Mutual Pharmaceutical Company v. Bartlett: A Win for the Defense and Common Sense

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I. INTRODUCTION

The 2013 summer term of the United States Supreme Court was undeniably noteworthy. Regardless of whether you agree with the decisions reached, it is impossible to deny that the Court ruled on sensitive and timely issues. Not surprisingly, the Court's decision in *Mutual Pharmaceutical Company v. Bartlett*, 133 S. Ct. 2466 (2013) did not garner the same attention as some other recent decisions. It did not involve a controversial social issue; it was not particularly glamorous. It involved a state law design claim against a generic pharmaceutical manufacturer, which in turn implicated federal preemption. Nevertheless, the *Bartlett* decision can aptly be described as a win for the defense and common sense. It also removed any doubt that implied preemption jurisprudence would be abandoned in favor of the "stop selling" rationale adopted by the First Circuit Court of Appeals.

It would not be an exaggeration to opine that every person reading this article is familiar with the concept of generic medications. From "store brand" pain relievers to generic antibiotics, generic medications can offer a cheaper, equally effective alternative to name-brand medication. The reason for the efficacy and widespread use of generic drugs can likely be attributed to the regulations that govern the manufacture and labeling of the generic medication. This regulatory scheme, which will be discussed in greater detail below, was placed at issue in

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the *Bartlett* case. And, more specifically, how these regulations square with state-law design defect claims.

The Court was presented with the question of whether state-law design defect claims based on the adequacy of a drug's warnings are pre-empted by federal law. This issue had to be resolved against the Court's holding in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) wherein it was determined that state failure-to-warn claims were pre-empted by federal law.

Before discussing the procedural history of *Bartlett*, two foundational concepts must be addressed: the regulations that a generic drug manufacturer must adhere to in accordance with the Federal Food, Drug, & Cosmetic Act and the concept of federal preemption.

II. FDA APPROVAL PROCESS

The Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, as amended, 21 U.S.C. §301 *et seq.*, requires drug manufacturers to gain approval from the United States Food and Drug Administration (FDA) before marketing any drug in interstate commerce. §355(a). In the case of a new brand-name drug, FDA approval can be secured only by submitting a new-drug application (NDA). An NDA is a compilation of materials that must include "full reports of [all clinical] investigations," §355(b)(1)(A), relevant nonclinical studies, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from source," 21 CFR §§314.50(d)(2) and (5)(iv) (2012). The NDA must also include "the labeling proposed to be used for such drug," 21 U. S. C. §355(b)(1)(F); 21 CFR §314.50(c)(2)(i), and "a discussion of why the [drug's] benefits exceed the risks under the conditions stated in the labeling," 21 CFR §314.50(d)(5)(viii); §314.50(c)(2)(ix). The FDA may approve an NDA only if it determines that the drug in question is "safe for use" under "the conditions of use prescribed, recommended, or

suggested in the proposed labeling thereof." 21 U. S. C. §355(d). In order for the FDA to consider a drug safe, the drug's "probable therapeutic benefits must outweigh its risk of harm." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U. S. 120, 140 (2000).

The process of submitting an NDA is both onerous and lengthy. *Bartlett*, 133 S. Ct. at 2471. In order to provide a swifter route for approval of generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, popularly known as the "Hatch-Waxman Act." *Id.* Pursuant to the Hatch-Waxman act, a generic drug may be approved without the same level of clinical testing required for approval of a new brand-name drug, provided the generic drug is identical to the already-approved brand-name drug in several key areas. *Id.*

First, the proposed generic drug must be chemically equivalent to the approved brand-name drug: it must have the same "active ingredient" or "active ingredients," "route of administration," "dosage form," and "strength" as its brand-name counterpart. *Id.* (quoting 21 U. S. C. §§355(j)(2)(A)(ii) and (iii)).

Second, a proposed generic must be "bioequivalent" to an approved brand-name drug. *Id.* (quoting §355(j)(2)(A)(iv)). Stated another way, it must have the same "rate and extent of absorption" as the brand-name drug. *Id.* (quoting §355(j)(8)(B)).

Third, the generic drug manufacturer must show that "the labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug." *Id.* (quoting §355(j)(2)(A)(v)).

Once a drug (whether generic or brand-name) is approved, the manufacturer is prohibited from making any major changes to the "qualitative or quantitative formulation of the drug

product, including active ingredients, or in the specifications provided in the approved application." *Id.* (quoting 21 CFR §314.70(b)(2)(i)). Generic manufacturers are also prohibited from making any unilateral changes to a drug's label. *See* §§ 314.94(a)(8)(iii), 314.150(b)(10) (approval for a generic drug may be withdrawn if the generic drug's label "is no longer consistent with that for [the brand-name] drug"). Reconciling the limitations imposed on generic drug manufacturers with state-law tort claims predicated upon design defect claims necessitates a brief discussion on the concept of federal preemption.

