No. 1101397

SUPREME COURT OF ALABAMA

WYETH, INC., et al.,

Defendants-Appellants,

v.

DANNY WEEKS AND VICKI WEEKS,

Plaintiffs-Appellees.

SUPPLEMENTAL BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, AS AMICUS CURIAE, REGARDING MUTUAL PHARMACEUTICAL CO. V. BARTLETT, 133 S. CT. 2466 (2013)

CERTIFIED QUESTION FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF ALABAMA, SOUTHERN DIVISION CASE NO.1:10-CV-00602-MEF-TFM

Attorneys for Amicus Curiae
The Chamber of Commerce of the United States of America:

Kate Comerford Todd (pro hac vice)
Email: KTodd@uschamber.com
NATIONAL CHAMBER LITIGATION CENTER, INC.
1615 H Street, NW
Washington, DC 20062
Telephone: (202) 463-5337
Facsimile: (202) 463-5346

Ed R. Haden
Email: ehaden@balch.com
BALCH & BINGHAM LLP
1901 Sixth Avenue North
Suite 1500
Birmingham, AL 35201-0306
Telephone: (205) 226-8795
Facsimile: (205) 488-5648

August 1, 2013

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Constitutional Provisions

Supplemental Brief
of the Chamber of Commerce the United States of America,
as Amicus Curiae, Regarding
***Mutual Pharmaceutical Co. v. Bartlett*,**
133 S. Ct. 2466 (2013)

In Mutual Pharmaceutical Co. v. Bartlett, 133 S. Ct. 2466 (2013), the U.S. Supreme Court held that because federal law bars generic drug manufacturers from making label changes, federal law preempted a state law design-defect claim that would have required a generic drug manufacturer to change its warning label. The Bartlett decision confirms that it is not the role of a court to "distort" existing law to make an end-run around preemption. Aside from that bedrock principle, Bartlett does not apply this to this case – which involves a state law claim against a brand-name drug manufacturer.

ARGUMENT

I. Bartlett's Holding That Federal Law Preempts State Common Law Claims That Would Require A Generic Drug Manufacturer To Change Its Warning Label Does Not Apply To The Claims In This Case Against A Brand-Name Manufacturer.

The plaintiff in Mutual Pharmaceutical Co. v. Bartlett, 133 S. Ct. 2466, 2472 (2013), ingested a generic form of the drug sulindac for shoulder pain. Upon sustaining

injuries, she sued the manufacturer of that generic drug for design defect under New Hampshire law. Id.

Relying on its earlier decision in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2581-82 (2011), the Supreme Court held that the plaintiff's state law design-defect claim was preempted by federal law that prevents generic drug manufacturers from changing the warning labels for their products:

> Given the impossibility of redesigning sulindac, the only way for Mutual to ameliorate the drug's "risk-utility" profile — and thus to escape liability — was to strengthen "the presence and efficacy of [sulindac's] warning" . . . . New Hampshire's design-defect cause of action imposed a duty on Mutual to strengthen sulindac's warnings.
>
> . . . .
>
> As PLIVA made clear, federal law prevents generic drug manufacturers from changing their labels . . . . Thus, federal law prohibited Mutual from taking the remedial action required to avoid liability under New Hampshire law.
>
> . . . .
>
> Because it is impossible for Mutual and other similarly situated manufacturers to comply with both state and federal law, New Hampshire's warning-based design-defect cause of action is pre-empted with respect to FDA-approved drugs sold in interstate commerce.

Bartlett, 133 S. Ct. at 2475, 2476-77(emphases added).

Bartlett's holding regarding preemption of claims against a generic manufacturer is not applicable to and should have no effect on the Weekses' claims against the brand-name manufacturers in this case. Both Ms. Bartlett and Mr. Weeks took generic drugs. Ms. Bartlett sued the company that manufactured the generic drug that she claimed harmed her, while Mr. Weeks is suing brand-name manufacturers that did not manufacture the generic drug that he claims harmed him.

II. Bartlett and Mensing Confirm That It Is Not The Judiciary's Duty To "Distort" Existing Jurisprudence To Evade Federal Preemption.

In Mensing, 131 S. Ct. at 2581-82, the Supreme Court majority[1] rejected the dissenters'[2] requests to "distort" existing law to allow generic drug consumers to seek common law remedies. In particular, the majority stated that "'it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre.'" Id. (quoting Cuomo v. Clearing House Ass'n,

[1] Justice Thomas authored the majority opinion in Mensing; he was joined by Chief Justice Roberts and Justices Scalia, Kennedy, and Alito.

