No. 13-956

IN THE

Supreme Court of the United States

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

v.

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

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

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the California appellate court correctly applied *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011), by holding that the federal Food, Drug, and Cosmetic Act ("FDCA") did not preempt Plaintiff Olga Pikerie's failure to warn claims against Defendant generic drug manufacturers, where federal regulations required or allowed Defendants to provide updated warnings and safety communications because the brand-name manufacturer had already revised its product labeling.

2. Whether the California appellate court correctly held that Ms. Pikerie's failure-to-warn claims against Defendant generic drug manufacturers are traditional state common-law claims, not "fraud-on-the-FDA" claims preempted under *Buckman Co. v. Plaintifffs' Legal Committee*, 531 U.S. 341 (2001).

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INTRODUCTION

This petition is not appropriate for review due to the Court's lack of jurisdiction over the California appellate court's interlocutory order. But even beyond the jurisdictional flaw, the decision below does not warrant review because the Food and Drug Administration (FDA) has proposed a regulatory revision that, if finalized, will undercut the premise for Petitioners' preemption argument, and because the case does not implicate a conflict among the circuits warranting review.

Petitioners also greatly exaggerate the impact of the decision below, which applies only to claims for injuries caused by a generic drug that occurred after a change to the brand-name labeling. Moreover, the questions are straightforward and correctly decided on the merits.

For these reasons, as discussed more fully below, the Court should deny the petition.

STATEMENT

This action was brought by plaintiff Olga Pikerie for injuries she sustained as a result of ingesting Petitioners' generic sodium alendronate drug products. Sodium alendronate belongs to a family of drugs known as bisphosphonates, and is primarily prescribed for treatment of osteoporosis in postmenopausal women. The brand-name version of the drug is called Fosamax, which is manufactured by Merck.

Long term treatment with sodium alendronate can cause the patient's bones to become brittle leading to an injury called a low impact atypical femur fracture, where the femur bone snaps in half with

minimal or even no trauma. In Ms. Pikerie's case, it occurred when she stood up from a park bench. Warning signs of an impending fracture often include groin or thigh pain, and can be diagnosed with radiographic scans and treated before the fracture occurs. Merck updated its brand-name label in 2010 and again in early 2011 to warn about the risk of femur fracture and the warning signs of an impending fracture. These changes occurred before Ms. Pikerie suffered her injuries, but Ms. Pikerie alleges Petitioners had not made corresponding changes to the labeling of their generic drugs nor had they communicated those changes to Ms. Pikerie's doctors.

Ms. Pikerie filed her action in Orange County Superior Court, and it was coordinated with other individual actions for discovery and pre-trial purposes. Her complaint contains traditional state law tort claims including claims for negligence and strict liability failure to warn about the risk of femur fracture and the warning signs of a fracture.

Petitioners contended in the coordinated sodium alendronate proceedings that this Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) precluded any "failure to warn" claims against it due to the operation of the Supremacy Clause and the doctrine of conflict preemption. Petitioners filed a demurrer, seeking dismissal of Ms. Pikerie's case on the theory that all her claims were preempted under *Mensing*. After full briefing and a hearing, the trial court overruled the demurrer.

To pursue an interlocutory appeal, Petitioners filed a petition for writ of mandate to the state appellate court. The appellate court denied the petition, holding that Ms. Pikerie's claims were not

preempted. The court explained that federal regulations did not make it impossible, prior to Ms. Pikerie's injury, for Petitioners to include in their generic drug labels a warning about femur fracture and warning signs of fracture, because such warning had already been included in the brand-name label. The addition of a warning, therefore, was not barred by the requirement that generic-drug labeling generally be the same as the labeling of the brand-name counterpart. Pet. App. 15a. The court further held that in these circumstances, unlike in *Mensing*, federal regulations allowed Petitioners to send a "Dear Doctor" letter or other communication to Ms. Pikerie's doctors informing them about risks contained in the FDA-approved label. Pet. App. 23a.[1]

The appellate court also rejected Petitioners' argument that Ms. Pikerie's claims are preempted by *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), finding that her claims "are not based on a fraud-on-they-FDA theory, but on state law tort principles of a drug manufacturer's duty to the consumers of its product." Pet. App. 20a.

Petitioners sought review in the Supreme Court of California, which was denied.

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[1] The petition claims, without citation, that one petitioner, Teva, submitted conforming label changes about six weeks after approval of the brand-name change. Pet. Brf. at 14, n.3. Teva never made this unsubstantiated assertion at any time in the trial court or appellate court proceedings. Under California pleading law, Ms. Pikerie's allegation that Teva and the other Petitioners did not update their label until after her injury must be accepted as true for the purposes of considering the demurrer. *Aubrey v. Tri-City Hosp. Dist.,* 2 Cal.4th 962, 966-67 (1992).

REASONS FOR DENYING THE PETITION

I. This Court Lacks Jurisdiction Because the Decision Below Is Not Final.

A. The Decision Is Not Final.

Under 28 U.S.C. §1257(a), this Court has jurisdiction to review "[f]inal judgments or decrees" of state courts. As the Court has explained, this limitation on its certiorari jurisdiction is no mere formality:

> This provision establishes a firm final judgment rule. To be reviewable by this Court, a state court judgment must be final "in two senses: it must be subject to no further review or correction in any other state tribunal; it must also be final as an effective determination of the litigation and not of merely interlocutory or intermediate steps therein. It must be the final word of a final court." *Market Street R. Co. v. Railroad Comm'n of Cal.*, 324 U.S. 548, 551 (1945). As we have recognized, the finality rule "is not one of those technicalities to be easily scorned. It is an important factor in the smooth working of our federal system." *Radio Station WOW, Inc. v. Johnson*, 326 U.S. 120, 124 (1945).

Jefferson v. City of Tarrant, 522 U.S. 75, 81 (1997).

The judgment below is not final in either of the two relevant senses. First of all, it is not an "effective determination of the litigation," but is "merely interlocutory or intermediate." *Id.* The case came to the appellate court on an interlocutory appeal from a trial court decision overruling a demurrer at the

earliest pleading stage. The appellate court affirmed the trial court decision and denied the petition, and so the proceedings are continuing at the trial court level. Pet. App. 28a. The case is far from over.

Secondly, the decision is not one that is "subject to no further review or correction in any state tribunal." *Jefferson,* 522 U.S. at 81. The appellate court heard an interlocutory appeal, and the California Supreme Court denied review. If ultimately Petitioners do not prevail in the case, they could again appeal the issue up through the California state-court system, seeking review by the California Supreme Court, and then by this Court if their appeals in the California system were unsuccessful.

In sum, the decision neither terminates the litigation nor is subject to no further review by the California state court system: It is not the "final word of a final court." *Market Street*, 324 U.S. at 551.

B. No Exception to the Finality Requirement Applies.

This Court has exercised its certiorari jurisdiction over state-court judgments that do not terminate a case in only a "limited set of situations in which we have found finality as to the federal issue despite the ordering of further proceedings in the lower state courts." *O'Dell v. Espinoza*, 456 U.S. 430 (1982) (per curiam). In *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469 (1975), the Court identified "four categories" of such cases. *Florida v. Thomas*, 532 U.S. 774, 777 (2001). This case fits none of those narrow categories.

The first *Cox* category covers cases in which "there are further proceedings – even entire trials –

yet to occur in the state courts but where for one reason or another the federal issue is conclusive or the outcome of further proceedings preordained," and "the judgment of the state court on the federal issue is deemed final" because "the case is for all practical purposes concluded." *Cox*, 420 U.S. at 479. Ms. Pikerie has so far prevailed against Petitioners' demurrer, but will still need to prove each element of her claims in litigation on the merits.

Cox's second category is confined to cases where "the federal issue, finally decided by the highest court in the State, will survive and require decision regardless of the outcome of the future state-court proceedings." *Cox*, 420 U.S. at 480. Here, the federal issue has not been finally decided by the state's highest court, which denied review but could later take up the issue. Moreover, if Ms. Pikerie does not ultimately prevail in the trial court, the federal issue here would not survive and require decision.

Cox category three comprises those unusual "situations where the federal claim has been finally decided, with further proceedings on the merits in the state courts to come, but in which later review of the federal issue cannot be had, whatever the ultimate outcome of the case." *Cox*, 420 U.S. at 481. This category encompasses cases in which state law offers no subsequent opportunity to obtain a court judgment over which this Court could exercise jurisdiction. *Id.* at 481-82. The parties here do not face such a situation. As explained above, Petitioners can seek further appellate review if they do not prevail, and they will also have the opportunity to request that the trial court apply any intervening decision that is determinative of the issue and binding on the court.

