No.

IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the First Circuit

PETITION FOR WRIT OF CERTIORARI

MICHAEL W. MCCONNELL
MICHAEL D. SHUMSKY
JOHN K. CRISHAM
KIRKLAND & ELLIS LLP
655 Fifteenth St. NW
Washington, DC 20005
(202) 879-5000
(202) 879-5200 (fax)
mcconne@kirkland.com
mshumsky@kirkland.com
jcrisham@kirkland.com

JAY P. LEFKOWITZ, P.C.
Counsel of Record
KIRKLAND & ELLIS LLP
153 East 53rd Street
New York, NY 10022
(212) 446-4800
(212) 446-4900 (fax)
lefkowitz@kirkland.com

Counsel for Petitioner Mutual Pharmaceutical Company, Inc.

July 31, 2012

QUESTION PRESENTED

Whether the First Circuit erred when it created a circuit split and held—in clear conflict with this Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)—that federal law does not preempt state law design-defect claims targeting generic pharmaceutical products because the conceded conflict between such claims and the federal laws governing generic pharmaceutical design allegedly can be avoided if the makers of generic pharmaceuticals simply stop making their products.

RULE 29.6 DISCLOSURE STATEMENT

Petitioner Mutual Pharmaceutical Company, Inc. ("Mutual") is a wholly owned subsidiary of URL Pharma, Inc., which is a wholly owned subsidiary of Takeda America Holdings, Inc., which is a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda Limited"). Shares of Takeda Limited are traded on the Tokyo Stock Exchange. No other publicly held corporation owns 10 percent or more of Mutual's stock.

TABLE OF CONTENTS

APPENDIX CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Constitutional Provisions, Statutes, and Regulations

Other Authorities

INTRODUCTION

Two terms ago, this Court's decision in *PLIVA, Inc. v. Mensing* foreclosed state-law tort claims targeting generic pharmaceutical products because federal law imposes "an ongoing federal duty of sameness" that precludes generic products from deviating in any material respect from their brand-name equivalents. 131 S. Ct. 2567, 2574-75 (2011) (quotation marks omitted). Since the Court decided that case, the Fifth, Sixth, Eighth, and Ninth Circuits (and literally dozens of state and federal trial courts) have concluded that this Court meant what it said: They categorically have rejected lawsuits targeting generic drug products, including lawsuits that seek to evade *Mensing*'s "sameness" rationale by claiming that generic manufacturers could avoid any conflict between their state tort duties and the federal sameness mandate by simply withdrawing their generic drug products from the market. *See Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011) (vacating its pre-remand opinion despite plaintiff's post-*Mensing* assertion that "there is nothing inconsistent with the Supreme Court decision about holding defendants liable for their failure to suspend sales," *see* Mot. For Leave to File Suppl. Br., *id.*, at *5 (filed Sept. 8, 2011)); *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011) (affirming judgment for generic manufacturers despite plaintiffs' post-*Mensing* claim that the defendants' "decision not to suspend sales and to continue selling their [generic product] is [both] actionable [and] wholly consistent with *Mensing*" because "no federal statute or regulation prohibited them from 'independently' suspending sales of their product," *see* Appellants' Supp. Ltr. Br., *id.*, 2011 WL 3662688,

*5-6 (filed Aug. 15, 2011)); *see also Demahy v. Actavis, Inc.*, 650 F.3d 1045, 1046 (5th Cir. 2011) (remanding case for the entry of judgment in favor of generic manufacturer after *Mensing*); *Gaeta v. Perrigo Pharms. Co.*, 469 Fed. App'x 556 (Feb. 27, 2012) (affirming summary judgment in favor of generic manufacturer after *Mensing*).

The First Circuit's decision in this case openly departs from the holdings of its sister circuits on this issue. And it blasts a gaping hole in *Mensing*, by adopting a rationale that concededly cannot be squared with that decision; that admittedly would have required a different result in that case; and that indeed would sound the death knell for conflict preemption of state-law claims targeting *any* federally regulated product.

In particular, the appellate court narrowly construed *Mensing* as applying only to those claims that are captioned "failure to warn," and therefore declined to apply *Mensing*'s "rationale" to claims that are captioned "design defect," App. 9a-10a—even though it candidly acknowledged that federal law grants generic drug manufacturers no more power to alter the design of their products than it does to alter the labeling of their products, and thus provides no principled basis for distinguishing between failure to warn and design defect claims for purposes of assessing federal law's preemptive effect. App. 10a ("[Petitioner] argues with some force that the generic maker also cannot alter the composition of the drug and so [*Mensing*]'s policy of encouraging generics by preempting state tort claims should extend to design defect as well as claims based on inadequate warning.").

In place of a logical explanation for distinguishing between these claims, the appellate court instead asserted that there is no conflict between state tort law and the federal regulatory regime governing generic drugs because federal law does not obligate generic manufacturers to produce their products in the first place. "[A]lthough Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway), it certainly can choose not to make the drug at all." *Id.* But as the court quickly acknowledged (with some understatement), there is an obvious "tension" between that rationale and *Mensing*, App. 11a, where the generic manufacturers likewise were free "not to make the drug at all." Were the holding below correct, *Mensing* thus would have come out the other way—as the appellate court once again conceded. App. 10a ("[A] generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug.").

As the First Circuit recognized, *Mensing*'s rejection of this radical theory of liability was no oversight. *See id.* ("[T]he FDCA might permit states to tell Mutual it ought not be [making its product] if risk-benefit analysis weights against the drug, *despite what the Supreme Court made of similar arguments in the labeling context*.") (emphasis added). The Eighth Circuit had advanced this very same rationale in its *Mensing* opinion, and this Court both reversed that judgment and then denied a petition for rehearing in which the *Mensing* plaintiffs reiterated the same argument. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009) ("The generic defendants were not compelled to market metoclopramide. If they realized their label

was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product."); *see also* Resps.' Petition for Reh'g, *Mensing*, 2011 WL 2874547, *1 (filed July 18, 2011) ("Respondents seek rehearing because … the Petitioner generic drug companies could have 'independently' complied with both state and federal law simply by suspending sales of generic metoclopramide.").

