No. 13-214

In The
Supreme Court of the United States

NOVO NORDISK A/S,

Petitioner,

v.

SUZANNE LUKAS-WERNER
and SCOTT WERNER,

Respondents.

On Petition For A Writ Of Certiorari To The Supreme Court Of Oregon

RESPONDENTS' BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Does this Court have jurisdiction to review either the state trial court's denial of Petitioner's motion to dismiss for lack of personal jurisdiction, or the subsequent denial of Petitioner's petition for writ of mandamus to the Oregon Supreme Court when that court declined to exercise its discretionary mandamus jurisdiction without a decision on the merits of Petitioner's claim and thus is not a "final judgment" under 28 U.S.C. § 1257(a)?

2. Notwithstanding the jurisdictional flaw, should the Court grant the petition to consider the fact-specific decision of the trial court that it has personal jurisdiction over Petitioner, a foreign drug manufacturer who, through its wholly owned U.S. subsidiary and the subsidiary's Oregon-based sales representatives, sold more than 1,000 prescriptions of the drug in Oregon, for injuries the drug caused in Oregon?

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INTRODUCTION

This is a product liability action in Oregon arising from the use of Activella, a drug prescribed for the treatment of menopause symptoms. Petitioner, the Danish manufacturer of the drug, moved to dismiss claims against it for lack of specific personal jurisdiction. Applying the Oregon Supreme Court's recent decision in *Willemsen v. Invacare Corp.,* 282 P.3d 867, *cert. den.,* 133 S. Ct. 984 (2013), the state trial court denied Petitioner's motion, and Petitioner filed a petition for writ of mandamus to the Oregon Supreme Court. That court declined to exercise its discretionary mandamus jurisdiction and denied Petitioner's petition without an opinion. Because this case is still pending in the Oregon trial court, and because the Oregon appellate courts have not yet considered – but may later consider – Petitioner's argument on specific personal jurisdiction, this Court lacks jurisdiction under 28 U.S.C. § 1257(a) to review the case. The petition for writ of certiorari should be denied.

Even if the Court had jurisdiction, this case would not merit review. The trial court's fact-specific decision does not warrant reconsideration of existing jurisdictional guideposts on personal jurisdiction. Moreover, the trial court's decision is correct. For both of these reasons, as well as the jurisdictional defect, the petition for writ of certiorari should be denied.

STATEMENT OF THE CASE

A. Factual Background

Oregon resident Suzanne Lukas-Werner suffered from symptoms of menopause. Her physician prescribed the hormone replacement therapy drug Activella to treat the symptoms, from 2004 to 2009. Lukas-Werner was diagnosed with hormone-dependent breast cancer in July 2009. Second Am. Complt. 2. Several epidemiological studies revealed that the hormones in Activella pose a significantly higher risk of breast cancer than other types of hormone therapy drugs. *Id.* at 3-6.

Petitioner Novo Nordisk NN A/S (hereafter NNAS) is a Danish company and a global manufacturer of prescription drugs. Pet. App. 75. NNAS developed, manufactured, packaged and labeled Activella in Europe under the name Kliogest. Pet. App. 77-78. In the 1990s, NNAS directed its wholly owned U.S. subsidiary, Novo Nordisk, Inc. (hereafter NNI) to apply to the Food and Drug Administration (hereafter FDA) for approval of Activella. Pet. App. 84-85. In 1998, the FDA approved Activella for marketing in the United States. Pet. App. 78-79.

NNI's sole business purpose is to market and sell drugs designed and manufactured by NNAS. NNAS used NNI as its exclusive distributor to promote, or "detail," Activella to physicians throughout the country. The U.S. market was a significant source of Activella sales. Pet. App. 78. After NNAS authorized the expansion of NNI's sales force for Activella, NNI hired an Oregon-based Activella sales force. Pet. App.

83, 87-88. NNI signed a consulting agreement with Suzanne Lukas-Werner's prescribing doctor – an Oregon physician – to assist with messaging and educational programs. Pet. App. 87. In 2007 alone, NNAS sold roughly 1,000 Activella prescriptions (tens of thousands of tablets) in Oregon. Pet. App. 88. NNAS developed and oversaw NNI's Activella marketing and sales training strategies. Pet. App. 86. NNAS helped develop messages for NNI to use in responding to concerns about the risk of breast cancer from Activella. Pet. App. 81-82.

