No. 13-956

IN THE
Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC., BARR PHARMACEUTICALS LLC, BARR LABORATORIES, INC., AND CARACO PHARMACEUTICAL INDUSTRIES, LTD.,

Petitioners,

v.

THE SUPERIOR COURT OF ORANGE COUNTY
(OLGA PIKERIE, *Plaintiff and Real Party in Interest*),

Respondent.

On Petition for Writ of Certiorari to the Court of Appeal of California For The Fourth Appellate District

REPLY TO BRIEF IN OPPOSITION

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INTRODUCTION

Plaintiff does not credibly dispute that the courts are split on the question presented because she cannot do so. After all, the appellate court admitted that its decision deepened a pre-existing split over the viability of state tort claims based on a generic drug manufacturer's alleged failure immediately to implement or otherwise disseminate newly approved warnings, *see* Pet. 19-21 & 32-33, and plaintiff never even attempts to address the broader split over the scope of this Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). *See* Pet. 25-26, 27-28. Nor does plaintiff meaningfully defend the appellate court's decision on the merits. Instead, her principal contention is that this Court lacks power to review the appellate court's decision because this case remains pending (along with nearly 200 coordinated cases this decision also controls). That assertion is meritless.

As plaintiff ultimately concedes, pending state-court proceedings do not bar review where "'reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action,' and 'refusal immediately to review the state-court decision might seriously erode federal policy.'" BIO 7 (quoting *Cox Broad. Corp. v. Cohn*, 420 U.S. 469, 482-83 (1975)) (further quotation omitted). Accordingly, this Court regularly exercises jurisdiction over interlocutory state-court decisions rejecting claims of federal preemption—including interlocutory decisions from the California Court of Appeal (as it did earlier *this Term*). *See, e.g.*, *CarMax Auto Superstores Cal., LLC v. Fowler*, 134 S.

Ct. 1277 (2014); *see also Preston v. Ferrer*, 552 U.S. 346 (2008).

Those authorities govern here. Reversing this decision would terminate the nearly 200 failure-to-update cases it controls (along with literally *thousands* of similar claims pending nationwide, *see* Pet. 22). Nor is there any question that letting these claims proceed "might seriously erode federal policy." As *Buckman* itself recognized, "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [statute]: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" 531 U.S. at 349 n.4 (second alteration in original; quoting 21 U.S.C. § 337(a)); *see also* Pet. 29-31.

This Court has jurisdiction, and given the conceded split on a question that affects literally thousands of cases, there is no basis for leaving the appellate court's evisceration of *Mensing* intact.

ARGUMENT

A. This Court Has Jurisdiction.

This Court long has taken a "pragmatic approach [to] determining finality" under 28 U.S.C. § 1257. *Cox*, 420 U.S. at 486-87. And as plaintiff admits, *Cox* and its progeny deem four well-defined categories of otherwise interlocutory decisions subject to this Court's jurisdiction—including cases where "'reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action,' and 'refusal immediately to review

the state-court decision might seriously erode federal policy.'" BIO 7 (quoting *Cox*, 420 U.S. at 482-83).

Because a federal preemption defense necessarily implicates important federal policies and by definition would terminate state-court proceedings, this Court repeatedly has reviewed interlocutory state-court decisions rejecting claims of federal preemption. *See, e.g.*, *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 177-79 (1988) (reviewing state-court decision rejecting preemption under the Atomic Energy Act despite pendency of remanded claims); *Belknap, Inc. v. Hale*, 463 U.S. 491, 497 n.5 (1983) (reviewing state-court decision rejecting preemption under the NLRA despite pendency of remanded claims); *Hudson Distribs., Inc. v. Eli Lilly & Co.*, 377 U.S. 386, 388-89 & n.4 (1964) (reviewing state-court decision rejecting preemption under the FTC Act despite pendency of remanded claims); *Local 438 Constr. & Gen. Laborers' Union v. Curry*, 371 U.S. 542, 548-49 (1963) (reviewing state court preliminary injunction that rejected federal preemption claims).