Nor is there is any doubt as to why this Court dismissed that theory. More than twenty years ago, it considered and rejected the so-called "choice of reaction" thesis, which held that federal law does not preempt state tort claims because "compliance with both federal and state law cannot be said to be impossible: [the defendant] can continue to use the [federally approved] label and can at the same time pay damages to successful tort plaintiffs." *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1542 (D.C. Cir. 1984). This Court, however, laid that theory to rest in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992) (plurality opinion) ("[S]tate regulation can be as effectively exerted through an award of damages as through some form of preventive relief.") (quotation marks omitted); *see also id.* at 548-49 (Scalia and Thomas, JJ., concurring in relevant part); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008) ("As the plurality opinion said in *Cipollone*, common-law liability is premised on the existence of a legal duty, and a tort judgment therefore establishes that the defendant has violated a state-law obligation. And while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing

conduct and controlling policy.") (quotation marks and citations omitted).

Despite the obvious incompatibility of its rationale with both *Mensing* and these well-settled principles, the First Circuit declared that "it is up to the Supreme Court" to make clear it stands by *Mensing*:

> [H]aving lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief.… [I]t is up to the Supreme Court to decide whether [*Mensing*] is to be enlarged to include design defect claims. Given the widespread use of generic drugs and the developing split in the lower courts … this issue needs a decisive answer from the only court that can supply it.

App. 11a (internal citations omitted).

With all due respect, that approach is unsustainable. This Court long ago made clear that the lower courts may neither reject rationales that this Court has accepted nor accept rationales that this Court has rejected; indeed, it has summarily reversed decisions that do just that. *See, e.g.*, *Pennsylvania v. Goldhammer*, 474 U.S. 28, 29-30 (1985) (summary reversal warranted because the lower court's "rationale is inconsistent with the rationale of the holding of this Court"); *see also Am. Tradition P'ship, Inc. v. Bullock*, 132 S. Ct. 2490, 2491 (2012) ("[The] arguments in support of the judgment below either were already rejected in

Citizens United, or fail to meaningfully distinguish that case."). To the extent the First Circuit nonetheless has asked this Court to provide "a decisive answer" to its circuit split-creating decision, however, we wholeheartedly agree. This case cries out for review by this Court, and perhaps even for summary reversal.

OPINIONS BELOW

The First Circuit's opinion is reported at 678 F.3d 30, and is reprinted at App. 1-24a. The appellate court's errata to that opinion is reprinted at App. 27-28a. The district court's opinion denying petitioner's renewed motion for judgment as a matter of law is reported at 760 F. Supp. 2d 220, and is reprinted at App. 29-103a. The district court's opinion granting in part and denying in part petitioner's motion for summary judgment is reported at 731 F. Supp. 2d 135, and is reprinted at App. 106-141a. The district court's unpublished order and opinion denying petitioner's motion for judgment on the pleadings is available at 2010 WL 3659789, and is reprinted at App. 142-202a.

JURISDICTION

The First Circuit issued its decision and entered judgment on May 2, 2012, *see* App. 25-26a, and therefore this petition is timely. Petitioners invoke this Court's jurisdiction under 28 U.S.C. § 1254(1).

PERTINENT CONSTITUTIONAL AND STATUTORY PROVISIONS

The Supremacy Clause of the U.S. Constitution provides:

> This Constitution, and the Laws of the United States which shall be made in

> Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. CONST. art. VI, cl. 2.

The pertinent provisions of the federal Food, Drug, and Cosmetics Act are set forth in the Appendix, App. 203-210a.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

In 1984, Congress amended the federal Food, Drug and Cosmetics Act ("FDCA") in order to expand access to affordable generic drugs by reducing barriers to generic market entry. Those amendments—commonly known as the Hatch-Waxman Act—gave birth to the modern generic drug industry, and during the past three decades have reduced pharmaceutical expenditures by trillions of dollars. *Mensing*, 131 S. Ct. at 2582 ("Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public.").

Before Hatch-Waxman, virtually all companies were required to file a New Drug Application ("NDA") to receive Food and Drug Administration ("FDA") approval to market a drug. As part of that process, NDA applicants must conduct extensive and costly clinical trials to prove the safety and efficacy of

a proposed new drug. Hatch-Waxman, however, drew sharp distinctions between branded and generic drug applicants. While brand companies seeking to market an innovative drug product must continue to submit full NDAs (including full clinical trial reports), *see Mensing*, 131 S. Ct. at 2574 (citing 21 U.S.C. § 355(b)(1), (d)), generic drug companies seeking to market copies of previously approved drugs may file an Abbreviated New Drug Application ("ANDA") that simply demonstrates the product's chemical and biological equivalence to a previously approved drug product (known as the "reference listed drug" or "RLD"). *See id.* (citing 21 U.S.C. § 355(j)(2)(A)).

To that end, the statute requires ANDA applicants to show that a generic drug is identical to its brand-name equivalent in all material respects. ANDA applicants therefore must show that the proposed generic drug contains "*the same*" active ingredient(s); employs "*the same*" route of administration (*e.g.*, oral or injected); presents "*the same*" dosage form (*e.g.*, tablet or capsule); and exhibits "*the same*" strength (*e.g.*, 20mg or 40mg) as the branded equivalent, in order to ensure that it will "have *the same* therapeutic effect" as the branded equivalent. 21 U.S.C. § 355(j)(2)(A)(i)-(iv) (emphases added); *Mensing*, 131 S. Ct. at 2574 n.2 (explaining that each generic drug must be "*identical* [to its branded equivalent] in *active ingredients, safety, and efficacy*") (emphasis added). In short, then, the design of a generic drug product must be identical to that of its brand-name counterpart.

