29, 2006). NN A/S's new VP of global marketing for HRT informed NNI that NN A/S would not hire additional sales force to promote HRT products in the U.S. Instead, de Mora instructed NNI to make do with its existing sales force. NN A/S later relented. *See* Ex. 16. NNEDDW002047 (email from Pablo de Mora to Finn Hansen). In this email exchange, de Mora explains that Jakob Riis

(Continued on following page)

14, 16 and Ex. 17. Although NN A/S's Rule 39C(6) deponent Anne Reker Cordt denied that NN A/S [8] had any involvement in making such decisions, both internal and publicly available documents show otherwise.[49] They establish that NN A/S developed,

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discussed the sales budget issue with Kare Schultz (both of NN A/S). Based on that discussion, de Mora approved the whole plan for promotion of HRT product. Ex. 17, NNEDDW0022088 is a Dec. 19, 2006 email from Eddie Williams (CEO of NNI) to de Mora regarding a post discussion and review with JRIS (Jakob Riis) and KSZ (Kare Schultz). "We plan to have a small sales force of 16 in the US to launch and also promote . . . " Later NN A/S authorized an expanded budget to hire additional Activella sales staff, which included Lisa Lebedz, in the Oregon sales territory. These unredacted images were viewed at the depository on May 9, 2012 and ordered on May 10, 2012. They have not yet been received, but we attached the available coding.

[49] At her deposition, Ms. Cordt was shown a series of emails to Pablo de Mora, Vice President of Global Marketing. She denied that Mr. de Mora was an employee of NN A/S and testified that he worked for "FemCare AG" in Switzerland, a subsidiary of NN A/S. Ex. 19, Cordt Dep. at 10:13-11:11 (Apr. 26, 2012). The Court would not permit plaintiffs' counsel to inquire further on Mr. de Mora's connection with NN A/S based on Ms. Cordt's representation that he did not work for NN A/S. *Id.* at 11:12-12:8. However, after the deposition, plaintiffs obtained two versions of Mr. de Mora's curriculum vitae, which show that from October 2006 through September 2010, he worked for NN A/S as Vice President of Marketing & Medical Affairs in the company's Zurich, Switzerland location. Ex. 20 and Ex. 21. According to NN A/S's Career web page, "Corporate Marketing is located at our headquarters in Denmark and Zurich . . . " Ex. 22. NN A/S describes the role of its Global Marketing operations, where Mr. de Mora worked, as follows: "Corporate marketing is responsible for strategic decision making regarding our products . . . In Global Marketing, we provide early business input into discovery projects and prepare long-term marketing strategies.

(Continued on following page)

directed and implemented strategic marketing plans for NNI to carry out in promoting Activella. From its Global Marketing headquarters in Zurich, NN A/S made sure that local sales reps properly executed the marketing strategy it had developed.[50] NN A/S worked closely with NNI to organize the budgeting and staffing of the U.S. HRT team.[51]

D. NN A/S's Activities Targeted in Oregon

1. Premarketing Studies

Five of the premarketing studies used in support of the Activella NDA petition to the FDA took place in Oregon.[52] The Protocol Review Board at NN A/S reviewed and approved the protocol for all Activella

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We prepare the markets for product launches and ensure execution of marketing strategies locally. We are also responsible for managing our global key opinion leader relationships successfully." *Id.*

[50] Ex. 22, Marketing and Sales – Novo Nordisk A/S webpage http://www.novonordisk.com/careers/business-areas/sales-and-marketing.asp# last visited May 7, 2012; and Ex. 02, at 28-29, 31.

[51] Ex. 23, NNEDDW002141 (Jan. 18, 2007 email to JRIS re US HRT organization team meeting.) The e-mail discusses Mr. de Mora and Julian Butler's trip to the USA and states, "Julian Butler is the contact from my team to US organization and he has already established a fruitful collaboration with Jim [Snider] and the US HRT team." The unredacted image was viewed at the depository on May 9, 2012 and ordered on May 10, 2012. It has not yet been received, but we attached the available coding.

[52] Ex. 06, Petrovich Dep. at 68:11-69:9; 70:11-70:21.

trials, including the trials in Oregon.[53] Although NNI's predecessor [9] NNPI carried out the trials,[54] the budget for the trials had to be approved by NN A/S, which provided the funding to NNPI.[55] NN A/S would regularly receive reports from NNPI of the status of the clinical studies, including those in Oregon.[56] The pills for each trial site, along with other trial supplies, came from NN A/S in Denmark. They were made or assembled by NN A/S and shipped to the U.S. for delivery to Oregon and other sites.[57]

2. Marketing Strategies

NN A/S sought to maximize sales of Activella and its other HRT products in the United States. It developed an integrated campaign consisting of "non-personal selling activities," *i.e.*, using interactive websites for physicians ("e-detail"), email, telephone, facsimile, advertising, newsletters and trained physician spokespeople to promote the drugs.[58]

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[53] Ex. 06, Petrovich Dep. at 47:22-48-51:6, 77:4-8.

[54] Ex. 06, Petrovich Dep. at 73:12-73:24; 79:5-79:17.

[55] Ex. 06, Petrovich Dep. at 77:9-78:10.

[56] Ex. 06, Petrovich Dep. at 80:7-80:15; 82:16-83:13.

[57] Ex. 06, Petrovich Dep. at 92:16-94:23; and Ex. 24, NNKLIMVII000115-000117 (Clinical Trial Supplies Shipment, IND No. 43,006).

[58] Ex. 04, NNAPUR081855-081893, at 081870-081881 (Nov. 2006 Powerpoint).

As part of a similar program, in July 2004 NNI hired Dr. Harp, plaintiff's prescribing doctor, as a consultant to "provide written feedback and input on the messaging and educational programs" after attending a two-hour Interactive Consultant Forum (ICF).[59]

Another marketing strategy used by NN A/S and NNI which involved Dr. Harp was a "non-personal sampling program" or a product request program. Facsimiles were sent to physicians throughout the U.S. who were high prescribers of Activella, based on IMS data obtained in 2005.[60] Dr. Harp responded affirmatively that she would like to participate in this program by receiving samples of Activella.[61]

[10] With NN A/S's approval, NNI hired Lisa Lebedz (formerly Wennstedt) as the Oregon sales rep for Activella. Ms. Lebedz used trained and paid

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[59] Ex. 25, NNAVCA001700-001705, novo nordisk® Health Care Provider Consulting Agreement with Kristina Harp, MD, executed July 13, 2004.

[60] Ex. 26, NNKLDA095593 (email describing non-personal sampling program organized by Gar Park, Brand Manager, at the direction of upper management to send faxes to doctors asking them if they would like samples). The unredacted version of this document was viewed in the depository, requested but not yet received. Attached is the available coding.

[61] Ex. 27, NNKLDA095596-095708 (113 page spreadsheet entitled Activella Responders or Sample Responder List) Dr. Harp is referenced at the top of page 37 and was one of 29 Oregon doctors who responded to fax requests. This document was viewed in the depository, requested but not yet received, Attached is the available coding.

physicians as spokespeople to educate other doctors about Activella.[62]. [sic] Dr. Catherine Crim, an OB/GYN from Tualatin Oregon, was paid and trained by NNI to speak at events using slides developed by NN A/S and NNI to promote Activella.[63] Ms. Lebedz also used a national speaker (likewise trained and paid by NNI) from California at a program in Eugene, Oregon.[64]

3. Sales of Activella Prescriptions

A significant portion of revenues from the sale of NN A/S's drugs came from Oregon. Its hormone replacement therapy drug Activella accounted for 18% of the state's market share among HRT competitors.[65] In 2007 alone, prescriptions of Activella in Oregon totaled nearly 10,000 units per year.[66] Plaintiffs

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[62] Ex. 28, Lisa Lebedz Dep. at 93:1-94:19 (Jan. 25, 2012).

[63] Ex. 28, Lisa Lebedz Dep. at 97:21-24, 103:8-10 (testimony that Dr. Crim received training by NNI in Dallas)

[64] Ex. 28, Lisa Lebedz Dep. at 115:2-6.

[65] Ex. 28, Lisa Labedz Dep. at 85:21-86:1.

[66] Defendant NNI has not yet produced documents reflecting the entire number of Activella prescriptions sold in Oregon and in the United States. However, based on what NNI has produced so far, plaintiffs were able to determine that in 2007 alone, Activella "units" or prescriptions totaled nearly 10,000. Ex. 29, a summary of Oregon Activella prescriptions written based on Lisa Lebedz's performance reports. Because the Court would not permit plaintiffs to obtain the total dollar volume of Activella sales in Oregon, plaintiffs cannot address the "sales volume" factor, which Justice Stevens addressed in *Asahi.*

estimate that Oregon prescriptions made up at least one percent of all Activella sales in the U.S.

[11] **III. POINTS AND AUTHORITIES**

A. <u>Personal Jurisdiction over NN A/S Attaches Under Oregon's Jurisdiction Statute.</u>

The Oregon Supreme Court applies a two-prong test in determining whether it has jurisdiction over a non-resident defendant: (1) Does the case fall within the terms of Oregon's jurisdiction statute, ORCP 4? And if so, (2) Does due process permit an Oregon court to exercise personal jurisdiction over the defendant in such a case? *State ex rel. Hydraulic Servocontrols Corp. v. Dale*, 294 Or 381, 384, 657 P 2d 211 (1982).

Relevant to the jurisdiction issue in this case is ORCP 4D, which provides:

> **Local injury; foreign act.** In any action claiming injury to person or property within this state arising out of an act or omission outside this state by the defendant, provided in addition that at the time of the injury, either:
>
> D(1) Solicitation or service activities were carried on within this state by or on behalf of the defendant; or
>
> D(2) Products, materials, or things distributed, processed, serviced, or manufactured by the defendant were used or consumed within this state in the ordinary course of trade.

(Emphasis added). Also relevant is ORCP 4L, the long-arm provision, which states:

> **Other actions.** Notwithstanding a failure to satisfy the requirement of sections B through K of this rule, in any action where prosecution of the action against a defendant in this state is not inconsistent with the Constitution of this state or the Constitution of the United States.

While these subsections of Rule 4 might appear redundant in light of the "catchall" or "long-arm" provision in subsection L, they are nevertheless significant. "Based as they are on facts which the United States Supreme Court has held to be adequate bases for jurisdiction, these more specific provisions serve to narrow the inquiry so that if a case falls within one of them, there is no need to litigate more involved issues of due process." *Hydraulic Servocontrols*, 294 Or at 384. If the plaintiff alleges facts that fit within any of the specific provisions, "that will ordinarily be the end of the matter." *Id.* at 384-385. If such facts are not present, then ORCP 4L comes into play, and the limits of due process must be considered. *Id.* at 385. Indeed, Rule 4L [12] "is a codification of our earlier holding that Oregon's jurisdictional statute, former ORS 14.035, was intended to reach the outer limits of due process." *Id.* at 384 n 2.