Because the California Supreme Court's denial of review "is to be given no weight insofar as it might be deemed that we have acquiesced in the law as enunciated in a published opinion of a Court of Appeal," *Trope v. Katz*, 11 Cal.4th 274, 287 n. 1 (1995), the California Supreme Court could also take up the merits of Petitioners' preemption argument in a later appeal. But even if the California courts in a subsequent appeal were to treat the court of appeal's "interlocutory ruling as 'law of the case,' that determination [would] in no way limit [this Court's] ability to review the issue on final judgment." *Jefferson*, 522 U.S. at 83. The third exception is thus inapplicable. *Id.*

Lastly, "the fourth category of such cases identified in *Cox* … covers those cases in which 'the federal issue has been finally decided in the state courts with further proceedings pending in which the party seeking review' might prevail on nonfederal grounds," and "'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.'" *Nike, Inc. v. Kasky*, 539 U.S. 654, 658-59 (2003) (opinion concurring in dismissal of writ) (quoting *Cox*, 420 U.S. at 482-83). This case falls well outside the fourth category. Again, because the California Supreme Court did not address the merits of the issue here, the issue has not been "finally decided in the state courts."

Moreover, denial of immediate review would not "seriously erode federal policy." The federal policy behind the FDCA is to protect the health and safety of consumers including those who take prescription drug

medications. The state common law claims are intended to compensate patients who are injured as a result of a manufacturer's failure to provide an adequate warning, and so the federal and state policies are aligned. *See Wyeth v. Levine*, 555 U.S. 555, 574, 578 (2009) (noting "state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings," and that the FDA's "longstanding position that state law is a complementary form of drug regulation"). In addition, even the FDA explicitly views its interests are aligned with the issues raised here. As explained below, the FDA has issued a proposed rule to revise its labeling regulations to allow generic manufacturers to initiate labeling changes to include new safety information in the same manner as brand-name manufacturers are currently permitted to do.

A thorough review of the *Cox* categories thus confirms that this case does not in any way present this Court with the opportunity to review "the final word of the court." *Market Street*, 324 U.S. at 551. Consequently, the Court lacks jurisdiction under section 1257(a), and the petition must be denied.

II. Review Is Unwarranted in Light of a Pending FDA Proposal To Revise Its Labeling Regulations.

Petitioners vastly exaggerate the effect of the California appellate court's decision on existing cases and future litigation. The reality is that the California decision applies only to a small subset of current cases – those where the plaintiff's injury occurred *after* a labeling change by the brand-name manufacturer, and even then the plaintiff will have to prove all the

elements of his or her state law tort claims including causation.

Further, in the future, the issue presented here is likely to have even less effect in light of the FDA's pending proposal to revise its labeling regulations. As mentioned above, the FDA has issued a proposal to revise its regulations to extend to generic manufacturers the ability to initiate labeling changes to add new safety warnings at any time to their generic labels without FDA pre-approval. This change will put the generic manufacturers on the same footing as the brand-name manufacturers. The proposed changes were published by the FDA in the Federal Register on November 13, 2013. *See* FDA, *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, 78 Fed. Reg. 67985 (Nov. 13, 2013), and the comment period ended on March 13, 2014. Additionally, the House Committee on Energy and Commerce, Subcommittee on Health held a hearing on the proposed rule on April 1. The FDA has indicated that it intends to finalize the rule by the end of the year.[2]

As noted in *Mensing*, the finding that the plaintiffs' claims against generic manufacturers in that case are preempted while claims against brand-name manufacturers are not "makes little sense …." *Mensing*, 131 S. Ct. 2581; *see id.* ("We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated."). The Court noted that the FDA and

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[2] *See* Unified Agenda of Regulatory and Deregulatory Actions, HHS/FDA, RIN: 0910-AG94 (Spring 2014), at http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201404 &RIN =0910-AG94.

Congress retained their authority to change this result, and the FDA has now initiated that process. As the final rules are expected to be implemented before the end of the year, in such case any decision by this Court if it decides to grant the petition will be moot as to any future conduct by generic manufactures with respect to changes to their generic labels.

III. There Is No Split of Authority That Merits Review.

Petitioners contend that there is a "deepened … circuit split" on its question presented. Pet. Brf. at i. Examination of the cases on which Petitioners rely, however, shows no conflict warranting review.