As this Court recognized in *Mensing*, it is precisely for that reason that generic product

labeling must at all times be "'the same as the labeling approved for the [brand-name] drug.'" *Mensing*, 131 S. Ct. at 2574 (quoting 21 U.S.C. § 355(j)(2)(A)(v) and citing *id.* § 355(j)(4)(G) (alteration in original)); *see also* FDA, Abbreviated New Drug Application Regulations—Final Rule, 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992) ("[T]he ANDA product's labeling must be the same as the listed drug product's labeling *because* the listed drug product is the basis for ANDA approval.") (emphasis added).

B. The *Mensing* And *Demahy* Cases

Despite the clarity of the statute's sameness requirement, the effect of that rule on state-law tort claims targeting generic pharmaceuticals was unsettled in the lower courts until two terms ago—when this Court decided a pair of cases addressing whether the sameness mandate preempts state tort claims that target generic pharmaceuticals. The first of those cases arose when plaintiff Gladys Mensing filed suit in the U.S. District Court for the District of Minnesota, alleging that she had been injured by long-term consumption of generic metoclopramide (the branded equivalent of which is called Reglan®). Her complaint asserted fourteen different causes of action, including strict liability for both design defect and failure to warn, negligent failure to warn, breach of warranties, misrepresentation, fraud, unfair trade practices, false advertising, and consumer fraud. *See* First Am. Compl., *Mensing v. Wyeth, Inc.*, No. 07-cv-3919 (D. Minn. filed Feb. 22, 2008). The generic manufacturers moved to dismiss her complaint in its entirety as preempted by Hatch-Waxman's sameness mandate, and the district court—treating all her

theories of liability (including design defect) as "essentially 'failure to warn' claims"—ordered an across-the-board dismissal. *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056, 1061 n.6 (D. Minn. 2008).

Mensing appealed, and the Eighth Circuit reversed. 588 F.3d 603. Though it acknowledged that Hatch-Waxman's sameness mandate prohibited the generic defendants from altering their product warnings, it nonetheless held that the generic defendants could have fulfilled their state-law duties without running afoul of that rule. First, it held that they "could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved." *Id.* at 608 (emphasis in original). Second, it held that the generic manufacturers could have fulfilled their state-law duties by "suggest[ing] that the FDA send out a warning letter." *Id.* at 610. Finally, and of special note here, it declared that compliance with state-law tort duties and federal law would not be impossible even if those avenues were *not* available to the generic manufacturers:

> The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product. Instead, they are alleged to have placed a drug with inadequate labeling on the market and profited from its sales. If Mensing's injuries resulted from their failure to take steps to warn their customers sufficiently of the risks from

> taking their drugs, they may be held liable.

Id. at 611.

While *Mensing* was unfolding in Minnesota, a similar case was proceeding in federal court in Louisiana. As in *Mensing*, plaintiff Julie Demahy alleged that she was injured after taking generic metoclopramide for many years, and her complaint likewise levied an array of state-law claims against the generic product's manufacturer, including failure-to-warn and design-defect claims under the Louisiana Products Liability Act, La. R.S. 9:2800.51 *et seq.*, the Louisiana Unfair Trade Practices and Consumer Protection Law, La. R.S. 51:1401 *et seq.*, and traditional tort theories. *See* Compl., *Demahy v. Wyeth*, No. 2:08-cv-03616-CJB-JCW (E.D. La. filed on removal June 2, 2008).

As in *Mensing*, the generic manufacturer moved to dismiss Demahy's claims on preemption grounds, but the district court denied its motion. The Fifth Circuit then affirmed, echoing the Eighth Circuit's conclusion that the generic defendant could have taken steps to initiate a labeling change by communicating with FDA, and further asserting that Hatch-Waxman's sameness requirement is limited to the period before FDA approval—such that generic companies unilaterally can alter their product labeling after approval through the so-called "Changes Being Effected" or "CBE" process. *Demahy v. Actavis, Inc.*, 593 F.3d 428, 436-46 (5th Cir. 2010).

This Court granted *certiorari* in both cases, and on June 23, 2011 issued a decision reversing both decisions and holding that "federal law preempts these lawsuits." 131 S. Ct. at 2581. The Court's

opinion began by rejecting the Fifth Circuit's assertion that the sameness requirement applies only pre-approval, holding that generic companies cannot utilize the CBE procedure to deviate from the branded product labeling because their labeling must continually be the "same as" the branded product labeling. *Id.* at 2575-76.

It next rejected the plaintiffs' claims that the defendants could have sent "Dear Doctor letters" warning healthcare professionals about the risks of long-term metoclopramide use. The Court observed that such "letters qualify as 'labeling'" subject to the sameness requirement, *id.* at 2576 (citing 21 C.F.R. § 202.1(l)(2) & 21 U.S.C. § 321(m)), and further emphasized that "if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *Mensing*, 131 S. Ct. at 2576 (citations omitted).

Finally, this Court rejected the appellate courts' assertions that the generic drug manufacturers at least could have "taken steps" to change the product labeling by alerting FDA to the need for stronger warnings. *Id.* at 2579-82. Even though federal law did not prohibit the generic manufacturers from sharing such information with FDA—and indeed, even though the Solicitor General's brief asserted that federal law required the generic defendants to do so—the Court held these claims preempted because FDA still would have had to authorize the use of different product warnings. *Id.* at 2581 ("[W]hen a party cannot satisfy its state duties without the Federal Government's special permission

and assistance … that party cannot independently satisfy those state duties for pre-emption purposes."). The Court therefore held that the plaintiffs' lawsuits were preempted in their entirety: "[B]ecause pharmacists, acting in full accord with state law, substituted generic metoclopramide [for brand-name Reglan®], federal law pre-empts these lawsuits. We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated." *Id.* (citation omitted).