B. <u>Oregon Has Adopted Its "Minimum Contacts" Due Process Analysis for Personal Jurisdiction from U.S. Supreme Court Precedent.</u>

The Due Process Clause of the Fourteenth Amendment requires that personal jurisdiction over a nonresident defendant be based on "minimum contacts" between the defendant and the forum state. *Id.* (citing *International Shoe Co. v. Washington*, 326 US 310, 316 (1945)).[67] In *Hydraulic Servicontrols*, the Oregon Supreme Court adopted the U.S. Supreme Court's analysis of minimum contacts in *World-Wide Volkswagen Corp. v. Woodson*, 444 US 286 (1980).[68] In *World-Wide Volkswagen*, plaintiffs brought a product liability action in Oklahoma against various defendants after plaintiffs' vehicle, which they purchased in New York, was struck and caught fire while plaintiffs were driving through Oklahoma. The defendant manufacturer did not challenge jurisdiction in Oklahoma, but the New York retailer and New York distributor defendants did. The Supreme Court noted that changes in modern transportation and the interstate nature of business transactions make it foreseeable that a foreign company's product could cause an injury in any state where it is sold. *World-Wide Volkswagen*, 44 US at 293.

> Hence if the sale of a product of a manufacturer or distributor . . . is not simply an

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[67] Attached as Ex. 15.

[68] Attached as Ex. 30.

> isolated occurrence, but arises from the efforts of the manufacturer or distributor to serve, directly or indirectly, the market for its product in the other states, it is not unreasonable to subject it to suit in one of those States if its allegedly defective merchandise has there been the source of injury to its owners or to others.

World-Wide Volkswagen, 44 US at 297.

The court held that foreseeability, though relevant, is not the only factor. Due process also requires the court to decide whether the defendant's conduct and connection with the forum state made it foreseeable that it could be haled into court there, and not any "unilateral activity" [13] of a plaintiff. *Id.* at 297-98. Because the New York distributor and retailer defendants did not directly or indirectly advertise or sell cars directly to Oklahoma residents, they could not have purposefully availed themselves of the privileges and benefits of Oklahoma law. *Id.* at 295. The plaintiffs' unilateral act of transporting the car from New York to Oklahoma could not satisfy the minimum contacts requirement under the Due Process clause. *Id.* at 298.

In *Hydraulic Servocontrols*, plaintiff brought a product liability action in Oregon alleging that a defective component of the engine of an aircraft caused it to crash in California, killing the Oregon decedent. The New York manufacturer of the component (Hydraulic) moved to dismiss for lack of personal jurisdiction, claiming it did no business in Oregon and had

no contacts there. The motion was denied, and the manufacturer petitioned for mandamus. *Hydraulic Servocontrols*, 294 Or at 383. Applying the *World-Wide Volkswagen* rationale, the court held that jurisdiction was proper. Even though Hydraulic did not do business directly in Oregon, it manufactured and sold the component to the aircraft manufacturer knowing that it would be incorporated into the engine of an aircraft that was sold in Oregon. *Id.* at 389. "Hydraulic, having sold a product with the intention of driving [sic] economic benefit from a national market, including Oregon, can expect to be hauled into court in Oregon when a product containing its allegedly defective servo actuator is purchased here and cause [sic] injury to a resident." *Id.*

A few years later, the U.S. Supreme Court reaffirmed its jurisdictional rule from *World-Wide Volkswagen* in a case involving a contract dispute between a Florida fast food franchisor and an out-of-state franchisee defendant. *Burger King v. Rudzewicz*, 471 U.S. 462 (1985).[69] Applying the *World-Wide Volkswagen* standard, the court noted that the Due Process Clause demands that individuals have "fair warning" that a particular activity may subject them to the jurisdiction of a foreign sovereign. *Burger King*, 471 U.S. at 472. The fair warning requirement [14] is satisfied "if the defendant has purposefully directed his activities at residents of the forum, and

[69] Attached as Ex. 31.

the litigation results from alleged injuries that arise out of or relate to those activities." *Id.*

The Oregon Supreme Court likewise adopted the "fair warning" requirement from *Burger King* and held that there must be "a relationship between the forum state and the subject matter of the particular litigation" to satisfy the minimum contacts requirement. *State ex rel Circus Circus Reno, Inc.*, 317 Or 151, 155, 854 P2d 461 (1993). Personal jurisdiction over a foreign defendant thus lies "if the action 'arises out of' defined activities by the defendant."

Since these cases were decided, however, the U.S. Supreme Court has attempted to clarify further what specific actions of a foreign company (in particular, those of a non-U.S. company) constitute sufficient "minimum contacts" with the forum state under the Due Process clause. Disagreement over which test should apply created a rift among the justices in *Asahi Metal Industry Co., Ltd. v. Superior Court of Cal., Solano Cty*, 480 US 102 (1987).[70] *Asahi* was an indemnification claim by a Taiwanese tire manufacturer against a Japanese company whose allegedly defective tire valve assembly component caused a tire to rupture and seriously injured two California motorcyclists (who had already settled out of the case). The Japanese manufacturer moved to dismiss for lack of personal jurisdiction. The company argued it had no

[70] Attached as Ex. 32.

contacts with California and that all of its sales to the tire company took place in Taiwan.

In a split decision, four members led by Justice O'Connor joined in an analysis requiring a foreign defendant to do "something more" than merely be aware of its product's entry into the forum state through the stream of commerce to satisfy the minimum contacts test. *Id.* at 111. Four other members led by Justice Brennan applied a pure stream of commerce standard and found that minimum contacts did exist, but under this factual circumstance, it would be unreasonable to exercise jurisdiction over the foreign company. *Id.* at 116. Justice Stevens [15] believed the court should not even consider the issue of minimum contacts because it could decide the case based on reasonableness alone. *Id.* at 121-22.

The divided decision in *Asahi* had no clarifying effect. It led to a split in states and federal circuits as to how the minimum contacts standard should be applied. For the next two decades, some courts followed Justice Brennan's broader "stream of commerce" analysis while others employed Justice O'Connor's narrower "stream of commerce plus" standard.

The Supreme Court tried again in 2011 to forge a clear definition of minimum contacts, this time in *J. McIntyre Machinery, Ltd. v. Nicastro*, ___ US ___, 131 S Ct 2780 (2011).[71] In *Nicastro*, a defective scrap

[71] Attached as Ex. 33.

metal machine manufactured by a United Kingdom company injured the New Jersey plaintiff, cutting off four fingers of his right hand. He brought a product liability suit against the manufacturer in New Jersey. The manufacturer moved to dismiss, alleging there was no personal jurisdiction over it because it had no contacts with New Jersey other than its product ending up there. *Id.* at 2790. The plaintiff provided evidence that the manufacturer intended for its U.S. distributor to sell the machines anywhere it could. *Id.* at 2791. The manufacturer also attended several scrap metal trade shows in the U.S., one of which was attended by the New Jersey purchaser of the machine that injured the plaintiff. *Id.* at 2791, 2795.

Once again, the court was unable to agree on a standard. The plurality opinion, written by Justice Kennedy and joined by three other justices, rejected the pure stream of commerce test set forth by Justice Brenner [sic] in *Asahi.* The plurality concluded it is not enough that the company is aware that its products are being marketed in the forum state; the company must have actively targeted the forum. *Id.* at 2788.

Justice Breyer, joined by Justice Alito, concurred with the judgment of the plurality, but not the analysis. Although the concurring justices agreed that the scant factual record in this case did not satisfy the *Asahi* minimum contacts standard, they declined to adopt the rigid plurality [16] rule, noting that it fails to account for the way modern companies market their products and target customers. *Id.* at 2972-74. Three justices (Ginsberg, Kagan and Sotomayor)

dissented from the plurality and concurring opinions, noting, "Inconceivable as it may have seemed yesterday, the splintered majority today turns the clock back to the days before modern long-arm statutes when a manufacturer, to avoid being hauled into court where a user is injured, need only Pilate-like wash its hands of a product by having independent distributors market it." *Id.* at 2795.

The fractured decisions in *Asahi* and *Nicastro* do not provide solid guidance to courts as to what specific types of actions by a foreign company will satisfy the minimum contacts required under the Due Process Clause. Indeed, these Supreme Court opinions "tell us what minimum contacts are *not* rather than what they *are* . . . " *Hydraulic Servocontrols Corp.*, 294 Or at 385 (emphasis added). The Oregon Supreme Court is presently grappling with this very issue in a mandamus proceeding pending before it in *Willemsen v. Invacare Corp. et al.*, Multnomah Co Cir Ct No 0902-01653, Supreme Ct No S059201 (Or).[72] Oral argument was held on May 3, 2012. An opinion is expected within the next few months. But as explained below, the unique facts of this case make clear that the exercise of personal jurisdiction over NN A/S is proper regardless of the standard the court ultimately adopts.

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[72] Ex. 41, Plaintiffs' Answering Brief;, Ex. 42, Relators' Opening Brief and Supplemental Excerpt of Records; and Ex. 45, Relators' Reply Brief and Supplemental Excerpt of Records, *Willemsen v. Invacare Corp. et al.*, Multnomah Co Cir Ct No 0902-01653, Supreme Ct No S059201 (Or);

C. <u>The Plurality Opinion in *Nicastro* Is Not Binding on This Court.</u>

At the July 6, 2011 hearing on jurisdictional discovery in this case, the Court wondered whether the plurality opinion by Justice Kennedy in *Nicastro* "really does change the landscape substantially."[73] It has not. Both the U.S. and Oregon Supreme Courts hold that where no single analysis, rationale or standard has been supported by a majority of the court, a plurality opinion [17] is not binding. *CTS Corp. v. Dynamics Corp. of America*, 481 US 69, 81 (1987)[74] (Because the "plurality opinion . . . did not represent the views of a majority of the Court, we are not bound by its reasoning."); *accord State v. Farber*, 295 Or 199, 208 n 11, 666 P2d 821 (1983) ("a four-person plurality is not binding precedent.").

Where, as here, "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. U.S.*, 430 US 188, 193 (1977)[75] (internal citations and quotation marks omitted). We are left, then, with Justice Breyer's concurrence in *Nicastro*.

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[73] Ex. 34, *Lukas-Werner, et al. v. Novo Nordisk, A/S, et al.*, Transcript of Proceedings at 32:22-23 (July 6, 2011).

[74] Attached as Ex. 35.

[75] Attached as Ex. 36.

In *Nicastro*, Justice Breyer concurred with the plurality's judgment on one narrow ground: "None of our precedents finds that a *single isolated sale*" to a buyer in the forum state constitutes a sufficient basis for asserting jurisdiction over a foreign defendant, even if the defendant intended that it be sold anywhere in the U.S. *Id.* at 2792 (emphasis added). Tellingly, Justice Breyer did not disavow Justice Brennan's stream-of-commerce analysis in *Asahi* or express a preference for Justice O'Connor's standard. Instead, he found that all three *Asahi* opinions "strongly suggested that a single sale of a product" would not suffice: Justice O'Connor required "something more" than the stream of commerce; Justice Brennan required a "regular and anticipated flow of commerce into the State, but not where that sale is only an eddy, *i.e.*, an isolated occurrence; and Justice Stevens believed "the volume, the value, and the hazardous character" of the product would affect the jurisdictional inquiry. *Id.* at 2792 (internal quotations omitted).

Missing in *Nicastro*, Justice Breyer concluded, was any showing of "regular flow" or "regular course" of sales of the manufacturer's goods in the forum state. *Id.* In the absence of a "regular flow" of goods, other evidence of purposeful availment in the forum might also include: [18] a list of potential customers in the forum state, *id.*; concern by the foreign defendant over U.S. litigation relating to its product; advice by the foreign company to its distributor in marketing the product throughout the United States,

id. (citing examples in dissenting opinion); or the foreign defendant's targeting of the forum state by selling products directly from its website. *Id.* at 2793.

