No. 09-____

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 Eleventh Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Are the states preempted under the Supremacy Clause of the Constitution from requiring additional safety information on a generic product label where the brand has not changed its label?

LIST OF PARTIES

The caption of the case contains the names of all parties to the appellate proceeding in the Fifth Circuit Court of Appeals.

CORPORATE DISCLOSURE STATEMENT

Actavis Group hf is a privately-held Icelandic company, and the parent corporation of Actavis Group PTC, ehf, which is the parent of petitioner Actavis Inc., a Delaware corporation. Actavis-Elizabeth, LLC, a subsidiary of Actavis Inc., is the successor to Purepac Pharmaceutical Co., Inc., which no longer exists. No publicly held corporation owns ten percent or more of Actavis Inc.'s stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

OTHER AUTHORITIES

OPINIONS BELOW

The decision of the Fifth Circuit Court of Appeals is reported at 593 F.3d 428 (5th Cir. 2010) and reprinted in the Appendix (App.___) at 1a-46a. The district court's decision is reported at 586 F. Supp. 2d 642 (E.D. La. 2008), and reprinted at App. 47a-91a.

JURISDICTION

The Fifth Circuit Court of Appeals rendered its decision on January 8, 2010. On April 5, 2010, Justice Scalia extended the time for petitioner to file a petition for a writ of certiorari to June 7, 2010. This Court has jurisdiction under 28 U.S.C. § 1254.

CONSTITUTIONAL, STATUTORY AND REGULATORY PROVISIONS INVOLVED

The pertinent provisions of U.S. Const., Art. VI, clause 2, 21 U.S.C. § 355 and 21 C.F.R. §§ 314.3, 314.70, 314.94, 314.97 and 314.150 are reproduced at App. 113a-131a.

INTRODUCTION

This petition, which arises from litigation seeking to hold a generic drug manufacturer liable under state products liability law for not adding safety information to the label of its product, is similar to the petitions in *Actavis Elizabeth, LLC v. Mensing*, No. 09-1039 (petition for cert. filed Feb. 25, 2010), and *Pliva, Inc. v. Mensing*, No. 09-993 (petition for cert. filed Feb. 19, 2010), on which this Court

recently requested the views of the Solicitor General. Review of these cases by this Court is appropriate because the lower courts have misinterpreted *Wyeth, Inc. v. Levine*, 129 S. Ct. 1187 (2009), disregarding crucial differences between the labeling responsibilities of generic drug manufacturers and those of manufacturers of branded drugs. *Wyeth* held that manufacturers of branded drugs can comply with a duty to warn imposed by state law by making a unilateral label change. 129 S. Ct. at 1196-99. Generic drug manufacturers cannot do the same because they must at all times adhere to the label of the branded drug.

The decision below squarely addressed generic drug manufacturers' ability to institute a label change, making this case an appropriate vehicle in which to resolve a question of urgent national importance. In *Mensing,* the Eighth Circuit declined to decide that issue, resolving the preemption issue on the alternative ground that a generic drug manufacturer may be able to harmonize its state and federal duties by merely proposing a label change to the Food and Drug Administration (FDA). *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009).

In addition to having been considered by the Fifth and Eighth Circuits, the issue of whether the Federal Food, Drug and Cosmetic Act (FFDCA) preempts state product liability claims against generic drug companies, based on an obligation to include safety information on their labels when the brand has not done so, is raised in cases currently pending in the Sixth and Ninth Circuits, and it has been decided by numerous district courts.

In general, the courts have read *Wyeth* too broadly, as if that decision swept away federal preemption for all drug product liability claims. The nearly uniform misapplication of *Wyeth* by the lower courts requires this Court's intervention now, before generic drug manufacturers are forced by the threat of liability to abandon their low-cost business model, which provides patients access to drugs at reduced prices as envisioned by Congress when it passed the Hatch-Waxman Amendments to the FFDCA (Hatch-Waxman).