The result should be no different here. As in those cases, reversing the appellate court's rejection of petitioners' preemption defense would end this case (along with nearly 200 companion cases this decision governs). Nor is there any doubt that these 200 cases "might seriously erode federal policy." *Cox*, 420 U.S. at 483. After all, Congress explicitly barred private parties from attempting to enforce the FDCA because doing so undermines the exclusive enforcement discretion Congress granted FDA and the "flexibility [through] which the FDA pursues difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349; *id.* at 349 n.4 ("The FDCA leaves no

doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance."); *id.* at 352 ("Congress intended that the [FDCA] be enforced exclusively by the Federal Government.").

Plaintiff claims those authorities are inapplicable "because the California Supreme Court did not address the merits of the issue here." BIO 7. But this Court has never construed § 1257 as barring its jurisdiction to review intermediate state-court decisions—including interlocutory ones—after a state Supreme Court denies discretionary review (least of all when three of the court's seven justices were recused, *see* Pet. App. 33a). In *Belknap*, for instance, this Court held that its "jurisdiction to affirm or reverse the Kentucky Court of Appeals on the preemption issue … is clear" despite the Kentucky Supreme Court's failure to review and decide the preemption question first. 463 U.S. at 497 & n.5. Only months ago, this Court exercised its § 1257 jurisdiction to GVR a petition and decision from the same court that issued this ruling, *CarMax*, 134 S. Ct. at 1277, despite pending proceedings; the California Supreme Court's failure to act; and the BIO's jurisdictional challenge. *See* BIO, *CarMax*, 2014 WL 230916 (filed Jan. 17, 2014). And this Court likewise has exercised plenary review over interlocutory California Court of Appeal decisions despite the state high court's lack of review. *See Preston*, 552 U.S. at 351. Those authorities foreclose any claim that § 1257 bars review here.

As a result, plaintiff ultimately claims that denying review here might "not seriously erode federal policy," since "the FDCA is [intended] to

protect the health and safety of consumers." BIO 7. But as this Court held in *Buckman*—which likewise involved state-law claims seeking compensation for injuries from products that allegedly violated the FDCA, 531 U.S. at 346-47—Congress determined that the FDCA's policies are best served by granting *the federal government* exclusive power to seek liability for alleged violations of the *federal laws* that govern these *federally-regulated* products: "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [FDCA]." 531 U.S. at 349 n.4; *id*. at 352 ("Congress intended that the [FDCA] be enforced exclusively by the Federal Government.").

Plaintiff of course disagrees with this assessment (as this Court might when it reaches the merits). But such disagreement has no bearing on this Court's jurisdiction. As *Belknap* noted when it *affirmed* the state intermediate court's rejection of a preemption defense, the fact that the Court might "affirm rather than reverse, thereby holding that federal policy would not be subverted by the Kentucky proceedings, is not tantamount to a holding that we are without power to render such a judgment; nor does it require us to dismiss this case." 463 U.S. at 497 n.5.

This Court has jurisdiction.

B. The Appellate Court's Conceded Split From Other Appellate Courts Warrants Review.

Plaintiff next tries to minimize the appellate court's deviation from its fellow appellate courts by asserting that the question presented affects only a

few cases. BIO 8-9. That disingenuous claim is meritless. As plaintiff well knows, *thousands* of cases present the precise question presented here—including the nearly 200 cases governed by this ruling, Pet. 12, and several thousand additional failure-to-update cases that have been coordinated in mass proceedings before other state courts and in which plaintiff's own lawyers serve as counsel. Pet. 5 (citing *In re Reglan/Metoclopramide Litig.*, 81 A.3d 80 (Pa. Super. Ct. 2013) (failure-to-update claims by nearly 2300 plaintiffs)); Pet. 22 (referencing *In re Reglan/Metoclopramide Cases*, No. CJC-10-004631 (Cal. Sup. Ct.) (failure-to-update claims by nearly 3000 plaintiffs); *In re Reglan Litig.*, No. ATL-L-3865-10-CT (N.J. Super. Ct.) (failure-to-update claims by nearly 300 plaintiffs); *In re Fosamax Litig.*, Case No. 282 (N.J. Super. Ct.) (failure-to-update claims by more than 200 plaintiffs).

