No. _____

In the
Supreme Court of the United States

GLAXOSMITHKLINE, LLC, PFIZER INC., BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., AND BOEHRINGER INGELHEIM USA CORPORATION,

Petitioners,

v.

SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA,

Respondent.

On Petition for Writ of Certiorari to the Court of Appeal of California, First District

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

The Supreme Court of California has created the tort of "warning-label liability," also known as "innovator liability," which lets users of a generic drug bring failure-to-warn claims against the manufacturer of the brand-name drug—even though the manufacturer had no role in making, marketing, or selling the generic. The rationale for the tort is that because a generic drug's label must mirror the branded drug's label, the brand-name manufacturer's labeling decisions are a proper basis for liability.

Regardless of the merits of this novel theory as a matter of state law, the Due Process Clause forbids California from haling an out-of-state brand-name manufacturer into court when generic-drug users claim they were injured by products that a *competitor* sold in the State. Specific jurisdiction is absent because a warning-label claim against a brand-name manufacturer does not "arise out of or relate to the defendant's contacts with the forum"—it relates to labeling decisions the defendant made in its home state. *Ford Motor Co. v. Mont. Eighth Jud. Dist. Ct.*, 592 U.S. 351, 359 (2021). And forcing a brand-name manufacturer to defend claims in California when it did not profit from generic sales in California is anything but "fair[]" or "reciprocal." *Id.* at 367–68. Not only does the manufacturer lose twice—a missed sale, and a lawsuit based on a competitor's sale—but it has no ability to "structure [its] primary conduct" to avoid claims based on a generic competitor's sales in California. *Id.*

The question presented is:

When a plaintiff alleges injury from the consumption of a generic drug, can the consumer's home state assert specific personal jurisdiction over an out-of-state brand-name manufacturer?

PARTIES TO THE PROCEEDING

GlaxoSmithKline, LLC, Pfizer Inc., Boehringer Ingelheim Pharmaceuticals, Inc., and Boehringer Ingelheim USA Corporation are the petitioners here and were the defendants-petitioners below.

Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC were defendants-petitioners below, but were subsequently dismissed from the underlying cases.

The Superior Court of California, Alameda County, is the respondent here and was the respondent below.

The Real Parties in Interest are the bellwether plaintiffs in the consolidated proceedings: Stephane Apodaca, as Guardian ad litem and parent of J.W.A., a minor; Jeffrey Bautista; Michael Caratti; Kenneth Cook; Sheldon Eiss; Annette Hughes; Steve Pratt; Joseph Riggio; John Russell; Anthony Stewart.

CORPORATE DISCLOSURE STATEMENT

GlaxoSmithKline LLC's sole member is GlaxoSmithKline Holdings (Americas) Inc., a Delaware corporation, which is a subsidiary of GSK Finance (No 2) Limited, a private limited company incorporated in England, which is a subsidiary of GlaxoSmithKline Finance plc, a public limited company incorporated in England, which is a subsidiary of GlaxoSmithKline Holdings Limited, a private limited company incorporated in England, which is a subsidiary of GSK plc, a publicly traded public limited company incorporated in England.

To the knowledge of GlaxoSmithKline LLC, none of the shareholders of GSK plc owns beneficially 10% or more of its outstanding shares. However, JPMorgan Chase Bank, N.A. ("JPM") serves as the Depositary for the Company's American Depositary Shares ("ADS") listed on the New York Stock Exchange, each representing two Ordinary Shares in GSK plc. In that capacity, JPM is the legal holder of more than 10% of the outstanding shares in GSK plc.

Pfizer Inc. is a publicly traded corporation. No publicly held corporation owns 10% or more of its stock, and Pfizer Inc. has no parent corporations.

Boehringer Ingelheim Pharmaceuticals, Inc. is a wholly owned subsidiary, directly or indirectly, of Boehringer Ingelheim USA Corporation and Boehringer Ingelheim Corporation, both privately owned corporations. No publicly held corporation owns 10% or more of the stock of Boehringer Ingelheim Pharmaceuticals, Inc.

Boehringer Ingelheim USA Corporation is a wholly owned subsidiary of Boehringer Ingelheim

International GmbH. No public corporation owns 10% or more of the stock of Boehringer Ingelheim USA Corporation.

STATEMENT OF RELATED PROCEEDINGS

In re Ranitidine Cases, No. JCCP 5150 (Super. Ct. Cal., Cty. of Alameda) (opinion issued December 8, 2022, denying motion to quash in relevant part)

GlaxoSmithKline LLC, et al. v. Super. Ct. of Alameda Cty., No. A166778 (Ct. App. Cal.) (opinion issued October 23, 2023, denying petition for a writ of mandate)

GlaxoSmithKline LLC, et al. v. Super. Ct. of Alameda Cty., No. S282560 (Cal.) (opinion issued Jan. 17, 2024, denying petition for review)

There are no additional proceedings in any court that are directly related to this case.