STATEMENT

A. Regulatory Framework

1. New Drugs

The process of bringing a new drug to market is expensive and time consuming. Under the FFDCA, a new drug may not be marketed until FDA has approved a new drug application (NDA). 21 U.S.C. §§ 331(d), 355(a). Before an NDA is submitted, the manufacturer must conduct a range of preclinical investigations, obtain FDA authorization to conduct human clinical trials designed to establish safety and efficacy, and then conduct those clinical studies. 21 U.S.C. § 355(i); 21 C.F.R. § 312.20. Once all of these studies have been completed, the sponsor must submit an NDA, containing "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective." 21 U.S.C. § 355(b)(1)(A). According to a recent study, the research to obtain approval of a single new drug can cost close to $1

billion.[1] Because FDA will find a drug safe and effective only under labeled conditions of use, FDA must review the drug label as part of the NDA process. 21 U.S.C. § 355(a), (b)(1)(F), (c)(1)(A), (d).

After a drug is approved, the brand manufacturer's obligations continue. Manufacturers must maintain records, conduct additional testing as directed, and advise FDA of significant adverse health consequences that are reported following the drugs introduction to the market (adverse event reporting). 21 U.S.C. § 355(k)(1); 21 C.F.R. § 314.80.

Further, as this Court held in *Wyeth* (129 S. Ct. 1187), when new information about the safety of a drug becomes apparent to the brand manufacturer, the brand manufacturer has the ability and obligation to change its label. 21 C.F.R. § 201.80(e). Through the "Changes Being Effected" (CBE) process, the brand can make such a change as soon as FDA receives the brand's supplemental application; it need not await FDA approval. 21 C.F.R. § 314.70(c)(6)(iii)(A), (C).

2. Generic Drugs

In 1984, Congress enacted Hatch-Waxman to streamline the process by which companies obtain approval of generic versions of brand drugs once the brand patents have expired (as extended by Hatch-Waxman). H. R. Rep. No. 98-857, pt. 2 at 8-9 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2686, 2692-93. The principal goal of the Act was to make available

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[1] Christopher Paul Adams & Van Vu Brantner, *Spending on New Drug Development*, 19 Health Econ. 130 (2010).

low cost generic drugs. *Serono Labs., Inc. v. Shahala*, 158 F.3d 1313, 1316 (D.C. Cir. 1998). Unlike the brand sponsor, which must submit scientifically valid clinical trials demonstrating safety and efficacy in order to obtain approval, the generic applicant can "piggyback" on the safety and effectiveness information that the brand submitted and must show only that its product is the same as the brand. *Purepac Pharm. Co. v. FDA*, 354 F.3d 877, 879 (D.C. Cir. 2004).

Under the Act, FDA will approve a generic drug for marketing upon proof that the drug (1) has the same active ingredient(s) as; (2) has the same route of administration, dosage form and strength as; (3) *has the same labeling as*; and (4) is bioequivalent to, the brand drug. 21 U.S.C. § 355(j)(2)(A)(i-v) (emphasis supplied). In other words, the thrust of Hatch-Waxman is that the generic must demonstrate that its product is a copy of the brand in every significant respect, including its labeling, so that once approved the generic version can be substituted for the brand without a physician's intervention. *See* FDA, Approved Drug Products with Therapeutic Equivalence Evaluations, p. iv (30th ed. 2010). The generic manufacturer is neither required to conduct the clinical studies needed to obtain approval of the brand product nor expected to master the clinical data that supports the various claims made on the product's label. Instead, the obligation of the generic manufacturer is to make a product that is a true copy of the brand.

Although a generic manufacturer is required to submit any adverse event reports that it receives

after a generic drug is approved, the vast majority of such reports do not go to the generic manufacturer, but instead go directly to FDA or to the brand manufacturer. *See* FDA, Manual of Policies and Procedures, Center for Drug Evaluation and Research, Office of Generic Drugs, Handling of Adverse Experience Reports and Other Generic Drug Postmarketing Reports, MAPP 5240.8 (Nov. 1, 2005).