Since *Nicastro*, courts have generally declined to adopt the plurality's decision or its rationale. For example, in *Graham v. Hamilton*, Case No. 3:11-609, 2012 WL 893748 (WD La Mar 15, 2012),[76] the district court held that the *Nicastro* concurrence did not choose between the *Asahi* plurality opinion and thus, the Fifth Circuit's stream-of-commerce test still applied. Personal jurisdiction in that case was adequate because there was evidence that "GM Canada places over 800,000 vehicles in the U.S. market each year, indicating that many of GM Canada's vehicles would likely be sold in Louisiana." *Id.* at *4. There was no specific targeting of Louisiana by GM Canada, but the nationwide distribution scheme reflected its intent to market the foreign products throughout the U.S.

Likewise, under either or both *Asahi* plurality "minimum contacts" standards, courts in Pennsylvania and New York held that the sale of the foreign defendant's defective product in the forum state, causing injury to forum plaintiff, constitutes purposeful availment and provides an adequate basis for the exercise of personal jurisdiction. *See*, *e.g. Merced v. Gemstar Group, Inc.*, Case No. 10-3054, 2011 WL

[76] Attached as Ex. 37.

5865964, at *5 n 1. (ED Pa Nov 22, 2011)[77] (holding that facts were not analogous to those in *Nicastro*, and an invoice of Italian defendant showing that the ultimate destination for the shipment of its product was to Pennsylvania was sufficient evidence that defendant targeted the forum); *cf. Sieg v. Sears Roebuck & Co.*, Case No. 3:10cv606, 2012 WL 610961 (MD Pa Feb 24, 2012)[78] (applying both *Asahi* plurality standards and holding that, unlike in *Merced*, personal jurisdiction was lacking because there was no evidence that the [19] Taiwanese defendant sold the defective product in Pennsylvania); *UTC Fire & Security Americas Corp., Inc.*, Case No. 10 Civ. 6692(LTS)(THK), 2012 WL 423349 (SDNY Feb 10, 2012)[79] (applying *Nicastro* concurrence, personal jurisdiction over Chinese manufacturer held proper based on evidence that manufacturer defendant directed and approved marketing activities of distributor, which in turn, sold manufacturer's batteries to at least one New York customer).

D. The Oregon Supreme Court's Impending Decision in *Willemsen* Will Likely Support Personal Jurisdiction over NN A/S.

The Oregon Supreme Court has recently taken under advisement in *Willemsen v. Invacare Corp. et al.*

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[77] Attached as Ex. 38.

[78] Attached as Ex. 39.

[79] Attached as Ex. 40.

the question of whether *Nicastro* alters its decision in *Hydraulic Servocontrols*, a factually similar case, which held that the minimum contacts requirement is satisfied where an out-of-state defendant places its product into the stream of commerce, which is then purchased in Oregon and injures a plaintiff there. The *Willemsen* plaintiffs argue that *Hydraulic Servocontrols* is still good law; the foreign defendant contends it is not.[80]

As is the case with many product liability suits, *Willemsen* has a long and circuitous procedural history, but the pertinent facts are as follows. Defendant CTE, a Taiwanese company, manufactured a battery charger which was used as a component in an electric wheelchair manufactured by defendant Invacare. The wheelchair was purchased in Oregon by Karlene Willemsen, an Oregon resident, who suffered from advanced multiple sclerosis.

In 2008, the wheelchair caught fire in Ms. Willemsen's bedroom and burned her to death. Her family brought a wrongful death action in Multnomah County in 2009 against several defendants, including CTE and Invacare. In 2010, CTE filed a motion to dismiss for lack of personal jurisdiction. After allowing discovery on jurisdiction and supplemental briefing, Hon. Richard Baldwin denied CTE's motion.

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[80] *Willemsen* appellate briefs are attached as Exhibits 41, 42, and 45.

[20] CTE petitioned the Oregon Supreme Court for a writ of mandamus, which was denied without opinion. CTE then petitioned the U.S. Supreme Court for *writ of certiorari.* That court granted the petition, vacated the judgment and remanded the case to the Oregon Supreme Court for further consideration in light of *Nicastro.* The parties have fully briefed the issue before the Oregon Supreme Court; on May 3, 2012 that court heard oral argument. It is uncertain when the court will decide, but plaintiffs estimate an opinion will issue no later than six months from now.

The jurisdictional facts in *Willemsen* are quite similar to those in *Hydraulic Servocontrols.* At its factory in Taiwan, defendant CTE manufactures battery chargers that are designed to be used in defendant Invacare's electric wheelchairs. Invacare, an Ohio company, sold 1,116 electric wheelchairs – 1102 of which contained CTE's chargers – in Oregon during the relevant period.[81] In its supply agreement with Invacare, CTE agreed to indemnify Invacare for any legal claims made against Invacare arising out of defects with its chargers. The agreement also required CTE to carry $1 million in liability insurance to cover product liability claims.[82] In *Hydraulic Servocontrols* the Oregon Supreme Court held that the sale in Oregon of a product containing the foreign defendant's defective component part, which injured an

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[81] Ex. 41, Plaintiffs' Answering Brief, *Willemsen* at 3.

[82] *Id.*

Oregon resident, created sufficient contacts to warrant the exercise of personal jurisdiction. 294 Or at 215.[83]

In its mandamus brief, CTE urges the Oregon Supreme Court to adopt Justice Kennedy's opinion, which it erroneously characterizes as a 6-3 majority decision in *Niacastro*[84] invalidating Justice Brennan's stream-of-commerce analysis in *Asahi.* However, as the *Willemsen* plaintiffs [21] correctly point out, the plurality opinion by Justice Kennedy is not binding on any court.[85] While the most narrow basis of Justice Breyer's concurring opinion is controlling, his concurrence neither adopted nor repudiated the competing standards in *Asahi*, nor did it announce a new standard. Indeed, Justice Breyer limited his decision to the bare factual record before him in that case. *Nicastro*, 131 S Ct at 2972 ("Accordingly, on the record present here, resolving the case requires no more than adhering to our precedents.").

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[83] The same day the Oregon Supreme Court decided *Hydraulic Servocontrols*, it also issued a decision in *State ex rel. La Manufacture Francaise Des Pneumatiques Michelin v. Wells*, 294 Or 296, 657 P2d 207 (1982). In that case, however, the court held that personal jurisdiction was lacking. Although defendant's tire injured an Oregon plaintiff, "no fact of substantive relevance, such as sale, use, accident or injury has been shown to have occurred in Oregon." *Id.* at 303.

[84] Ex. 42, Relators' Opening Brief at 17, *Willemsen.*

[85] Ex. 41, Plaintiffs' Answering Brief at 22-25, *Willemsen.*

At most, Justice Breyer's concurrence would bar personal jurisdiction only in cases in which there is a "single isolated sale" of the out-of-state defendant's product to the forum state without any other evidence of purposeful availment, such as "special state-related design, advertising, advice, marketing" or other activity. *Id.* at 2792. Thus, if the *Willemsen* court does alter its test for minimum contacts, it will likely do so narrowly. The factual record in *Willemsen* shows that the sales in Oregon of wheelchairs containing CTE's batteries were not a "single isolated" event but rather, a "regular flow" of over a thousand products. It is unlikely under these facts that the *Willemsen* court will find that the exercise of personal jurisdiction over CTE is improper or unreasonable. It is even less likely that the *Willemsen* decision will repudiate personal jurisdiction over NN A/S, as explained below. On the contrary, plaintiffs believe that the *Willemsen* decision will compel this Court to find there is a sound basis in this case to exercise personal jurisdiction over NN A/S.

E. The Facts Support the Court's Exercise of Personal Jurisdiction over Defendant NN A/S.

Jurisdiction over NN A/S is proper no matter which analysis this Court applies. It is certainly proper under each of the *Asahi* tests discussed in Justice Breyer's concurrence in *Nicastro.* It is undisputed that NN A/S manufactures the drug Activella

in its headquarters country of Denmark and has intentionally placed hundreds of thousands of Activella pills in the U.S. stream of commerce. NN A/S directed its subsidiary NNP, later renamed NNI, to develop a [22] comprehensive, nationwide sales network. Oregon was one of the sales territories. Sales of Activella in Oregon were part of the regular and anticipated flow of commerce into Oregon, not an "isolated occurrence."

Through its U.S. subsidiary, NN A/S regularly sold hundreds of prescriptions to Oregon women each month. An NNI sales representative in Oregon regularly called on Dr. Harp while she was prescribing Activella to Ms. Lukas-Werner, an Oregon resident. Ms. Lukas-Werner was later diagnosed and treated for breast cancer in Oregon. Her lawsuit "arises out of" her use of NN A/S's drug Activella and the injury it caused. On these facts, NN A/S had "fair warning" that the sales of Activella may subject it to jurisdiction here. *See Burger King*, 471 US at 472 (the fair warning requirement is satisfied if the defendant has purposefully directed its activities at residents of the forum and the litigation results from injuries that "arise out of or relate to" those activities).

Jurisdiction attaches even under the *Nicastro* plurality's more exacting "state targeting" test. Justice Kennedy acknowledged that "[t]he defendant's conduct and the economic realities of the market the defendant seeks to serve will differ across cases."

Nicastro, 131 S Ct at 2790.[86] Indeed, one significant factor the plurality found missing in *Nicastro* was evidence that the U.S. distributor was selling the product under the direction or control of the foreign manufacturer. *Id.* at 2786.[87] Justice O'Connor's plurality opinion in *Asahi* also identified this factor as one that would establish sufficient minimum contacts: "Additional conduct of the defendant may indicate [23] an intent or purpose to serve the market in the forum State, for example . . . marketing the product through a distributor who has agreed to serve as the sales agent in the forum State." *Asahi*, 480 U.S. at 112. Another important factor the court found missing in *Asahi* was "evidence that Asahi designed its product in anticipation of sales in California." *Id.* at 113. This Court itself commented that evidence of NNI's

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[86] As counsel for the foreign defendant conceded at the close of his oral argument to the Supreme Court in *Nicastro*, companies with "sophisticated distribution networks," such as automobile manufacturers like Volkswagen and Toyota would be subject to personal jurisdiction in any state they sold their products, even though their U.S. distributors were "independent.". [sic] Ex. 44, *J. McIntyre Machinery, Ltd. v. Nicastro*, Sup Ct Dkt No 09-1343, Tr. Oral Argument at 61-62 (Jan. 11, 2011).

[87] At oral argument, the justices immediately and repeatedly raised the question of to what degree the foreign company directed or controlled the means by which the distributor sold the product. The very first question asked (by Justice Scalia) was, "When you say 'its distributor,' was this distributor at all controlled by the defendant?" Ex. 44, *J. McIntyre Machinery, Ltd. v. Nicastro*, Tr. Oral Argument at 3. Justice Scalia then noted that the distinction between distributing a company's product versus being "its distributor" was a loaded concept. *Id.* at 4.