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PETITION FOR WRIT OF CERTIORARI

This petition presents a recurring question of critical importance to mass tort pharmaceutical product-liability litigation: Can a court assert specific jurisdiction over a manufacturer of a brand-name drug in connection with a claim alleging that a *generic* version of the drug sold by a competitor injured the plaintiff? Most courts do not even recognize such claims because "traditional common law tort principles" make a manufacturer "liable for injuries caused by its own product," and not for injuries caused by the products of other companies. *Schrock v. Wyeth*, 727 F.3d 1273, 1285 (10th Cir. 2013). But other courts, including the high courts of California and Massachusetts, have seen things differently, holding that a brand-name manufacturer can be liable to users of generic drugs under a theory of "warning-label liability," also known as "innovator liability," because the generic label must mirror the label of the name-brand product. *See, e.g.*, *T.H. v. Novartis Pharms. Corp.*, 407 P.3d 18, 22 (Cal. 2017).

This petition does not challenge the authority of state courts to adopt warning-label liability as a matter of substantive state law. Rather, the question is whether a plaintiff armed with a warning-label claim can hale an out-of-state brand-name manufacturer into court in the plaintiff's home state, even though the manufacturer did not sell the offending product there.

Under this Court's precedent, the answer is "no." Specific personal jurisdiction "must be based on intentional conduct by the *defendant* that creates the necessary contacts with the forum," *Walden v. Fiore*,

571 U.S. 277, 286 (2014) (emphasis added), and "the *suit* must arise out of or relate to the defendant's contacts with the forum," *Bristol-Myers Squibb Co. v. Super. Ct. of Cal., S.F. Cnty.*, 582 U.S. 255, 262 (2017) (emphasis modified). The sole basis for warning-label liability—as the name suggests—is the labeling decisions of the brand-name company. Those decisions generally (as here) take place in the brand-name manufacturer's home state and thus cannot support specific jurisdiction elsewhere.

Allowing a plaintiff injured by a competitor's generic product to sue the brand-name manufacturer in the plaintiff's home state also flouts bedrock "fairness" principles. *Ford Motor Co. v. Mont. Eighth Jud. Dist. Ct.*, 592 U.S. 351, 360 n.2 (2021). Once the applicable patent expires, the brand-name manufacturer has no way to prevent its competitor from selling the generic product in a particular state. The brand-name manufacturer does not profit from the sale of a generic product and thus does not receive the reciprocal "benefit[]" that is vital to the jurisdictional *quid pro quo*. *Id.* at 367. If anything, the brand-name manufacturer is harmed twice; it loses a sale, and then it must fight a lawsuit directed against it instead of the competitor that pocketed the purchase price.

Yet courts in California have repeatedly allowed plaintiffs alleging injury from generic medications to exercise specific jurisdiction over brand-name manufacturers, even though no conduct related to the generic drug took place in the state. In the decision below, the superior court and California Court of Appeal held that thousands of plaintiffs claiming that

the generic version of Zantac (ranitidine) had caused them to develop cancer could assert specific jurisdiction over Petitioners, who manufactured and/or sold brand-name versions of Zantac at various times. Although Petitioners are out-of-state companies and never sold generic ranitidine in California, the superior court reasoned that "[t]he fact that [Petitioners] and the generic manufacturers all sold [over-the-counter] Zantac or ranitidine with the same label and [Petitioners] were responsible for the content of that common label meets the 'relating to' standard" for personal jurisdiction. App.30a.

This approach not only threatens to (re)unleash boundless product-liability litigation in California, *contra Bristol–Myers Squibb*, 582 U.S. 255 (holding that the defendant was not subject to specific jurisdiction where the marketing and sale of its product in California was not related to the plaintiffs' claims), but creates a square split with the federal MDL court that oversaw tens of thousands of parallel claims by plaintiffs from 37 states alleging injuries caused by ranitidine. As that court correctly explained, the contacts that brand-name manufacturers might establish with a state in selling their *own* medications "do not relate to the claim[s]" against them involving injuries caused by third-party generic medications. *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 546 F. Supp. 3d 1192, 1213 (S.D. Fla. 2021).

This disagreement on personal jurisdiction deserves review now in this uniquely appealing vehicle. Warning-label claims have become a fixture of pharmaceutical product-liability litigation,

especially in California, and such claims create outsized liability risks that have strong potential to drive the resolution of the case. Whenever a drug loses patent protection, generic alternatives to the brand-name product soon take over the market, accounting for *over 90%* of sales by recent federal estimates.[1] Thus, in any litigation involving a drug that has been around long enough, a huge percentage of the plaintiffs will be users of generic products. And because failure-to-warn and design-defect claims against generic manufacturers are preempted under *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), a warning-label liability claim against the brand-name manufacturer is the go-to suit for consumers of a generic drug. Sure enough, large pharmaceutical product-liability litigations often feature a host of warning-label claims in which the brand-name manufacturer's liability exposure overwhelmingly rests on products that the manufacturer did not sell.

Despite the frequency with which warning-label claims arise, the foundational personal-jurisdiction question tends to evade review. When a court denies a motion to dismiss for lack of personal jurisdiction, interlocutory appeal is typically unavailable (especially in federal court). And appellate review after final judgment is illusory because, in practice, the "vast majority" of mass-tort cases involving warning-label liability claims are "resolved by

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[1] U.S. Food & Drug Admin., Office of Generic Drugs 2022 Annual Rep. at 1, available at https://www.fda.gov/media/165435/download?attachment

settlement" due to "the sheer magnitude of the risk, in terms of dollar value, of trials." *In re Gen. Motors LLC Ignition Switch Litig.*, 427 F. Supp. 3d 374, 394 (S.D.N.Y. 2019) (Furman, J.).