It is no surprise that so many cases present this issue. Generic drugs are widely prescribed, and branded labeling changes are common (indeed, FDA approved at least eleven labeling revisions last week alone, FDA, *New and Generic Drug Approvals*, *available at* http://tinyurl.com/FDA-Labeling-Revisions (verified June 9, 2014)). But as the Petition explained, it is practically impossible for generic manufacturers to update their labeling the same day FDA approves new branded versions, and FDA long has exercised its enforcement discretion by declining to target the inevitable gaps between its approval of a branded labeling change and the implementation of the approved change by generic drug manufacturers. Pet. 3. Even so, the novel failure-to-update theory now being pursued in these

many thousands of cases would allow for the imposition of state tort liability whenever a generic manufacturer fails immediately to update and disseminate the new labeling—even after a single day's lag.

Plaintiff nonetheless asserts that this issue soon "will be moot" because FDA recently *proposed* a regulation that in certain circumstances would let generic manufacturers alter their labeling without FDA pre-approval. BIO 9-10. But that proposal is not retroactive, so it would have no impact on the thousands of pending failure-to-update cases noted above. Pet. 11-12 n.1. And it is far from clear that FDA will implement that proposal anyway. Insofar as it would let generics "add new safety warnings at any time … without FDA pre-approval," BIO 9, it conflicts directly with the statute's sameness requirement for generic product labeling—as the Solicitor General recognized and this Court held in *Mensing* and *Bartlett*. *See, e.g.*, *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2480 (2013) (finding federal preemption based on "*Congress's decision* to regulate the manufacture and sale of generic drugs in a way that … leaves generic drug manufacturers incapable of modifying either the drugs' compositions or their warnings") (emphasis added); Br. for the United States as *Amicus Curiae*, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, at 20 (filed Mar. 2, 2011) (rejecting plaintiffs' claims that generic drug manufacturers can unilaterally alter their labeling and noting the "*statutory mandates* that a generic drug … bear labeling [that is] 'the same as the labeling approved for the [branded equivalent],' 21 U.S.C. § 355(j)(4)(G).") (emphasis added).

Given the obvious conflict between the Agency's proposal and Hatch-Waxman's plain language, FDA in March received scores of comments condemning the proposed regulation. In April, Congress erupted when FDA testified that it proposed this rule after privately consulting with the plaintiffs' bar—*but not with physicians, pharmacists, or industry*. Letter from House Energy & Commerce Comm. to Hon. M. Hamburg, Apr. 22, 2014, at 2, *available at* http://tinyurl.com/Upton-Letter (quoting testimony by FDA) (verified June 9, 2014). And last month, the House declared that it "is deeply concerned with FDA's proposed rule" because it "fails to provide a net health benefit to consumers and providers," and therefore ordered FDA to report back to Congress before proceeding. H. COMM. ON APPROPRIATIONS, 113TH CONG., AGRICULTURE, RURAL DEVELOPMENT, FDA, AND RELATED AGENCIES APPROPRIATIONS BILL OF 2015, at 60-61 (Comm. Print 2014). Put simply, the uncertain future of FDA's proposal provides no basis for forcing the generic industry to face the *in terrorem* threat of liability in literally thousands of pending cases that the proposed rule would not affect even if it were adopted over widespread public and Congressional objection.

Plaintiff's attempt to downplay the circuit split on this question is equally meritless. She first asserts that the Fifth Circuit's decision in *Morris v. PLIVA, Inc.*, 713 F.3d 774 (2013), does not actually conflict with this decision or *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013), because it was based on pleading inconsistencies rather than "a conflict preemption analysis on the failure to update issue." BIO 11. That assertion is frivolous. Though *Morris* did cite the "logical[] incoheren[ce]" of plaintiffs'

claims as *one reason* why such claims would be futile, it *also* held that § 337(a) and *Buckman* squarely preempt such claims: "Second, a claim that PLIVA breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted. 21 U.S.C. § 337(a); *see Buckman*, 531 U.S. at 349 n.4." 713 F.3d at 777 (internal citation shortened). Plaintiff never acknowledges that independent holding, which the Fifth Circuit recently reiterated. *Lashley v. Pfizer, Inc.*, __ F.3d __, 2014 WL 661058, at *3 (5th Cir. Feb. 21, 2014).