Generic drugs have the same labeling as their brand counterparts. 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8)(iii). This means that generic drugs must have the same warnings as the brand. If the brand does make a labeling change, it is the generic manufacturer's responsibility to mirror that change in its own label. *See* FDA, Guidance for Industry, Revising ANDA Labeling Following Revision of the RLD Labeling (May 2000) (ANDA Labeling Revision Guidance). If the brand does not make a labeling change, however, the generic manufacturer may not make a unilateral change to its own label. Making changes that render the generic label different from the label of its reference listed drug is prohibited by the statute and regulations that require the generic label to be the same as the brand label *at all times*. If a generic does not maintain the same label as the brand, FDA can remove the generic from the market. 21 C.F.R. § 314.150(b)(10).

Generic drugs are an important component of efforts to control healthcare costs. In the last decade (1999-2008), generic medicines saved the American

health care system more than $734 billion, with approximately $121 billion in savings in 2008 alone.[2]

B. Proceedings Below

Julie Demahy brought this action alleging that she suffered from tardive dyskinesia, a serious movement disorder, which she alleges was caused by the drug metoclopramide. At the time Demahy took metoclopramide, it was being sold under the brand name Reglan by Schwarz, which had purchased the NDA from Wyeth, Inc. in 2001, and under its generic name metoclopramide by Purepac Pharmaceutical Co., which was purchased by petitioner Actavis. Demahy alleges in her complaint that her physician prescribed metoclopramide to her for more than four years. App. 96a-97a.

Demahy also alleges that Wyeth, as a successor to A.H. Robbins, "expressly warranted to some physicians that Reglan and/or metoclopramide was safe in long-term use," App. 102a, even though such a claim by Wyeth would have been contrary to Reglan's explicit labeling, which limited use to 12 weeks duration.[3] Demahy claims that Actavis is

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[2] *See* IMS Health & Generic Pharm. Ass'n, *Economic Analysis, Generic Pharmaceuticals 1999-2008: $734 Billion in Health Care Savings* (May 2009), available at http://gphaonline.org/sites/default/files/$734%20Billion%20in%20Generic%20Savings%20GPhA.pdf.

[3] The Reglan label in effect during the relevant time can be found at www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory.

liable under Louisiana products liability law for failing to include warnings about the risk of tardive dyskinesia from prolonged use in addition to those on the Reglan label.

Actavis moved to dismiss all of Demahy's claims on federal preemption grounds. The district court held that Demahy's failure to warn claims were not preempted. Reviewing that decision as an interlocutory appeal under 28 U.S.C. § 1292, the United States Court of Appeals for the Fifth Circuit affirmed. While acknowledging that Hatch-Waxman required that Actavis' product have the same label as Reglan at the time it was approved, the Fifth Circuit held that, just like the brand manufacturer in *Wyeth*, Actavis could have changed its label after approval if there was new safety information and that therefore Demahy's claim was not preempted. App. 23a-33a.[4]

REASONS FOR GRANTING THE WRIT

I. THE FIFTH CIRCUIT INCORRECTLY DECIDED AN IMPORTANT QUESTION OF FEDERAL LAW THAT SHOULD BE SETTLED BY THIS COURT.

In *Wyeth*, this Court held that the manufacturer of a *branded* drug could comply with

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[4] The Court rejected Demahy's contention that Actavis could have communicated directly with physicians about the risks associated with prolonged use of metoclopramide without FDA approval. App. 34a-35a. The Court also held that Actavis could have proposed a labeling change to the FDA. *Id.* That issue is raised in the *Mensing* petitions, but Petitioner has limited this petition to the issue of preemption of a state requirement that the generic change its label where the brand has not.

both federal law governing labeling and a duty to warn imposed by state products liability law because the manufacturer could change the label unilaterally pending FDA approval under the CBE regulation, 21 C.F.R. § 314.70(c)(6)(iii)(A), (C). 129 S. Ct. at 1996-99. Contrary to the text of governing statutes and regulations, the Fifth Circuit held that manufacturers of generic drugs may also make unilateral label changes under the CBE regulation.