But this case is special, because California state courts require defendants to appeal personal-jurisdiction issues via interlocutory petition. The decision below is thus a clean, early-stage vehicle. No case-specific facts were relevant to the superior court's decision to assert jurisdiction over the warning-label liability claims. The court simply determined that, under this Court's personal-jurisdiction precedents, the plaintiffs' claims concerning generic drugs "relate to" Petitioners' marketing and sale of their own brand-name products in California.

Review at this juncture is especially appropriate because the decision below is part of a now-established pattern of courts in California asserting jurisdiction over warning-label liability claims brought against out-of-state brand-name manufacturers. *See, e.g.*, *Whaley v. Merck & Co.*, No. 3:21-cv-1985, 2022 WL 1153151 (S.D. Cal. Apr. 12, 2022); *Leon v. URL Pharma, Inc.*, No. 2:22-cv-8539, ___ F. Supp. 3d ___, 2023 WL 6119112 (C.D. Cal. Sept. 15, 2023). These decisions frequently come from federal courts where, again, appellate review is all-but illusory. This Court should seize the opportunity to bring much-needed clarity to this frequently litigated but hard-to-reach issue.

OPINIONS BELOW

The superior court's opinion granting the motion to quash is reproduced at App.1–17. The superior court's subsequent opinion denying the motion to

quash in relevant part is reproduced at App.18–55. The superior court's order implementing its ruling on the motion to quash is reproduced at App.56–74. The California Court of Appeal's opinion is reproduced at App.75–77. The Supreme Court of California's denial of the petition for review is reproduced at App.78.

JURISDICTION

The Supreme Court of California issued its opinion denying review of the California Court of Appeal's decision on January 17, 2024. On March 13, 2024, Justice Kagan extended the time for filing a petition for certiorari to and including June 15, 2024. This Court has jurisdiction under 28 U.S.C. §1257(a).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Due Process Clause of the Fourteenth Amendment, U.S. Const. amend. XIV, § 1, provides:

> [N]or shall any State deprive any person of life, liberty, or property, without due process of law.

California Code of Civil Procedure § 410.10 provides:

> A court of this state may exercise jurisdiction on any basis not inconsistent with the Constitution of this state or of the United States.

STATEMENT OF THE CASE

I. History of Zantac.

Ranitidine, better known by its brand name Zantac, was one of the best-selling antacid medications in the world for several decades. A

predecessor company of Petitioner GlaxoSmithKline LLC discovered ranitidine in 1976, and the FDA granted the company's new drug application (NDA) to sell prescription Zantac in 1983. Within a few years, Zantac became the most popular prescription medication globally, used by tens of millions to treat ulcers, gastroesophageal reflux disease, and other gastric conditions.

The FDA granted an NDA to sell Zantac over the counter in 1995. The NDA for over-the-counter Zantac, and thus the right to sell the product and revise its label, was transferred to several different companies over the years. GlaxoSmithKline held the NDA from 1995 to 1998; Petitioner Pfizer from 1998 to 2006; Petitioner Boehringer Ingelheim from 2006 to 2017; and Sanofi until the product was discontinued in 2019.[2] Everyone agrees that no Petitioner is a "citizen[] of California." App.4, 25.

GlaxoSmithKline's patent on ranitidine expired in 1997, allowing generic competitors to enter the market. Sales of brand-name Zantac fell as a result. Due to its declining market share, GlaxoSmithKline stopped selling prescription Zantac in the United States in 2017.

In 2019, a private online pharmacy called Valisure submitted a citizen petition to the FDA with test results purporting to show that some ranitidine products, under certain conditions, contained dangerous levels of the carcinogenic molecule NDMA.

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[2] Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC are not Petitioners because they were recently dismissed from the underlying bellwether cases.

In re Zantac (Ranitidine) Prods. Liab. Litig., 644 F. Supp. 3d 1075, 1092 (S.D. Fla. 2022). The FDA rejected the validity of Valisure's results, including because "the laboratory equipment that Valisure used to test for NDMA actually *created* NDMA." *Id.* Even so, the FDA requested a voluntary withdrawal because some testing showed NDMA levels exceeding the FDA's "conservative" daily limit by an amount which, according to the FDA, a person could reach merely by eating a single meal of grilled or smoked meat. *Id.* at 1092–93.

The Valisure allegations—since debunked by an FDA "human clinical trial" and "many epidemiological studies"—nonetheless saw the filing of tens of thousands of personal-injury lawsuits, some of which were curiously "filed simultaneously with the Valisure petition to the FDA." *Id.* at 1093. Because there had been a large market for generic ranitidine for over twenty years, many thousands of plaintiffs brought warning-label liability claims against Petitioners. Many cases were non-removable, including more than two thousand that were coordinated in the California proceedings below. But cases that were filed in or removed to federal court, including warning-label claims filed in 37 different states, were eventually coordinated in a federal MDL in the Southern District of Florida in February 2020.