B. Proceedings Below

Respondents Suzanne Lukas-Werner and her husband, Scott Werner, filed suit in Multnomah County, Oregon on September 9, 2010, naming NNI, NNAS, and Dr. Kristina Harp, the prescribing physician, as defendants.[1] On March 30, 2011, NNAS filed a motion to dismiss for lack of specific personal jurisdiction. At a hearing on the motion, the trial court granted Petitioner's motion on June 1, 2012, holding that Respondents failed to prove that NNAS directly targeted Oregon physicians. The court believed that such evidence was required for the exercise of personal jurisdiction under *J. McIntyre Machinery, Ltd. v. Nicastro,* 131 S. Ct. 2780 (2011). Pet. App. 5-6.

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[1] Suzanne Lukas-Werner's physician prescribed her a generic version of Activella for a year. Respondents initially named Breckendridge, the generic manufacturer, as a defendant, but that defendant was later dismissed.

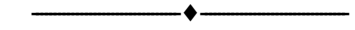
Before the trial court signed the order, the Oregon Supreme Court decided *Willemsen v. Invacare Corp.,* 282 P.3d 867 (2012). *Willemsen* was a product liability action involving a defective battery charger manufactured by CTE, a Taiwanese company, and incorporated into motorized wheelchairs made in the United States.

The issue on appeal in *Willemsen* was whether an Oregon court could properly exercise personal jurisdiction over a foreign manufacturer who sold more than 1,000 battery chargers in Oregon and who signed an indemnity agreement with the U.S. manufacturer obligating it to comply with all applicable U.S. federal, state and local regulations. After this Court decided *Nicastro,* it granted the petition, vacated the lower court's order and remanded the case to the Oregon Supreme Court to reconsider *Willemsen* in light of *Nicastro. China Terminal & Elec. Corp. v. Willemsen,* 132 S. Ct. 75 (2011). The Oregon Supreme Court in *Willemsen* applied Justice Breyer's concurring analysis in *Nicastro* to the facts of the case and held the exercise of personal jurisdiction was proper. The foreign manufacturer again petitioned for writ of certiorari, and this Court denied it.

After the *Willemsen* decision issued, the trial court below reconsidered its ruling and directed the parties to submit supplemental briefs. Pet. App. 7. Applying *Willemsen* to the facts of this case, the court denied Petitioner's motion to dismiss. Pet. App. 8-11. The trial court found there was a significant volume of sales in Oregon of NNAS's Activella pills, and that

the sales of Activella in Oregon were not fortuitous. *Id.* at 8-9. The court also held that the sales of Activella were not "attenuated" because the distributor of Activella in Oregon and the U.S. was a wholly owned subsidiary of NNAS, not a completely independent distributor. *Id.* at 9. The trial court further concluded that the exercise of personal jurisdiction did not violate due process because the evidence showed that NNAS is a large global company and anticipated the need to defend itself against this very sort of claim. *Id.* at 9-10.

On February 14, 2013, NNAS filed a petition for alternative writ of mandamus to the Oregon Supreme Court. On May 16, 2013, the Oregon Supreme Court denied the petition without opinion. *Id.* at 18.



REASONS FOR DENYING THE WRIT

I. The Court Lacks Jurisdiction Because the Judgment Below Is Not Final.

Petitioner asks this Court to review directly the state trial court's denying NNAS's motion to dismiss for lack of specific personal jurisdiction. In the alternative, Petitioner seeks review of what it calls a "judgment" by the Oregon Supreme Court in denying Petitioner's application for a writ of mandamus. The Court, however, lacks jurisdiction to review either order.

A. Denial of a Petition for Writ of Mandamus Is Not a Decision on the Merits.

Mandamus in Oregon "is an extraordinary remedial process which is awarded not as a matter of right," but on equitable principles and in the exercise of judicial discretion. *State ex rel. Fidanque v. Paulus,* 688 P.2d 1303, 1307 (Or. 1984) (quoting *Buell v. Jefferson County Court,* 152 P.2d 578, 581), *reh'g den.,* 154 P.2d 188 (Or. 1944). The denial of a petition for an alternative writ of mandamus is therefore an exercise of discretion not to accept jurisdiction. The Oregon Supreme Court may find, for example, that mandamus is not an appropriate vehicle to review an issue that would otherwise warrant it, based on the procedural history of the specific case. *See State ex rel. Carlile v. Frost,* 956 P.2d 202, 209 (Or. 1998).