While the CBE regulation explicitly permits the brand manufacturers to add a warning to their labels without FDA approval, the FDA law and regulations explicitly *prohibit* a generic manufacturer from making any change, including the addition of a warning, to the label of its products, if that change causes its label to deviate from that of the brand. That prohibition makes it impossible for the manufacturer of a generic drug to satisfy a state jury's determination that it has a duty to add a warning not found on the label of the brand drug, preempting such state failure-to-warn claims.

The FFDCA and FDA's implementing regulations require a generic drug to have the same label as the brand. 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8)(iii).[5] One of the grounds for not approving a generic drug is that the labeling proposed for the drug is not the same. 21 U.S.C. § 355(j)(4)(G). Although the Fifth Circuit acknowledged that a generic drug label has to mirror the brand at the time of approval, it concluded that

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[5] The statute and regulations do permit certain differences in labeling that are not applicable here. *See* 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8)(iv).

the FDA's requirements for approving a generic drug cease to matter after approval. App. 16a-37a.

That conclusion is wrong: a generic drug is required to have labeling that is identical to the brand *at all times*. If the brand drug changes its labeling after a generic is on the market, the generic must revise its label. *See* ANDA Labeling Revision Guidance at 4. Likewise, even if FDA requires labeling changes for the brand, as it did when it revised the prescription drug label format, the generic must wait until the brand changes its label before making the changes. *See* Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products, 71 Fed. Reg. 3922, 3928 (Jan. 24, 2006). If a generic does not maintain the same label as the brand, FDA can remove the generic from the market. 21 C.F.R. § 314.150(b)(10).

In concluding that the same labeling requirement applies only at the time of approval, the Fifth Circuit ignored a central FDA regulation that defines "abbreviated application". The term is defined as an "application described in 314.94 *including all amendments and supplements* to the application." 21 C.F.R. § 314.3 (emphasis added). Thus, the same labeling requirement set out in 21 C.F.R. § 314.94, which applies in the first instance to "[a]bbreviated applications", applies by reference to ANDA amendments and supplements. Any change made in a supplement, pursuant to the CBE regulation, is therefore subject to the same labeling requirement, *i.e.*, the labeling in the supplement must also mirror the brand label. Thus, a generic

drug manufacturer can invoke the CBE regulation, but only to conform the generic drug's label to a change already made by the brand.

The Fifth Circuit cites an FDA regulation, 21 C.F.R. § 314.97, which explicitly states that a generic drug applicant must comply with the CBE regulation, 21 C.F.R. § 314.70, to support its assertion that the generic manufacturer may unilaterally add warning information to its label. App. 26a-27a. While section 314.97 requires a generic drug manufacturer to use the CBE process to change its label to match a change in the brand label, the Fifth Circuit was wrong in finding that it provides any authority for the generic manufacturer to unilaterally change its label. As explained above, such unilateral changes are prohibited by sections 314.3 and 314.94(a)(8)(iii).

In *Wyeth,* this Court held that "it is not impossible for Wyeth to comply with its state and federal law obligations." 129 S. Ct. at 1204. According to this Court, "[t]he CBE regulation permitted Wyeth to unilaterally strengthen its warning." *Id.* at 1199. But generic manufacturers do *not* have the ability to unilaterally change their label in a manner that is different from the brand. It is legally impossible for them to satisfy a jury-imposed duty to add warnings that differ from the warnings on the brand label.

Nevertheless, even though prior to *Wyeth* the lower courts often held that the FFDCA preempted failure to warn claims against generic

manufacturers,[6] since the *Wyeth* decision, the lower courts have generally reached the opposite result. District courts have relied on the erroneous rationale adopted by the Fifth Circuit[7] or the incomplete rationale of the Eighth Circuit,[8] or they have left the reasoning unclear.[9]

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[6] *See, e.g.*, *Gaeta v. Perrigo Pharms. Co.*, 672 F. Supp. 2d 1017, 1020-21 (N.D. Cal. 2009) (on motion for reconsideration); *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R, 2009 WL 736200 (W.D. Ky. Mar. 4, 2009), (denying reconsideration in light of *Wyeth* of 582 F. Supp. 2d 861, 868-69 (W.D. Ky. 2008)); *Bolin v. Smithkline Beecham Corp.*, No. 08-60523-CIV, 2008 WL 3286973, at *8 (S.D. Fla. Aug. 7, 2008); *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056, 1063-64 (D. Minn. 2008), *rev'd*, 588 F.3d 603 (8th Cir. 2009).

