No. 21-2001

IN THE

Supreme Court of the United States

CHARLES ARTISS,

Petitioner,

v.

WESTLAKE PHARMACEUTICALS, INC.

Respondent.

On Writ of Certiorari to the
Supreme Court of the State of Ames

JOINT APPENDIX

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SUPREME COURT OF THE UNITED STATES

ORDER LIST

Certiorari Granted

September 17, 2021

21-2001

The petition for a writ of certiorari is granted on the following two questions:

1. Whether a court may exercise specific personal jurisdiction over a brand-name pharmaceutical manufacturer that promotes and sells a drug in the forum State when the plaintiff was injured by a generic version of the same drug--which was required by law to copy the branded drug's key features.

2. Whether Ames Stat. § 5101 comports with due process to the extent it conditions registration to do business in the State on consent to general personal jurisdiction in the State's courts.

SUPREME COURT OF AMES

Charles Artiss, *Appellant*, v. Westlake Pharmaceuticals, Inc., *Appellee.*	Docket No. 20-53

BOND, J., for a unanimous Court:

Charles Artiss alleges that he suffered debilitating side effects from taking denzoampheredrine (DZ), a medication used to treat anxiety. Artiss further alleges that the label for the drug failed to disclose material risks. Defendant Westlake Pharmaceuticals markets DZ under the brand name Luxin. The DZ Artiss took is a generic copy of Luxin manufactured by a third party. Under a theory of "design liability," sometimes described as "innovator liability," Artiss has sued Westlake, alleging that as the holder of the New Drug Application for DZ, Westlake had the power and the duty to change the label for the drug (and the generic manufacturer did not). The superior court dismissed Artiss's claim for lack of personal jurisdiction, and Artiss appeals.

On appeal, we address two questions. The first is whether Artiss may assert specific jurisdiction on the theory that his claims arise out of or relate to

Westlake's conduct—even though Artiss was not injured by Westlake's product, but instead by a competitor's.

The second question is whether, if specific jurisdiction is lacking, Artiss may assert consent jurisdiction under the State of Ames's consent-to-jurisdiction statute, Ames Stat. § 5101(a), which provides that every foreign business that registers to do business in Ames must consent to jurisdiction in the courts of Ames. Specifically, the question is whether this statute is consistent with the due process requirements of the federal Constitution.

For the reasons set forth below, we rule for Westlake on both questions, and affirm the dismissal of this case.

BACKGROUND

I. Legal Background

Understanding the genesis of this claim requires understanding a little bit about the process by which drugs are approved. In general, when a manufacturer wants to bring a new drug to market, it must submit to the Food and Drug Administration a New Drug Application (NDA) for agency approval. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013). The NDA process is cumbersome and expensive, involving clinical trials and an extended back and forth with the FDA. *See ibid.* During the process, the FDA determines whether the drug is safe and effective for its intended use, and also determines, in collaboration with the

manufacturer, the content of the label, which contains warnings of potential risks of using the drug. At the culmination of a successful NDA process, the manufacturer receives the right to market the drug, consistent with the terms of the NDA. These drugs are usually marketed under brand names, like Luxin, which is Westlake's version of DZ.

Later (typically after the patents protecting a drug expire or are deemed invalid), generic manufacturers can enter the market for the drug. Society likes generic drugs because they are much cheaper than their name-brand counterparts. That is due, in part, to the fact that generic manufacturers do not have to go through the entire drug development or NDA process. Instead, the FDA has a fast-track procedure called the Abbreviated New Drug Application (ANDA) process. To obtain an ANDA, the generic manufacturer does not have to show that the drug it intends to market is safe and effective. Instead, it just has to show that the drug it is going to produce and market is exactly the same as a drug that already has an NDA. If the generic manufacturer does so, the FDA does not force it to duplicate the effort of the brand manufacturer. But, importantly, the generic manufacturer cannot change anything—including the drug label—on its own. *See Mut. Pharm. Co.*, 570 U.S. at 477.

As explained in the introduction, this case arises under the theory of "design liability," sometimes called "innovator liability," which largely emerged after the

Supreme Court's decisions in *Wyeth v. Levine*, 555 U.S. 555 (2009), and *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). In that duo of cases, the Supreme Court held that federal law did not preempt state-law claims against brand-name pharmaceutical manufacturers alleging defects in the warning labels on their drugs—but it does preempt indistinguishable claims against generic manufacturers.