Activella-related activities in Oregon done under the direction of NN A/S could be probative that NN A/S deliberately targeted Oregon.[88]

Such evidence is present here. NN A/S used its subsidiary NNI to gain entry of Activella in the U.S. market. NN A/S approved the protocol for NNI to complete the clinical studies in the U.S. to obtain FDA approval for Activella. Several of these study sites were in Oregon. NN A/S directly supplied the pills and other materials for the Oregon trials. Under NN A/S's direction, NNI carried out the Oregon clinical investigations and kept NN A/S apprised of their status. NN A/S not only approved NNI's budgets for the premarketing studies on Activella; it also approved and funded the budget for hiring and training sales staff to sell Activella after the drug came on the market in the U.S. NN A/S sent its own employees to the U.S. to work at NNI to implement NN A/S's global marketing strategies for Activella. NN A/S had the final say on the content of the Activella label and the marketing messages NNI used to promote the drug. Pursuant to a marketing program developed by NN A/S, NNI hired Dr. Harp to provide feedback and input on the messaging and educational programs about Activella and to participate in a sampling program. Another Oregon physician, Dr. Catherine Crim, was trained and paid as a spokesperson for Activella.

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[88] Ex. 34, Tr. of Proceedings at 42-43, 46-47, *Lukas-Werner v. Novo-Nordisk*, No. 1009-13177 (Multnomah Cty Cir Ct Or Jul. 6, 2011).

On at least two occasions, Dr. Crim made Activella presentations to Oregon physicians.

Given its oversight of Activella testing, labeling and marketing in Oregon and other states, NN A/S surely had fair notice from the markets it sought to serve that it could be subject [24] to personal jurisdiction in Oregon courts. This is the very type of purposeful availment all nine justices in *Nicastro* agreed would satisfy Due Process concerns.

F. Personal Jurisdiction over NN A/S Does Not Offend "Fairness" Principles.

NN A/S maintains that the exercise of personal jurisdiction over it is inconsistent with "fair play and substantial justice" and thus violates the Due Process Clause of the United States Constitution. NN A/S Mot. at 9-10 (quoting *International Shoe Co. v. Washington*, 326 US 310, 316 (1945). Of course, the Supreme Court has consistently held that the defendant's purposeful availment to the rights and privileges of the forum state implicitly satisfies Due Process "fairness" requirements:

> Hence if the sale of a product or of a manufacturer or distributor . . . is not simply an isolated occurrence, but arises from the efforts of the manufacturer or distributor to serve, directly or indirectly, the market for its product in other states, it is not unreasonable to subject it to suit in one of those States if its allegedly defective merchandise

> has there been the source of injury to its owners or to others.

Asahi, 480 US at 110 (quoting *World-Wide Vokswagen*, 444 US at 297).

Nevertheless, the Supreme Court developed a separate analysis to assure that the contacts between the defendant and the forum are such that it is reasonable to require the foreign company "to defend the particular suit which is brought here." *World-Wide Volkswagen*, 444 US at 292. This "fairness" test was elaborated in *Asahi*, 480 US at 113-115 and has also been adopted in Oregon. *See Circus Circus*, 317 Or at 159-60. In determining the reasonableness of asserting jurisdiction, the court must consider: (1) the burden on the defendant; (2) the interest of the forum state; (3) the plaintiff's interest in obtaining relief; (4) the interstate judicial system's interest in obtaining the most efficient resolution of controversies; and (5) the shared interest of the several states in furthering fundamental social policies. *Asahi*, 480 US at 113. The balance of these factors favors the exercise of jurisdiction over NN A/S, as explained below.

[25] **1. The burden on the defendant**

NN A/S complains that it would suffer great burden and expense defending itself from lawsuits in the U.S. Def. Mot. at 13. However, the Supreme Court has noted, "When minimum contacts have been established, often the interests of the plaintiff and the forum in the exercise of jurisdiction will justify even

the serious burdens place on the alien defendant." *Asahi*, 480 US at 114. Moreover, the burdens of inconvenience have been substantially relaxed over the years due largely to a "fundamental transformation in the American economy." *World-Wide Volkswagen*, 444 US at 292-293. "[M]odern transportation and communication have made it much less burdensome for a party sued to defend himself in a State where he engages in economic activity." *Id.* at 293 (internal citations omitted).

Any burden to NN A/S of defending itself in Oregon is outweighed by the economic benefits it has derived through its involvement in testing and marketing Activella in Oregon. Outside the context of litigation, travel to the U.S. has not been an obstacle to NN A/S. The company prides itself on the culture of "mobility" it has created. NN A/S sends employees to its business units around the world, including the U.S., to carry out its global marketing strategies.[89] NN A/S explicitly recognizes that operating on a global basis exposes the company to liability for its conduct.[90]

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[89] *See*, *e.g.*, Ex. 02, NN A/S 2005 Annual Report at 28-29.

[90] *Id.* at 31. *See also* Ex. 01, NN A/S Annual Report 2011, at 24. Ex. 18, NNKLDA086025-31 May 9, 2005 Powerpoint slides entitled HT Strategic Options. Ex. 43, NNKLDA086085 May 24, 2005 email between Klaus Davidson and Michael Shalmi stating: "Initial input from KSZ and JBR is that they do not wish to divest and they perceive the milking scenario to have a higher value than the offer from Solvay." KSZ is Kare Schults and JBR is Julia Butler, both upper management at NN A/S. Both of these unredacted images were viewed at the depository on May

(Continued on following page)

And in fact, NN A/S has used the U.S. legal system as a convenient and effective forum to protect its commercial interests and sue competitors.[91]

[26] **2. The interest of the forum state**

The U.S. Supreme Court has suggested that a state's interest in exercising jurisdiction is heightened when one of its own citizens suffers injury from an unsafe product. *See Asahi*, 480 US at 114-15. Through its laws and statutes, Oregon has a strong interest in protecting its consumers from the tortious conduct of manufacturers and sellers of defective products, particularly when such conduct causes injury within the state's borders. *See Estate of Schwartz v. Philip Morris Inc.*, 206 Or App 20, 49 (2006); *Parrott v. Carr Chevrolet, Inc.*, 351 Or 537, 561 (2001). Oregon's product liability law also "undoubtedly creates an additional deterrent to the manufacture of unsafe components." *Asahi*, 480 US at 115. The state's interest in consumer health and safety weighs in favor of the exercise of personal jurisdiction.

3. The plaintiff's interest in obtaining relief

Likewise, Mr. and Mrs. Lukas-Werner have a compelling interest in pursuing their claims against

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9, 2012 and ordered on May 10, 2012. The images have not yet been received, but we attach the available coding.

[91] Ex. 02, NN A/S Annual Report 2005, at 50; Ex. 01, NN A/S Annual Report 2011, at 87.

both NNI and NN A/S in Oregon, rather than in Denmark. NN A/S argues vigorously that it is not a proper defendant in this case because as a foreign parent, it maintains "separate and distinct corporate entities"; thus the conduct of NNI cannot be imputed to NN A/S. Def. Mot. at 12. Counsel for NNI further assures the Court it will not claim at trial that NN A/S was responsible for failing to warn.[92] These arguments miss the point entirely, and they ignore the factual record that has only recently begun to unfold in this case.

Plaintiffs seek recovery from NN A/S not because it is a "deep pocket" or out of concern that NNI cannot pay a judgment against it. *Au contraire*, the unredacted documents that plaintiffs have been able to begin reviewing in recent days directly contradict Ms. Reker Cordt's sworn testimony. They show not only that NN A/S had ultimate authority over key marketing, labeling and budgeting decisions relating to Activella; NN A/S was also complicit with NNI in deciding which studies on breast cancer would (or would not) be done on Activella and how [27] safety information would (or would not) be communicated to healthcare providers in Oregon and elsewhere.

Indeed, it was NN A/S that developed the strategy for responding to concerns about HRT and breast cancer risks. It was NN A/S, not NNI, that decided

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[92] Ex. 34, Tr. of Proceedings, *Lukas-Werner* at 46 (Jul. 6, 2011).

what studies were sufficient to investigate the breast cancer risk of Activella. It was NN A/S, not NNI, that decided what the breast cancer warning in the Activella label would say. It was NN A/S, not NNI, that ultimately decided to organize a personal sales force, including the Oregon sales representative, to promote Activella. It was NN A/S, not NNI, that decided what scientific training the sales reps would receive. And it was NN A/S, not NNI, that decided what information concerning Activella would be provided to Dr. Harp and other Oregon doctors.

Based on the evidence plaintiffs have unearthed to date, there is a real likelihood that a jury will find NN A/S at least partly at fault for causing Ms. Lukas-Werner's breast cancer. NN A/S is thus a legitimate and indispensible defendant in this case.

4. The interstate judicial system's interest in efficient resolution of controversies

For similar reasons, the laws and procedures of the U.S. tort system "should be such as to permit the injured party to join all parties in the normal distribution chain who may be liable, in a single law suit and in a single forum, as a matter of logical judicial economy, as well as convenience." *Merced v. Genstar Group, Inc.*, 2011 WL 5865964, at *5.[93] As the *Merced* court noted, the manufacturer of the defective

[93] Attached as Ex. 38.

product is probably the most indispensible defendant in the distribution chain. *Id.* It makes little sense to force plaintiffs to bring separate claims in separate countries for conduct that transpired between NN A/S and its wholly owned and controlled U.S. subsidiary/ distributor.

[28] **5. The shared interest of the several states in furthering societal policies.**

This factor requires a court to consider "the procedural and substantive policies of other *nations* whose interests are affected by the assertion of jurisdiction" by Oregon courts. *Asahi*, 480 US at 115. The *Asahi* court cautioned, "Great care and reserve should be exercised when extending our notions of personal jurisdiction into the international field." *Id.* Unfortunately, the Supreme Court has little guidance on how to balance the interests of U.S. and foreign policies in weighing this factor other than to conduct "a careful inquiry into the reasonableness of the assertion of jurisdiction in the particular case." *Id.* It thus appears that this final consideration depends on which way the balance tips when applying the other four factors, as well as the strength of the contacts between the foreign defendant and the forum state. Here, the balance of the "fairness" factors, combined with the defendant's strong contacts with Oregon, tips decidedly in favor of holding NN A/S accountable in this jurisdiction.

IV. CONCLUSION

NN A/S could have structured its course of dealings differently. It could have given NNI complete autonomy in the testing, marketing, sale and labeling of Activella. Or it could have licensed Activella to an unrelated U.S. company whose responsibility it was to obtain FDA approval and to organize its own distribution and sales network. By distancing itself through multiple levels of separation, NN A/S might have successfully avoided contact with Oregon, a strategy Justice Ginsburg described as washing one's hands "Pilate-like" of personal jurisdiction. But NN A/S deliberately chose a hands-on approach to the creation and distribution of its products, right down to the local level. It is what NN A/S proudly describes as "The Novo Nordisk Way of Management."[94] While laudable, this approach creates a reasonable expectation that NN A/S will have to answer for its conduct in Oregon and other markets where it makes strategic decisions. NN A/S admits to shareholders that it has assumed this risk. Fairness demands the exercise of personal jurisdiction by this Court over NN A/S.

For these reasons, plaintiffs ask the Court to deny defendant NN A/S's motion to dismiss.

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[94] Ex. 02, NN A/S Annual Report 2005, at 5, 7.

Respectfully submitted this 16th day of May, 2012.