II. The Federal MDL Court Dismisses Warning-Label Claims for Lack of Personal Jurisdiction.

The MDL court held in December 2020 that courts outside of Petitioners' home states[3] lacked personal jurisdiction over warning-label liability claims. *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 510 F. Supp. 3d 1175 (S.D. Fla. 2020). Plaintiffs from California and Massachusetts (which is the only other state to recognize warning-label liability) repleaded in an attempt to establish specific jurisdiction, but the MDL court dismissed their claims again in June 2021. *In re Zantac*, 546 F. Supp. 3d at 1214. The MDL court applied this Court's decision in *Ford* and concluded that, although Petitioners had some contacts with California and Massachusetts because they had sold their *own* medications there, those "sales and marketing activities" could not support specific jurisdiction for warning-label claims brought by consumers of *competitors'* generic medications. Such claims, the MDL court explained, "do not relate to the core conduct that constitutes the rationale" for warning-label liability: "a brand-name manufacturer's *labeling decisions* regarding its own product." *Id.* at 1212 (emphasis added). If Petitioners' in-state conduct that is irrelevant to the plaintiffs' theory of liability could nonetheless "relate to" the plaintiffs' claims, then "the phrase 'relate to' would have no 'real limits.'" *Id.* at 1213 (quoting *Ford*, 582 U.S. at 362).

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[3] Each Petitioner is incorporated in Delaware. GlaxoSmithKline, Pfizer, and Boehringer Ingelheim have their U.S. headquarters in Pennsylvania, New York, and Connecticut, respectively.

Despite this decision's significant impact on their claims, plaintiffs could not appeal the dismissal of the warning-label liability theories because the district court had not entered final judgment. *See Cartee v. Boehringer Ingelheim Pharms., Inc.*, No. 21-10305, 2022 WL 16729151 (11th Cir. Nov. 7, 2022) (per curiam) (dismissing appeal of warning-label liability ruling for lack of jurisdiction). In December 2022, the MDL court granted summary judgment to Petitioners in nearly all remaining cases after excluding Plaintiffs' general-causation experts' opinions as unreliable under Fed. R. Evid. 702, noting that none of the many epidemiological studies conducted after the voluntary withdrawal had found a causal link between ranitidine use and cancer. *In re Zantac*, 644 F. Supp. 3d at 1093; *see id.* at 1094 ("[T]here is no scientist outside this litigation who concluded ranitidine causes cancer.").

III. The California Superior Court Rejects the MDL Decision and Asserts Personal Jurisdiction Over Petitioners.

The ranitidine plaintiffs whose cases were not removed include thousands of claimants in California. Their cases were coordinated in the Superior Court of Alameda County in March 2021.

Petitioners moved to quash for lack of personal jurisdiction all warning-label liability claims brought by the bellwether plaintiffs. Plaintiffs opposed the motion, relying heavily on the opinion of the California district court in *Whaley*, 2022 WL 1153151, which disagreed with the MDL court's analysis and asserted specific jurisdiction over an out-of-state brand-name company to hear a warning-label liability claim. The

Whaley court determined that the plaintiff's claims related to the defendant's forum contacts because the defendant had "advertised, marketed, and sold the [brand-name] product in California, which included the allegedly deficient warning label." *Id.* at *7.

The superior court initially found the federal MDL court's opinion "persuasive" and granted the motion. App.7. In doing so, it stressed that its decision did not leave plaintiffs without a substantive remedy: they "could assert their claims in a court where jurisdiction was proper." *Id.* at App.10.

But the superior court later reversed itself and issued an order denying the motion to quash in relevant part. App.18. Adopting the reasoning from *Whaley* that it had previously rejected, the superior court concluded that "[t]he fact that [Petitioners] and the generic manufacturers all sold OTC Zantac or ranitidine with the same label and the Brand Defendants were responsible for the content of that common label meets the 'relating to' standard" of the specific-jurisdiction test. App.30.

The superior court then entered an order applying its ruling to each of the bellwether cases. App.56–74. In that order, the court clarified that it was asserting jurisdiction over Petitioners even for warning-label liability claims that arose *after* Petitioners stopped marketing and selling over-the-counter Zantac. For example, although GlaxoSmithKline stopped selling over-the-counter Zantac in 1998, the court asserted jurisdiction over GlaxoSmithKline in the case of a plaintiff who only began using generic over-the-counter ranitidine in 2012—*fourteen years* after

GlaxoSmithKline had last sold the brand-name over-the-counter product in California. App.67.[4]

IV. The California Court of Appeal Denies a Petition for a Writ of Mandate.

Petitioners sought a writ of mandate, which in California is the proper method for contesting a court's assertion of personal jurisdiction. The California Court of Appeal, First Appellate District, denied the petition. App.75. The court stated that "California state courts and federal courts in California have without exception rejected jurisdictional claims similar to those made by petitioners." App.76. The Court of Appeal also noted that "the superior court's challenged rulings … present pure questions of law based on undisputed facts." App.75.

Petitioners then sought review in the Supreme Court of California, which denied their petition on January 17, 2024. App.78

REASONS FOR GRANTING THE PETITION

I. There is a Nationwide Split on Whether a Court May Assert Specific Jurisdiction Over a Brand-Name Manufacturer for Claims Alleging Injuries by a Generic Product.