The disparate results in *Wyeth* and *PLIVA* come down to the Supreme Court's application of the doctrine of impossibility preemption, which holds that when it is impossible for a defendant to comply with both federal and state law, the state law must yield to the laws of the superior sovereign. In *Wyeth*, federal law did not prohibit the brand manufacturer from altering its label to conform to state law requirements. That is because brand manufacturers have a degree of control over the content of their labels: they can apply directly to the FDA to make changes to the label; and they can implement certain changes to the label (including adding warnings) while that application is pending. *See Wyeth*, 555 U.S. at 573.

Generic manufacturers, on the other hand, have no similar ability. Instead, federal law always requires the generic manufacturer's drug (and label) to be identical to the name-brand counterpart. *See PLIVA*, 564 U.S. at 613. The only way a generic manufacturer could change its label would be to ask the brand manufacturer holding the NDA to lobby the FDA for a label change, and hope the process works out. *See id*. at 619. The Supreme Court described this as a "Mouse

Trap game," and noted that it is not generally even attempted. *Ibid*. The Court held that because the generic manufacturer effectively had no power to change its label, it was impossible for the manufacturer to comply with both federal law (which required the label to stay the same) and state law (which required the label to change), and so the claim was preempted. *See id.* at 620-21.

As the Court acknowledged in *PLIVA*, its decision left people injured by generic drugs (*i.e.*, the majority of consumers) without any remedy at law. *See* 564 U.S. at 625. In response, some States, including this one, recognized a new theory of liability against brand manufacturers, which holds that when brand manufacturers make design decisions that injure people, the manufacturer is liable—even if it did not manufacture the product that injured the plaintiff. Thus, a brand manufacturer can be held liable for the defective design of a generic drug, provided the generic, in fact, embodies the brand manufacturer's design in the relevant respect. This theory has been described as "design liability" or as "innovator liability" in the literature. While it is somewhat controversial, this State has embraced it, and that rule is not at issue today.

This case concerns the State's response to a different line of Supreme Court precedents, dealing with personal jurisdiction. In *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011), and *Daimler AG v. Bauman*, 571 U.S. 117, 136-37 (2014), the Court held that a corporation is only "at home,"

and therefore subject to general personal jurisdiction, in its principal place of business or state of incorporation. This rule sharply limited the availability of general jurisdiction, which some courts (including courts in this State) previously held applied whenever a corporation had continuous and systematic contacts with a forum State. *See Daimler*, 571 U.S. at 137.

Some States, including this one, reacted to *Daimler* by enacting statutes that require a corporation to consent to jurisdiction in the State as a condition of registering to do business there. In Ames Session Law 2015-05, the legislature recognized that the Supreme Court had limited the scope of general jurisdiction, and sought to restore the status quo *ante* through the vehicle of consent, which it read to be outside the Supreme Court's reasoning. The legislature added a new provision to the Ames Statutes providing, in relevant part, that "[i]ncorporation, registration, or carrying on continuous business within this State is hereby conditioned upon consent to jurisdiction by the State's courts." Ames Stat. § 5101(a). The statute thus provides that any corporation that registers to do business in the State is subject to general jurisdiction here. *Ibid*.

II. Factual Background

This case is at the pleading stage, and so these facts are taken from Artiss's complaint. Artiss alleges that in 2017, after a car accident brought on substantial anxiety, his physician prescribed DZ, and his pharmacy dispensed generic DZ

manufactured by Santos Laboratories, a generic competitor to Westlake's Luxin. The drug is designed to treat anxiety, and there are documented cases of blood clots as a side effect. Artiss, who was predisposed to clotting as a result of his accident, suffered from clotting and experienced a severe stroke, which rendered him permanently and seriously disabled. He alleges that the warning label on the DZ he took did not disclose the risk of blood clots, and that Westlake had previously downplayed the risk—but after Artiss was injured, Westlake changed the label to add a warning. Artiss took DZ and suffered his injury in the State of Ames.

Westlake is incorporated in Delaware and has its principal place of business in Trenton, New Jersey, but it does business nationwide, including in Ames. Thus, Westlake registered to do business in Ames in 2005, and it has renewed its registration every two years, including after the jurisdictional statute was updated to add its consent provision. Registration requires Westlake to file paperwork with the State. Doing business here without registering may result in a $500 fine, and would also prevent Westlake from taking care of other corporate formalities (*e.g.*, obtaining a state tax ID number, obtaining a certificate of occupancy for an office it owns or leases, etc.), which could carry additional consequences. In effect, registration is a necessary prerequisite to lawfully doing substantial business in Ames.