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[Certificate Of Service Omitted In Printing]

APPENDIX H

IN THE CIRCUIT COURT
OF THE STATE OF OREGON

FOR THE COUNTY OF MULTNOMAH

SUZANNE M. LUKAS-WERNER, and SCOTT WERNER, wife and husband, Plaintiffs, v. NOVO NORDISK A/S, a Denmark corporation, et al.; NOVO NORDISK INC.; a Delaware corporation; BRECKENRIDGE PHARMACEUTICAL, INC., a Delaware corporation; and KRISTINA HARP, M.D., an Oregon citizen, Defendants.	Case No.: 1009-13177 SPECIALLY APPEARING DEFENDANT NOVO NORDISK A/S' BRIEF IN SUPPORT OF THE COURT'S JUNE 1, 2012 ORDER DISMISSING NOVO NORDISK A/S FOR LACK OF PERSONAL JURISDICTION **ORAL ARGUMENT REQUESTED**

Specially appearing defendant Novo Nordisk A/S ("NN A/S") submits this brief in Support of the Court's June 1, 2012 Order Dismissing Plaintiffs' claims against it on the grounds that this Court lacks specific personal jurisdiction over NN A/S, because in assessing the limits of constitutional due process, there is no evidence that NN A/S availed itself in any way as to the State of Oregon so as to support

the constitutional exercise of personal jurisdiction. Indeed, plaintiffs' operative pleadings assert only claims for alter ego or piercing the corporate veil as a basis to assert personal jurisdiction over NN A/S, claims which plaintiffs admittedly abandoned in their brief in opposition.[1] Based on the pleadings filed herein, as a matter of record, this alone is a legally and factually proper basis to grant NN A/S motion to dismiss. Plaintiffs have the burden to plead and prove the basis for personal jurisdiction (*Showalter v. Edwards and Associates, Inc.,* 112 Or App 472, 476, 831 P.2d 58 (1992)) and have failed to do so.

[2] There is no basis to overturn the Court's prior ruling because there is no evidence of record to support a claim that NN A/S itself, through NNI or even others purposefully availed itself of the forum State of Oregon as to the design, labeling, manufacture, marketing or as to any other aspect of Activella®. Plaintiffs have totally failed to meet their burden of proof as to facts supporting the constitutional exercise of personal jurisdiction.[2] Plaintiffs fail in two

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[1] Plaintiffs' Response, Page 1, fn. 1. Plaintiffs likewise in the same footnote abandoned any claim for general jurisdiction over NN A/S.

[2] At the hearing on June 1, 2012, counsel for NN A/S moved this Court to strike most of plaintiffs' "proffered evidence" as being inadmissible, including lack of foundation and hearsay. For example, plaintiffs did not establish that any of the proffered documents were business records. Indeed it was clear much of what plaintiffs offered was hearsay, double hearsay or plaintiffs' self-serving spin. The Court did not formally rule on NN A/S' oral motion. NN A/S is simultaneously filing a motion to

(Continued on following page)

critical ways. First, there is no admissible evidence as to the volume of sales of Activella® in Oregon (indeed, neither NNI or NN A/S sell directly into the State of Oregon), and, second, the other evidence the *Willemsen* court considered in assessing whether it would be fundamentally unfair to haul CTE into court in Oregon is nonexistent here. The Court should enter the Order dismissing NN A/S that has been proposed by NN A/S and agreed to as to form by plaintiffs.

Alternatively, in light of the Oregon Supreme Court's granting of a motion to stay discovery as to CTE in the *Willemsen* case (*See* Order attached hereto as Exhibit 1), this Court should similarly (a) stay its ruling on its *sua sponte* reconsideration, or (b) stay further proceedings against NN A/S pending final resolution of the *Willemsen* case on CTE's petition for certiorari. Moreover, in finding that Justice Breyer's concurrence was controlling, and that *Nicastro*'s restrictions on personal jurisdiction was limited to circumstances in which there had been only an isolated sale of a product in the jurisdiction, the *Willemsen* court did not, in NN A/S' view, properly assess *Nicastro* or the limits of constitutional due process. Indeed, the narrowest ground upon which Justices Breyer and Alito agreed with the plurality was that the "stream of commerce plus" test from Justice O'Connor's opinion in *Asahi Metal,* as it

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strike such proffered evidence by plaintiffs for purpose of the record, as it consists of inadmissible evidence.

guided the *Nicastro* decision, and indeed in *Asahi* there were tens of [3] thousands of sales within the forum state.[3] It is undeniably clear that the "something more" that would support personal jurisdiction under the test adopted by six (6) of the justices, including Justices Breyer and Alito, could not be the mere volume of sales, because that was not the "something more" intended or in fact identified by Justice O'Connor in *Asahi Metal.* This Court itself recognized that Justice Breyer's opinion was more stringent than the plurality, or in the *Nicastro* plurality or Justice Breyer's concurring opinion[4] wherein Justice Breyer states . . . "I cannot reconcile so automatic a rule with the Constitutional demand for "minimum contacts" and "purposeful availment," each of which rests upon a particular notion of defendant

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[3] The record reflects the sale of approximately 1,350,000 Asashi valve assemblies from 1978 through 1982, to Cheng Shin the tire tube manufacturer. Cheng Shin maintained approximately 20% of its U.S. sales were made in California. This would be in excess of 250,000 units. *Asahi Metal Industry Co., Ltd. v. Superior Court of California, Solano County, 480 US. 102, 106 (1987).*

[4] The Court stated, "The more I read Justice Breyer's concurring opinion, the more I think he doesn't even go as far as Justice O'Connor in *Asahi* . . . , He does emphasize that he thinks you have to retain the inquiry between the defendant – the forum – and he italicizes forum – and the litigation – and to look at the defendant's contacts – again italicized – with that forum. . . . : And he points out that minimum contacts and purposeful availment are actually two separate elements that have to be met. Transcript of June 1, 2012 Hearing on NN A/S' Motion to Dismiss, attached hereto as Exhibit 2, at 58:10-25.

focused fairness.[5] This speaks to the significantly increased likelihood of success by CTE in its petition for certiorari and provides more reason, if the Court is not going to uphold its own Order, to grant the alternative relief.

POINTS AND AUTHORITIES

I. THERE IS NO BASIS ON THE RECORD IN THIS CASE TO DISTURB THE COURT'S RULING.

This Court found no factual basis in the record to support the constitutional exercise of personal jurisdiction over NN A/S. At the hearing on NN A/S' Motion to Dismiss, the Court held as follows: "And I think there is an absence of a showing that NN A/S targeted Oregon, even through NNI . . . " (Transcript of June 1, 2012 Hearing, attached hereto as Exhibit 2, at 60:3-4.) Nothing has [4] changed that undeniable fact.

The Oregon Supreme Court, in its most recent ruling in *Willemsen v. CTE,* concluded that evidence of only one sale of the product at issue was the controlling basis for Justice Breyer's concurrence in *Nicastro. Willemsen* Slip Op. at 12-13. The Oregon Supreme Court seemingly concluded that Justices Breyer and Alito would find the exercise of personal jurisdiction constitutional so long as there was a regular flow of business from the out-of-state defendant

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[5] *Nicastro*, 131 S.Ct. at 2793.

into the forum state, even though the concurrence never says so. However, even the *Willemsen* decision recognized that flow of a product into the forum by itself would not be enough. There would still need to be an assessment of the fundamental fairness of hauling the out-of-state/foreign defendant into the forum. *Id.* at 18. Under the *Willemsen* analysis of sales volume alone, it's not enough. While NN A/S disagrees with the *Willemsen* court's reading of the *Nicastro* opinion, for purposes of this brief NN A/S will first address the lack of evidence in the record (a) regarding sales of Activella® within Oregon, and (b) that NN A/S purposefully availed itself of the forum State of Oregon.

Although Plaintiffs made the assertion in their response to NN A/S's motion to dismiss that "a significant portion of revenues from the sale of NN A/S's drugs came from Oregon," there is no evidence in the record to support this claim. Plaintiffs previously admitted that they "cannot address the 'sales volume' factor, which Justice Stevens addressed in *Asahi.*" *See* Plaintiffs' Response, Page 10, fn.66. In fact, the sole piece of evidence offered by plaintiffs in opposition to NN A/S's motion to dismiss regarding sales of Activella® in Oregon is inadmissible. *See* Exhibit 29 to Plaintiffs' Response. It consists of what plaintiffs purport to be Lisa Labedz's performance reports showing combined data of some nature for Washington and Oregon from July 2007 through January 2008. Instead it is actually a plaintiff-created chart, which has no foundation in the record. The underlying

documents are not provided to the Court, and there is zero testimony as to what the underlying documents actually are, what the data shows, how they were compiled, whether they are accurate, [5] how to interpret the data, and whether the documents would constitute business records. Further the totals from the documents, whatever they are, do not identify specific total numbers for Oregon, contrary to plaintiffs' claim. *See* Plaintiffs' Response, Page 10, Exhibit 29. Plaintiffs' self-serving efforts to extract such information are unfounded and inadmissible and must be rejected.

There was simply no record evidence before the Court when it ruled on NN A/S's motion to dismiss regarding the volume of sales of Activella® in Oregon. It was plaintiffs' burden to prove all facts necessary to support personal jurisdiction over NN A/S, which they failed to do. Accordingly, the ruling in *Willemsen* does not control in this case, as there is no such evidence. Indeed, the Court has recognized that plaintiffs failed to develop the necessary factual record to oppose NN A/S' Motion to Dismiss. At the Court's June 1, 2012 hearing on NNA/S' Motion to Dismiss, the Court questioned plaintiffs' counsel concerning whether there was any evidence that NN A/S knew Oregon was being targeted as to Activella® by NN A/S:

> THE COURT: But that's just the point. What's the evidence that they knew the distributor was selling that product there in Oregon?

Transcript of June 1, 2012 Hearing, at 51:6-8. The response of plaintiffs' counsel to the Court's question was summarized by the Court as follows:

> THE COURT: You keep – You are talking in circles, Ms. O'Leary, but I think you have answered by question.

Transcript of June 1, 2012 Hearing, at 52:2-4 (excerpts attached as Exhibit 2),

As noted, in ruling upon NN A/S's motion to dismiss, the Court concluded that there was an absence of evidence showing that NN A/S itself or through NNI targeted Oregon. Transcript of Hearing on NN A/S's Motion to Dismiss (June 1, 2012), Ex. 2, at 60: 3-13. Plaintiffs attributed this lack of proffered evidence to the Court's ruling prohibiting disclosure of the total dollar volume of Activella® sales in Oregon. *See* Plaintiffs' Response to NN A/S's Motion to Dismiss, Page 10, fn. 66. This is undeniably a mischaracterization. The Court permitted plaintiffs to engage in broad [6] discovery regarding "NN A/S' purposeful conduct within the State of Oregon related to the design, manufacture, labeling, marketing, whatever it is – as broad an issue you can define it – of Activella and such conduct as shown either directly through its own employees or through its agents." Transcript of July 6, 2011 Hearing, at 46:25-47:5, excerpts attached hereto as Exhibit 3. This specifically included sales of Activella® within Oregon. *See id.* at 41:17-23. *See* Transcript of January 19, 2012 Hearing, at 60:23-61:3, excerpts attached hereto as

Exhibit 4.[6] Seemingly plaintiffs now recognize their failure and want to improperly and belatedly supplement the record which as it stood on June 1, 2012 was devoid of admissible evidence.

