SCOTUS: State Law Design-Defect Claim Alleging Inadequate Drug Label Warning is Pre-empted by Federal Law

On June 24, 2013, the United States Supreme Court issued an opinion in *Mutual Pharmaceutical Co., Inc.* v. *Bartlett*,[1] finding that state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law under *PLIVA, Inc.* v. *Mensing*.[2] Under the Supremacy Clause, state laws are impliedly pre-empted where it is impossible for a party to simultaneously comply with both state and federal requirements. In *Bartlett*, the Court determined that it was impossible for Mutual Pharmaceutical ("MP") to comply with both the federal duty of a generic drug maker not to alter a drug's label or chemical composition, and the state duty to either strengthen the drug's warnings or change its design to prevent it from being "unreasonably dangerous." The Court found that the First Circuit's reasoning – that MP could escape the impossibility of complying with both its federal and state-law duties by ceasing sale of the drug or continuing to sell and paying compensation as a cost of doing business – was incompatible with the Court's pre-emption jurisprudence. The Court, in a 5-4 opinion, reversed the First Circuit and reaffirmed the protection *PLIVA* grants generic drug manufacturers faced with the impossibility of complying with both U.S. Food and Drug Administration ("FDA") and state requirements.

I. Factual Background and Procedural History[3]

Clinoril is a brand name version of a nonsteroidal anti-inflammatory drug ("NSAID") called "sulindac," which the FDA approved in 1978. When Clinoril's patent expired, the FDA approved a generic sulindac manufactured by MP. In 2004, Karen L. Bartlett was prescribed Clinoril for shoulder pain. Her pharmacist gave her a generic form manufactured by MP instead. Respondent soon developed an acute case of toxic epidermal necrolysis – a side effect of sulindac and other popular NSAIDs in a very small percentage of patients – and was left severely physically disabled. In 2005, after Bartlett was already suffering from the adverse reaction to the drug, the FDA recommended changing the label of sulindac to warn against toxic epidermal necrolysis.

Bartlett sued MP in New Hampshire state court, asserting both failure-to-warn and design-defect claims. MP removed the case to federal court. The failure-to-warn claim was ultimately dismissed by the District Court, based on the prescribing doctor's admission that he had not read the warning label or package insert. A jury found MP liable on the remaining design-defect claim and awarded Bartlett over $21 million in damages. The First Circuit Court of Appeals affirmed, distinguishing *PLIVA* – where the Court held that failure-to-warn claims against generic drug manufacturers are pre-empted by the FDCA's[4] prohibition on changes to generic drug labels – by arguing that MP was free to cease production of the drug, and thus comply with both the FDCA and New Hampshire law.[5]

II. Applicable State and Federal Regulations

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act." Under the Act, a generic drug may be approved without the same level of

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[1] *Mutual Pharmaceutical Co., Inc.* v. *Bartlett*, No. 12-142, slip op. (U.S. June 24, 2013), *available at* http://www.supremecourt.gov/opinions/12pdf/12-142_8njq.pdf (the "*Opinion*").

[2] *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011) ("*PLIVA*").

[3] The factual background is summarized from the background set forth in the *Opinion*.

[4] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301.

[5] *Bartlett* v. *Mutual Pharmaceutical Co., Inc.*, 678 F.3d 30, 37 (1st Cir. 2012).

testing required for a new brand-name drug, as long as the generic drug displays the same label and is chemically equivalent to the brand-name drug.[6] Once sale is approved, manufacturers of the generic drug are prohibited from making any changes to a drug's label which would make it inconsistent with that of the brand-name drug.

This duty potentially conflicts with the New Hampshire tort law requirement that drug manufacturers ensure their products are not "unreasonably dangerous" for their foreseeable uses. The New Hampshire Supreme Court has found the State requirement can be satisfied by changing either a drug's chemical composition or warning label.[7]

III. The Decision of the U.S. Supreme Court

The United States Supreme Court rejected the First Circuit's reasoning that MP could escape the impossibility of complying with both its FDCA and New Hampshire duties by "choosing not to make [sulindac] at all."[8] Pre-emption cases, according to Justice Alito's majority opinion, presume that an actor seeking to satisfy both its federal and state-law responsibilities is not required to stop acting altogether in order to avoid liability.[9] As *PLIVA* noted, if the option of ceasing production defeated a claim of impossibility, impossibility pre-emption would be "all but meaningless."[10]

While *PLIVA* held that federal law prevents generic drug manufacturers from changing their labels in a failure-to-warn context, the Court found it applied directly to the design-defect claim in *Bartlett*. As the record noted, sulindac, due to its one-molecule chemical composition, is "chemically incapable of being redesigned."[11] Therefore, the Court concluded that the only way for MP to escape liability in New Hampshire would be to strengthen the warnings on sulindac's label – something it could not do under the FDCA after *PLIVA*.