Westlake also maintains an office in Ames. That office is principally a marketing office. The employees there include representatives who visit physicians in the State to give them information about Westlake's products, as well as others who field inquiries about Westlake's drugs over the phone. Westlake also markets its drugs on television, in print, and on the Internet, in ways that reach the Ames market.

Westlake also sells drugs to Ames Distro, Inc., a drug distributor in Ames that delivers Westlake's medicines to pharmacies and physicians' offices throughout the State. Artiss alleges that Westlake has sold Luxin to patients throughout the State of Ames.

After his stroke, Artiss brought a separate action against Santos, which was dismissed on impossibility preemption grounds under *PLIVA*. He also brought this action against Westlake, alleging that Westlake had control over the contents of the drug label, and had a duty to disclose the risk of clotting so that its generic counterparts would also be required to disclose that risk. Artiss alleges that Westlake's conduct factually and proximately caused his injuries because if Westlake had used a different label, Santos would have followed suit, and the marketing materials relating to Luxin (and therefore DZ in general) would have disclosed the risk of clotting to Artiss and his physician.

The Superior Court granted Westlake's motion to dismiss the action for lack of personal jurisdiction. Artiss timely appealed.

ANALYSIS

On appeal of a decision dismissing an action for lack of jurisdiction, our review is *de novo* and we construe all facts in favor of the nonmoving party. We consider first whether Artiss can assert specific personal jurisdiction on the ground that his injuries "arise out of or relate to" Westlake's contacts with Ames. Second, we ask whether the Ames jurisdictional statute's consent provision comports with due process as applied. We conclude that the answer to both questions is "no."

I. Specific Jurisdiction

Ames's jurisdictional statute allows courts of the State to exercise specific personal jurisdiction to the extent permitted by the federal Constitution. Specific personal jurisdiction exists when the defendant has at least minimum contacts with the forum State, and the plaintiff's injury arises out of or relates to those contacts. Here, Artiss alleges that Westlake has robust contacts with Ames, including registration, an office here, marketing, and drug sales, including of Luxin.

It is less clear, however, that Artiss's claims arise out of or relate to any of those contacts. At its core, the theory of liability Artiss presents is that Westlake was negligent or reckless with respect to the drug's label. He does not allege, however, that the label was formulated in Ames.

It is also important that Artiss did not take Westlake's drug, but instead took the product manufactured by a generic competitor. Had Artiss taken Luxin, there is no doubt that he would be able to sue here, even though the label was not formulated here. But that is because Westlake itself would have sent the defective label into the State on its own products. Here, however, Westlake's role in the creation of Santos's generic label was more attenuated, and in any event did not occur here.

Artiss responds that under the Supreme Court's recent decision in *Ford Motor Co. v. Montana Eighth Judicial District Court*, 141 S. Ct. 1017 (2021), he has enough to get across the line. In *Ford*, the Supreme Court held that courts in Montana and Minnesota could adjudicate product defect claims against Ford based on automobile crashes that occurred in those States, which injured residents of those States, even though the subject vehicles were not purchased, designed, or manufactured in the States. *See id.* at 1022. The Court explained that *Ford* had purposefully availed itself of doing business in the States, including by promoting, selling, and servicing the same model vehicle in those States, and that even though there was no causal relationship between those contacts and the plaintiffs' claims, the claims still "related to" the contacts for purposes of personal jurisdiction. *See id*. at 1026-29. Artiss argues that under *Ford*, Westlake is subject to specific personal jurisdiction because it purposefully availed itself of doing business in

Ames, its conduct was a but-for cause of his injury, and the generic product is sufficiently closely related to Luxin that Westlake is subject to jurisdiction.

We are not persuaded. Of course, there is a sense in which the events that injured Artiss could be said to relate to Westlake's conduct in Ames: He was injured by a product that is chemically indistinguishable from the one Westlake sells in Ames, which would not be prescribed and sold to the same degree without Westlake's marketing efforts, and which was rendered less safe by Westlake's labeling decisions, which were made elsewhere but manifested in Ames. And Artiss has a point that Westlake has done substantial business in Ames, including vis-à-vis DZ. Indeed, it seems entirely a matter of luck that his pharmacist dispensed generic DZ instead of Luxin—and crediting his allegation that generic DZ is chemically indistinct from Luxin, he would have suffered the same injury either way. In that sense, a decision letting Westlake off the hook may seem arbitrary.