Federal and state courts overseeing pharmaceutical product-liability cases are in disarray about whether they have jurisdiction to hear warning-label liability claims brought by consumers of generic

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[4] The superior court granted the motion to quash as to certain claims against Pfizer in three of the bellwether cases, but only because the plaintiffs had consented to dismissal. App.65, App.70–71.

drugs against out-of-state brand-name manufacturers. Indeed, in this very case, the superior court overseeing thousands of non-removable California claims reached contradictory results. It initially adopted the reasoning of the federal MDL court overseeing all federal court claims and dismissed the warning-label liability claims for lack of personal jurisdiction, but then reversed itself to align with other California-based courts that have addressed the same question.

A. The MDL Court Held that Warning-Label Liability Claims Do Not "Relate to" the Brand-Name Manufacturer's Marketing and Sale of Its Own Products.

The federal MDL court concluded, after an exhaustive analysis of the warning-label liability caselaw and this Court's recent decision in *Ford*, that it lacked specific jurisdiction over warning-label liability claims filed outside Petitioners' home states. The court took note of *Ford*'s holding "that a 'strict causal relationship between the defendant's in-state activity and the litigation' is not necessary to meet the 'relate to' part" of the "arise out of or relate to" standard." *In re Zantac*, 546 F. Supp. 3d at 1204 (quoting *Ford*, 592 U.S. at 362). *Ford* "emphasized," however, that "although a causal relationship is not required, '[t]hat does not mean anything goes.'" *Id*. at 1205 (quoting *Ford*, 592 U.S. at 362). "[T]he phrase 'relate to' incorporates real limits, as it must to adequately protect defendants foreign to a forum." *Ford*, 592 U.S. at 362.

With those principles in mind, the MDL court concluded that the plaintiffs had "not sufficiently

alleged that [Petitioners'] contacts 'relate to' Plaintiffs' claims." *In re Zantac*, 546 F. Supp. 3d at 1212. Although Petitioners had contacts in the forum states—"sales and marketing activities" related to their *own* medications—those activities "do not relate to the core conduct that constitutes the rationale for holding brand-name manufacturers liable for claims brought by consumers of generic bioequivalent products": "a brand-name manufacturer's labeling decisions regarding its own product." *Id.* Because alleged "misrepresentations made in the course of sales and marketing" of Zantac "are not necessary to state a misrepresentation claim premised on the innovator-liability theory," those activities "do not give rise to 'jurisdictionally relevant' contacts between the brand-name manufacturers and the forum." *Id.* at 1213 (quoting *Walden*, 571 U.S. at 289). The MDL court reasoned that, if it "were to nonetheless find specific personal jurisdiction because of [Petitioners'] forum-based marketing and sales contacts relating to their *own products*, conduct that the Court has concluded is not 'jurisdictionally relevant,' … the phrase 'relate to' would have no 'real limits,'" contrary to this Court's guidance in *Ford*. *Id.*

B. California Courts Hold that, Under *Ford*, Warning-Label Liability Claims "Relate to" the Brand-Name Manufacturer's Marketing and Sale Activities.

Several courts in California have rejected the MDL court's analysis and asserted specific jurisdiction over warning-label liability claims brought against out-of-state brand-name companies. The first such decision came in *Whaley*, 2022 WL 1153151. *Whaley*

observed that, in *Ford*, this Court considered the defendant's "marketing, servicing, and selling of the same vehicle models in the forum states" to be "related to" the plaintiffs' claims, even though the plaintiffs had bought their vehicles elsewhere. *Id.* at *6 (citing *Ford*, 592 U.S. at 365). *Whaley* reasoned that, similarly, the brand-name manufacturers had "marketed and sold" in California their brand-name product (the drug Singulair), which "includ[es] the warning label which forms the basis of Plaintiff's claim" involving a generic version of Singulair. *Id.* *Whaley* rejected the defendants' attempt to distinguish *Ford* on the ground that the plaintiffs' warning-label liability claims targeted a *different* product—a generic drug made by a different company—than the product the defendants had sold. *Whaley* also acknowledged that its reasoning was "in tension with" the MDL court's conclusion that "a name-brand manufacturer's advertisements for a name-brand drug cannot be jurisdictionally relevant" to a warning-label liability claim. *Id.* at *8.

Since *Whaley*, several other California district courts, in addition to the superior court in this case, have adopted *Whaley*'s reasoning and asserted specific jurisdiction over warning-label liability claims. *See Leon*, ___ F. Supp. 3d ___, 2023 WL 6119112, at *5; *Bueno v. Merck & Co.*, 626 F. Supp. 3d 1154, 1159 (S.D. Cal. 2022); *Rosewolf v. Merck & Co.*, 635 F. Supp. 3d 830, 838 (N.D. Cal. 2022); *Haddad v. Merck & Co.*, No. CV 22-2151, 2022 WL 17357779, at *5 (C.D. Cal. Aug. 11, 2022); *see also Barnes v. Merck & Co.*, 648 F. Supp. 3d 283, 291 (D. Mass. 2023); *McLaughlin v. Merck & Co.*, No. 22-40041, 2023 WL 2743308, at *3 (D. Mass. Mar. 31, 2023).