Instead, she claims *Morris really* addressed whether generic manufacturers could be held liable for failing to disseminate updated labeling to physicians through direct correspondence. BIO 11. *Morris* certainly rejected such claims as well. Pet. 32-33; *see also Lashley*, 2014 WL 661058, at *2-3. But it is unclear why plaintiff thinks that limiting *Morris* to that holding would help her: After all, the appellate court expressly rejected *Morris*, Pet. App. 27a-28a, and plaintiff herself concedes the Eleventh Circuit subsequently joined *Morris* on this point. BIO 12 (citing *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013)); *see also* Pet. 17-18, 33. So have the Sixth Circuit and the Florida Court of Appeal. *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 398 (6th Cir. 2013) (quoting *Morris*); *Dietrich v. Actavis, Inc.*, __ So.3d __, 2014 WL 2101318, at *1 (Fla. Dist. Ct. App. May 21, 2014) (relying on *Morris* and *Guarino*). Plaintiff says she disagrees with the many cases that reject the decision here, BIO 14—though she never actually responds to the analysis in those decisions, *see* Pet. 32-33—but that is not a reason to deny review in the face of an expressly-

acknowledged split on an issue that affects literally thousands of pending cases nationwide.

In any event, plaintiff's quibbles over the extent of the split in the narrow context of generic-drug liability miss the broader point—which is that questions over *Buckman*'s scope have sharply divided the courts for nearly 13 years. Plaintiff's merits arguments only illustrate the point. She initially asserts that *Buckman* is limited to "pure 'fraud-on-the-FDA' claims," BIO 12; *see also id.* 15, as the appellate court held here. Pet. App. 19a-21a. But as the Petition explained, that narrow view of *Buckman* is impossible to square with the unqualified language of § 337(a), and numerous courts thus have applied *Buckman*'s interpretation of § 337(a) to cases well outside the fraud-on-the-FDA context and in non-generic drug cases. Pet. 25-28 (collecting cases). The appellate court's decision squarely conflicts with those authorities.

Plaintiff next argues that even if *Buckman* extends beyond "fraud-on-the-FDA" claims, it is limited to claims that "d[o] not exist independently under state tort law." BIO 15. But plaintiff never responds to the fact that her complaint relies entirely on petitioners' alleged violations of federal law to ground her claims, Pet. 13-15 (quoting complaint), which in turn led her repeatedly to argue below that petitioners' purported "'violation of a federal regulation … form[s the] basis for a negligence claim under a negligence *per se* evidentiary standard.'" Pet. 25 (quoting plaintiff's briefs). Yet the lower courts regularly reject such claims under § 337(a) and *Buckman,* even outside the generic-drug context. *Id.* 25-26 (citing cases). Plaintiff's claims thus frame

the lower courts' division of authority on this question in the sharpest possible relief.

Plaintiff does not even attempt to downplay the extent of the circuit split on this question. Instead, she asserts those many cases are wrongly decided: In her words, "where the state-law duties parallel federal requirements, as they do here, such claims in 'no way' 'conflict with the federal regulations,' and thus there is no basis 'for them to be impliedly preempted.'" BIO 16 (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010)); *id.* at 13 (asserting that cases rejecting such allegedly parallel claims—including the Fifth Circuit's decision in *Morris*—conflict with *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011)). But again, this disagreement among the lower courts presents an issue for this Court to resolve on the merits, not a basis for denying review in the face of a split that plaintiff's BIO only underscores.

The bottom line is straightforward: Whether viewed narrowly through the lens of claims based on a generic drug manufacturer's alleged failure immediately to implement or otherwise disseminate newly approved warnings, or more broadly through the lens of widespread disagreement over the appropriate scope of preemption under § 337(a) and *Buckman*, the state and federal courts of appeal are deeply and intractably divided—as the appellate court repeatedly acknowledged here. Pet. App. 21a, 27a-28a. Until this Court provides clarity, however, the decision in this case (along with companion mass proceedings involving thousands of cases against dozens of generic manufacturers) threatens to subject the generic drug industry to conflicting

judgments and potentially ruinous liability despite FDA's sensible exercise of its exclusive enforcement discretion. Given the compelling federal interests at stake here, there is no sound reason to defer consideration of the well-developed issues raised by the question presented.

CONCLUSION

For the foregoing reasons, the Court should grant this petition and reverse the judgment.

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Respectfully submitted,

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