The bottom line, however, is that Artiss did not take Luxin, and he does not allege that any of the work done to determine Luxin's label happened in Ames. The key difference between this case and *Ford*, in our view, is that the Ford Motor Company was being held liable for defects in Ford automobiles. Here, Artiss seeks to hold Westlake liable for its competitors' products—products from which Westlake will make no money. While we accept that principles of foreseeability

and causation might allow a court to hold Westlake liable for defects in Santos's label, we do not believe that such claims arise out of or relate to Westlake's contacts with the State of Ames. *See In re: Zantac (Ranitidine) Prod. Liab. Litig.*, 2021 WL 2682602, at *13-14 (S.D. Fla. June 30, 2021) (finding no personal jurisdiction in innovator liability case); *Henry v. Angelini Pharma, Inc.*, 2020 WL 1532174, at *4 (E.D. Cal. Mar. 31, 2020) (same); *Stirling v. Novartis Pharms. Corp.*, 2020 WL 4259035, at *3 (Idaho Dist. July 13, 2020) (same).

II. Consent Jurisdiction

We consider next whether Artiss may assert consent jurisdiction under the Ames jurisdictional consent statute, Ames Stat. § 5101. It is undisputed that the statute's consent provision applies to Westlake, which has registered to do business in the State. The only question, then, is whether the provision is constitutional.

Although the question is close, we conclude that the answer is "no." The amendment to the jurisdictional statute appears to be an effort to circumvent the Supreme Court's decision in *Daimler*. Under *Daimler*, it appears clear to us that a plaintiff cannot assert general jurisdiction over a defendant merely because the defendant is registered to do business in a State; instead, the defendant must be "at home" there. Thus, if a State enacted a statute declaring that every defendant that registers in the State is subject to personal jurisdiction, that would be inconsistent with *Daimler*. It is hard to see how adding the label of "consent" allows the State

to accomplish what it cannot mandate. For constitutional due process limitations to mean anything, they must stand up to clever efforts to legislate around them.

We acknowledge, though, that the matter is not free from doubt. After all, a corporation may consent to personal jurisdiction even when jurisdiction would not otherwise exist (for example, by expressly waiving a meritorious jurisdiction defense). We also see the point that it may be a perfectly reasonable *quid pro quo* for a State with a population of 3 million people to determine that the price of access to the Ames market is liability when products (or, in this case, designs) cause injury to the State's residents. And perhaps the consent is not as artificial or coerced as Westlake makes it out to be. After all, corporations do not *have to* do business in the State of Ames; they could forgo that business instead; and the statute expressly puts them on notice that they will be subject to jurisdiction if they continue to do business in the State, and lets them withdraw their consent by withdrawing from the State.

Precedent is also conflicted on this matter. On the one hand, there is what we deem to be the clear implication of *Daimler* that a corporation cannot be subject to general jurisdiction in any State in which it is not "at home." On the other hand, in *Pennsylvania Fire Insurance Co. of Philadelphia v. Gold Issue Mining & Milling Co.*, 243 U.S. 93 (1917), the Supreme Court held that by appointing an agent to receive process in a State, a corporation effectively consented to suit there.

Pennsylvania Fire has not been explicitly overruled—and that has led to some wrangling in other courts about whether it remains good law after *Daimler*. *Compare Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 769 (Fed. Cir. 2016) (O'Malley, J., concurring) (arguing that consent by registration remains valid after *Daimler*), *and Bors v. Johnson & Johnson*, 208 F. Supp. 3d 648, 655 (E.D. Pa. 2016) (finding consent-by-registration valid after *Daimler*) *with Pattanayak v. Mastercard, Inc.*, 2021 WL 960856, at *4 (D.N.J. Mar. 12, 2021) (concluding that *Daimler* has superseded the reasoning of cases holding that registration can validly constitute consent to jurisdiction) *and In re Asbestos Prod. Liab. Litig. (No. VI)*, 384 F. Supp. 3d 532, 540 (E.D. Pa. 2019) (similar); *see also Chufen Chen v. Dunkin' Brands, Inc.*, 954 F.3d 492, 498 (2d Cir. 2020) (acknowledging complexity of the issue and construing state statute not to condition registration on consent to jurisdiction); *Stacker v. Intellisource, LLC*, 2021 WL 2646444, at *5 (D. Kan. June 28, 2021) (similar); *Lehman Bros. Holdings Inc. v. LendingTree, LLC*, 2021 WL 1087695, at *7 (D. Minn. Mar. 22, 2021) (similar).

Having surveyed the legal landscape, we conclude that after *Daimler*, a State cannot constitutionally condition registration to do business on consent to personal jurisdiction. We accordingly hold that Ames Stat. § 5101 is unconstitutional as

applied in this case, and cannot furnish a basis for personal jurisdiction over Westlake.

CONCLUSION

For the foregoing reasons, the judgment of the Superior Court is affirmed, and the case remains dismissed for want of personal jurisdiction. This order constitutes a final judgment in this action.

FILED: JULY 6, 2021

AMES SUPERIOR COURT

Charles Artiss, *Plaintiff*, v. Westlake Pharmaceuticals, Inc. *Defendant.*	Docket No. 19-505

OPINION AND ORDER

This matter is before the Court on Westlake Pharmaceuticals, Inc.'s motion to dismiss the complaint for lack of personal jurisdiction. The essential facts are that Westlake, a mostly out-of-state pharmaceutical company that has registered to do business in the State of Ames and does some marketing here, is responsible for the labeling of Luxin, an anxiety medication. Westlake's label determines the content of the labels used by Luxin's generic competitors, which are required by federal law to include the same warnings. Plaintiff was injured by a generic version of Luxin, and he alleges that the label failed to properly disclose the risks of taking the drug.

Because federal preemption law prevents plaintiff from recovering from the generic manufacturer, he brought this claim against Westlake instead. Westlake argues that none of its conduct in Ames gives rise to plaintiff's claims, and further

argues that to the extent the Ames consent statute, Ames Stat. § 5101, subjects it to general jurisdiction, the statute is unconstitutional.

The Court agrees with Westlake. Although Westlake does have some contacts with this State, the claims in this case do not arise out of or relate to those contacts. Instead, they arise out of and relate to Westlake's labeling decisions, which the complaint does not allege occurred here. So specific personal jurisdiction does not lie.

General jurisdiction also is lacking. The consent statute provides that every corporation that registers to do business in this State consents to jurisdiction here. Ames Stat. § 5101(a). But it is axiomatic that a statute cannot create jurisdiction that the Constitution would prohibit. The legislature could not, for example, pass a statute saying that courts here have jurisdiction over everybody, everywhere. Nor could it pass a statute saying that anybody who does business anywhere consents to general jurisdiction here.

Under that principle, the Ames statute cannot stand. In *Daimler AG v. Bauman*, 571 U.S. 117, 136-37 (2014), the Court held that general jurisdiction is only available where a defendant is "at home," *i.e.*, its principal place of business or incorporation—and not every place the corporation chooses to do business. It is undisputed that Westlake's place of incorporation is Delaware, and its principal place of business is New Jersey, such that Westlake is not "at home" in Ames.

Although Westlake is certainly free to affirmatively consent to jurisdiction in Ames, the legislature cannot simply deem Westlake to have consented to jurisdiction in every single case. To allow that result would render *Daimler* a dead letter in any State that chose not to follow that decision.

For the foregoing reasons, Westlake's motion to dismiss is granted, and this action is dismissed.

s/Judge Anjali Subramanian

Superior Court

DATED: May 20, 2020

AMES SUPERIOR COURT

Charles Artiss, *Plaintiff*, v. Westlake Pharmaceuticals, Inc. *Defendant.*	Docket No. _____

COMPLAINT

1. This is a personal injury action based on negligent and reckless failure to warn the public of known risks of using the drug product denzoampheredrine (DZ), which is used to treat anxiety. Defendant Westlake Pharmaceuticals, Inc. (Westlake) first created and marketed DZ under the brand name Luxin—and in the process determined the contents of the drug's label. Despite knowing that DZ frequently leads to blood clots that can cause stroke, Westlake did not warn physicians and users of the risk of clotting. As a result, plaintiff Charles Artiss suffered a debilitating stroke that has rendered him permanently disabled. Artiss seeks compensatory and punitive damages for his injuries.

I. Parties and Jurisdiction

2. At all relevant times, Artiss has been an adult resident of the State of Ames.

3. Westlake is a corporation incorporated in the State of Delaware with its principal place of business in Trenton, New Jersey.