Therefore, a denial of a petition for an alternative writ of mandamus is not a final judgment and does not foreclose later review on appeal to the state appellate courts. In *North Pacific Steamship Co. v. Guarisco,* 647 P.2d 920 (Or. 1982), the defendants, like NNAS in this case, petitioned for and were denied review by mandamus of the trial court's jurisdictional ruling that it had personal jurisdiction over the defendants. After the trial court issued its decree, defendants sought review of that same ruling on appeal. The Oregon Supreme Court rejected the plaintiff's assertion that defendants' challenge to jurisdiction

had been determined by the court's refusal to grant a petition for writ of mandamus:

> Where a trial court holds that it has personal jurisdiction over a defendant, we have permitted the defendant to challenge such a ruling either through petition for mandamus or through appeal. Mandamus, an extraordinary remedy, is a discretionary writ and not a writ of right. It follows that when this court denies a petition for mandamus without ruling on the merits of the petitioner's claim, such a denial does not necessarily preclude consideration of the issue upon appeal.

Id. at 924 n. 3. *See also State ex rel. Ware v. Hieber,* 515 P.2d 721, 723 (1973) (in cases where the trial court has held it has personal jurisdiction, Oregon has permitted mandamus to be used to test such a ruling, noting that "[t]he ruling could also be tested by appeal.").

The Oregon Supreme Court has also made clear that an order denying a petition for discretionary review does not indicate approval of the lower court's ruling. "[A] denial of review carries no implication that the decision or the opinion of the Court of Appeals was correct." *1000 Friends of Oregon v. Board of County Commissioners,* 584 P.2d 1371, 1372 (Or. 1978).

Contrary to NNAS's argument, the Oregon Supreme Court's denial of NNAS's petition for writ of mandamus was not a final judgment on the issue of personal jurisdiction. Nor is the trial court's order a

final judgment. NNAS can seek relief of that order by appeal at the appropriate time, just as the defendants did in *North Pacific Steamship*.

This case is not, as NNAS contends, on the same postural footing as other cases in which the Court granted certiorari from mandamus proceedings in state court. In *Burnham v. Superior Court of California,* 495 U.S. 604 (1990), the California Court of Appeal issued an opinion on the merits, holding that there was a "valid jurisdictional predicate for *in personam* jurisdiction" and that the defendant was "present in the forum state." *Id.* at 608. In *Nicastro,* the New Jersey Supreme Court affirmed the Superior Court Appellate Division's denial of mandamus and "issued an extensive opinion with careful attention to this Court's cases and to its own precedent" in affirming the lower court's mandamus denial. *Nicastro,* 131 S. Ct. at 2785. Likewise, *Goodyear Dunlop Tires Operations, S.A. v. Brown,* 131 S. Ct. 2846, 2852-53. (2011) came to this Court from a detailed written opinion on the merits by the North Carolina Court of Appeals. And in *Calder v. Jones,* 465 U.S. 783, 787 (1984), the state court of appeal issued a detailed opinion reversing the trial court's order, after which the California Supreme Court denied review.

Here, the Oregon Supreme Court issued no opinion on the merits. In the exercise of its discretion, it simply denied NNAS's petition for mandamus without comment. It took no position on whether the trial court's order was correct. The issue may still be appealed after final judgment in the trial court.

Section 1257(a) grants this Court jurisdiction to review only "[f]inal judgments or decrees" of state courts. As this Court has explained, this limitation on its certiorari jurisdiction is no mere formality:

> This provision establishes a firm final judgment rule. To be reviewable by this Court, a state court judgment must be final "in two senses: it must be subject to no further review or correction in any other state tribunal; it must also be final as an effective determination of the litigation and not of merely interlocutory or intermediate steps therein. It must be the final word of a final court." *Market Street R. Co. v. Railroad Comm'n of Cal.,* 324 U.S. 548, 551 (1945). As we have recognized, the finality rule "is not one of those technicalities to be easily scorned. It is an important factor in the smooth working of our federal system." *Radio Station WOW, Inc. v. Johnson,* 326 U.S. 120, 124 (1945).

Jefferson v. City of Tarrant, 522 U.S. 75, 81 (1997).

The decisions below are not final in either of the two relevant senses. There was no final judgment on the merits of NNAS's personal jurisdiction argument by Oregon's highest court, and the litigation has not been terminated. Nor is the trial court's order one that is "subject to no further review or correction in any state tribunal." *Id.* NNAS can seek review of the order by route of appeal to the Oregon Court of Appeals and the Oregon Supreme Court. The trial court's order, and the Oregon Supreme Court's denial

of the petition for mandamus seeking interlocutory review, do not constitute the "final word of a final court." *Market St.,* 324 U.S. at 551. For this reason, the Court lacks jurisdiction under 28 U.S.C. § 1257(a), and the petition for writ of certiorari should be denied.

B. None of the *Cox* Exceptions to the Jurisdictional Requirement of Finality Apply.

This Court has identified four narrow categories of cases in which it has treated a state-court decision as a final judgment on the federal issue even though additional state-court proceedings were yet to come. *See Cox Broadcasting Corp. v. Cohn,* 420 U.S. 469 (1975). This case does not fit within any of those categories.

The first two categories pertain to cases in which (1) "the federal issue is conclusive or the outcome of further proceedings preordained," or (2) the federal issue "will survive and require decision regardless of the outcome of future state-court proceedings." *Id.* at 479-80. These categories do not apply here because the outcome of this case is not preordained. Either party may prevail; if NNAS prevails at trial, the question presented will be mooted and will no longer require decision. *Jefferson City,* 522 U.S. at 77. The third category, which covers cases in which "later review of the federal issue cannot be had, whatever the ultimate outcome of the case," likewise does not apply. As *Cox* explained, this category is limited to

cases in which the state's law offers *no* subsequent opportunity to obtain a court judgment over which this Court could exercise jurisdiction. *See id.* at 481-82. Here, NNAS does not face such a situation. As explained above, it can appeal the decision if it does not prevail before the trial court.

NNAS argues that the fourth category identified in *Cox* applies here. That category "covers those cases in which 'the federal issue has been finally decided in the state courts with further proceedings pending in which the party seeking review' might prevail on nonfederal grounds, 'reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action,' and 'refusal immediately to review the state-court decision might seriously erode policy.'" *Nike, Inc. v. Kasky,* 539 U.S. 654, 658-59 (2003) (opinion concurring in dismissal of writ) (quoting *Cox,* 420 U.S. at 482-83).

The fourth *Cox* exception does not apply to this case because the personal jurisdiction issue has not been "finally decided in the state courts." Denial of mandamus is not a final decision on the federal issue, and NNAS may raise the issue later in an appeal after judgment.

Furthermore, denial of immediate review would not "seriously erode federal policy." As this Court has acknowledged, the question of state-court jurisdiction over a foreign defendant "arises with great frequency in the routine course of litigation." *Nicastro,* 131 S. Ct. at 2785 (plurality opinion). If NNAS were

correct that the fourth *Cox* category applies in this instance, then the Court would automatically review *every* case in which a state court finds personal jurisdiction over a foreign defendant. The resulting burden to the Court's docket would seriously erode the purpose and underlying policies of 28 U.S.C. § 1257(a). *See North Dakota State Bd. of Pharmacy v. Snyder's Drug Stores, Inc.,* 414 U.S. 156, 159 (1973). This Court has cautioned that exceptions to the requirement should apply "[o]nly in very few situations, where intermediate rulings may carry serious public consequences." *Id.* This is not such a case. The Court could not have intended for the fourth exception in *Cox* to be read so broadly that it swallowed the finality rule.

Because the court lacks jurisdiction under § 1257(a), the petition must be denied.

II. The Decision Below Does Not Merit Review.

This case does not raise any unusual issues, such as "recent changes in commerce and communications, many of which are not anticipated by our precedents." *Nicastro,* 131 S. Ct. at 2791 (Breyer, J., concurring). Nor does it implicate modern or novel concerns. The fact-specific ruling here does not warrant revisiting basic jurisdictional rules, given that the Court considered similar issues only two years ago in *Nicastro.*

In *Nicastro,* this Court recognized that the question of personal jurisdiction must be analyzed on the

particular facts of the case. *Nicastro,* 131 S. Ct. at 2789 (plurality opinion). "The defendant's conduct and the economic realities of the market the defendant seeks to serve will differ across cases, and judicial exposition will, in common-law fashion, clarify the contours of that principle." *Id.* at 2790.

NNAS exaggerates the status of post-*Nicastro* decisions, claiming they are awash in confusion and conflict with one another. To the contrary, courts have applied *Nicastro* to the specific facts before them. Different outcomes result not from different interpretations of *Nicastro*, but from different facts and the relationships of the specific defendant to the particular forum.

One example cited by NNAS is *Dow Chemical Canada ULC v. Fandino,* 134 Cal. Rptr. 3d 597 (2012). On remand from this Court in the wake of *Nicastro*, the California Court of Appeal held that California lacked personal jurisdiction over the foreign defendant. NNAS maintains that *Dow*'s fact pattern is analogous to the facts at issue in the Oregon Supreme Court's decision in *Willemsen.* But the Canadian defendant in *Dow* manufactured and sold its fuel tanks to an unrelated Canadian airplane manufacturer, exclusively in Canada, pursuant to purchase order agreements entered into in Canada. *Id.* at 599. In contrast, the Taiwanese defendant in *Willemsen* sold its battery chargers to a U.S. wheelchair manufacturer, pursuant to an agreement entered into in the U.S., which obligated the manufacturer to obtain product liability insurance to cover any injuries its

batteries may cause to purchasers. Facts matter. Under *Nicastro,* jurisdiction over the defendant existed in *Willemsen* but not in *Dow*.

Furthermore, the facts supporting personal jurisdiction in this case are stronger than those in *Dow* and other cases where the foreign manufacturer sold its products through an unrelated company that had complete control over the channel of distribution. NNAS distributed its product through NNI, its wholly owned U.S. subsidiary, and had a direct hand in NNI's Activella sales and marketing strategy. Through NNI's Oregon-based sales force, NNAS sold a steady and substantial volume of Activella tablets in Oregon.

The trial court reasonably found that the flow of Activella sales in Oregon satisfied both the plurality opinion and Justice Breyer's concurring analysis in *Nicastro.* Pet. App. 8-9. The court also concluded that NNAS's contacts were not fortuitous or attenuated and thus met the standard for purposeful availment. "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." *Id.* at 9. *See Nicastro,* 131 S. Ct. at 2788 (plurality opinion) (noting that "a defendant may in an appropriate case be subject to jurisdiction without entering the forum . . . as where manufacturers or distributors 'seek to serve' a given State's market"); *see also Asahi Metal Industry Co., Ltd. v. Superior Court of California,*

Solano County, 480 U.S. 102, 112 (1987) (O'Connor, J.) (additional conduct of the defendant indicating purposeful availment may include "marketing the product through a distributor who has agreed to serve as the sales agent in the forum State").

Furthermore, as the trial court found, evidence in the record shows that NNAS anticipated the need to defend itself against this very sort of claim. Pet. App. 10. The court also found that NNAS "is clearly a very large, global company." *Id.* Therefore, the fairness concerns raised by Justice Breyer in *Nicastro* are not present here. *See Nicastro,* 131 S. Ct. at 2794-95. The court did not err in holding that Oregon has specific personal jurisdiction over NNAS. The facts here meet the requirements for personal jurisdiction under both the plurality and concurring opinions in *Nicastro.*

Finally, although NNAS did not make the argument below, it contends here that this Court should announce a new, higher standard for deciding whether personal jurisdiction exists in product liability cases when the foreign defendant is a global pharmaceutical company that obtained FDA approval for their drugs through a U.S. subsidiary. NNAS asks the Court to find, as a matter of law, that the Due Process Clause forbids states from exercising jurisdiction over all such foreign drug manufacturers. This argument is incorrect on the merits. But more important, because NNAS did not raise the argument below, the Court should not consider it. *See Air Courier Conference of America v. American Postal Workers Union*

AFL-CIO, 498 U.S. 517, 522-23 (1991); *Taylor v. Freeland & Kronz,* 503 U.S. 638, 645-46 (1992).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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