No. _____

IN THE SUPREME COURT OF THE UNITED STATES

TAKEDA PHARMACEUTICAL CO. LTD., ET AL.

Applicants,

v.

PAINTERS & ALLIED TRADES DISTRICT COUNCIL, 82 HEALTH CARE FUND, ET AL.

Respondents.

APPLICATION TO THE HON. ELENA KAGAN FOR AN EXTENSION OF TIME WITHIN WHICH TO FILE A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Pursuant to Supreme Court Rule 13(5), Takeda Pharmaceutical Co. Ltd., Takeda Pharmaceuticals U.S.A. Inc., and Eli Lilly and Company (collectively, "Applicants"), hereby move for an extension of time of 30 days, to and including December 6, 2025, 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 November 6, 2025.

In support of this request, Applicants state as follows:

1. The United States Court of Appeals for the Ninth Circuit rendered its decision on June 16, 2025 (Exhibit 1), and denied a timely petition for rehearing on August 8, 2025 (Exhibit 2). This Court has jurisdiction under 28 U.S.C. §1254(1).

2. This case concerns the certification, under Federal Rule of Civil Procedure 23(b)(3), of an allegedly multi-billion-dollar fraud class. In 1999, Applicant Takeda obtained approval from the Food and Drug Administration ("FDA") for Actos, a treatment for type-2 diabetes. D.Ct.Dkt.127 at 8, 11. Since its approval, Actos' FDA-approved label has disclosed a potential link between use of the treatment and an increased risk of bladder cancer. *See* D.Ct.Dkt.247 at 5-6. In 2010, the FDA issued a "Drug Safety Communication" that again highlighted this potential connection, but stated that, "[a]t this time, FDA has not concluded that Actos increases the risk of bladder cancer." *Id.* (emphasis omitted). A year later, the FDA approved a new label for Actos that reflected new data available, and it once again noted that, while recent studies suggested a potential risk of bladder cancer, there was "insufficient data" to definitively establish a causal relationship between the two. *Id.* at 6.

3. In 2014, respondent Painters & Allied Trades District Council, 82 Health Care Fund ("Painters") brought this RICO action seeking billions in damages for Applicants' supposed concealment of information about Actos' side effects. D.Ct.Dkt.1. Painters does not allege that it was harmed by taking Actos. Instead, it posits that Applicants knew about the risks that were "revealed" in 2010 but hid them from the public, thereby encouraging millions of physicians across the nation to overprescribe Actos—and, in turn, causing thousands of third-party payors ("TPPs") like Painters to reimburse those prescriptions. *See* D.Ct.Dkt.229 at 22-28. Painters accordingly sought to certify a class comprising all TPPs that reimbursed five or more Actos prescriptions from 1999 to 2010. *Id.* at 3-4.

4. Under basic Rule 23 principles and this Court's caselaw, it should have been easy to conclude that this is not the stuff of class-wide litigation. For one thing, both Article III and RICO require that each plaintiff seeking to recover individual damages show that she has suffered an injury. *See TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021); 18 U.S.C. §1964(c). This Court, too, has recognized many times that a plaintiff seeking class certification must show that the class as a whole "suffer[ed] the same injury." *E.g.*, *E. Tex. Motor Freight Sys., Inc. v. Rodriguez*, 431 U.S. 395, 403 (1977). Painters nonetheless acknowledges that at least some, and potentially many, class members suffered no injury at all, much less the same injury as their fellow travelers. D.Ct.Dkt.247 at 11. And the fact that class members could have avoided injury in various ways—*e.g.*, because physicians would have prescribed Actos even if "fully" informed of its risks—only drives the point home. *See id.*

5. In a similar vein, this Court's decision in *Wal-Mart Stores, Inc. v. Dukes* warns courts against amalgamating highly individualized actions that cannot be adjudicated on a class-wide basis except via "[t]rial by [f]ormula." 564 U.S. 338, 367 (2011). That, however, is precisely what Painters proposed here. As mentioned, RICO requires a showing that the individual seeking to recover suffered injury to their "business or property," and that such injury came about "by reason of" the alleged misconduct. 18 U.S.C. §1964(c). This Court has further held that causation requires a RICO plaintiff to show that "someone relied on the defendant's misrepresentations." *Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. 639, 658 (2008). Given the highly personal nature of these elements, fraud claims like the ones

asserted here are generally "unsuited for treatment as a class action." Fed. R. Civ. Pro. 23, advisory committee's note to 1966 amendments.

6. Recognizing that it would be impossible to prove actual injury and causation for each class member without needing thousands of mini trials, Painters proposed to square that circle through an expert report purporting to show that TPPs that reimbursed five or more "independent" Actos prescriptions had a 98.5% chance of having been harmed. D.Ct.Dkt.229 at 30-31. The report did not perform a regression analysis for the entire decade covered by the class period or include all possible independent variables, and it wrongly assumed that any one prescription was independent of another. Absent that key assumption, the report's author stated that nearly half of Actos prescriptions written from 1999-2010 would have been written even if Applicants had not "concealed" the drug's risks. D.Ct.Dkt.247 at 39.

7. Despite the apparent predominance of member-specific issues, the district court certified the TPP class. *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 674 F.Supp.3d 799 (C.D. Cal. 2023). To its credit, the court admitted that Applicants would be entitled to depose tens of thousands of physicians to challenge Painters' showings of class-wide injury and causation. *Id.* at 829-30. It also said that there was a "real and significant risk … that individualized factual determinations would swamp common ones." *Id.* at 830. Indeed, in the district court's estimation, it was an "open question whether a class of TPPs [can] successfully leverage common evidence of the kind offered here … without running into the need for individualized analysis." *Id.* at 828-29.

