IN THE
SUPREME COURT OF THE UNITED STATES

No. ___

GLAXOSMITHKLINE, LLC, PFIZER INC., BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM USA CORPORATION, SANOFI US SERVICES INC., AND SANOFI-AVENTIS U.S. LLC,

Applicants,

v.

SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA,

Respondent.

APPLICATION TO THE HON. ELENA KAGAN FOR AN EXTENSION OF TIME WITHIN WHICH TO FILE A PETITION FOR A WRIT OF CERTIORARI TO THE COURT OF APPEAL OF CALIFORNIA, FIRST APPELLATE DISTRICT

Pursuant to Supreme Court Rule 13(5), GlaxoSmithKline LLC, Boehringer Ingelheim Pharmaceuticals, Inc., Pfizer Inc., Boehringer Ingelheim USA Corporation, Sanofi US Services Inc., and Sanofi-Aventis U.S. LLC (petitioners-defendants below, hereinafter "Applicants"), hereby move for an extension of time of 60 days, to and including June 14, 2024, for the filing of a petition for a writ of certiorari. Unless an extension is granted, the deadline for filing the petition for certiorari will be April 16, 2024.

In support of this request, Applicants state as follows:

1. Applicants' forthcoming petition for a writ of certiorari arises from the coordinated proceedings in California state court of the cases of hundreds of plaintiffs

who allege that their use of the popular antacid medication Zantac (with the active ingredient ranitidine), and/or its generic equivalents, caused them to develop cancer.

2. Many of the plaintiffs in the coordinated proceedings seek to hold Applicants, each of which formerly held the rights to market brand-name Zantac, liable for injuries allegedly caused by generic ranitidine, which was manufactured and sold by other companies. Under this Court's decision in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), failure-to-warn claims against generic manufacturers are preempted because federal law requires generic drugs to bear the same label as the brand-name product. Since *Mensing*, many plaintiffs who allege injuries from generic drugs have sought to avoid preemption by filing suit against brand-name companies under a theory called "warning-label liability" or "innovator liability." According to the theory, a brand-name company can be held liable for injuries allegedly caused by a generic drug—even though the brand had no role in manufacturing, marketing, or selling that drug—because the brand is responsible for any alleged inadequacies in the label of other companies' generic product.

3. The "overwhelming national consensus" rejects warning-label liability on the ground that holding a company liable for injuries allegedly caused by a different company's product violates "traditional common law tort principles." *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1285 (10th Cir. 2013). But some courts, including the Supreme Court of California, have chosen to adopt warning-label liability. *See T.H. v. Novartis Pharms. Corp.*, 407 P.3d 18 (Cal. 2017).

4. State courts may be free to adopt warning-label liability as a matter of substantive state law, but the Due Process Clause bars them from imposing liability on an out-of-state company for injuries allegedly caused by a product that an independent third party sold in the forum. A court cannot assert specific personal jurisdiction over a brand-name company based on the *generic* company's decision to market and sell its products in the forum. And the brand-name company's promotion and sale of *its own* products in the forum cannot support specific jurisdiction either, because claims based on the use of generic drugs do not "arise out of or relate to" activities regarding brand-name products. *Ford Motor Co. v. Montana Eighth Judicial Dist. Ct.*, 592 U.S. 351, 359 (2021); *see also Bristol–Myers Squibb Co. v. Superior Ct. of Cal., San Francisco Cty.*, 582 U.S. 255, 262 (2017) (finding defendant's efforts to promote the drug at issue could not support specific jurisdiction over otherwise unrelated claims).

5. Accordingly, in June 2021, the federal court overseeing the Zantac multi-district litigation dismissed all warning-label liability claims filed in jurisdictions outside Applicants' home states for lack of personal jurisdiction. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, 546 F. Supp. 3d 1192 (S.D. Fla. 2021). The MDL court applied this Court's decision in *Ford Motor Company v. Montana Eighth Judicial District Court*, 592 U.S. 351 (2021), and determined there was no basis for specific jurisdiction in most States, including California, because the only activities by brand-name companies that "relate to" warning-label liability claims are the companies' labeling decisions, which take place in the States where they have their

headquarters. 546 F. Supp. 3d at 1213. The brands' efforts to promote and sell their own products in States like California have nothing to do with the innovator-liability theory, and thus are not "jurisdictionally relevant" activities. *Id*. (quoting *Walden v. Fiore*, 571 U.S. 277, 289 (2014)).