[2] Justice Sotomayor authored the dissenting opinion; she was joined by Justices Ginsburg, Breyer, and Kagan.

L.L.C., 557 U.S. 519, 556 (2009) (Thomas, J., concurring in part and dissenting in part) (some internal quotation marks and brackets omitted)). In the same way, the majority wrote that it would "not distort the Supremacy Clause in order to" guarantee plaintiffs a remedy and reiterated that "[a]s always, Congress and the FDA retain the authority to change the law and regulations if they so desire." Id.

Following Mensing, the majority[3] in Bartlett, 133 S. Ct. at 2480, acknowledged that "[r]espondent's situation is tragic and evokes deep sympathy," but concluded that "a straightforward application of pre-emption law requires that the judgment below be reversed." Rejecting the impetus to distort settled law to achieve a particular policy outcome, the Court instead reaffirmed that "sympathy for [a party] does not relieve us of the responsibility of following the law." Id. at 2478.

The U.S. Supreme Court's conclusions in Mensing, 131 S. Ct. at 2582, that "[w]e will not distort the Supremacy

[3] Justice Alito authored the majority opinion in Bartlett; he was joined by Chief Justice Roberts and Justices Scalia, Kennedy, and Thomas. Justice Sotomayor authored a dissent in which Justice Ginsburg joined; Justice Breyer authored a separate dissent in which Justice Kagan joined.

Clause" and in Bartlett, 133 S. Ct. at 2478 that "sympathy . . . does not relieve us of the responsibility of following the law," confirm that the appropriate role of the Judiciary is to interpret the law, not to make new law.

Like the United States Constitution, the Alabama Constitution separates the judicial power to interpret law from the legislative power to balance policy considerations and make law. See Ala. Const. art. III, § 42 (1901); id. at § 43 ("[T]he judicial [department] shall never exercise the legislative and executive powers, or either of them; to the end that it may be a government of laws and not of men."). This Court has traditionally respected that separation - even when it might mean denying an injured plaintiff a remedy. See, e.g., Alabama State Docks Terminal Ry. v. Lyles, 797 So. 2d 432, 439 (Ala. 2001) ("The doctrine of separation of powers prevents this Court from fashioning, from whole cloth, some unique legal remedy suited to Lyles's alleged wrong; fashioning such a remedy would be within the province of the Legislature, subject nonetheless to the constraints of Art. III, § 14 [sovereign immunity].").

Moreover, constitutional considerations aside, this Court has recognized that the Judiciary is (as a practical matter) ill-suited to address the complex policy concerns better left to the political branches:

> [C]ourts must not intrude into realms of policy exceeding their institutional competence. The judicial branch lacks the fact-finding ability of the legislature, and the special expertise of the executive departments. . . . [Courts] should not attempt to balance the detailed and competing elements of legislative or executive decisions.

Ex parte Cranman, 792 So. 2d 392, 410 (Ala. 2000) (internal quotation marks and citations omitted.); accord Riegel v. Medtronic, 552 U.S. 312, 325 (2008) (rejecting the request to "turn somersaults to create" a distinction that would permit state-law claims to proceed against medical device manufacturer).

The Supremacy Clause commands that state law must give way when federal policymakers have spoken. Accordingly, this Court must respect the federal FDA's decision to preempt claims against generic drug manufacturers. Critically, though, in so doing, this Court must also suppress the impulse to "turn somersaults," Riegel, 552 U.S. at 325, or to "fashion[], from whole cloth, some unique legal remedy [against brand-name drug manufacturers]

suited to [Mr. Weeks's] alleged wrong" caused by ingestion of a generic drug. Lyles, 797 So. 2d at 439.[4]

The corollary to the rule that courts should not manipulate existing law to create remedies, of course, is that the political branches can do so. And indeed, this Court has recognized that it is for the political branches to balance competing public policies and determine whether to provide relief from legislative bars to individual recovery. See, e.g., Cranman, 792 So. 2d at 399 n.9 (stating that in sections "§ 41-9-60 to -74, Ala. Code 1975, . . . the Legislature established the Board of Adjustment, . . . recogniz[ing] a moral obligation [to] extend[] a measure of compensation . . . when the rule of

