Design-Defect Claims

# Courts Increasingly Recognize Federal Preemption of Claims Involving All FDA-Approved Medications

By Derek M. Stikeleather and Brian M. Lands

**The implied-preemption doctrine should bar *all* design-defect claims against the manufacturers of medication approved by the U.S. Food and Drug Administration, and here's why.**

After the Supreme Court's landmark decisions in *Wyeth v. Levine* (2009), and *PLIVA v. Mensing* (2011), some in the defense bar prematurely mourned the death of the federal preemption doctrine in product liability cases against manufacturers of *brand-name* medications. Believing that they had lost the preemption war over branded products, many practitioners narrowly focused on the extent to which *Mensing's* holding preempted failure-to-warn claims against *generic* manufacturers. And the Supreme Court's 2013 decision in *Mutual Pharmaceutical Company v. Bartlett* seemed to fit this narrative because it endorsed preemption in the context of generic medications. *Bartlett* applied implied preemption broadly to state law tort claims involving a generic medication's label *and* its chemical formulation.

In the initial rush to compose a bright-line rule that seemingly harmonized the three pharmaceutical preemption decisions—*i.e.*, which preempted claims involving generic medicines but did not preempt those involving brand-name medicines—most practitioners failed to appreciate *Mensing's* scope and its extension in *Bartlett*. Closer analysis shows that the implied-preemption doctrine spelled out by all three cases and culminating in *Bartlett*

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should bar *all* design-defect claims against the manufacturers of medication approved by the U.S. Food and Drug Administration (FDA), regardless of whether the product is generic or branded. Because manufacturers cannot change any FDA-approved medication's chemical composition without restarting the entire FDA approval process, design-defect allegations that impose a duty on pharmaceutical manufacturers to alter a product's chemical composition simply cannot be harmonized with federal regulations that bar such unilateral changes.

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This article examines *Bartlett's* reach and explains why pharmaceutical defendants can never simultaneously comply with (1) state design-defect laws requiring safer, "alternatively designed" products *and* (2) federal regulations restricting companies from altering the chemical composition of FDA-approved drugs. Accordingly, manufacturers of FDA-approved drugs faced with state law design-defect claims should always invoke federal preemption. *Bartlett* is incompatible with any alleged duty to design a medication differently, either before or after FDA approval.

## Background: Design-Defect, the "Risk-Utility" Test, and Preemption Principles

Section 402A of the Second Restatement of Torts generally conditions design-defect liability on a product being sold in a "*defective condition unreasonably dangerous.*" *Restatement (Second) of Torts*, §402A (Am. Law Inst. 1965) (emphasis added). Courts have struggled with how to determine best whether a product is "defective" or "unreasonably dangerous." Historically, they resolved design-defect claims with a "consumer expectation test." *Id.* at cmt. g. But most courts have abandoned that in favor of a multi-factor "risk-utility" test. *See* Dan B. Dobbs *et al.*, 2 *The Law of Torts* §§453 and 456 (2d ed. 2011).

The "risk-utility" test's most important factors are the feasibility and reasonableness of an "alternative design." Some jurisdictions require an actual alternative design, but others require only a *feasible* alternative design to prove defectiveness. Regardless of the risk-utility approach's rigor, "alternative design" is a key component of any design-defect claim. And the alternative-design requirement acts as the lynchpin of any federal preemption argument when plaintiffs allege a state law duty to alter an FDA-approved medication's chemical composition.

Federal preemption is a doctrine based on the Constitution's Supremacy Clause, which makes federal law "the supreme Law of the Land." U.S. Const. art. VI, cl. 2. The United States Supreme Court has recognized three types of federal preemption: express, field, and conflict. Conflict preemption can be further divided into impossibility and obstacle preemption. The relevant doctrine here—*impossibility preemption*—asks whether an actor can simultaneously comply with state and federal law. If "it is impossible for a private party to comply with both state and federal requirements," federal law preempts state law. *Bell v. Pfizer, Inc.*, 716 F.3d 1987, 1094 (8th Cir. 2013).

In the pharmaceutical context, federal regulations prohibit "major changes" to the "qualitative or quantitative formulation" of FDA-approved drugs (*i.e.*, altering the chemical composition). 21 C.F.R. §314.70(b)(2)(i). Thus, it would be impossible for a pharmaceutical manufacturer to refrain from making major changes to a drug's formulation while simultaneously complying with a state law duty to market a safer, "alternatively designed" product. In that situation, federal law preempts state law.