[7] *Dorsett v. Sandoz, Inc.*, No. CV 06-7821 AHM (AJWAx), 2010 WL 1174204, at *17-18 (C.D. Cal. Mar. 26, 2010); *Vitatoe v. Mylan Pharms., Inc.*, Civil Action No. 1:08CV85, 2010 WL 1008788, at *15 (N.D.W. Va. Mar. 5, 2010); *Munroe v. Barr Labs., Inc.*, 670 F. Supp. 2d 1299, 1302-03 (N.D. Fla. 2009); *Stacel v. Teva Pharms. USA*, 620 F. Supp. 2d 899, 907 (N.D. Ill. 2009); *Bartlett v. Mut. Pharm. Co.,* 659 F. Supp. 2d 279, 296-305 (D.N.H. 2009).

[8] *Swicegood v. Pliva, Inc.*, No. 1:07-CV-1671-TWT, 2010 WL 1138455, at *6 (N.D. Ga. Mar. 22, 2010); *Weilbrenner v. Teva Pharms. USA, Inc.,* Civil Action No. 7:08-CV-23 (HL), 2010 WL 924915, at *7 (M.D. Ga. Mar. 10, 2010); *Fulgenzi v. Wyeth, Inc.*, 686 F. Supp. 2d 715, 722 (N.D. Ohio 2010); *Couick v. Wyeth, Inc.*, No. 3:09-cv-210-RJC-DSC, 2009 WL 4644394, at *3 (W.D.N.C. Dec. 7, 2009).

[9] It is unclear whether the district court considered any argument specific to generic manufacturers in *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262 (W.D. Okla. 2009), which was decided a week after this Court's decision in *Wyeth v. Levine*. The decisions in *Pustejovsky v. Wyeth, Inc.*, No. 4:07-CV-103-Y, 2009 WL 3336032 (N.D. Tex. Sept. 4, 2009), and *Kellogg v. Wyeth,*

The lower courts' confusion about the proper scope of this Court's decision in *Wyeth* is itself a basis for granting certiorari.

II. PROMPT RESOLUTION OF THE QUESTION PRESENTED IS IMPORTANT TO PRESERVING THE ABILITY OF GENERIC DRUG COMPANIES TO CONTINUE TO PRODUCE LOW COST DRUGS.

This case is an appropriate vehicle to decide a question of national importance that should be settled by this Court, as the Court did with respect to branded drugs in *Wyeth*. Although a division among the Circuits would be an additional reason to grant review, this Court should not wait for the outcome of the appeals now pending before the Sixth and Ninth Circuits.[10]

Low-priced generic drugs now account for nearly 75% of prescription drugs sold in this country, and are an important component of efforts to control healthcare costs.[11] The Fifth Circuit decision,

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Inc., 612 F. Supp. 2d 437 (D. Vt. 2009), are unclear about the rationale for rejecting preemption.

[10] Argument in three pending appeals in the Sixth Circuit is scheduled on June 9, 2010. *Smith v. Wyeth, Inc.*, No. 09-5460 (6th Cir.); *Morris v. Wyeth, Inc.*, No. 09-5509 (6th Cir); *Wilson v. PLIVA, Inc.*, No. 09-5466 (6th Cir.). The Ninth Circuit has not yet scheduled argument in *Gaeta v. Perrigo Pharms. Co.*, No. 09-15001 (9th Cir. filed Jan. 6, 2009).