Moreover, the distribution of Activella®, a prescription medicine, is very different than the direct sale of CTE's battery chargers to Invacare in *Willemsen*. NN A/S manufactures Activella®. NN A/S provides Activella® for NNI, which is a Delaware corporation with its principal place of business in Princeton, New Jersey. Declaration of Anne Reker Cord at ¶¶ 13-14. NN A/S did not sell Activella® in Oregon or to any Oregon-based distributor. *Id.* at ¶¶ 13, 16-17. NN A/S does not control the distribution system by which a legally separate indirect subsidiary, NNI, sells Activella® within the United States. *Id.* at ¶¶ 7-13. NN A/S ships Activella® to NNI's third-party logistics provider in Indianapolis, Indiana. *Id.* at ¶ 13. That concludes NN A/S' involvement. NN A/S provides Activella® to NNI. 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, NNI does not market directly to pharmacies in Oregon, but rather it sells to wholesale

[6] The Court, however, required plaintiffs to work out a confidentiality agreement that would be acceptable to non-party IMS, a company that tracks physician prescriptions and treats such data as proprietary and confidential. *See id.* In fact, documents related to sales were produced to the database available to plaintiffs. *See* Affidavit of Bryan Mouber, attached hereto as Exhibit 7.

distributors. See Declaration of Jim Snider attached hereto as Exhibit 5, at ¶ 5. *See* Reker-Cordt Declaration attached hereto as Exhibit 6, at ¶¶ 13-14. The wholesalers in turn sell to pharmacy chains and individual pharmacies in the U.S., including the State of Oregon. See Declaration of Jim Snider at ¶ 7. Plaintiffs cannot rely upon sales of Activella® in Oregon to establish personal jurisdiction because it is not NN A/S that [7] makes those sales. Indeed, it is not even NNI. See Declaration of Jim Snider at ¶ 8.

Plaintiffs failed to develop an adequate factual record that would support personal jurisdiction under *Willemsen*. As noted, NN A/S maintains that sales numbers, even if they existed, as to Activella® by NNI (which they do not) do not support personal jurisdiction as to NN A/S. Virtually all of plaintiffs' claim as to the factual basis to exercise personal jurisdiction over NN A/S are plaintiffs' supposition and wishful thinking. The *Willemsen* decision acknowledged that in addition to the volume of sales it was necessary to assess whether even if there was a regular course of sales or flow of business it would be fundamentally unfair to exercise jurisdiction over CTE. *Willemsen* Slip Op, Pg. 18. It recognized the need for "something more." The Oregon Supreme Court identified the "something more" facts it considered relevant to that analysis:

> "As an initial matter, . . . Additionally, in the master supply agreement between CTE and Invacare, CTE promised that its battery chargers would comply with all federal,

> state, and local laws. CTE thus voluntarily undertook to bring its battery chargers into compliance with the laws of the various states in which Invacare sold them. Finally, as part of the master supply agreement, CTE agreed that it would "continuously have on file with [Invacare] a current Certificate of Insurance showing evidence of products and general liability coverage for bodily injury, personal injury and property damage in the amount of one million dollars ($1,000,000) per occurrence." In selling its battery chargers to Invacare, CTE anticipated the need to defend against the very sort of claim that plaintiffs have brought here, and it agreed to obtain insurance as a hedge against the cost of doing so." (*Willemsen* Slip Op at 19.)

No such facts exist here. Indeed, as noted, plaintiffs offer no evidence whether NNI actually had a supply contract with NN A/S, or for that matter with anyone. Justice Breyer noted in his *Nicastro* concurrence that (a) there was no "something more" such as special state-related design, advertising, advice, marketing, or anything else, or (b) that the British manufacturer "purposefully availed itself of the privilege of conducting activities" within the forum state (Nicastro at 2792). As noted, this Court made the same no "something more" finding; as such, this Court, having found no basis to assert specific personal jurisdiction, this case is in a much different position than in [8] *Willemsen* The Oregon Supreme

Court analyzed the importance and sanctity of the fact findings of the trial court as follows:

> As noted, ORCP 21 A authorizes Oregon trial courts to consider "affidavits, declarations and other evidence" in determin[ing] the existence or nonexistence of the facts supporting" the defense of a lack of personal jurisdiction. It thus authorizes a state trial court to determine the facts and draw reasonable inferences from undisputed facts in the course of deciding whether it has personal jurisdiction over an out-of-state defendant. As a matter of state law, when a trial court has engaged in that enterprise, we construe the facts and draw all reasonable inferences consistently with the trial court's ruling. (*Willemsen* Slip Op, pg. 121, fn. 10.)

Here the record makes clear, as this Court found, there is no factual record on which to base personal jurisdiction. Further, it is critical to apply the fact-based "something more" analysis of Justice Breyer to answer to the case at hand, as did the Oregon Supreme Court in *Willemsen.* First, NN A/S is not simply an out-of-state defendant, but is a foreign company. As noted: "Great care and reserve should be exercised when extending our notions of personal jurisdiction into the international field." *United States v. First National City Bank,* 379 U.S. 378, 404, 85 S.Ct. 528, 542, 13 L.Ed.2d 365 (1965) (Harlan, J., dissenting). The balancing of interests was explained by Justice O'Connor in *Asahi* as follows: "The procedural and substantive interests of other nations in a

state court's assertion of jurisdiction over an alien defendant will differ from case to case. In every case, however, those interests, as well as the Federal interest in Government's foreign relations policies, will be best served by a careful inquiry into the reasonableness of the assertion of jurisdiction in the particular case, and 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."

Here, NNI is a Delaware corporation and as demonstrated in discovery has more than sufficient assets to respond to any reasonable judgment that might be rendered, up to Twenty-Five Million U.S. Dollars ($25,000,000.00). Here the addition of NN A/S as a defendant adds nothing as NNI has and will fully respond to all of plaintiffs' claims.

[9] **II. CTE WILL SEEK CERTIORARI FROM THE U.S. SUPREME COURT**

CTE will file a petition for certiorari to the U.S. Supreme Court. Indeed, even the Oregon Supreme Court recognized that the U.S. Supreme Court is likely to intervene in the *Willemsen* appeal. Within an hour of CTE's filing of a motion to stay merits-based discovery (Exhibit 9) pending pursuit of the writ, the Oregon Supreme Court granted a 90-day stay of proceedings against CTE. (Exhibit 1) As noted the Supreme Court of the United States after *Nicastro* did enter what is colloquially referred to as a GVR

(grant, vacate and remand) Order in *Willemsen*. The fact the Supreme Court did so increases the likelihood the U.S. Supreme Court will grant certiorari.

Whether the Supreme Court accepts certiorari in *Willemsen* should be known this fall. If this Court reverses its decision dismissing NN A/S, it will impose a massive, burdensome discovery process upon NN A/S which is both unwarranted and avoidable. NN A/S has never previously produced Activella®-related discovery materials in any U.S. case, and there is no reason to do so now. Such discovery will thus be very expensive and time-consuming. Moreover, if the U.S. Supreme Court reverses the Oregon Supreme Court on the *Willemsen* decision, that burden and expense will all have been imposed unnecessarily. The Oregon Supreme Court itself, by staying all discovery, recognized that it would be inappropriate to subject CTE to such potentially unnecessary discovery. The same is true as to NN A/S here. NN A/S respectfully requests in the alternative that the Court either (a) stay determination of its *sua sponte* motion to reconsider its prior ruling pending a determination of the *Willemsen* case in the U.S. Supreme Court, or (b) that the Court at least stay discovery as to NN A/S pending such a ruling.

III. THE OREGON SUPREME, COURT'S *WILLEMSEN* OPINION DERIVES FROM JUSTICE BREYER'S REJECTION OF THE FACTUAL RECORD THAT WAS ACCEPTED BY THE PLURALITY IN *NICASTRO*.

Six (6) justices of the U.S. Supreme Court concurred in a finding that there was no personal jurisdiction over the foreign manufacturer in *J. McIntyre Machinery, Ltd. v. Nicastro,* 131 S Ct 2780 (2011). Each of these justices relied upon Justice O'Connor's "stream of commerce plus" test from *Asahi Metal. See Nicastro,* 131 S Ct at 2790 and 2792. Each of these six (6) justices accepted that [10] the court has rejected the notion that a defendant's amenability to suit travels with the chattel and that these must be purposeful availment of the forum by the out-of-state/foreign defendant, and that there must be "something more" than mere sales of the product within the forum state to support an exercise of personal jurisdiction. *Id.* at 2788 and 2792. Plaintiffs admitted such. (*See* Transcript of June 1, 2012 Hearing, attached hereto as Exhibit 2, at 29:20-30:21. Indeed this is the narrowest ground upon which Justices Breyer and Alito joined the plurality, and the only proper reading of the *Nicastro* decision as applied here or in *Willemsen.* Based on the Court's findings, NN A/S was entitled to be dismissed. If the Supreme Court grants CTE's petition, there can be little doubt that the *Willemsen* decision will be reversed, all the more reason that if this Court does not sustain its prior Order, for this Court to grant the alternate relief requested.

CONCLUSION

For the reasons above and those set forth in Novo Nordisk A/S' Motion to Dismiss, Novo Nordisk A/S respectfully requests that this Court decline to set aside its June 1, 2012 ruling dismissing Novo Nordisk A/S.

DATED: August 9, 2012.

OF COUNSEL FOR SPECIALLY
APPEARING DEFENDANT
NOVO NORDISK A/S

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BAKER STERCHI COWDEN & RICE
Pat Lysaught, Admitted Pro Hac Vice

By: /s/ Patrick Lysaught

[Exhibit 5 Attached. Other Exhibits Omitted In Printing]

[EXHIBIT 5]

IN THE CIRCUIT COURT OF
THE STATE OF OREGON

FOR THE COUNTY OF MULTNOMAH

SUZANNE M. LUKAS-WERNER, and SCOTT WERNER, wife and husband, Plaintiffs, v. NOVO NORDISK A/S, a Denmark corporation; NOVO NORDISK INC., a Delaware corporation; BRECKENRIDGE PHARMACEUTICAL, INC., a Delaware corporation; and KRISTINA HARP, M.D., an Oregon citizen, Defendants.	Case No.: 1009-13177 DECLARATION OF JIM SNIDER IN SUPPORT OF SPECIALLY APPEARING DEFENDANT NOVO NORDISK A/S' REPLY IN SUPPORT OF ITS MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION **ORAL ARGUMENT REQUESTED**

I, Jim Snider, being duly sworn upon my oath, hereby declare under penalty of perjury, that:

1. I have personal knowledge of the facts set forth herein and submit this Declaration in support of Specially Appearing Defendant Novo Nordisk A/S' Reply in Support of Its Motion to Dismiss for Lack of Personal Jurisdiction.

2. I am an employee of Novo Nordisk Inc. familiar with the supply chain of Activella 1.0 mg 17-β estradiol/0.5 mg NETA® and Activella 0.5 mg 17-β estradiol/0.1 mg NETA® (collectively referred to as "Activella®").

3. NN A/S manufactures the Activella® tablets sold in the United States.

4. NN A/S ships Activella® tablets to a warehouse in Indiana managed by MD Logistics.

5. MD Logistics distributes units of Activella® for sale to the distribution centers of what

6. The largest direct trade consumers (wholesale distributors) in terms of volume are Amerisource Bergren, Cardinal Health, and McKesson.