III. A PRIMER ON PRE-EMPTION

Regardless of whether federal pre-emption is a concept that you removed from your mental rolodex immediately after studying for the bar exam or comprises a routine part of your practice, a brief primer (refresher) on pre-emption might be helpful in analyzing the rationale of the *Bartlett* decision.

Pre-emption may be either expressed or implied, and "is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977); *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983); *Fidelity Fed. Sav. & Loan Assn. v. De la Cuesta*, 458 U.S. 141, 152-153 (1982).

The Supremacy Clause provides that the laws and treaties of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U. S. Const., Art. VI, cl. 2. Accordingly, it has long been settled that state laws that conflict with federal law are "without effect." *Maryland* v. *Louisiana*, 451 U. S. 725, 746 (1981); *see also Gade* v. *National Solid Wastes Management Assn.*, 505 U. S. 88, 108 (1992) ("[U]nder the Supremacy Clause, from which our pre-emption doctrine is derived, any

state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield" (internal quotation marks omitted)). This fairly straightforward concept is known as express pre-emption.

In the absence of express pre-emption, the Supreme Court has found implied pre-emption when it is "impossible for a private party to comply with both state and federal requirements." *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990); *see also Florida Lime & Avocado Growers, Inc., v. Paul*, 373 U.S. 132, 142-43 (1963) ("A holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design when compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce"). In *Bartlett*, the Court analyzed whether it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on sulindac's label and its federal-law duty not to alter sulindac's label.

IV. PROCEDURAL HISTORY

Karen Bartlett sustained severe and permanent injuries after taking sulindac, a generic non-steroidal anti-inflammatory (NSAID) manufactured by Mutual Pharmaceutical Company. *Bartlett v. Mutual Pharmaceutical Co., Inc*., 678 F.3d 30, 34 (1st Cir. 2012). Sulindac is known to cause, in rare instances, Stevens-Johnson Syndrome and toxic epidermal necrolysis ("SJS/TEN"). *Id.* In December 2004, Bartlett's doctor prescribed sulindac under the brand-name Clinoril made by the original provider; Bartlett's pharmacist dispensed generic sulindac. *Id.*

In early 2005, Bartlett developed SJS/TEN. TEN is diagnosed when 30 percent of more of the outer skin layer on a patient's total body surface area has deteriorated, been burned off, or turned into an open wound. *Id.* In Bartlett's case, TEN affected 60-65 percent of Bartlett's

body. *Id.* She spent 70 days at Massachusetts General Hospital, including more than 50 days spent in the burn unit. *Id.*

Bartlett brought various claims against Mutual in New Hampshire state court, including claims for breach of warranty, fraud, and negligence. Bartlett also brought product liability claims against Mutual for design defect, failure to warn, and manufacturing defect.

New Hampshire has adopted the doctrine of strict liability in tort as set forth in Section 402A of the Restatement (Second) of Torts. 133 S. Ct. at 2473. As such, pursuant to New Hampshire tort law, "[o]ne who sells any product in a defective condition unreasonably dangerous to the user of consumer or to his property is subject to liability for physical harm thereby caused" even though he "has exercised all possible care in the preparation and sale of the product." *Id.*

New Hampshire product liability law requires a manufacturer to design his product reasonably safely for the uses which he can foresee and to ensure that the product designed, manufactured, and sold is not unreasonably dangerous. *Id.*

Mutual removed the case to federal court on diversity grounds. *Bartlett*, 678 F. 3d at 34. Ultimately, all claims except for the design defect claim were disposed of by the district court via summary judgment or voluntarily dismissed by Bartlett. *Id.* Notably, the district court dismissed Bartlett's warning claim because her prescribing doctor admitted that he had not read the box label or insert. *Id.*

At trial, the core design defect theory was narrowed to a contention that sulindac's risks outweighed its benefits making it unreasonably dangerous to consumers despite the fact that the FDA had never withdrawn its statutory "safe and effective" designation that the original manufacturer had secured on which Mutual was entitled to piggyback. *Id.* at 34-35.