According to Petitioners, *Fulgenzi v. PLIVA, Inc.,* 711 F.3d 711 F.3d 578 (6th Cir. 2013) and the California appellate decision here conflict with the decisions in *Morris v. PLIVA, Inc*., 713 F.3d 774 (5th Cir. 2013), and *Huck v. Trimark Physicians Group*, 834 N.W.2d 82 (Table) (Iowa Ct. App. 2013), *pet. for review granted*, No. 3-129/12-0596.

Of first note, *Huck* is not a decision "by a state court of last resort." Supreme Ct. Rule 10, subdiv. (a) and (b). To the contrary, *Huck* is currently under review by the Iowa Supreme Court, which heard argument in the case in January 2014. Moreover, the decision is not published, and under Iowa rules of procedure, "[u]npublished opinions or decisions shall not constitute controlling legal authority." Iowa R. App. Pro. 6.904(c) (Mar. 2013). Thus, *Huck* offers no support for Petitioners' claimed conflict and does not support review by this Court.

Moreover, no split amongst the federal circuit courts merits review in this case.

The Sixth Circuit in *Fulgenzi* held that a plaintiff could assert state law failure to warn tort claims against a generic manufacturer that failed to include warnings in its generic drug label that had been included in the updated brand-name drug label. The court, looking to *Mensing*, held that because "compliance with both federal and state duties [was] no longer impossible," the plaintiff's claims were not barred under the conflict preemption doctrine. *Fulgenzi*, 711 F.3d at 582. In contrast, the Fifth Circuit in *Morris* did not perform a conflict preemption analysis on the failure to update issue under *Mensing*. Instead, the court upheld the district court's discretionary dismissal based on the pleading, specifically, that the district court had not abused its discretion in denying the plaintiff's motion to amend to add a new claim for failing to add the warnings from the updated brand-name label, because the plaintiff had argued that even that updated label was inadequate. *Morris*, 713 F.3d at 777. Thus, *Morris* is not in conflict with the conflict preemption analysis performed by the appellate court here and in *Fulgenzi* with regard to the claims based on the failure to warn by not updating the label.

Morris instead addresses whether the plaintiff's claims based on the defendant generic manufacturer's failure to send a "Dear Doctor" letter or other communication to her doctors containing the information from the FDA-approved label are preempted. The court held that these claims are preempted unless the brand-name company first sent "such" letters, because the letters otherwise might suggest a therapeutic difference between the branded and generic forms of the drug. *Id.* at 777. This conclusion reflects a misunderstanding of *Mensing*,

which was not discussing a Dear Doctor letter to convey information on the current FDA-approved brand-name labeling, but a "Dear Doctor letter that contained substantial new warning information [that] would not be consistent with the drug's approved labeling." *Mensing*, 131 S. Ct. at 2576. The Eleventh Circuit in *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013), also briefly cited by Petitioners, reaches a similar holding. But *Fulgenzi* never addressed this issue, and so there is no conflict amongst the circuits on this particular preemption issue either.

Petitioners spend the bulk of their brief discussing the issue of whether a plaintiff's state law tort claims against a generic manufacturer are preempted as pure "fraud-on-the-FDA" claims under *Buckman*. Both the decision below and the Sixth Circuit in *Fulgenzi* have rejected Petitioner's argument. *See Fulgenzi*, 711 F.3d at 586-87 and Pet. App. 13a-15a. As *Fulgenzi* explained on like facts, the plaintiff's suit "is not even premised on violation of federal law, but rather on an independent state duty," and therefore is not preempted by *Buckman*. *Id.* at 586.

Petitioners claim that this holding conflicts with *Morris*. There, however, the court addressed the applicability of *Buckman* in a single, conclusory sentence: "Second, a claim that PLIVA breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted." *Morris*, 713 F.3d at 777 (citing *Buckman,* 531 U.S. 349 n. 4). This single sentence, accompanied by no explanation or analysis, does not represent a conflict on this issue. First of all, the statement is dicta, as the court already

had held the district court did not abuse its discretion in denying the plaintiff leave to amend based on a pleading issue, as discussed above.