7. The direct trade consumers (wholesale distributors) sell to pharmacy chains and individual pharmacies throughout the United States, including Oregon.

8. NNI does not sell Activella® directly to pharmacy chains or individual pharmacies in the United States, including Oregon.

I hereby declare that the above statement is true to the best of my knowledge and belief, and that I understand it is made for use as evidence in Court, and is subject to penalty for perjury.

Dated: May 22, 2012

/s/ J D Snider
Jim Snider

/s/ Virginia S. Thornton 5/22/2012
Virginia S. Thornton
Notary Public. New Jersey
My Commission Expires 9-7-2016

APPENDIX I

U.S. Census Bureau
U.S. Bureau of Economic Analysis
NEWS
U.S. Department of Commerce •
Washington, D.C. 20230

FOR IMMEDIATE RELEASE
8:30 A.M. EDT TUESDAY, JUNE 4, 2013

For information on goods contact:
U.S. Census Bureau:
Matthew Przybocki 301-763-3148
Maria Iseman 301-763-2311

For information on services contact:
U.S. Bureau of Economic Analysis:
Technical: Edward Dozier 202-606-9559
Media: Jeannine Aversa 202-606-2649

CB 13-98 BEA 13-24, FT-900 (13-04)

U.S. INTERNATIONAL TRADE
IN GOODS AND SERVICES

Annual Revision for 2012

Part A: Seasonally Adjusted

Exhibit 7. Imports of Goods by End-Use Category and Commodity

In millions of dollars. Details may not equal totals due to rounding. The commodities in this exhibit are ranked on the year-to-year change within each major commodity grouping.
(-) Represents zero or less than one-half unit of measurement shown.

Item (1)	Annual 2012	Annual 2011	Annual 2010	2012-2011 Change	2011-2010 Change
Total, Balance of Payments Basis	**2,302,714**	**2,239,991**	**1,938,950**	**62,722**	**301,041**
Net Adjustments	27,394	31,936	25,094	-4,543	6,843
Total, Census Basis	**2,275,320**	**2,208,055**	**1,913,857**	**67,265**	**294,198**
Foods, feeds, and beverages	**110,258**	**107,477**	**91,748**	**2,781**	**15,729**
Feedstuff and foodgrains	5,869	4,602	3,656	1,266	946
Other foods	11,478	10,555	9,387	923	1,167
Meat products	8,525	7,711	7,175	815	535
Fruits, frozen juices	12,259	11,687	10,405	572	1,282
Wine, beer, and related products	8,913	8,533	7,890	379	644
Bakery products	8,811	8,483	7,633	328	851
Alcoholic beverages, excluding wine	6,556	6,297	5,648	259	649
Vegetables	9,941	9,699	8,770	241	930
Nuts	2,007	1,884	1,477	123	406
Dairy products and eggs	1,690	1,586	1,410	104	176
Tea, spices, etc.	1,852	1,753	1,443	98	311
Fish and shellfish	16,622	16,575	14,635	46	1,940
Nonagricultural foods, etc.	720	742	695	-22	47
Food oils, oilseeds	5,932	6,247	4,234	-315	2,013
Cocoa beans	996	1,425	1,251	-428	174
Cane and beet sugar	2,280	2,790	1,984	-510	806
Green coffee	5,808	6,906	4,055	-1,099	2,851
Industrial supplies and materials	**730,374**	**755,823**	**603,104**	**-25,449**	**152,718**
Crude oil	312,800	331,582	252,161	-18,782	79,422
Gas-natural	8,742	13,567	17,402	-4,825	-3,835
Liquefied petroleum gases	6,351	9,963	12,158	-3,612	-2,195
Other precious metals	12,575	15,675	9,579	-3,100	6,096
Natural rubber	3,382	4,773	2,820	-1,390	1,952
Fuel oil	45,511	46,879	33,789	-1,368	13,089
Nuclear fuel materials	4,665	5,658	5,641	-993	17
Copper	5,816	6,770	5,087	-954	1,683
Petroleum products, other	50,117	50,918	38,002	-801	12,916
Nickel	2,885	3,605	2,946	-720	658
Chemicals-inorganic	7,981	8,646	6,358	-666	2,289
Pulpwood and woodpulp	3,360	4,024	3,891	-664	133
Bauxite and aluminum	10,873	11,533	10,482	-660	1,050
Chemicals-organic	24,762	25,400	20,417	-638	4,983
Steelmaking materials	8,580	9,000	7,315	-420	1,685
Zinc	1,513	1,810	1,585	-297	225
Tin	834	979	760	-145	218
Newsprint	1,344	1,464	1,377	-120	87
Blank tapes, audio & visual	987	1,100	1,197	-113	-97
Electric energy	1,914	2,015	2,071	-102	-56
Cotton cloth, fabrics	1,259	1,357	1,199	-98	158
Cotton, natural fibers	86	94	66	-8	28
Materials, excluding chemicals	1,454	1,433	1,282	21	151
Nonferrous metals, other	4,369	4,346	3,548	22	798
Paper and paper products	6,913	6,888	6,668	25	219
Hides and skins	226	188	173	39	15
Leather and furs	655	590	567	64	24
Sulfur, nonmetallic minerals	1,646	1,581	1,100	65	481
Wool, silk, etc.	758	681	572	78	109
Hair, waste materials	939	856	759	83	96
Glass-plate, sheet, etc.	1,203	1,107	1,090	96	17
Synthetic rubber – primary	3,244	3,134	2,292	110	842
Nontextile floor tiles	2,484	2,373	2,162	111	211
Synthetic cloth	6,008	5,894	5,110	114	785
Finished textile supplies	4,222	4,019	3,666	204	353

Plywood and veneers	2,222	1,930	1,948	292	-18
Coal and related fuels	3,258	2,944	2,143	314	801
Chemicals-fertilizers	16,132	15,817	11,495	314	4,322
Stone, sand, cement, etc.	4,122	3,798	3,684	324	114
Farming materials, livestock	1,701	1,355	1,146	346	209
Plastic materials	14,582	14,106	12,077	476	2,028
Lumber	4,123	3,498	3,514	625	-16
Finished metal shapes	17,387	16,721	14,315	666	2,405
Chemicals-other, n.e.c.	11,834	11,071	9,350	763	1,721
Shingles, wallboard	7,803	6,879	6,812	923	68
Iron and steel, advanced	9,459	8,510	7,120	949	1,390
Iron and steel mill products	20,873	19,795	14,393	1,078	5,402
Iron and steel products, n.e.c.	9,999	8,725	6,846	1,274	1,879
Nonmonetary gold	17,833	16,401	13,107	1,431	3,294
Industrial supplies, other	28,147	26,561	23,737	1,587	2,823
Tobacco, waxes, etc.	10,440	7,809	6,122	2,631	1,688
Capital goods, except automotive	**548,614**	**510,850**	**449,387**	**37,764**	**61,463**
Telecommunications equipment	52,797	48,475	47,582	4,322	893
Electric apparatus	42,848	38,747	35,133	4,101	3,615
Industrial machines, other	48,052	45,091	35,659	2,961	9,432
Excavating machinery	12,707	9,776	5,930	2,932	3,846
Drilling & oilfield equipment	11,698	9,047	7,348	2,650	1,700
Industrial engines	23,799	21,363	16,804	2,437	4,559
Materials handling equipment	13,276	11,098	8,133	2,178	2,966
Engines-civilian aircraft	16,456	14,306	12,640	2,150	1,666
Parts-civilian aircraft	13,375	11,372	9,869	2,003	1,503
Metalworking machine tools	11,661	9,741	6,435	1,920	3,306
Computer accessories	56,460	54,803	61,952	1,657	-7,150
Generators, accessories	22,132	20,623	18,469	1,509	2,155
Agricultural machinery, equipment	9,324	8,069	6,492	1,255	1,576
Medicinal equipment	31,557	30,433	27,360	1,124	3,073
Measuring, testing, control instruments	18,412	17,512	14,824	901	2,688
Computers	65,760	64,900	55,286	860	9,614
Photo, service industry machinery	15,842	15,161	13,825	681	1,335
Wood, glass, plastic	6,141	5,511	4,865	630	647
Civilian aircraft	10,289	9,891	8,774	398	1,117
Nonfarm tractors and parts	2,577	2,235	1,501	342	735
Railway transportation equipment	1,694	1,412	1,179	282	233
Laboratory testing instruments	5,649	5,439	4,531	211	907
Pulp and paper machinery	4,302	4,134	3,350	168	784
Business machines and equipment	4,744	4,580	4,432	164	148
Marine engines, parts	1,042	969	887	73	82
Semiconductors	40,234	40,170	31,228	63	8,943
Food, tobacco machinery	3,093	3,046	2,528	47	518
Vessels, except scrap	13	2	3	12	-1
Spacecraft, excluding military	132	166	96	-33	69
Commercial vessels, other	112	166	104	-54	62
Specialized mining	704	769	575	-64	194
Textile, sewing machines	1,729	1,844	1,594	-115	250
Automotive vehicles, parts, and engines	**297,813**	**254,615**	**225,097**	**43,197**	**29,519**
Consumer goods	**516,342**	**514,124**	**483,225**	**2,218**	**30,900**
Apparel, textiles, nonwool or cotton	39,377	36,975	31,736	2,402	5,239
Furniture, household goods, etc.	25,613	23,630	23,001	1,983	629
Household appliances	22,266	20,894	19,845	1,372	1,049
Cell phones and other household goods, n.e.c.	81,284	80,275	71,453	1,009	8,822
Artwork, antiques, stamps, etc.	9,799	8,798	8,070	1,001	729
Toiletries and cosmetics	8,692	7,871	6,986	821	885
Stereo equipment, etc	6,761	5,974	6,059	787	-85
Footwear	19,111	18,336	16,879	776	1,457
Apparel, household goods-nontextile	8,637	8,051	6,973	586	1,078
Toys, games, and sporting goods	33,466	32,960	34,840	507	-1,881
Motorcycles and parts	3,059	2,607	1,781	452	825
Camping apparel and gear	9,043	8,631	7,715	412	916
Cookware, cutlery, tools	7,812	7,446	7,055	366	391
Gem stones, other	3,404	3,114	2,840	291	274

Other consumer nondurables	13,403	13,224	12,592	179	632
Pleasure boats and motors	2,316	2,146	1,875	169	271
Rugs	2,048	1,923	1,745	124	178
Glassware, chinaware	2,137	2,062	2,034	75	29
Nursery stock, etc.	1,621	1,547	1,483	74	64
Musical instruments	1,622	1,583	1,512	39	71
Photo equipment	5,350	5,343	5,946	7	-603
Recorded media	907	925	899	-19	26
Books, printed matter	3,623	3,649	3,738	-26	-89
Apparel, household goods – wool	3,241	3,327	3,057	-86	270
Jewelry	12,091	12,339	10,423	-248	1,916
Numismatic coins	1,933	2,538	1,717	-605	821
Televisions and video equipment	32,843	33,497	37,779	-654	-4,282
Gem diamonds	20,196	22,299	18,599	-2,103	3,700
Apparel, household goods – cotton	47,435	50,392	49,138	-2,957	1,254
Pharmaceutical preparations	87,253	91,768	85,454	-4,515	6,314
Other goods	**71,920**	**65,166**	**61,296**	**6,754**	**3,870**

(1) Detailed data are presented on a Census basis. The information needed to convert to a BOP basis is not available.