The matter went to trial in late August and early September 2009 and lasted for 14 days. *Id.* at 35. Bartlett called a number of witnesses to her suffering and treatment, including two experts: a burn surgeon and a pharmacologist/toxicologist who was crucial to the design defect claim. *Id.*

The pharmacologist/toxicologist sought to establish from incident reports made to the FDA and other information that sulindac had a worse record of causing SJS/TEN than other available drugs and that sulindac had a safety profile similar to other drugs deemed dangerous enough to have been withdrawn from the market. *Id.* Valdecoxib, another NSAID sold under the brand-name Bextra, was withdrawn from the market in 2005. *Id.*

Interestingly, Mutual elected not to put on an affirmative case of its own and, instead, cross-examined Barlett's experts. *Id.*

After several days of deliberation, the jury found for Bartlett and awarded $21.06 million in compensatory damages. *Id*. The district court denied Mutual's motion for judgment as a matter of law and motion for new trial and an appeal to the First Circuit Court of Appeals followed.

On appeal, Mutual argued that the district court misunderstood New Hampshire law on design defect claims; that such claims as to generic drugs are preempted under federal law; that causation was not proved; that Bartlett's expert evidence was inadmissible on multiple grounds; that instructions as to label warnings were inaccurate; that misconduct by Bartlett's counsel required a new trial; and that damages were excessive and required a new trial. *Id.*

With respect to pre-emption, the First Circuit stated that, "the most far-reaching of Mutual's objections is that Bartlett's design defect claim is preempted by the Federal Food, Drug, and Cosmetic Act 21 U.S.C. § 301 et seq. ("FDCA"), and--in particular--by the Drug

Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355(j)(2)(A)) ("Hatch-Waxman Amendments"), and its regulations." *Id.* at 36.

The appellate court cited *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) wherein the Supreme Court held that the FDCA preempts failure-to-warn claims against generic drug manufacturers because they, unlike brand-name manufacturers, cannot unilaterally change their labels. Thus, they cannot comply with both federal label standards and state law requirements deviating from those standards. *Id.* at 37. Because the generic manufacturer cannot alter the labeling, PLIVA held that Congress could not have wanted the manufacturer of generic drugs to pay damages under state law for a label that the FDA required. *Id.*

Mutual argued that the generic maker is similarly prohibited from altering the chemical composition of the drug and, thus, argued that *PLIVA's* policy of encouraging generics by preempting state law claims should extend to design defects claims as well based on inadequate warning. *Id.* However, the First Circuit was not persuaded that *PLIVA* extended to design defect claims and noted that, "whether 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." *Id.* The appellate court further noted that, because prescription drugs and their warnings are closely regulated by the FDA, Congress might explicitly, or the Supreme Court by implication, have preempted state design defect or inadequate warning claims that allow state juries to second-guess the FDA's seal of approval. But the statute contains no general preemption provision. The appellate court cited *Wyeth v. Levin*e, 555 U.S. 555, 575 (2009), in which the Supreme Court rejected implied preemption, saying that "Congress did not intend

FDA oversight to be the exclusive means of ensuring drug safety and effectiveness," and that state law serves as a "complementary form of drug regulation." *Wyeth*, 555 U.S. at 578.

The First Circuit reasoned that although *Wyeth's* holding was technically limited to failure-to-warn claims, its logic applies to design defect claims as well. *See Wyeth*, 555 U.S. at 574 (state tort suits "motivat[e] manufacturers to produce safe and effective drugs and to give adequate warnings").

In rejecting Mutual's pre-emption argument premised on its inability to alter the composition of sulindac the appellate court stated, "although Mutual cannot legally make sulindac in another composition, it can certainly choose not to make the drug at all." *Bartlett*, 678 F. 3d at 37.

The First Circuit went on to say, "not only has the Supreme Court not yet said it would extend *PLIVA*'s exception to design defect claims, but—while the generic maker has no choice as to label—the decision to make the drug and market it in New Hampshire is wholly its own." *Id.* at 38.

In other words, the First Circuit opined that Mutual could solve any perceived issue by ceasing the sale of sulindac. The First Circuit refused to apply *PLIVA'*s holding to design defect claims in the absence of a clear mandate from the Supreme Court. In sum, the First Circuit found that neither the FDCA nor the FDA's regulation's preempted the design defect claim and affirmed the verdict. Mutual then petitioned the Supreme Court for a writ of certiorari.

V. ANALYSIS AND OPINION BY THE SUPREME COURT

The Supreme Court was presented with a simple question, albeit one of particular significance: whether state-law design-defect claims that turns on the adequacy of a drug's

warnings are pre-empted pursuant to the court's holding in *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011).

The Court noted that the First Circuit correctly identified the predicament facing Mutual. Redesign of sulindac was not possible for two reasons.