The Court noted that when federal law forbids an action that state law requires, the state law is pre-empted. "In every instance in which the Court has found impossibility pre-emption, the 'direct conflict' between federal and state-law duties could easily have been avoided if the regulated actor had simply ceased acting." The Court found that accepting the First Circuit's "stop selling" rationale would make not only *PLIVA*, but also the vast majority of impossibility pre-emption cases wrongly decided and noted that "[t]he incoherence of the stop-selling theory becomes plain when viewed through the lens of our previous cases."[12]

The Court noted that the lengthy dissent by Justice Sotomayor was correct in that federal law does not establish a safe harbor for drug companies.[13] According to the majority, however, it does prevent them from taking certain remedial measures. The Court found that when New Hampshire law imposed a duty to take such remedial measures, it directly conflicted with federal law, making it impossible for MP to comply with both state and federal requirements, rendering the state-law pre-empted.[14]

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[6] Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §355(j)(2)(A).

[7] *Opinion* at 9.

[8] *Bartlett*, 678 F.3d at 37.

[9] *Opinion* at 15.

[10] *Id.* (citing *PLIVA* at 2579).

[11] *Opinion* at 11 (citing *Bartlett*, 678 F.3d at 37).

[12] *Opinion* at 15.

[13] Justice Breyer wrote a separate dissent on other grounds.

[14] *Opinion* at 17 (citing *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995)).

The dissent also argued that the Court ignored Congress' efforts to preserve state common-law liability. The five justice majority, however, welcomed Congress' resolution of the pre-emption questions that arise in the prescription drug context. Since the FDCA's treatment of prescriptions drugs, however, includes neither an express pre-emption clause nor an express non-pre-emption clause, the Court divined an intent to pre-empt state tort law from the duties the FDCA explicitly places on generic drug manufacturers.[15]

Finally, the Court distinguished *Bates* v. *Dow Agrosciences LLC*,[16] precedent which, according to the dissent, contradicts the Court's holding. *Bates* held a Texas state-law design-defect claim concerning a specific Dow pesticide not to be pre-empted by the federal requirements in FIFRA.[17] The *Bates* Court did so, however, because the design-defect claim in question was not a "requirement" for labeling or packaging, but merely an incentive a manufacturer might take to avoid an unfavorable jury verdict. In *Bartlett*, according to the Court, the duty to redesign sulindac's label was part of a common-law duty articulated by the New Hampshire Supreme Court, rather than merely an action MP might have taken to avoid adverse jury verdicts.[18]

IV. Significance of the Decision

The decision of the Supreme Court in *Bartlett* makes clear that pharmaceutical manufacturers, when faced with the impossibility of complying with both FDCA and state regulations concerning the labeling and chemical composition of generic drugs, may treat the applicable state law as pre-empted, and will be shielded from liability for tort claims turning on the adequacy of a drug's warnings. The Court noted, however, that it was not addressing state design-defect claims that paralleled the federal misbranding statute thus leaving open the possibility of state law-based litigation in circumstances where such claims coincide with claims that might be asserted under federal law.[19]

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If you have any questions about the issues addressed in this memorandum or if you would like a copy of any of the materials mentioned, please do not hesitate to call or email Charles A. Gilman at 212.701.3403 or cgilman@cahill.com; Jon Mark at 212.701.3100 or jmark@cahill.com; John Schuster at 212.701.3323 or jschuster@cahill.com; or Michael B. Weiss at 212.701.3041 or mweiss@cahill.com.

[15] *Opinion* at 20.

[16] *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005).

[17] Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136.

[18] *Opinion* at 19.

[19] *Opinion* at 14 n.4.