NOTE: For information on data sources, nonsampling errors and definitions, see the information section on page A-1 of the FT-900 release, or at www.census.gov/ft900 or www.bea.gov/newsreleases/international/trade/tradnewsrelease.htm.

APPENDIX J

2012 NAICS Total All Merchandise Imports to Oregon

Partner	2009	2010	2011	2012
World	11,944,368,472	13,473,096,389	16,464,403,033	16,569,820,164
Japan	3,059,601,901	3,185,508,811	3,720,471,836	3,979,620,619
China	1,876,646,397	2,354,998,152	2,980,800,229	2,962,169,975
Canada	2,071,723,046	2,509,615,363	2,919,909,416	2,636,169,607
South Korea	517,881,471	920,945,811	1,129,836,812	1,607,334,599
Mexico	403,874,078	565,627,742	673,060,301	638,292,042
Germany	480,063,729	664,490,047	829,790,380	532,492,224
Russian Federation	113,746,383	351,118,151	393,237,694	429,333,561
Singapore	98,301,334	168,406,931	475,570,475	374,846,306
Taiwan	202,343,415	259,939,378	352,796,205	316,907,943
Viet Nam	271,811,060	251,105,875	272,549,518	276,200,082
Netherlands	151,240,732	58,840,318	162,612,151	243,446,049
Israel	93,868,952	41,427,282	291,473,013	233,880,905
Hungary	4,865,878	67,644,769	180,417,760	202,926,898
India	120,236,749	110,618,287	116,115,571	194,529,685
Thailand	149,791,512	172,632,658	176,504,186	187,033,867
Indonesia	161,493,397	226,286,956	164,996,682	183,879,764
Malaysia	164,229,531	179,727,863	163,801,007	133,769,646
France	144,505,897	212,059,182	136,013,450	128,536,582
United Kingdom	259,197,591	121,033,124	125,501,655	116,542,550
Italy	81,419,797	87,433,032	108,678,649	107,007,546
Czech Republic	14,618,993	12,783,932	25,910,543	65,120,455
Brazil	93,151,577	91,063,380	79,389,368	63,951,173
Chile	48,614,772	56,604,884	67,883,501	59,198,532
Austria	46,136,381	46,606,218	57,962,237	55,157,232
Sweden	45,093,362	40,726,646	54,504,581	52,087,041
Philippines	53,701,591	38,337,638	44,359,333	50,006,919
Spain	316,571,099	12,344,189	14,406,764	49,006,780
Switzerland	29,404,228	77,351,958	52,908,872	45,730,350
Norway	5,144,066	6,357,083	3,889,193	42,381,863
Kazakhstan	3,132	5,594,733	34,416,154	39,267,024
Costa Rica	11,030,365	20,250,407	32,281,976	38,249,657
Guatemala	3,217,775	25,488,017	33,027,284	33,416,790
New Zealand	28,397,644	31,617,903	35,839,466	31,738,318
Australia	41,115,125	79,811,593	48,779,416	29,302,334
Hong Kong	34,619,412	20,214,977	23,373,338	27,172,012
Sri Lanka	25,538,276	25,783,040	29,360,587	25,655,530
Trinidad and Tobago	15,673,002	8,489,336	7,500	23,787,126
Peru	27,051,515	22,980,466	14,042,432	22,434,309
Romania	2,601,294	10,245,294	13,799,853	21,354,212
Slovakia	7,513,359	8,899,381	16,475,173	21,265,863
Finland	43,179,656	17,865,868	27,271,976	19,388,902
Argentina	4,795,285	5,403,481	10,353,427	16,512,274
Belgium	20,589,008	19,857,441	17,102,352	15,292,639
Ireland	8,695,504	9,353,285	26,201,499	14,729,754
Ecuador	13,742,198	32,009,796	20,102,794	14,618,428
Bangladesh	5,444,041	12,017,295	11,157,991	13,144,427
Kuwait	19,900	2,192	2,049,688	12,727,301
South Africa	16,730,768	20,941,001	25,791,032	12,647,361
Denmark	411,052,649	12,574,763	47,399,764	11,547,035
Turkey	9,676,083	9,967,348	10,327,379	10,900,479
Portugal	5,182,847	21,154,991	6,186,201	10,742,827
Colombia	18,051,028	16,316,617	18,165,949	10,281,514
Pakistan	10,702,734	15,754,279	9,498,269	8,313,980
Poland	2,467,109	8,059,910	11,167,286	8,223,648
Cambodia	20,248,592	14,381,379	11,928,732	7,859,477
Saudi Arabia	3,581,380	9,786,765	51,450,035	7,420,462
Estonia	784,189	5,924,470	8,417,260	6,869,668
Bulgaria	2,561,513	4,014,636	4,815,609	5,986,182

Luxembourg	2,672,999	4,129,812	2,790,170	5,875,351
Oman	735,552	3,649,729	0	5,368,855
Slovenia	1,934,451	4,466,893	5,770,284	5,199,723
Venezuela	1,376,388	4,188,276	3,975,014	4,696,198
Nicaragua	5,367,649	7,129,800	3,637,914	4,603,401
Uruguay	1,612,072	2,114,464	3,733,893	4,398,549
Honduras	1,687,587	2,331,770	3,199,900	4,293,732
Egypt	2,912,483	5,975,974	3,826,890	4,126,893
Jordan	675,352	585,210	1,810,072	3,854,659
Namibia	17,142	215,136	1,933,105	2,983,880
El Salvador	1,751,860	3,156,804	4,073,355	2,541,586
Bolivia	1,974,407	3,750,147	3,648,751	2,393,799
United Arab Emirates	10,324,915	12,579,440	17,478,319	2,315,896
Guyana	158,292	824,109	2,183,967	2,033,893
Ukraine	681,866	1,441,106	5,604,018	1,891,158
Lao People's Democratic Republic	25,350	509,210	1,433,659	1,693,852
Côte d'Ivoire	1,676,080	1,115,354	942,414	1,595,976
Nepal	1,232,672	861,598	1,386,191	1,536,168
Lithuania	5,237,739	314,869	656,908	1,411,405
Congo	334,058	118,001	32,072	1,239,568
Greece	1,855,130	803,924	840,009	1,225,360
Paraguay	1,243,213	1,035,684	1,044,351	1,153,982
Kenya	242,292	970,091	976,142	1,125,201
Ethiopia	1,365,338	1,788,100	619,402	1,071,947
Albania	114,690	2,524,641	1,914,973	972,447
Tunisia	171,960	296,555	491,216	927,701
Macau, SAR of China	7,523,949	3,115,940	671,108	913,973
Marshall Islands	0	75,865	1,775,000	850,000
Morocco	183,218	515,750	764,511	788,323
Ghana	1,419,305	790,693	764,413	717,138
Zimbabwe	1,628,984	1,934,344	901,547	678,964
Croatia	169,883	413,631	393,058	509,219
Papua New Guinea	420,154	206,231	177,390	424,475
Mauritius	151,974	548,267	1,295,592	422,895
Nigeria	359,239	389,829	404,172	388,248
Serbia	145,655	544,535	214,252	370,353
Dominican Republic	330,303	653,390	348,643	332,018
Uganda	85,503	73,400	827,967	330,744
Latvia	1,242,322	132,891	106,223	279,878
Tanzania, United Republic of	254,815	67,790	258,192	266,679
Anguilla	0	0	184,090	256,673
Rwanda	0	142,329	108,430	251,782
Cameroon	468,286	88,839	335,082	231,071
Gabon	160,018	254,547	31,788	208,184
Jamaica	25,470	13,390	20,229	205,882
Panama	282,454	1,600,495	104,169	190,976
Bahrain	1,168,754	73,762	69,224	182,942
Senegal	0	334,872	92,000	168,045
Cyprus	0	35,000	0	166,198
Uzbekistan	67,406	100,608	93,346	151,733
Madagascar	262,921	115,626	111,905	150,992
Suriname	9,552	40,812	52,833	142,585
Fiji	477,570	489,515	95,190	129,201
Lebanon	87,636	125,469	110,233	111,035
Macedonia	8,808	26,988	22,346	106,631
Belize	0	0	0	98,637
Liechtenstein	6,564	15,108	54,576	91,941
Democratic Republic of Congo	20,000	32,008	10,375	73,698
Malta	20,510	12,520	72,082	64,311
Afghanistan	845,226	4,965,189	1,078,139	62,662
Bermuda	3,074	5,000	5,135	61,106
Belarus	4,149,919	98,063	119,383	55,306
Azerbaijan	0	0	401	45,264

Haiti	18,722	5,342	21,650	39,036
Togo	0	0	3,500	37,734
Bosnia and Herzegovina	55,176	91,577	38,640	36,681
Qatar	117,872	20,788	25,004	34,621
Burkina Faso	146,279	2,536	577	34,518
Georgia	42,000	18,502	2,902	31,275
Moldova, Republic of	6,103	53,363	60,626	20,104
Iceland	125,755	48,893	14,138	19,354
British Virgin Islands	0	0	198,244	15,000
Monaco	12,486	3,816	8,174	14,829
Vanuatu	0	9,464	2,188	13,983
Cocos (Keeling) Islands	0	0	1,992	13,146
French Polynesia	12,674	52,449	22,673	11,008
Mali	10,124	3,119	8,102	9,609
Guinea	0	41,518	0	9,580
Aruba	0	0	0	8,948
Saint Kitts and Nevis	10,000	18,475	25,412	8,882
Malawi	10,345	12,771	4,033	8,070
Bahamas	0	0	2,200	7,690
Sierra Leone	12,334	37,705	29,847	5,125
Cape Verde	0	0	0	5,022
Curacao	0	0	0	3,150
Christmas Island	0	0	0	3,006
New Caledonia	360	0	0	2,864
Benin	0	0	0	2,461
Niger	441	2,825	0	1,290
Cayman Islands	0	0	0	1,052
Cook Islands	0	0	48,039	596
Mongolia	30,896	0	4,583	260
Zambia	0	0	0	0
Yemen	0	0	0	0
Tokelau Islands	0	7,024	28,595	0
Syrian Arab Republic	389,903	33,255	0	0
Swaziland	0	0	3,640	0
Svalbard and Jan Mayen Island	0	0	0	0
San Marino	0	26,639	37,059	0
Samoa	95,537	4,052	163,320	0
Saint Lucia	0	1,386	0	0
Saint Helena	0	0	0	0
Pitcairn Islands	0	0	0	0
Netherlands Antilles	0	3,375	18,000	0
Mozambique	63,833	39,856	731,024	0
Montserrat	0	0	10,719	0
Montenegro	0	0	0	0
Liberia	0	5,625	0	0
Lesotho	0	0	502,707	0
Kyrgyzstan	1,223	0	15,420	0
Iraq	30,422	0	517,944	0
Iran	250,091	202,271	0	0
Guadeloupe	0	0	0	0
Grenada	0	0	0	0
Greenland	16,597	0	0	0
Gibraltar	0	0	2,494	0
Equatorial Guinea	0	56,956	5,391	0
Djibouti	3,988	965,037	0	0
Central African Republic	0	0	23,665	0
Brunei	0	0	2,714	0
Botswana	0	2,553	0	0
Barbados	0	19,500	0	0
Antigua and Barbuda	0	0	0	0

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