II. This Case Is a Clean Vehicle for an Important Issue that Evades Review.

The question of which courts have jurisdiction to hear warning-label claims against brand-name manufacturers is central to pharmaceutical product-liability litigation. Generic drugs command a vast share of the American pharmaceutical market—an "estimated … *91%* of all prescriptions in the United States are filled as generic[s]"—and thus compose a large share of potential liability for personal-injury claims.[5]

That ubiquity is because, once patent protection for a medication expires (or if generic manufacturers manage to circumvent patent protection earlier, *e.g.*, 21 U.S.C. §355(j)(2)(A)(vii)), sales of less-expensive generic drugs quickly overtake sales of the more expensive brand-name product. Accordingly, in any product-liability case involving an off-patent drug, many, if not the majority of, plaintiffs will be individuals who used a generic medication. And armed with a warning-label liability theory, they will be able to target the brand-name manufacturer who did *not* benefit from that majority of sales, but whose deep pockets are enticing just the same.

Recent litigation confirms that these claims have become a fixture of product-liability litigation. Although the highest courts of only two states have recognized the warning-label theory, that has not stopped plaintiffs from asserting this theory to maximize the defendant's potential exposure and ratchet up the settlement pressure. In fact, the

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[5] 2022 Annual Rep., *supra* n.1, at 1 (emphasis added).

federal MDL plaintiffs in the *Zantac* litigation pursued warning-label liability claims under the laws of no less than *thirty-five* states and territories, in addition to California and Massachusetts. 510 F. Supp. 3d at 1195 & n.6. Although the MDL court rightly rebuffed that effort, other plaintiffs have since pursued warning-label liability claims against Petitioners in state courts in Nevada, Illinois, Pennsylvania, Connecticut, and Delaware, as well as California. In each case, the plaintiffs have argued for the especially expansive form of warning-label liability recognized in California, under which a brand-name company can be liable for alleged deficiencies in the generic label even *after* the company relinquishes the NDA to another brand-name manufacturer.

This now-familiar pattern demands certainty about where warning-label claims should be brought. Are they proper only in the defendant's home state, which is where the defendant made the critical labeling decisions? Or can they also be brought in the state where the plaintiff used a competitor's generic drug simply because the defendant, at some point in time, marketed its own brand-name product there?

The conflicting positions on the issue are well-defined. The MDL court applied *Ford* and held that the brand-name manufacturer's activity of selling its own product in the forum state is detached from the plaintiff's theory of liability based on the generic drug's warning label and thus cannot "relate to" the plaintiff's claims; otherwise, "the phrase 'relate to' would have no 'real limits.'" *In re Zantac*, 546 F. Supp. 3d at 1213 (quoting *Ford*, 592 U.S. at 362). The

California view, by contrast, is that brand-name companies subject themselves to perpetual specific jurisdiction in the forum state by having sold their own products there, even in the distant past, with the same allegedly inadequate label that appeared on the generic drugs the plaintiff used.

The absence of appellate authority on the question is not a reason to delay review. On the contrary, it illustrates why this Court should take this opportunity to resolve an evasive yet important question. Although personal jurisdiction is an oft-litigated issue in pharmaceutical suits, the issue frequently skirts appellate scrutiny: In circumstances where a motion to dismiss claims based on the use of *generic* products is granted, appeal is unlikely because claims based on the use of *brand-name* products still must be adjudicated. That subsequent adjudication frequently results in the trial court identifying multiple other grounds on which to reject the plaintiffs' claims (such as, as in the MDL, the insufficient and unreliable evidence plaintiffs proffered that ranitidine causes cancer), or in the settlement of those claims, thus mooting an appeal. And in the mirror-image scenario when a court denies a motion to dismiss for lack of personal jurisdiction, not only is interlocutory review typically unavailable, but final-judgment review is often illusory because the "vast majority" of these mass-tort cases are "resolved by settlement" due to "the sheer magnitude of the risk, in terms of dollar value, of trials." *Gen. Motors*, 427 F. Supp. 3d at 394 (Furman, J.).

Appellate review was available here only because, unlike most jurisdictions, California requires

defendants to challenge personal-jurisdiction rulings through an interlocutory petition for a writ of mandate. *See State Farm Gen. Ins. Co. v. JT's Frames, Inc.*, 104 Cal.Rptr.3d 573, 580 (Ct. App. 2010).[6] This Court thus has a perfect opportunity to resolve a critical jurisdictional question.

The decision below is a clean vehicle for doing so. As the California Court of Appeals noted when it denied the petition for a writ of mandate, "the superior court's challenged rulings … present pure questions of law based on undisputed facts." App.75. The sole, dispositive question is whether a court can assert specific jurisdiction over a warning-label liability claim based on the brand-name company's sale of its own products in the forum state. This Court should take the opportunity to resolve that question now and eliminate the pall of jurisdictional uncertainty that will otherwise hang over pharmaceutical product-liability litigation for years to come.

III. The California Court of Appeal Erred in Asserting Personal Jurisdiction Over the Warning-Label Liability Claims.

Forcing a brand-name manufacturer to defend in California claims alleging harm caused by products that other companies sold there eliminates any "real limits" for specific jurisdiction and invites the "anything goes" approach that *Ford* rejected. 592 U.S.