The plaintiffs in those cases then petitioned this Court for rehearing, emphasizing the Eighth Circuit's pre-*Mensing* assertion that the generic manufacturers could have complied with both the federal sameness mandate and their state-law tort duties *without* requiring FDA's involvement—and thus that their claims were not preempted under *Mensing*'s rationale:

> Petitioners could have satisfied their duty under state tort law by suspending sales of the product with a label that they knew or should have known was inadequate. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009). That course of action was always available to them and could have been accomplished independently, without any action by the FDA. Thus, it was not impossible for the Petitioners to comply with both federal and state law: they 'could independently do under federal law what state law requires of' them.

Resps.' Petition for Reh'g, *Mensing*, 2011 WL 2874547, at *2 (parenthetical omitted); *see also id.* at

*1 ("The Court overlooks the fact that the Petitioner[s] could have 'independently' complied with both state and federal law simply by suspending sales of generic metoclopramide with warnings that they knew or should have known were inadequate.").

This Court denied the petition. *Actavis Elizabeth, LLC v. Mensing*, 132 S. Ct. 56 (2011); *PLIVA, Inc. v. Mensing*, 132 S. Ct. 55 (2011). On remand in *Mensing*, the Eighth Circuit explicitly vacated the portion of its earlier opinion holding that the generic manufacturers could be held liable for failing to withdraw their products despite plaintiff's supplemental brief asserting that "nothing in federal law prohibited the Generic Drug Company Appellees from suspending sales of their drug, an action the companies could have taken entirely on their own initiative," Mot. for Leave to File Supp. Br., *Mensing v. Wyeth, Inc.*, No. 08-3850, at 4 (8th Cir. filed Sept. 8, 2012). *See Mensing*, 658 F.3d at 867 ("The Supreme Court having reversed the judgment of this court and remanded this action for further proceedings in light of its opinion in *PLIVA, Inc. v. Mensing*, … we now vacate Sections I, II, and IV of our opinion in *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009)."). The Fifth Circuit likewise vacated its prior opinion in *Demahy* and ordered the entry of judgment in favor of the generic manufacturer. *See Demahy*, 650 F.3d at 1046.

C. Proceedings Below

On January 8, 2008, Respondent filed suit in New Hampshire state court, alleging that she suffered injuries after ingesting generic sulindac, a non-steroidal anti-inflammatory drug manufactured by

petitioner. App. 1-4a. As in the cases giving rise to *Mensing*, Respondent's complaint raised an array of state-law tort claims—including causes captioned failure-to-warn and design-defect—and Petitioner moved for judgment on the pleadings after removing the case to the U.S. District Court for the District of New Hampshire.

On September 30, 2009, the district court (Laplante, J.) rejected petitioner's federal preemption argument in its entirety, reasoning with respect to respondent's design-defect claim that "[w]hile one way to avoid violating state law in this way would be to redesign Sulindac to remove the alleged defect before distributing the drug (or otherwise to meet the standard of care), another way to do so would be to refrain from distributing it at all." App. 165a. After that decision, all of Respondent's claims were dismissed—either voluntarily or by order of the district court—with the exception of Respondent's state-law design defect claim. App. 4-5a.

That single claim proceeded to trial over a 14-day period in August and September 2010. The jury eventually awarded Respondent over $21 million in damages, App. 5a, and the district court denied Petitioner's post-trial motions (including its renewed preemption defense). App. 29-103a. Petitioner timely appealed to the First Circuit, and on May 2, 2012—despite this Court's decision in *Mensing* and the overwhelming consensus among the lower courts that *Mensing* forecloses these claims—the First Circuit affirmed.

The appellate court began its analysis of the preemption issue by asserting that "[w]hether and to what extent the FDCA preempts design defect claims

against generic drug manufacturers is a question of exceptional importance that the Supreme Court has yet to decide." App. 8a. Yet rather than starting its analysis of that question with *Mensing* (or the dozens of cases that have addressed generic liability after *Mensing*), the appellate court instead turned to this Court's prior decision in *Wyeth v. Levine*, 555 U.S. 555 (2009)—a case that involved *neither* design-defect claims *nor* the federal regulatory scheme governing generic drugs. App. 8-9a. According to the appellate court, however, *Wyeth* established a blanket rule "that state law serves as a 'complementary form of drug regulation,'" App. 9a (quoting *Wyeth*, 555 U.S. at 578), and it asserted without reference to the post-*Mensing* landscape that "[t]he lower courts agree that the FDCA does not preempt state tort suits against drug manufacturers." *Id*.

The appellate court acknowledged that *Wyeth* did not actually address design-defect claims at all, *id*. & n.2 ("*Wyeth*'s holding was technically limited to failure-to-warn claims.") (citing 555 U.S. at 568, 573, 574), but baldly declared that "its logic applies to design defect claims as well." *Id*. (quoting 555 U.S. at 574 for the proposition that "state tort suits 'motivate manufacturers to produce safe and effective drugs *and* to give adequate warnings'") (emphasis in original).

In contrast to this "general no-preemption rule," App. 11a, the First Circuit claimed that *Mensing* merely "carved out an exception to *Wyeth*, finding that the FDCA preempts *failure-to-warn* claims against *generic* drug manufacturers … [because] the generic maker cannot alter the labeling." App. 9-10a

(emphases in original); App. 10a ("[T]he Supreme Court [has] not yet said it would extend [*Mensing*]'s exception to design defect claims."). But the court did not explain how the design-defect claim at issue here can be distinguished from the failure-to-warn claims it said were at issue in *Mensing*. App. 7a (conceding that New Hampshire has adopted *Restatement (Second) Torts* § 402A, cmt. k, such that design-defect liability hinges on the absence of an adequate warning). And it acknowledged that targeting the product's design instead of its label did not in any event provide a conceptually coherent basis for distinguishing *Mensing*: Just as *Mensing* held that federal law precludes manufacturers from altering generic product labeling, the appellate court expressly conceded that under federal law "Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)." App. 10a.

The court nonetheless concluded that generic drug manufacturers like Petitioner can escape the clear conflict between their state-law duties and federal sameness obligations by "choos[ing] not to make the drug at all; and the FDCA might permit states to tell Mutual it out not be doing so if risk-benefit analysis weighs against the drug." *Id.* Yet it once again conceded that this rationale likewise was impossible to square with *Mensing*, where the very same arguments had been made and rejected. App. 11a (admitting that this claim is "in tension" with "*[Mensing]*'s rationale" because "a generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug"); App. 10a-11a (suggesting that "the Supreme Court might be less ready to deprive Bartlett of her remaining

avenue of relief … *despite what the Supreme Court made of similar arguments in the labeling context*.") (emphasis added).

Faced with a choice between what it called the "logic" of *Wyeth* and the "rationale" of *Mensing*, the court ultimately punted the issue to this Court—declaring that it would allow the jury's verdict to stand unless and until this Court instructs otherwise:

> [I]t is up to the Supreme Court to decide whether *PLIVA*'s exception is to be enlarged to include design defect claims. Given the widespread use of generic drugs and the developing split in the lower courts, this issue needs a decisive answer from the only court that can supply it.

App. 11a (internal citations and reference omitted). This petition follows.

REASONS FOR GRANTING THE WRIT

The First Circuit plainly erred when it created a circuit split by holding that federal law does not preempt state law design-defect claims targeting generic pharmaceutical products on the ground that the conceded conflict between such claims and the federal laws governing generic pharmaceutical design allegedly can be avoided if the makers of generic pharmaceuticals simply stop making their products. Given the lopsided split created by the appellate court's decision; the appellate court's admission that its reasoning cannot be squared with *Mensing*; the fact that its approach to preemption otherwise has been rejected by this Court for more

than twenty years; and the court's own request for "a decisive answer from [this] court," this Court should grant the writ and reverse the decision, perhaps even summarily.

A. The First Circuit's Opinion Cannot Be Squared With *Mensing*, As Every Other Appellate Court Has Recognized And The First Circuit Itself Conceded.

Since this Court decided *Mensing*, every other appellate court that has considered whether state law design-defect claims survive that decision has found them to be preempted. *Gaeta*, 469 Fed. App'x 556; *Mensing*, 658 F.3d 867; *Smith*, 657 F.3d 420; *Demahy*, 650 F.3d 1045. So have scores of state and federal district courts, which uniformly have rejected the First Circuit's remarkable claim that generic manufacturers can be held liable under state law for declining to pull their federally approved products off the shelf. *See, e.g.*, *Aucoin v. Amneal Pharm., LLC*, 2012 WL 2990697, at *10 (E.D. La. July 20, 2012); *Johnson v. Teva Pharm. USA, Inc.*, 2012 WL 1866839, at *4 (W.D. La. May 21, 2012); *Eckhardt v. Qualitest Pharm. Inc.*, 2012 WL 1511817, at *7 (S.D. Tex. Apr. 30, 2012); *Lyman v. Pfizer, Inc.*, 2012 WL 368675, at *4 (D. Vt. Feb. 3, 2012); *In re Darvocet*, 2012 WL 718618, at *3 (E.D. Ky. Mar. 5, 2012); *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, __, 2012 WL 272889, at *3 (E.D.N.Y. Jan. 30, 2012); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 662 (D. Md. 2011); *In re Fosamax*, 2011 WL 5903623, at *6 & n.5 (D.N.J. Nov. 21, 2011); *Stevens v. PLIVA, Inc.*, 2011 WL 6224569, at *2 (W.D. La. Nov. 15, 2011).

This overwhelming nationwide consensus is not surprising. Before *Mensing* reached this Court, the

Eighth Circuit had advanced the very same theory embraced by the First Circuit's decision here. It held:

> The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product. Instead, they are alleged to have placed a drug with inadequate labeling on the market and profited from its sales. If Mensing's injuries resulted from their failure to take steps to warn their customers sufficiently of the risks from taking their drugs, they may be held liable.

Mensing, 588 F.3d at 611.

Needless to say, this Court *reversed* that judgment, albeit without specifically referencing the Eighth Circuit's "they could have stopped selling the product" argument. And it again rejected the argument when the *Mensing* plaintiffs attempted to revive it in a post-decision petition for rehearing, Resps' Petition for Reh'g, *Mensing*, 2011 WL 2874547, at *1 ("Respondents seek rehearing because … the Petitioner generic drug companies could have 'independently' complied with both state and federal law simply by suspending sales of generic metoclopramide."). *See* 132 S. Ct. 55 (denying petition for reh'g); 132 S. Ct. 56 (same).

Since that time, every other appellate court has (and scores of trial courts have) followed this Court's lead in rejecting the Eighth Circuit's pre-*Mensing*

rationale for imposing liability on generic product manufacturers. *See, e.g.*, *In re Darvocet*, 2012 WL 718618, at *3 (highlighting the rejection of this claim in *Mensing* and the fact that Sixth and Eighth Circuits rejected it after it was raised by plaintiffs in post-*Mensing* briefs); *Gross*, 825 F. Supp. 2d at 662 (same); *Fullington v. PLIVA, Inc.*, 2011 WL 6153608, at *6 (E.D. Ark. Dec. 12, 2011) ("[Plaintiff] contends that … the generic manufacturers could have complied with both state and federal law by simply pulling the drug off the market entirely. While the Eighth Circuit in *Mensing* agreed with this argument, the Supreme Court reversed the Eighth Circuit's judgment in *Mensing*. The Eighth Circuit then vacated the portions of its *Mensing* opinion that addressed preemption, including the section adopting the argument that impossibility preemption did not apply because the manufacturers could pull the drug from the market.") (citation omitted).

The First Circuit, by contrast, deemed *Mensing* to be a narrow and essentially unprincipled exemption from what it called *Wyeth*'s "general no-preemption rule" for state tort claims under the FDCA, App. 11a—characterizing *Mensing* as a narrow "exception to *Wyeth*, finding [only] that the FDCA preempts *failure-to-warn* claims against *generic* drug manufacturers." App. 9-10a (emphases in original); *see also* App. 10a ("[T]he Supreme Court [has] not yet said it would extend *PLIVA*'s exception to design defect claims.").

That assertion fundamentally misconstrues both *Wyeth* and *Mensing*. *Mensing* was not an arbitrary and unprincipled "exception" to *Wyeth*. As *Mensing* instead took pains to explain, both decisions reflect a

single, entirely coherent principle: that drug manufacturers may be held liable under state law if and only if the federal laws governing their drug products authorize them to change the allegedly offensive elements of those products without prior FDA approval. It is that consistent principle that led the Court to allow failure-to-warn claims against brand manufacturers but reject them against generic manufacturers. *See Mensing*, 131 S. Ct. at 2582 ("It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme.").

The appellate court thus fundamentally erred in asserting that *Wyeth* somehow established a "general no-preemption rule" with respect to state tort claims implicating the FDCA. Instead, as the First Circuit's decision elsewhere recognized, *Wyeth* reasoned only that federal law does not preempt state law failure-to-warn claims against brand manufacturers *because federal law expressly empowers such companies to unilaterally alter the warnings in their product labeling*. *See* App. 9a n.2 ("Because the FDA's 'changes being effected' regulations … permit brand-name manufacturers to strengthen their labels unilaterally … [*Wyeth*] concluded it is possible for brand-name manufacturers to comply with both

federal labeling requirements and state tort law effectively requiring a stronger label.") (internal citation omitted; discussing *Wyeth*, 555 U.S. at 568, 573).

The opposite is true of generic manufacturers. Hatch-Waxman's "sameness" mandate expressly precludes them from unilaterally altering either the label or design of their generic drug products. *Mensing*, 131 S. Ct. at 2574 & n.2 (explaining that the statute requires each generic drug to be "identical [to its branded equivalent] in active ingredients, safety, and efficacy" as well as in "the safety and efficacy labeling") (quotations and original alterations omitted). As a result, *Mensing* is not an exception to *Wyeth*; these two cases stand for the very same principle, and the First Circuit was dead wrong in suggesting that *Wyeth* somehow established a blanket "no-preemption rule" whose "logic" should apply here. App. 9a, 11a.

The appellate court nonetheless asserted that *Mensing* might be limited to claims that are captioned "failure to warn" as opposed to "design defect." App. 10a ("[T]he Supreme Court [has] not yet said it would extend [*Mensing*]'s exception to design defect claims."). But the court offered no rationale for distinguishing between failure-to-warn and design-defect claims. And there is none. In the prescription-drug context, failure-to-warn and design-defect claims are one and the same: even the First Circuit conceded that under *comment k*,[1]

---

[1] *Restatement (Second) of Torts* § 402A comment k (1965) ("There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their

design-defect liability is predicated on the absence of an adequate warning. App. 7a ("[A]n ordinary consumer would hardly know *without further warning* that sulindac or any other ordinary analgesic carries a risk of the kind of ill effects and suffering that Bartlett encountered.") (emphasis added); *id.* ("Mutual could still have avoided liability by proving that sulindac was unavoidably unsafe but was highly useful *and had an adequate safety warning*.") (emphasis added; citing *Restatement (Second) Torts* § 402A cmt. k and the district court's analysis of *comment k*, App. 125a-128a (denying Mutual's motion for summary judgment because "the adequacy of Sulindac's safety warning is a matter of genuine dispute on this record" and because the adequacy of the warning is "a trialworthy issue")). These bedrock tort principles, of course, explain why the district court in *Mensing* treated all of Ms. Mensing's claims as "essentially failure-to-warn claims" for preemption purposes, including her strict-liability design-defect claim. *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056, 1061 n.6 (D. Minn. 2008). And it likewise is why this Court later held in *Mensing*

---

intended and ordinary use. These are especially common in the field of drugs…. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician…. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use.").

that "federal law pre-empts *these lawsuits*." 131 S. Ct. at 2581 (emphasis added).

But even if there were some daylight between "failure to warn" and "design defect" claims—and again, the First Circuit failed to identify any—there still would be no basis for distinguishing between them for Hatch-Waxman preemption purposes. As the First Circuit once again conceded, federal law gives generic manufacturers no more power to alter a generic product's design than it does to alter its labeling: Given Hatch-Waxman's sameness mandate, generic companies like "[Petitioner] cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)." App. 10a.

Because the same "sameness" principle on which *Mensing* turned thus applies equally to claims labeled both "failure to warn" and "design defect," countless courts (as the First Circuit openly acknowledged) have rejected the appellate court's unprincipled attempt to distinguish between such claims for post-*Mensing* preemption purposes. App. at 10-11a & n.3 (identifying the "developing split in the lower courts," which the First Circuit itself created); *see also Aucoin*, 2012 WL 2990697, at *9 ("Defendant could not alter the design of the drug without violating federal law and this duty of sameness, making it impossible for Defendant independently to comply with both federal and state law. As such, this Court joins numerous other lower courts that have considered this issue and found the failure-to-warn reasoning of *Mensing* equally applicable to a design defect claim."); *Johnson*, 2012 WL 1866839, at *4 ("The FDCA likewise prevented

the Generic Defendants from altering unilaterally the design of the drug itself.... Accordingly, [plaintiff] cannot show that an alternative drug design was available to the Generic Defendants, and her design defect claims will be dismissed as preempted"); *Eckhardt*, 2012 WL 1511817, at *7 ("Generics were required to produce a drug that was equivalent to the brand-name drug and were not free to unilaterally pursue a safer alternative design in order to comply with state law. The design defect claim is thus preempted and therefore dismissed."); *Lyman*, 2012 WL 368675, *4 ("The Generic Defendants' 'federal duty of sameness' … applies to the design or composition of the drug as well as to its labeling. Applying the *Mensing* holding requires dismissal of the Lymans' design claims as well.") (citation omitted; quoting *Mensing*, 131 S. Ct. at 2575); *In re Darvocet*, 2012 WL 718618, *3 (rejecting design defect claims because "the Generic Defendants, bound by their 'ongoing federal duty of sameness,' were powerless to change" the product's design) (quoting *Mensing*, 131 S. Ct. at 2575); *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d at __, 2012 WL 272889, at *3 ("[T]he federal duty of sameness also applies in the context of generic drug design, and federal law preempts state laws imposing a duty to change a drug's design on generic drug manufacturers") (citation and quotation marks omitted); *In re Fosamax*, 2011 WL 5903623, at *6 ("[I]t was not lawful under federal law for the [generic manufacturers] to do what state law required of them because FDA requires [the] generic [product] to have the same active ingredient as" its branded equivalent) (citation and quotation marks omitted); *Stevens*, 2011 WL 6224569, at *2 ("Under

the same federal law analyzed in *Mensing*, a generic pharmaceutical product must be the same as [its branded equivalent] in active ingredients, safety and efficacy and hence, as was the case with labeling, federal law pre-empts state laws imposing the duty to change a drug's design.") (citation omitted).

B. The First Circuit's Stop-Manufacturing Theory Only Exacerbates The Conflict Between Its Decision And This Court's Precedents.

The First Circuit nonetheless sought to evade this obvious conflict between the federal sameness mandate and state law design-defect claims by asserting that Petitioner could simply stop making its generic product—and thereby could comply simultaneously with both its federal obligations and state tort-law duties. App. 10a ("[A]lthough [Petitioner] cannot legally make sulindac in another composition … it certainly can choose not to make the drug at all."). Rather than solving the conflict between the appellate court's decision and this Court's precedents, however, that line of reasoning only exacerbates it.

As the First Circuit again acknowledged, this very same end-run around federal law's preemptive effect was attempted and rejected in *Mensing*: "[A] generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug," yet *Mensing* nonetheless foreclosed any claim challenging generic product warnings. App. 11a; *see also* App. 10a ("[A generic drug manufacturer] can choose not to make the drug at all; and the FDCA might permit states to tell [the company that] it ought not be doing so if risk-benefit analysis weighs

against the drug, *despite what the Supreme Court made of similar arguments in the labeling context*.") (emphasis added).

There is no doubt why that theory was rejected: Accepting it would "render conflict pre-emption largely meaningless because it would make most conflicts between state and federal law illusory." *Mensing*, 131 S. Ct. at 2579. After all, the same argument "could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct altogether." *In re Darvocet*, 2012 WL 718618, at *3 (citing *Mensing*, 131 S. Ct. at 2579); *see also In re Fosamax*, 2011 WL 5903623, at *6 n.5 ("Plaintiffs insist that Generic Defendants could have simply removed alendronate sodium from the market. Whatever the merit of that contention, it is essentially a re-argument of *Mensing*.").

Indeed, the conflict between this line of reasoning and this Court's prior precedents is not limited to *Mensing*; it flies in the face of nearly two decades of decisions rejecting the so-called "choice of reaction" theory pioneered by the D.C. Circuit's 1984 decision in *Ferebee v. Chevron Chemical Co*. That case famously rejected a federal preemption defense based on EPA's approval of pesticide product labeling under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), on the ground that "compliance with both federal and state law cannot be said to be impossible: [the defendant] can continue to use the EPA-approved label and can at the same time pay damages to successful tort plaintiffs." 736 F.2d at 1542. The "choice" of what to do, *Ferebee* asserted, was the defendant's: Faced with a possible

award of damages under state law, the defendant could either "choose" to keep its label and pay out tort verdicts, or else "choose not to send [its product] into Maryland." *Id.* at 1543.

Suffice it to say, *Ferebee*'s assertion that this "choice" sufficed to evade federal law's preemptive effect was widely panned in the lower courts—including by the First Circuit, which explained that the supposed "choice" of paying monetary damages or altering one's course of conduct is "akin to the free choice of coming up for air after being underwater." *Palmer v. Liggett Grp., Inc.*, 825 F.2d 620, 627 (1st Cir. 1987); *see also MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994) ("[T]his argument is sophistry. If plaintiffs could recover large damage awards because the herbicide was improperly labeled under state law, the undeniable practical effect would be that state law *requires* additional labeling standards not mandated by FIFRA; it cannot be presumed that businesses wish to bring about their own economic suicide.") (emphasis in original); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 370 (7th Cir. 1993) ("[D]amages actions, just like regulatory mandates, cause companies to modify their economic decisions. It would be silly to pretend that federal lawmakers, seeking to occupy a whole field of regulation, wouldn't also be concerned about the distorting effects of tort actions."); *Worm v. Am. Cyanamid Co.*, 970 F.2d 1301, 1307 (4th Cir. 1992) ("We find the distinction illusory. … Implicit in the Worms' argument is a notion that common law tort duties are not regulatory. But surely a jury verdict resulting from a pesticide manufacturer's failure to warn of the dangers of the product has an effect no different from a legislatively enacted state regulation

requiring the insertion of a specific warning on the pesticide label.").

The issue eventually reached this Court in *Cipollone*, and this Court decisively rejected *Ferebee*'s claim that state-law damage awards do not constitute state regulatory "requirements" that conflict with federal law:

> As we noted in another context, 'state regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.'

Cipollone, 505 U.S. at 521 (quoting *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008) ("As the plurality opinion said in *Cipollone*, common-law liability is premised on the existence of a legal duty, and a tort judgment therefore establishes that the defendant has violated a state-law obligation. And while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy.") (internal quotation marks and citation omitted).

As these cases make clear, this Court long ago recognized that requiring manufacturers of federally regulated products to withdraw their products from the market or else face state-law damage awards does not *avoid* the conflict between federal law and state tort-law obligations. It *exacerbates* that conflict and effectively inverts the Supremacy Clause, by

ensuring that the state law requirements come out on top every time. Indeed, the First Circuit's attempt to revive this long-discredited approach would toll the bell for conflict preemption of state tort claims involving *any* federally regulated product, since no federal statute that we can identify compels manufacturers to market their products in interstate commerce (and since this Court's recent decision in *The Healthcare Cases*, 132 S. Ct. 2566 (2012), would cast grave doubt on the constitutionality of such a requirement in any event). In short, because the manufacturer of *any* product can in theory "choose" to stop selling that product in any given State, no federal requirement ever could generate a preemptive conflict under the First Circuit's radical approach.

Allowing the First Circuit's decision to stand would be particularly pernicious in this context, and it is hard to imagine a result more at odds with this federal scheme. Hatch-Waxman's whole aim, after all, was to make generic copies of approved brand-name drugs widely available to the public and thereby lower healthcare costs; as *Mensing* itself observed, "it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public." 131 S. Ct. at 2582. The First Circuit acknowledged as much: "There is no doubt that Congress wanted to reduce medical costs by spurring generic copycat drugs [and *Mensing*] held that Congress cannot have wanted the generic to pay damages under state law for a label that the FDA required." App. 10a. But the appellate court simply didn't care—casually asserting that it would refuse to apply *Mensing* to any claim not captioned

"failure to warn" unless and until this Court made clear that it meant what it said. App. 11a ("Bartlett having lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief."); *id.* ("[I]t is up to the Supreme Court to decide whether [*Mensing*]'s exception is to be enlarged to include design defect claims. Given the widespread use of generic drugs and the developing split in the lower courts, this issue needs a decisive answer from the only court that can supply it.") (internal citations omitted).

C. This Court Should Consider Summary Reversal.

The First Circuit's rejection of this Court's precedents is so transparent that the Court should consider summary reversal. The panel recognized that there is no logical difference between design-defect and failure-to-warn claims for purposes of assessing preemption under the Hatch-Waxman Act. App. 10a ("Mutual argues with some force that the generic maker also cannot alter the composition of the drug and so [*Mensing*]'s policy of encouraging generics by preempting state tort claims should extend to design defect as well as claims based on inadequate warning."). The panel acknowledged that this Court considered and rejected the very same theory of liability when it reviewed the Eighth Circuit's decision in *Mensing*. *Id.* ("[T]he FDCA might permit states to tell Mutual it ought not be [selling its product] *despite what the Supreme Court made of similar arguments in the labeling context*.") (emphasis added). And the panel conceded that the

"rationale" of *Mensing* applies no less here than it did there. App. 11a.

Even so, the panel declined to follow the logic of this Court's decisions, choosing instead to adopt a rationale that it admitted would have produced the opposite outcome in *Mensing*. *Id*. ("[A] generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug."). And the panel effectively dared this Court to say that *Mensing* meant what it said. "Bartlett having lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief." *Id*. Yet as *Mensing* explained, it was not "mere chance" that Ms. Bartlett's pharmacist supplied a generic; that was the anticipated and intended consequence of the Hatch-Waxman Act, which lowers the cost of health care for all of us. 131 S. Ct. at 2581. And she did not "lose" her warning claim; the "special, and different, regulation of generic drugs" under federal law meant that the Constitution bars states from imposing liability on a manufacturer that has no ability to change its product. *Id*.

Perhaps, to use *Mensing*'s words, "from the perspective of [the First Circuit], finding pre-emption here but not in *Wyeth* makes little sense." *Id*. But in our hierarchical system, lower courts may not decline to apply this Court's rationales to materially indistinguishable cases merely because of policy disagreement—and this Court likewise has made clear that summary reversal is appropriate where the lower courts adopt a rationale that this Court has rejected. *See, e.g.*, *Goldhammer*, 474 U.S. at 29-

30 (summary reversal warranted because the lower court's "rationale is inconsistent with the rationale of the holding of this Court."); *see also Am. Tradition P'ship, Inc.*, 132 S. Ct. at 2491.

Given the First Circuit's own request for "a decisive answer" to its circuit split-creating decision, App. 11a, however, we respectfully submit that this Court should supply it. The petition should be granted, and the Court should consider summarily reversing the appellate court's decision.

CONCLUSION

For the foregoing reasons, the petition should be granted and the appellate court's judgment reversed.

July 31, 2012

Respectfully submitted,

JAY P. LEFKOWITZ, P.C.
Counsel of Record
KIRKLAND & ELLIS LLP
153 East 53rd Street
New York, NY 10022
(212) 446-4800
(212) 446-4900 (fax)
lefkowitz@kirkland.com

MICHAEL W. MCCONNELL
MICHAEL D. SHUMSKY
JOHN K. CRISHAM
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005
(202) 879-5000
(202) 879-5200 (fax)
mcconne@kirkland.com
mshumsky@kirkland.com
jcrisham@kirkland.com

Counsel for Petitioner Mutual Pharmaceutical Company, Inc.