4. Westlake holds the approval for the New Drug Application (NDA) for DZ. It is the original developer and manufacturer of DZ, and is the entity responsible for first bringing the drug to market and promoting its use to physicians and patients. Before the onset of generic competition, sales of DZ earned more than $1 billion annually for Westlake.

5. Westlake has a substantial presence in the State of Ames. The company first registered to do business in the State in 2005, as foreign corporations seeking to do substantial business in the State are required to do. Every two years, the company has renewed its registration, maintaining its corporate presence in Ames.

6. Westlake also has a physical presence in Ames, including an office in Holmes City that employs more than 40 people. Most of the employees in the Holmes City office are representatives, or detailers, who travel to the offices of physicians in Ames to promote Westlake's drugs to prescribers. These detailers also host events, including speaking programs, in the State of Ames to promote Westlake products. On information and belief, the Holmes City office also includes representatives who take phone calls from physicians and distributors for purposes of promoting prescriptions and sales.

7. In addition to these in-person promotional efforts, Westlake advertises its drugs on television, in print, and on the Internet, including in markets that reach the

State of Ames. These advertisements include the drug Luxin, which is Westlake's branded version of DZ.

8. Westlake distributes drugs to pharmacies and physicians' offices in the State of Ames through a contract with Ames Distro, Inc., a drug distributor that is incorporated in and headquartered in Ames. Through the Ames Distro network, Westlake's products are available throughout the State.

9. Westlake has promoted, sold, and delivered doses of DZ (branded as Luxin) throughout the State of Ames, and continues to do so.

10. Based on these facts, Westlake is subject to personal jurisdiction in the State of Ames. First, its registration in the State expressly constitutes consent to general jurisdiction under Ames Stat. § 5101(a). Specifically, Westlake has maintained and renewed its registration in Ames after § 5101 was enacted in 2015, thus affirmatively consenting to jurisdiction here.

11. Second, Westlake has purposefully availed itself of the privilege of conducting business in the State of Ames, and the claims in this case arise out of or relate to Westlake's contacts with the forum, supporting specific personal jurisdiction.

12. Had Westlake not developed and marketed Luxin, Artiss's injuries in Ames would never have occurred.

13. The generic products sold in Ames embody Westlake's design, including the exact drug label that Westlake has adopted for its version of DZ. It was entirely foreseeable to Westlake that any defects in its design would manifest as adverse reactions in the Ames population—including patients who take the branded version of DZ and those who take generic DZ.

14. Moreover, Westlake has promoted DZ in the State of Ames through in-person promotions and media marketing, increasing demand for both the branded and generic versions of the drug. Because pharmacies are generally free to swap generic versions of DZ for the branded one, Westlake has always known that by developing the market for Luxin, it was necessarily developing the market for generic DZ, too. Westlake's promotional efforts in the State of Ames foreseeably caused physicians in Ames to prescribe generic DZ with greater frequency, leading to injuries in Ames.

II. Factual Allegations

15. Westlake obtained NDA approval for DZ in 2002 and brought the product to the market under the brand name Luxin.

16. Clinical studies and experience about Luxin have showed, since at least 2010, that one side effect of the drug is the possibility of an increased incidence of blood clots—especially in patients that were susceptible to clotting for other reasons. Although the number of patients that have suffered from severe clotting is

relatively small, adverse clotting outcomes have been linked to patients taking Luxin by robust scientific literature. In particular, the literature showed that patients taking Luxin, who suffered a serious physical injury (like a car accident), the incidence of severe clotting was materially higher.

17. Notwithstanding the clear scientific evidence, Westlake has never attempted to add warnings about clotting to the label for Luxin. Instead, when lawsuits have been filed against Westlake alleging that Luxin's label is defective, the company has argued that the link between DZ and clotting is unsubstantiated and speculative.

18. The patents protecting Luxin from generic competition expired in 2012, at which point generic competitors entered the market using the Abbreviated New Drug Application (ANDA) process. The generic equivalents of Luxin are required, by law, to be chemically identical to Luxin, and to bear the same label warnings.

19. Generic manufacturers of DZ have no ability to unilaterally alter their labels. Instead, they, like patients and physicians, know that only Westlake can make those changes. Generic manufacturers also know that once Westlake makes changes, generic manufacturers are legally obligated to follow suit. They accordingly rely on Westlake to make appropriate changes to the label.

20.In early 2016, Artiss was injured in a car accident. Artiss physically recovered in September 2016. But he continued to suffer from anxiety that inhibited his ability to work.

21.In March, 2017, Artiss sought help from a physician who prescribed a regular course of treatment that included talk therapy as well as DZ to manage his anxiety.

22. The prescription did not specify whether the pharmacy should dispense Luxin or generic DZ. The pharmacist chose to dispense the less expensive generic version of DZ manufactured by Santos Laboratories, Inc. (Santos).

23. Santos markets DZ pursuant to approval of its ANDA, which shows that in all material respects, including the chemical composition and the label, Santos's DZ product is identical to Westlake's DZ product. In fact, Santos's product is chemically identical to Luxin, and bears the same warning label.

24.Approximately one month after he started taking DZ, Artiss experienced a severe ischemic stroke that has resulted in permanent brain damage.

25.Ischemic strokes are caused when arteries are blocked, often by blood clots, preventing blood from flowing to the brain.

26.Physicians treating Artiss's stroke determined that it was caused by massive blood clots preventing the flow of blood to his brain. They determined that Artiss's blood was more likely to clot as a result of injuries sustained in his car accident,

but also determined, based on the year and a half between the accident and the stroke, that the accident alone was unlikely to have caused the clotting.

27. The actual cause of the blood clots, and therefore the stroke, was DZ.

28. As a result of the stroke, Artiss lost his ability to walk and speak clearly. He also suffers from memory loss, inability to focus for extended periods of time (more than 5 minutes), and confusion.

29. As a result of the stroke, Artiss will require constant medical care and assistance with basic life activities for the remainder of his life, which has also likely been significantly shortened by the stroke.

30. As a result of the stroke, Artiss is now unable to work in his chosen field (software programming), or to seek similar gainful employment.

31. As a result of the stroke, Artiss's relationships with his family and friends have been permanently damaged.

32. In 2019, Westlake finally updated the label for Luxin by adding a warning regarding the risk of blood clots in patients who are otherwise prone to them. Nothing about the risk of clotting had changed. The update constitutes an admission that the prior label was inadequate.

33. Westlake had comprehensive information about the potential side effects of DZ, having developed the drug, marketed it, and observed its effects on patients for more than a decade. Westlake was aware of the robust scientific literature

showing that for patients susceptible to clotting, DZ was likely to cause it. Nevertheless, for years, it refused to change its label.

34. Westlake's refusal to timely add a warning to the label for DZ was unreasonable and reckless, and exposed patients such as Artiss to substantial risk.

35. Had Westlake timely updated its label, warnings about clotting would have appeared on the bottle for DZ, as well as in the marketing materials that Westlake issued.

36. As a result of appropriate warnings, physicians would have been less likely to prescribe DZ to a patient that had suffered a physical injury, or would have considered prescribing DZ in conjunction with blood thinners or other medications that could mitigate the risk of blood clots.

37. Had Westlake timely updated its label, generic manufacturers would have updated their labels, too.

38. Had Westlake timely updated its label, there is a high probability that Artiss would not have been injured.

39. Westlake's steadfast refusal to update its label, despite known risks, was accordingly the factual and proximate cause of Artiss's injuries.

Causes of Action

I. Negligence

40. The foregoing paragraphs are incorporated as if fully stated herein.

41. Westlake had a duty of care to any person using drugs designed by Westlake, including Artiss. As the NDA holder, Westlake was responsible for the design of DZ and the content of its label. Westlake was also the only entity with the power unilaterally to alter the label. And it was foreseeable to Westlake that generic competitors would follow its design and copy its label, because they are legally required to do so. Thus, Westlake knew or should have known that any decisions it made with respect to its labeling would also manifest in generic equivalents to its products.

42. Westlake knew or should have known that use of DZ elevates the risk of blood clots to an unacceptable level in patients who are already susceptible to clotting.

43. Despite this knowledge, Westlake chose not to update the label for DZ to warn of the risk of clotting.

44. By failing to update its label to account for risks that it knew or should have known, Westlake breached its duty of care as the designer of DZ.

45. Because Westlake did not update its label to warn of the risk of clotting, its marketing efforts for DZ also did not mention the risk of clotting, which meant that physicians and patients were unaware of the risk. Indeed, if a physician or patient had pointedly asked a Westlake representative whether clotting was a material risk,

the representative would have had to answer "no" because of the content of the label.

46. Westlake's decision not to update the label for DZ to warn of the risk of clotting foreseeably caused generic manufacturers not to update their labels to warn of that risk.