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[6] This Court has often resolved personal-jurisdiction issues on review of petitions for a writ of mandate filed in California state court. *See, e.g.*, *Bristol–Myers Squibb*, 582 U.S. at 260; *Asahi Metal Indus. Co. v. Super. Ct. of Cal., Solano Cty.*, 480 U.S. 102 (1987); *Kulko v. Super. Ct. of Cal., City & Cty. of S.F.*, 436 U.S. 84 (1978).

at 362. The defining feature of specific personal jurisdiction is that it extends only to claims that "arise out of or relate to" the out-of-state defendant's contacts with the forum. *Id*. at 359. Those contacts must be created "by the defendant"—not by other parties. *Walden*, 571 U.S. at 286. And the exercise of "jurisdiction [must] treat[] [the defendant] fairly," including by ensuring that there is "reciproc[ity]" between the "benefits" enjoyed by the defendant and the "obligations" the state imposes, as well as by allowing defendants to "structure [their] primary conduct to lessen or avoid exposure." *Ford*, 592 U.S. at 360, 367–68.

Allowing generic-drug consumers to assert specific jurisdiction over brand-name manufacturers violates these principles in two key ways.

First, a warning-label claim does not "relate to" the contacts the brand-name manufacturer created with the forum state. Under the unique warning-label theory, the only reason the brand-name manufacturer can be held liable for its competitors' generic products is that the brand-name manufacturer's labeling decisions for its own product also determine the contents of the generic drug's label. *See T.H.*, 407 P.3d at 33 ("[T]he plaintiff's claim here is not that [the drug] is defectively designed or inherently dangerous. It is that [the drug's] *warning label* failed to mention the risk to fetal brain development, and that [the brand-name manufacturer] was responsible for the *deficient label*.") (emphases added).[7] In the words of

[7] *Accord T.H.*, 407 P.3d at 39–41 (all emphases added):

the *Zantac* MDL court, the "labeling decisions" are the "forum-based contact" that "clearly relate[s] to a[] [warning-label] liability claim." 546 F. Supp. 3d at 1214. So because Petitioners here did *not* make their labeling decisions in California, they never "create[d] the necessary contacts with the forum." *Walden*, 571 U.S. at 286. Plaintiffs are free to try to pursue their warning-label claims, but they must do so in a court

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> The negligence causes of action are potentially viable because of the allegedly deficient representations in Novartis's *warning label*. Novartis is not being sued for dangers inherent in the generic terbutaline manufactured by some other entity. Nor do plaintiffs claim that any product manufactured by Novartis caused them harm. They claim instead that allegedly deficient representations and omissions in Novartis's *warning label* caused them harm. *The fact that Novartis also manufactured a product is extrinsic to the analysis* and does not insulate it from liability for its alleged misrepresentations ….
>
> What warning label liability stems from is Novartis's failure to warn about a drug's risks, not its production of a defective drug. The complaint alleges that Novartis and aaiPharma were concurrent tortfeasors whose liability stemmed from failure to warn, *because each negligently failed to update the warning label*.

See also, e.g., *Rafferty v. Merk & Co.*, 92 N.E.3d 1205, 1209, 1220 (Mass. 2018) (all emphases added):

> [A] plaintiff … may bring a common-law recklessness claim against the brand-name manufacturer if it intentionally failed to update the *label on its drug* ….
>
> [A] brand-name manufacturer that intentionally fails to updated the *label on its drug* to warn of an unreasonable risk of death or grave bodily injury … will be held responsible for the resulting harm.

with general jurisdiction over Petitioners or where the labeling decisions actually occurred.

It is no answer, as the superior court and *Whaley* asserted, to say that Petitioners sold Zantac in California "with the same label" that appeared on the generic product. App.30. If Petitioners had *never* marketed Zantac in California, under Plaintiffs' theory that fact would not diminish Petitioners' substantive warning-label liability one bit. As long as generic manufacturers sold their own ranitidine products in California, Petitioners would face warning-label liability claims because of their control of the brand-name label—which is a single, nationwide label approved by the FDA—regardless of whether they ever sold their own medications in California. Conduct with no bearing on a plaintiff's theory of liability does not sufficiently "relate to" a plaintiff's claims.

Nor does *Ford* provide any support for asserting specific jurisdiction over Petitioners, as the superior court and *Whaley* thought. *Ford* held that a company's sale of products in a forum may allow specific jurisdiction for injuries caused by similar products sold by *that same company*, but that logic does not extend to injuries involving products sold by *a different company*.