First, the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based. 133 S. Ct. at 2475 (citing 21 U. S. C. §§355(j)(2)(A)(ii)-(v) and (8)(B); 21 CFR §320.1(c)). Consequently, the Court of Appeals was correct to recognize that "Mutual cannot legally make sulindac in another composition." *Id.* (quoting 678 F. 3d at 37). Indeed, were Mutual to change the composition of its sulindac, the altered chemical would be a new drug that would require its own NDA to be marketed in interstate commerce. *Id*. *See* 21 CFR §310.3(h) (giving examples of when the FDA considers a drug to be new, including cases involving "newness for drug use of any substance which composes such drug, in whole or in part").

Second, because of sulindac's simple composition, the drug is chemically incapable of being redesigned. *Id*. (quoting 678 F. 3d at 37 ("Mutual cannot legally make sulindac in another composition (nor it is apparent how it could alter a one-molecule drug anyway.")).

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" in such a way that the warning "avoid[ed] an unreasonable risk of harm from hidden dangers or from foreseeable uses." *Id.* (quoting *Vautour* v. Body Masters Sports Industries, Inc. 784 A. 2d 1178, 1182 (N.H. 2011)); s*ee also Chellman v. Saab-Scania AB*, 637 A. 2d 148, 150 (N.H. 1993) ("The duty to warn is part of the general duty to design, manufacture and sell products that are reasonably safe for their foreseeable uses. If the

design of a product makes a warning necessary to avoid an unreasonable risk of harm from a foreseeable use, the lack of warning or an ineffective warning causes the product to be defective and unreasonably dangerous" (internal citation omitted)).

Thus, New Hampshire's design-defect cause of action imposed a duty on Mutual to strengthen sulindac's warnings. 133 S. Ct. at 2475. Consistent with New Hampshire law, the jury was presented with evidence relevant to, and was instructed to consider, whether Mutual had fulfilled its duty to label sulindac adequately so as to render the drug not "unreasonably dangerous." In holding Mutual liable, the jury determined that Mutual had breached that duty. *Id.* at 2476.

The Supreme Court reiterated that state-law design defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law pursuant to the *PLIVA* decision.

The Court further noted that the First Circuit's rationale, that Mutual could escape the impossibility of complying with both its federal and state law duties by choosing to stop selling sulindac, is incompatible with the Court's pre-emption cases, which have presumed that an actor seeking to satisfy both federal and state law obligations is not required to cease acting altogether. The Court expressly rejected this "stop-selling" rationale as "incompatible with our preemption jurisprudence." 133 S. Ct. at 2477.

The Court made clear its outright rejection of the "stop selling" rationale and noted, "the incoherence of the stop-selling theory becomes plain when viewed through the lens of our previous cases. 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." *Id.* Affirmation of the First Circuit's "stop selling"

rationale would have meant that *PLIVA* and the vast majority—if not all—of the cases in which the Court has found impossibility preemption, were wrongly decided. *Id.* at 2478.

The Court did not overlook or minimalize the injuries Bartlett sustained after taking sulindac and instead acknowledged that "the dreadful injuries from which products liabilities cases arise often engender passionate responses." *Id.* at 2478. However, the Court accurately stated that, "sympathy for the respondent does not relieve us of the responsibility of following the law." *Id.* The Court further noted that, "[a] combination of factors combined to produce the rare and devastating injuries that respondent suffered: the FDA's decision to approve the sale of sulindac and the warnings that accompanied the drug at the time it was prescribed, the decision by respondent's physician to prescribe sulindac despite its known risks, and Congress' decision to regulate the manufacture and sale of generic drugs in a way that reduces their cost to patients but leaves generic drug manufacturers incapable of modifying either the drugs' compositions or their warnings." *Id.* at 2480. Nevertheless, the Supreme Court concluded that "straightforward application of pre-emption law requires that the judgment below be reversed." *Id.*

The *Barlett* decision is significant in several respects. First, the Supreme Court made clear its rejection of the stop selling rationale as a solution to impossibility pre-emption. As discussed in the opinion, a contrary holding would have rendered impossibility pre-emption a nullity. Second, the *Bartlett* decision clearly extended *PLIVA's* holding to encompass state-law design defect claims in addition to state-law claims premised on inadequate warnings. This decision can appropriately be characterized as a victory for generic drug manufacturers who, prior to the *Bartlett* decision, faced the prospect of state-law liability arising for product labeling and composition. Because generic drug manufacturers previously faced state-law liability for, arguably, the two most critical aspects any generic drug (labeling and composition) that it was

unequivocally forbidden from altering, *Bartlett* can aptly be considered a win for the defense and common sense. While the full ramifications and impact of *Bartlett* decision remain to be seen, it will hopefully facilitate access to generic medications by reducing the likelihood that generic drug manufacturers will be forced to defend costly product liability suits.