[11] IMS Health & Generic Pharm. Ass'n, *Economic Analysis, Generic Pharmaceuticals 1999-2008: $734 Billion in Health Care Savings* (May 2009), available at

however, threatens to undercut this success by imposing on the generic drug industry some of the burdensome and duplicative requirements that Hatch-Waxman sought to eliminate.

Congress designed a bifurcated regime for the manufacture of pharmaceuticals. As described above, companies that manufacture branded "pioneer" drugs must conduct extensive testing on the safety and effectiveness of their products prior to approval. Generic drug manufacturers are absolved from conducting such studies as long as they can demonstrate that their product is the same as the brand. Under the system designed by Congress, generic companies are not required to conduct, understand or interpret the clinical trials on safety and efficacy previously conducted by the brand manufacturer to obtain approval of the pioneer drug. Nor are they in possession of any post-marketing data generated in the years that the brand marketed its product without generic competition, which is often more than a decade.

Generic drug companies are required to report adverse events involving their products to the FDA, but they are not required to conduct any post-approval safety analyses. In fact, even after a generic drug is approved, the vast majority of adverse event reports go directly to FDA or the branded drug

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http://gphaonline.org/sites/default/files/$734%20Billion%20in%20Generic%20Savings%20GPhA.pdf (generic medicines saved the American health care system more than $734 billion between 1999 and 2008 with approximately $121 billion in savings in 2008 alone).

manufacturer.[12] The bottom line is that, under the statutory scheme, generic companies are not required to and do not monitor or analyze the information needed to determine if a labeling change is appropriate.

The parade of district courts that have already followed the Fifth and Eighth Circuits into error threatens to force a restructuring of the drug industry from one in which development and monitoring expenses are borne by pioneer drug manufacturers who receive an extended patent monopoly, to one in which generic drug manufacturers must develop their own analytical capabilities or must exit the business under threat of state tort liability. Generic drug manufacturers will be required to invest the substantial sums of money and time needed to analyze the underlying safety data and to collect and evaluate new data. Such an outcome could diminish the ability of generic drug companies to continue to sell their products at the substantially reduced prices currently charged, as Congress intended. *See* Brief of the Generic Pharm. Ass'n as Amicus Curiae, *Pliva, Inc. et al. v. Mensing*, *Actavis Elizabeth, LLC v. Mensing*, Nos. 09-993 & 09-1039, 16-20 (filed Apr. 21, 2010).

The facts of this case highlight the problem with holding the generic manufacturer liable. According to the Complaint, Wyeth as successor to A.H. Robbins, which manufacturered the brand,

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[12] *See* FDA, Manual of Policies and Procedures, Center for Drug Evaluation and Research, Office of Generic Drugs, Handling of Adverse Experience Reports and Other Generic Drug Postmarketing Reports, MAPP 5240.8 (Nov. 1, 2005).

"expressly warranted to some physicians that Reglan and/or metoclopramide was safe in long-term use, knowing that physicians would share the information with other physicians in their community . . . ." App. 102a. As explained above, metoclopramide was never approved for use of more than 12 weeks. *See* p. 7, *supra*. Since generic companies do not rely on traditional advertising to physicians,[13] there is no sound public policy reason to hold them liable for injuries allegedly resulting from unapproved uses that they did not promote.

The decisions of the lower courts create tremendous uncertainty that should be resolved by this Court so that the industry will know with clarity whether its companies are required to change their entire business model. The financial impact on this industry, which is so vital to patient care and efforts to control national health care costs, is by itself a sufficient reason to grant certiorari.

CONCLUSION

The petition for a writ of certiorari should be granted. If the Court does not grant certiorari in this case and grants certiorari in *Pliva, Inc. v. Mensing*, No. 09-993, and *Actavis Elizabeth, LLC v. Mensing*,

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[13] *See New Initiative to Improve Availability of Generics*, at www.fda.gov/ForConsumers/ConsumerUpdates/ucm151180.htm (last visited June 3, 2010); *Facts and Myths About Generic Drugs*, at www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm (last visited June 3, 2010).

No. 09-1039, it should hold this case until it issues its decision in the *Mensing* cases.

Respectfully submitted,

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