Secondly, *Morris*'s conclusory statement is in tension with the Fifth Circuit's prior decision in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), which held that claims against a medical device manufacturer for failure to warn using means required by the FDA regulations are not preempted under *Buckman*. *Hughes*, 631 F.3d at 769. This intra-circuit tension should be resolved by the Fifth Circuit, not by this Court.

IV. The California Appellate Court Correctly Applied *Mensing* and *Buckman*.

The court below really answered three preemption questions, all of which are straightforward, time tested and unremarkable, and not deserving of discretionary review by this Court, especially in light of the fact that the analysis of these questions at the federal circuit court and state high court level is scant or nonexistent.

The first question is whether Ms. Pikerie's claim based on inadequate labeling is preempted under the impossibility preemption doctrine as applied by *Mensing*. Because generic manufacturers are not only permitted but required to revise labeling to conform to brand-name labeling revisions, the argument that this claim is preempted based on "impossibility" is meritless. *See Wyeth*, 555 U.S. at 570. Notably, although this was the main issue addressed below and in *Fulgenzi*, the petition does not discuss it.

The second question is whether claims based on Petitioners' failure to send a "Dear Doctor" letter or other communication to doctors containing safety information from the FDA-approved label is preempted. In *Mensing*, the Court held that a claim based on the failure to send a letter was preempted because such communication was barred by FDA regulation. *See Mensing*, 131 S. Ct. at 2576. There, however, the Court was referring to a letter "that contained substantial new warning information" that was not approved for inclusion in the labeling. *Id*. *Mensing* did not hold that a Dear Doctor letter to advise doctors of new information *included* in FDA-approved labeling is preempted. Indeed, the analysis suggests the opposite. Unlike the situation in *Mensing*, here, such a letter would not have included "additional warnings," *id*., but rather the specific warnings that had been added to the FDA-approved labeling. *See also* Br. for U.S. as *Amicus Curiae* Supporting Respondents, p. 18, *PLIVA v. Mensing*, No. 09-993 (Mar. 2011) (stating "To be sure, *nothing in the FDCA or the FDA's regulations categorically forbids an ANDA holder [generic drug manufacturer] from unilaterally sending a DHCP [Dear Doctor] letter*." (emphasis added); and stating "But the particular letter respondents envision [containing additional warning information not in the FDA-approved label] would only be appropriate in tandem with corresponding change to the drug's approved labeling.").

The third question, and the one on which Petitioners are newly focused, is whether Ms. Pikerie's claims are precluded under the implied preemption theory addressed in *Buckman*.

In *Buckman*, the Court held that a so-called "fraud-on-the-FDA" claim was impliedly preempted by the Medical Device Amendments to the FDCA. Specifically, the Court addressed a claim brought against a medical device manufacturer's consultant who had submitted fraudulent information to the FDA in the application for approval of a device, and so owed no direct duty to the plaintiff under state tort law. This unusual claim, the Court explained, was not premised on an underlying state-law duty, but rested solely on a claim that the defendant violated a duty it owed to the FDA under federal law. *Buckman,* 531 U.S. at 352-53. The Court held that the claim was in "conflict" with the FDA's own responsibility to police fraud against it in accordance with its own objectives, and since the claim did not exist independently under state tort law it was barred under the implied preemption doctrine. *Id*. at 350.

Buckman does *not* support preemption in this case, which presents the situation that existed for the brand-name drug manufacturers in *Wyeth*. A brand-name manufacturer is required under federal regulations to change its drug label "as soon as there is reasonable evidence of an association of a serous hazard with a drug," and can use the "Changes Being Effected" procedure to unilaterally make that change without FDA pre-approval. *Wyeth*, 555 U.S. at 572 (citing 21 C.F.R. §201.80(e) and stating "Wyeth had a duty to provide a warning that adequately described the risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval."). Similarly, a generic drug manufacturer is required by federal regulations to change its generic drug label as soon as it becomes aware of a change in the brand-name drug label that includes new risk

information, and can use the CBE procedure to make that change. *Mensing*, 131 S.Ct. at 2575 (citing 21 C.F.R. §314.94(a)(8)(iv) and stating the FDA "interprets the CBE regulation to allow changes to the generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label").

In sum, 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." *Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010). Accordingly, on the facts of this case, *Buckman*'s analysis is inapplicable.

CONCLUSION

For the foregoing reasons, Ms. Pikerie respectfully requests that the Court deny the petition.

June 4, 2014

Respectfully submitted,

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