Specifically, *Ford* allowed plaintiffs injured in Minnesota and Montana by their second-hand Ford vehicles to sue Ford in those states—even though Ford had not made the initial sales of those vehicles in those states—because at the end of the day "Ford did substantial business in [those] State[s]" by "among other things, advertising, selling, and servicing the

model of vehicle the suit claims is defective." 592 U.S. at 355. In drawing this relationship between the plaintiffs' defective vehicles and Ford's promotion of the same car models in Minnesota and Montana, however, this Court repeatedly stressed that *all* the vehicles were Ford's products: "Ford … encourages a resale market for *its* products." *Id.* (emphasis added). "Ford urges Montanans and Minnesotans to buy *its* vehicles." *Id.* at 365 (emphasis added). "[A] company th[at] purposefully avail[s] itself of [a state's] auto market 'has clear notice' of its exposure in that State to suits arising from local accidents involving *its* cars." *Id.* at 363 (emphasis added and citation omitted). Simply put, it was Ford's "systematic[] serv[ing of] a market in [the forum states] for *the very vehicles* that the plaintiffs allege malfunctioned and injured them in those States" that created the "strong relationship between the defendant, the forum, and the litigation" and provided "the essential foundation of specific jurisdiction." *Id.* at 365 (emphasis added and citation omitted).

A basic counterfactual proves the point. Consider if the plaintiffs in *Ford* had purchased used Chevrolets—not Fords—but then tried to sue Ford in Minnesota and Montana on the theory that Chevrolet had copied Ford's allegedly defective vehicle designs. Their suits would not have made it past a motion to dismiss, let alone to this Court. Ford's contacts in Minnesota and Montana were designed to "foster[] an ongoing relationship between Ford and *its* customers" and "encourage Montanans and Minnesotans to become lifelong *Ford* drivers." *Id.* at 356, 365 (emphases added). An injury to a Chevrolet driver has no relationship to those contacts.

Second, even if there were a plausible relationship between Petitioners' sale of their own medications in California and the warning-label liability claims involving competitors' generic medications, basic principles of "fair[ness]" would preclude specific jurisdiction. *Id.* at 360. Specific jurisdiction is "founded … on an idea of reciprocity between a defendant and a State." *Id.* And the defendant must have the ability to "structure its primary conduct to lessen or avoid exposure to a given State's courts," as well as the right to "sever[] its connection with the State." *Id.* at 360, 364.

Allowing plaintiffs who purchased a competitor's product to sue the brand-name manufacturer in their home states violates these principles at every turn. To begin, there is nothing fair about requiring a brand-name manufacturer who *lost* a sale to a competitor to defend a claim involving the competitor's product in the state where that sale was made. The competitor walks away with the plaintiff's money and no liability, while the brand-name manufacturer is forced to defend its competitor's product in a foreign forum. There is no relevant "benefit[]" to the brand-name manufacturer from the sale of the generic drug in the forum state, let alone one that can support a "reciprocal obligation[]" to defend claims concerning those generic products. *Id.* at 367–68. All the more so because the volume of litigation arising from generic sales will often dwarf that from brand-name sales, given that generics occupy over 90% of the prescription-drug market. 2022 Annual Rep., *supra* n.1, at 1. Any purported "reciprocal" relationship between the brand-name manufacturer's profits and

the brand-name manufacturer's litigation risk is, therefore, grossly disproportionate.

Moreover, the brand-name manufacturer has little ability to "avoid exposure" or "sever[] its connection with the State." *Ford*, 592 U.S. at 360, 364. Needless to say, a brand-name manufacturer is powerless to stop its competitors from selling their allegedly offending products in California—even if it would very much like to.

The decision below illustrates this powerlessness and resulting unfairness. Under California's version of warning-label liability, a brand-name company can remain liable for alleged deficiencies in the generic label even *after* the company transfers the NDA (and thus the ability to update the drug's label) to another brand-name manufacturer—purportedly because it is foreseeable to the original manufacturer that the subsequent owner will rely on its predecessor's labeling decisions.[8] In this case, for example, plaintiffs who first started using over-the-counter Zantac in the 2010s have brought warning-liability claims against GlaxoSmithKline, which relinquished the approval for over-the-counter Zantac and stopped selling the product in California (or anywhere else) in 1998. Yet according to the superior court, GlaxoSmithKline is subject to specific jurisdiction for

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[8] *See T.H.*, 407 P.3d at 23, 40–47 (permitting liability for the company that "stopped manufacturing [the drug] and sold all rights to the drug in 2001, six years before plaintiffs' injury"). Three justices dissented from this aspect of the ruling, noting that it "would extend indefinitely a drug manufacturer's duty to warn." *Id.* at 48 (Corrigan, J., dissenting).

those claims because of activities that it ceased more than a decade before the claims arose.

The upshot of this rule is that, once a brand-name manufacturer sells its own products in California, it may remain subject to specific jurisdiction for warning-label claims *forever*, even if it cuts ties with the state, surrenders control of the brand-name medication, and stops selling the medication altogether. As long as *generic* companies independently decide to keep selling their products in California, new warning-label liability claims will arise, and brand-name manufacturers will face specific jurisdiction based on their past sales. That sort of perpetual personal jurisdiction violates the Due Process Clause, which guarantees out-of-state defendants the right to "do something about th[eir] exposure." *Ford*, 592 U.S. at 363–64 (citing *World–Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980)).

CONCLUSION

The answer to the question presented is straightforward: a brand-name manufacturer's sale of *its own* product in a state neither relates to, nor is a fair basis for that state asserting jurisdiction over, claims involving generic products sold by competitors. The answer to this question, which will often evade review, has enormous consequences for the structure of nationwide pharmaceutical product-liability litigation. This Court should grant review and reverse.

Respectfully submitted,

JUNE 14, 2024

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