[4] In a case materially identical to this one – involving fraud and misrepresentation claims brought against brand-name Reglan manufacturers by a plaintiff who had ingested only generic metoclopramide – a unanimous panel of the U.S. Court of Appeals for the Eleventh Circuit recently refused to allow the plaintiff's suit to proceed. It did so even while recognizing that "the disposition of this case may leave [the plaintiff] and those similarly situated without a remedy"; any "redress," the Eleventh Circuit said, "lies with Congress or the [state] legislature, not with this Court." Guarino v. Wyeth, LLC, No. 12-13263, 2013 U.S. App. LEXIS 12966, *22-*23 (11th Cir. June 25, 2013). The court said that it was "steel[ed] . . . in [its] determination" that plaintiff had no cause of action by the "legion" of identical cases – the "mountain of authority" – so holding in identical cases. Id. at *21.

sovereign immunity exempts the State and its respective agencies from suit"). Accordingly, any change to address the "unfortunate hand" dealt to plaintiffs, Mensing, 131 S. Ct. at 2581, should be undertaken by Congress or the FDA, not this Court.

CONCLUSION

Bartlett's holding that federal drug-labeling regulations preempt certain state law claims against generic drug manufacturers does not apply to this case against brand-name drug manufacturers. But Bartlett's recognition that the Judiciary should not "distort" existing law in an effort to engineer a remedy for a sympathetic plaintiff applies directly to this case.

The Court should grant the Application for Rehearing, withdraw the Opinion, and issue a new opinion that answers the certified question in the negative.

Respectfully submitted this 1st day of August, 2013.

/s/ Ed R. Haden
One of the Attorneys for Amicus Curiae The Chamber of Commerce of the United States of America

OF COUNSEL:
Ed R. Haden
Email: ehaden@balch.com
BALCH & BINGHAM LLP
1901 Sixth Avenue North
Suite 1500
Birmingham, AL 35201-0306
Telephone: (205) 226-8795
Facsimile: (205) 488-5648

Kate Comerford Todd (pro hac vice)
Email: KTodd@uschamber.com
NATIONAL CHAMBER LITIGATION CENTER, INC.
1615 H Street, NW
Washington, DC 20062
Telephone: (202) 463-5337
Facsimile: (202) 463-5346

CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2013, the foregoing was filed with the Clerk of the Court and served on the following by U.S. Mail, first-class postage, pre-paid or electrically upon the following parties and participants:

William L Bross, IV
Email: wlbross@hgdlawfirm.com
William Lewis Garrison, Jr.
Email: wlgarrison@hgdlawfirm.com
Christopher Boyce Hood
Email: chood@hgdlawfirm.com
HENINGER GARRISON DAVIS, L.L.C.
2224 1st Avenue North
Birmingham, AL 35203
Telephone: (205) 326-3336
Facsimile: (205) 326-3332

Steven Frank Casey
Email: scasey@joneswalker.com
David A. Lester
Email: dlester@joneswalker.com
JONES WALKER WAECHTER POITEVENT
CARRERE & DENEGRE, LLP
One Federal Place, Suite 1100
1819 5th Avenue North
Birmingham, AL 35203
Telephone: (205) 244-5200
Facsimile: (205) 244-5400

Richard A. Dean
Email: rdean@tuckerellis.com
Hugh M. Stanley
Email: hstanley@tuckerellis.com
TUCKER, ELLIS & WEST LLP
1150 Huntington Building
925 Euclid Avenue
Cleveland, OH 44115
Telephone: (216) 592-5000
Facsimile: (216) 592-5009

William Christopher Waller, Jr.
Email: cwaller@ball-ball.com
BALL, BALL, MATTHEWS & NOVAK, P.A.
P. O. Box 2148
Montgomery, AL 36102-2148
Telephone: (334) 387-7680
Facsimile: (334) 387-3222

Christopher Gadsden Hume, III
Email: chume@ball-ball.com
BALL, BALL, MATTHEWS & NOVAK, P.A.
107 Saint Francis Street, Suite 2515
Mobile, AL 36602
Telephone: (251) 338-2721
Facsimile: (251) 338-2722

Richard Oetheimer
Email: roetheimer@goodwinprocter.com
GOODWIN PROCTER LLP
Exchange Place
53 State Street
Boston, MA 02109
Telephone: (617) 570-1000
Facsimile: (617) 523-1231

Jonathan I. Price
Email: jprice@goodwinprocter.com
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
Telephone: (212) 813-8800
Facsimile: (212) 355-3333

/s/ Ed R. Haden
Of Counsel