6. Several federal district courts in California, however, have subsequently disagreed with the MDL court's analysis and asserted specific jurisdiction over warning-label liability claims. *See, e.g.*, *Whaley v. Merck & Co.*, No. 3:21-cv-1985, 2022 WL 1153151 (S.D. Cal. Apr. 11, 2022); *Leon v. URL Pharma, Inc.*, No. 2:22-cv-8539, 2023 WL 6119112 (C.D. Cal. Sept. 15, 2023).

7. In this litigation, Applicants moved to quash all warning-label liability claims in cases selected for bellwether discovery and trial on February 14, 2022. The superior court initially found the MDL court's reasoning "persuasive" and granted the motion on July 25, 2022. (Exhibit 1). But the superior court subsequently granted reconsideration and, siding with the California federal district courts, denied the motion to quash on December 8, 2022. (Exhibit 2).

8. Applicants filed a petition for a writ of mandate reversing the denial of the motion to quash in the California Court of Appeal on December 21, 2022. The Court of Appeal summarily denied the petition on October 23, 2023, stating that "Petitioners have failed to establish that the superior court erred in denying their motion to quash." (Exhibit 3).

9. Applicants then filed a petition for review in the California Supreme Court, which was denied on January 17, 2024. (Exhibit 4).

10. The superior court's split decision in this case—initially agreeing with the MDL court's analysis and granting Applicants' motion to quash; then reversing itself, siding with certain federal district courts in California, and denying the motion—illustrates the need for clarity on the jurisdictional requirements for warning-label liability claims.

11. Warning-label liability claims are now fixtures of pharmaceutical product-liability litigation, particularly mass-tort litigation that clogs the federal courts' dockets. Whenever the patent for a drug expires, generic alternatives to the brand-name product soon acquire a significant share of the market. In any litigation involving a drug that has been on the market long enough, therefore, a substantial share of the plaintiffs will be users of generic products, who will bring warning-label liability claims against the brand-name defendants unless squarely foreclosed by the applicable state law.

12. Despite the frequency with which it arises, the jurisdictional question raised by warning-label liability claims tends to evade appellate review. When a court denies a motion for lack of personal jurisdiction, in most jurisdictions, interlocutory review is unavailable. The Court has an opportunity to intervene in this case only because in California, unlike in federal court and most state courts, challenges to personal jurisdiction can *only* be reviewed through an interlocutory petition. Even when a court grants a motion to dismiss warning-label liability claims, an appeal will typically be premature because other claims will remain in the litigation—either because the individual plaintiff also alleges use of brand-name

products, or because the court is overseeing an MDL or other coordinated proceeding in which many other plaintiffs took the brand-name drug. In most jurisdictions other than California, appellate review is possible after final judgment, but in practice the "vast majority" of the mass-tort cases that feature warning-label liability claims are "resolved by 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.).

13. This Court's intervention is necessary to resolve the division of authority regarding the power of state courts to assert specific jurisdiction over warning-label liability claims—a recurring question with enormous consequences for pharmaceutical product-liability litigation. Otherwise, courts in California and other jurisdictions recognizing warning-label liability will continue to assert jurisdiction against out-of-state defendants to adjudicate claims concerning products the defendants had no role in manufacturing or selling.

14. There is good cause to grant an extension, which will give Applicants and their counsel adequate time to coordinate with one another and properly to prepare a petition. An extension to June 14, 2024 would accommodate the undersigned counsel's obligations in other matters, including *inter alia* a four-week trial in the District of New Jersey from March 18 to April 12, 2024 (*In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, D.N.J. No. 10-md-2875), oral argument in the Supreme Court of Delaware on April 17, 2024 (*Dematic Corp. v. Fortis Advisors, LLC*, Del. No. 180, 2023) and on a motion to dismiss in the Delaware Court of

Chancery on March 18, 2024 (*In re SwervePay Acquisition LLC*, Del. Ct. Ch. No. 2022-447). In the absence of an extension, those obligations and others will significantly impede counsel's ability to assist Applicants in preparing a well-researched and comprehensive petition that would assist the Court in evaluating the decisions of the California state courts in this matter. An extension will also give adequate time for each of the Applicants to review and approve the petition before filing.

15. Applicants thus request a 60-day extension for Applicants to prepare a petition that fully addresses the important issues raised by the decision below and that frames the issues in a manner that will be most helpful to the Court.

WHEREFORE, for the foregoing reasons, Applicants request that an extension of time to and including June 14, 2024, be granted within which Applicants may file a petition for a writ of certiorari.

Respectfully submitted,

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RULE 29.6 STATEMENT

Applicant 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.

Applicant 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.

Applicant 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.

Applicant 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.

Applicants Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC are indirect subsidiaries of Sanofi, a *société anonyme* organized under the laws of France and traded on the Paris Stock Exchange and NASDAQ. Sanofi owns 100% of the stock in both Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC.