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No. 09-1501

IN THE
Supreme Court of the United States

ACTAVIS, INC.,
Petitioner,
v.

JULIE DEMAHY,
Respondent.

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

REPLY BRIEF FOR PETITIONERS

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Petitioner seeks certiorari on the question, squarely presented by the decision of the Fifth Circuit, of whether the states are preempted by the Federal Food, Drug, and Cosmetic Act and Food and Drug Administration (FDA) regulations from requiring a manufacturer of a generic drug to add safety information to its label without FDA approval, where the brand drug has not changed its label. The issue is a purely legal question and one that requires this Court's swift intervention, so that generic drug companies may know whether they have unilateral authority to change their product labels, which the FDA had previously instructed was prohibited by federal law. Without this Court's intervention, generic drug companies will be forced to bear the cost of thousands of lawsuits, while waiting for courts to resolve the legal issue presented by Actavis's petition for certiorari, potentially forcing them to abandon their low-cost business model that has been the basis for tremendous healthcare savings in this country.

In her Opposition, Respondent offers barely any defense of the Fifth Circuit's holding that a generic drug manufacturer may make a unilateral change to its label through the "Changes Being Effected" (CBE) process, and she has chosen not to respond to Petitioner's argument that such a change is flatly prohibited by FDA's regulations. *See* Petition at 9-11. Instead, Respondent contends that certiorari should not be granted because a decision in this case would be an "advisory opinion." As we demonstrate below, however, a decision in this case favorable to Petitioner would not be advisory because

it will eliminate one of Respondent's discrete theories for liability, thus affecting the types of evidence that would be introduced at trial and potentially the outcome on remand. Because the issue presented is a purely legal question, there is no obstacle to deciding it now rather than waiting for the conclusion of trial and a final judgment.

I. A RULING PREVENTING RESPONDENT FROM PURSUING AN INVALID THEORY OF LIABILITY AT TRIAL IS NOT AN ADVISORY OPINION.

Although Respondent devotes considerable attention to the merits of the preemption issue in her Brief in Opposition, she offers little defense of the Fifth Circuit's holding that the manufacturer of a generic drug may unilaterally make changes to its label under the CBE regulation. As demonstrated in the petition in this case and the petitions and amicus brief filed in *Acatvis Elizabeth, LLC v. Mensing*, No. 09-1039 and *Pliva, Inc. v. Mensing*, No. 09-993, that holding was erroneous. Whether or not Respondent may proceed under other theories of liability – an issue presented in *Mensing* but not in this case – a decision by this Court precluding Respondent from relying on the CBE regulation will have a direct and dramatic effect on the trial of this case and the many other such cases pending across the country.

Respondent breezily contends that the petition should be denied because it asks the Court to render an "advisory opinion." Opp. at 7-9. The prohibition against advisory opinions is rooted in the Article III limitation on judicial power to "cases" or

"controversies." *See Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239 (1937). In order to be justiciable, there must be "a real and substantial controversy" admitting of "an immediate and definitive determination of the legal rights of the parties in an adversary proceeding." *Id.* at 241. The doctrine protects against determination of disputes that are of "a hypothetical or abstract character," "academic," or "moot." *Id.* at 240. This is not the circumstance here, where Petitioner and Respondent "remain adverse, and 'valuable legal rights . . . will be directly affected to a specific and substantial degree by the decision of the question of law.'" *Asarco Inc. v. Kadish*, 490 U.S. 605, 619 (1989).

Here, a decision reversing the Fifth Circuit's holding that a generic drug manufacturer may make unilateral label changes will directly and specifically affect the legal rights of Respondent and Petitioner in their ongoing litigation. If this Court holds that federal law prohibits a generic manufacturer from making a unilateral label change, Respondent will be unable to proceed on its theory that Petitioner had a duty to warn by changing its label prior to the time the brand had changed its label. Instead, Respondent will have to proceed on a completely different theory and to establish that Petitioner had a duty to seek permission from FDA to change its label, and that FDA would have approved that change. Petitioner's liability will be limited to this alternative theory, which is not described in her complaint below (App. 92a-112a), and Respondent will be required to make an entirely different factual showing at trial than would be required if she is permitted to proceed under the theory that Petitioner

may unilaterally change its label, including possibly presenting evidence on whether FDA would have granted a request for a label change.

The Fifth Circuit has already ruled against Respondent's claim that Actavis had a duty to communicate directly with physicians about the claimed risks of metoclopramide, absent prior FDA approval. App. 34a-35a. Respondent's primary theories will thus be eliminated, changing the evidence, jury instructions, and course of the entire trial. Review by this Court is appropriate where the decision "is fundamental to the further conduct of the case." *United States v. General Motors Corp.*, 323 U.S. 373, 377 (1945).

The only case cited by Respondent, *Herb v. Pitcairn*, 324 U.S. 117 (1945), does not support her advisory opinion argument. *See* Opp. at 8. *Herb* addresses the situation in which a challenge to one of several alternative rulings would not have affected the final judgment. 324 U.S. at 125-26. In that case, the Supreme Court decided to seek clarification from the state court as to whether the final judgment rested – independently and in total – on a state law ground, such that a decision on the issue of federal law could not have changed the judgment or afforded any relief to the petitioner. In such a case, providing an opinion on that point of federal law is advisory because it affects nothing between the parties below. In the present case, as explained above, the alternative theories of liability lead to very different proceedings in the lower court and potentially to a different result. While Respondent's failure to warn claim may survive even if this Court rules in

Petitioner's favor, the primary theory of liability will be preempted and Respondent will have a much more difficult time proving her case.

Just as reviewing the decision on a motion to exclude evidence is appropriate because it raises an important issue regarding the conduct of the upcoming trial, *see Oliver v. United States*, 466 U.S. 170 (1984), so too will a decision in this case provide clarity on an important legal issue and narrow the issues for trial. The question in this case is one of pure law, involving interpretation of statutes and FDA regulations, and Respondent has not pointed to any factual development that could possibly clarify the issue any further. Indeed, this case is comparable to *Weyhrauch v. United States*, 130 S. Ct. 2971 (2010) (remanded for further consideration in light of the decision in *Skilling v. United States*, 130 S. Ct. 2896 (2010)), where the Court granted certiorari last term on a question related to just one particular theory of honest services fraud. *See Weyhrauch v. United States*, 129 S. Ct. 2863 (2009) (granting petition for writ of certiorari). Even if the Court had resolved the question presented in that case against the government, the honest services fraud prosecution still could be pursued under a different theory. *See United States v. Weyhrauch*, 548 F.3d 1237, 1247 (9th Cir. 2008) (noting that the allegations could support an alternative theory of honest services fraud). That is exactly the situation here, where this Court's decision will resolve the most important theory, although it may not dispose entirely of Respondent's case. The fact that a claim may go forward on a very different theory does not make a decision "advisory."

II. THE ISSUE IS IMPORTANT AND MERITS IMMEDIATE REVIEW EITHER ALONE OR IN CONJUNCTION WITH *MENSING*.

The Fifth Circuit's holding that generic drug manufacturers are allowed to make unilateral label changes has national importance. The decision effectively imposes severe financial obligations on generic drug manufacturers nationwide because of the risk of liability in a court in the Fifth Circuit. Under the system designed by Congress, generic companies are not required to conduct clinical trials or to engage in the difficult and expensive work of monitoring and analyzing the information to determine if a labeling change is appropriate. If the Fifth Circuit's decision stands, new litigation and other costs may be imposed on generic companies by state law, which may diminish the ability of generic companies to provide a low cost product to consumers. This petition presents an issue of great importance, and a purely legal question, that can and should be resolved now. This issue can be resolved on its own, or in conjunction with the petitions in *Mensing*, which raise closely related questions.*

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* On May 24, 2010, the Court requested the Solicitor General's views in *Mensing*, which also raises the legal issue Petitioners have urged this Court to decide. Accordingly, Petitioners respectfully request that the Court consider the *Mensing* and *Demahy* petitions at the same time.

Respectfully submitted,

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