8. Under this Court's caselaw, that should have been the end of this inquiry. But under Ninth Circuit governing law, a class may be certified regardless of how many class members were unharmed—and thus unable to recover or even get into federal court—and regardless of whether the plaintiff has offered a common method for removing such members before trial. *See Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 669 (9th Cir. 2022) (en banc); *Ruiz Torres v. Mercer Canyons Inc.*, 835 F.3d 1125, 1137 (9th Cir. 2016). When it comes to representative proof, moreover, the Ninth Circuit has made it clear that courts within the circuit need not "rigorously analyze" such proof at all at the certification stage. *Senne v. Kansas City Royals Baseball Corp.*, 934 F.3d 918, 947 (9th Cir. 2019). Applying that precedent, the district court certified the TPP class, even though thousands of TPPs were, by all accounts, uninjured. *Painters & Allied Trades*, 674 F.Supp.3d at 823-24. In doing so, the district court simply accepted "at face value" Painters' expert report, without "prejudg[ing] its accuracy," ignoring the report's flaws and its inability to serve as common proof here. *Id.* at 824 & n.88.

9. A split panel of the Ninth Circuit affirmed. Like the district court, the majority more or less accepted Painters' expert report at face value, simply describing its "findings" without subjecting it to a rigorous assessment. Exhibit A at 6-9. Having accepted the report as common proof, the majority found that common issues predominated because injury and causation could be established via expert report. *Id.* at 10. The court also reaffirmed that a class may be certified even if it contains

uninjured members, and made clear that it sees no need for a "trial plan to screen out" the thousands of uninjured TPPs in this case. *Id.* at 11.

10. Judge Miller dissented. He described why the flawed report could not serve as common proof and why individualized inquiries into the millions of prescribing decisions would be necessary and would thus swamp any common issues in the case. Exhibit A, Dissent at 9-14. Painters, Judge Miller perceived, was effectively seeking certification of a fraud-on-the-market class, minus the presumption that makes such an action viable elsewhere. *Id.*, Dissent at 1.

11. Applicants intend to file a petition for certiorari demonstrating that the decision below deepens a well-recognized split, creates a new one, and is irreconcilable with Rule 23 and this Court's precedents to boot.

12. The Ninth Circuit's decision here exacerbates a deep split over whether and in what circumstances classes containing uninjured members may be certified under Rule 23(b)(3). Whereas most circuits either refuse to certify such classes or certify only if the portion of unharmed class members is *de minimis* and there is a class-wide winnowing mechanism, the Ninth, Seventh, and Eleventh Circuits permit certification of classes with more than a small number of uninjured members. *See, e.g.*, *Olean*, 31 F.4th at 669; *Kohen v. Pac. Inv. Mgmt. Co.*, 571 F.3d 672, 677 (7th Cir. 2009); *Cordoba v. DIRECTV, LLC*, 942 F.3d 1259, 1277 (11th Cir. 2019). This Court has twice granted certiorari on this significant issue, *see Lab. Corp. of Am. Holdings v. Davis*, 145 S.Ct. 1133 (2025); *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442 (2016), and this petition will offer a clean opportunity to finally provide an answer.

13. The decision below also creates a new split over whether representative evidence may be used to establish predominance when liability depends on a chain of independent individual actions. The Ninth Circuit, as this case exemplifies, believes that the answer to that question is yes. For that court, this is simply a question of whether the representative evidence proffered is sophisticated enough to show that there is a high probability that the class members suffered injury as a result of unlawful conduct. *See* Exhibit A at 4-6. Other courts, heeding this Court's teachings from *Wal-Mart*, hold that certain claims require such individualized proof that no amount of representative evidence is capable of establishing predominance. The Second Circuit, for example, vacated an order certifying a class identical to the one here because, under its prior precedents, elements like causation and reliance are not amenable to class-wide proof. *See UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010). As the court there explained, the "nature" of the showing needed to establish those elements "thwarts any attempt to" establish predominance "through generalized proof." *Id*. at 135.

14. Applicants' counsel, Paul D. Clement, was not involved in the proceedings below and requires additional time to prepare a petition that fully addresses the important issues raised by the decision below in a manner that will be most helpful to the Court. Mr. Clement has substantial argument obligations between now and November 6, 2025. He is scheduled to present oral argument before Sixth Circuit on October 23, 2025, in *In re: East Palestine Train Derailment*, No. 25-3342 (6th Cir.); and the Second Circuit on October 29, 2025, in *Petersen Energia*

Inversora, S.A.U. v. Argentine Republic, No. 23-7463 (2d Cir.). Mr. Clement also has substantial briefing obligations, including a response brief in *Association of American Universities v. Department of Energy*, No.25-1727 (1st Cir.), due October 24, 2025; a petition for rehearing in *Finesse Wireless LLC v. AT&T Mobility LLC*, No.24-1039 (Fed. Cir.), due on October 24, 2025; and an opening brief in *United States v. Pramaggiore*, No. 25-2463 (7th Cir.), due November 14, 2025. Applicants' counsel thus requests a modest extension.

WHEREFORE, for the foregoing reasons, Applicants request that an extension of time to and including December 6, 2025, be granted within which Applicants may file a petition for a writ of certiorari.

Respectfully submitted,

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