47. This failure to warn of the risks of clotting foreseeably caused Artiss's debilitating injuries, which would not have occurred had he and his physician known that DZ carries an elevated risk of clotting in patients who have suffered physical injuries.

II. Recklessness

48. The foregoing paragraphs are incorporated as if fully stated herein.

49. Westlake ignored a clear and obvious risk of clotting in failing to update the label for DZ, ignoring warnings coming from clinical experience, studies, and even other lawsuits against Westlake that put it on notice of the risk.

50. Westlake's behavior was serious enough to constitute reckless disregard for the risk that blood clots would seriously injure users of DZ, including Artiss.

51. That reckless behavior factually and proximately caused Artiss to suffer debilitating injuries.

Prayer for Relief

Artiss respectfully prays that this Court:

1. Award compensatory damages in an amount to be determined at trial.

2. Award punitive damages to the extent permitted by law.

3. Provide such other relief as may be just and proper.

Artiss demands a trial by jury on all issues so triable.

s/Felix Chao

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5100 S. Ames Blvd
City of Bork, Ames

Attorney for Plaintiff

June 20, 2019

AMES STATUTES

§ 5101 Consent to Jurisdiction

(a) Corporate Consent to General Jurisdiction. The courts of this State shall exercise general personal jurisdiction over any corporation, partnership, limited partnership, or association that is: (1) incorporated under the laws of this State; (2) registered as a foreign entity doing business in this State; or (3) engaged in continuous business within this State such that registration as a foreign entity is required by law. Incorporation, registration, or carrying on continuous business within this State is hereby conditioned upon consent to jurisdiction by the State's courts.

(b) Withdrawing Consent to General Jurisdiction. A corporation, partnership, limited partnership, or association that is subject to jurisdiction under subsection (a) may withdraw its consent to general jurisdiction by ceasing to be incorporated and/or registered in this State, and by ceasing all substantial business activities within the State. Such withdrawal shall take effect immediately, but shall not be retroactive to conduct that occurred while the consent was in place. Withdrawal of consent to general jurisdiction under subsection (a) does not eliminate any other basis for jurisdiction that may exist at law.

AMES SESSION LAWS

Session Law No. 2015-05

Sec. 1 Findings and Purpose.

(1) The courts of this State play an essential role in ensuring that the people of this State have access to justice.

(2) When corporations and other entities purposefully avail themselves of the privilege of doing business in this State, it is right and fair that they expect to be haled into this State's courts for claims, whether in tort or in contract, brought about by their conduct.

(3) Consistent with that understanding, it has been the general rule that corporations systematically transacting business in the State are subject to general jurisdiction in the State's courts.

(4) Recent decisions of the Supreme Court of the United States have cast doubt as to whether the courts of this State retain general jurisdiction over foreign businesses that transact substantial business within the State. These decisions, however, say nothing about the circumstances in which a corporation or other entity may consent to general jurisdiction.

(5) The status quo is likely to result in substantial additional litigation over jurisdiction. Such litigation is distracting and wasteful, and inhibits access to justice.

(6) It is appropriate for the legislature to clarify the scope of personal jurisdiction by expressly providing that corporations and other entities doing substantial business in the State remain subject to general jurisdiction here because, by choosing to continue doing business after the date of this statute, they are on notice that doing so shall constitute consent to the general jurisdiction of the courts of this State.

Sec. 2 Operative provision

There is hereby added to the Ames Statutes a new Section 5101, which provides:

(a) Corporate Consent to General Jurisdiction. The courts of this State shall exercise general personal jurisdiction over any corporation, partnership, limited partnership, or association that is: (1) incorporated under the laws of this State; (2) registered as a foreign entity doing business in this State; or

(3) engaged in continuous business within this State such that registration as a foreign entity is required by law. Incorporation, registration, or carrying on continuous business within this State is hereby conditioned upon consent to jurisdiction by the State's courts.

(b) Withdrawing Consent to General Jurisdiction. A corporation, partnership, limited partnership, or association that is subject to jurisdiction under subsection (a) may withdraw its consent to general jurisdiction by ceasing to be incorporated and/or registered in this State, and by ceasing all substantial business activities within the State. Such withdrawal shall take effect immediately, but shall not be retroactive to conduct that occurred while the consent was in place. Withdrawal of consent to general jurisdiction under subsection (a) does not eliminate any other basis for jurisdiction that may exist at law.