## *Bartlett*: Impossibility Preemption and Design-Defect Liability

In *Bartlett*, the Supreme Court considered whether a pharmaceutical manufacturer of a generic medication could simultaneously comply with its federal obligations and state design-defect law. 133 S. Ct. 2466 (2013). The Court recognized that New Hampshire's design-defect regime required manufacturers to "ensure that the products they design, manufacture, and sell are not 'unreasonably dangerous.'" To satisfy that duty under the state's "risk-utility" test, a manufacturer could either alter the drug's composition or labeling.

Federal regulations typically do not allow manufacturers to alter a drug's composition without prior FDA approval. A 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.* at 2471. It must also be "bioequivalent" and have the same labeling as the approved brand-name drug. *Id.* The *Bartlett* Court further noted that under 21 C.F.R. §314.70(b)(2)(i), "[o]nce 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.*

Applying impossibility preemption in *Bartlett*, the Court held that "state-law design defect claims… that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally [doing the same]." *Id.* at 2479. The Court acknowledged that under 21 C.F.R. §314.70(b)(2)(i), pharmaceutical manufacturers could not comply with state laws requiring them to alter the chemical composition of their products. *Id.*

## *Bartlett's* Application to Generic Prescription Drugs and Beyond

*Bartlett's* application to design-defect cases involving prescription, generic medications generates little, if any, controversy. *See, e.g., Mitchell v. Actavis Pharmaceuticals*, No. 5:15-CV-147-TBR, 2016 WL 2643031 (W.D. Ky. May 6, 2016); *Houston v. United States*, No. 15-2411, 2016 WL 403310 (7th Cir. Feb. 3, 2016). But its extension to over-the-counter (OTC) and branded products has proved more ardu-

ous. The U.S. District Court for the Eastern District of Louisiana held that impossibility preemption did not apply to a design-defect claim involving a brand-name OTC product. *Hunt v. McNeil Consumer Healthcare*, 6 F. Supp. 3d 694 (E.D. La. 2014). Without analyzing the defendant's competing state and federal obligations, the *Hunt* court found that *Bartlett* was inapplicable because of a "savings clause" in the statute governing non-prescription drugs, which "expressly preserve[d] product liability actions" from express preemption. That same year, the U.S. District Court for the Eastern District of Pennsylvania held that *Bartlett* did not apply to OTC drug cases. *Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717 (E.D. Penn. 2014). Citing *Bartlett* and *Hunt,* the *Brown* court reasoned only that the Supreme Court's "preemption cases do not extend to the manufacturers of [brand-name or non-prescription] products." *Id.* at 721.

Fortunately, most courts wisely have not followed *Hunt* and *Brown* because the two opinions fail to analyze the defendants' competing state and federal obligations or otherwise account for 21 C.F.R. §314.70(b)(2)(i). Instead, courts have increasingly recognized that *Bartlett* applies beyond generic drugs. But they have done so incrementally.

First, courts recognized implied preemption of design-defect claims that alleged a duty to change a drug's formulation *after* its approval. In *Sullivan v. Aventis, Inc.*, a defendant argued that impossibility preemption barred a plaintiff's design-defect claim alleging that its brand-name fertility drug caused birth defects. No. 14-CV-2939-NSR, 2015 WL 4879112 (S.D.N.Y. Aug. 13, 2015). Recognizing that New York law followed a "risk-utility" approach to determine whether a product was reasonably safe, the court identified "the availability of a safer design" as a critical factor. *Id.* at *5. Brand-name drug manufacturers can defeat liability under New York law by choosing a safer design for a drug or by strengthening the drug's warning.

Despite finding impossibly preemption inapplicable because federal law did not prevent a brand-name manufacturer from (1) strengthening a drug's warning or (2) altering its design, the *Sullivan* court acknowledged that under *Bartlett*, *a manufacturer is restricted from altering the design of a drug post-FDA approval.* Declining to find the plaintiff's design-defect claim preempted, the court held only that no authority was presented that "federal law… restricts a brand-name drug manufacturer from designing a reasonably safe product *prior* to FDA approval." The *Sullivan* court, thus, recognized that it was impossible to harmonize state law obligations to alter the chemical composition of an FDA-approved drug with federal regulations prohibiting the same.

Subsequent cases developed *Sullivan's* post-approval rationale to preempt claims that a defendant can alter the design of its FDA-approved, brand-name drug. In *Rheinfrank v. Abbott Laboratories, Inc.*, the court held that impossibility preemption applied when a plaintiff alleged that an anti-epileptic drug caused her daughter's birth defects. 137 F. Supp. 3d 1035 (S.D. Ohio 2015). Citing *Bartlett*, the *Rheinfrank* court rejected the plaintiff's design-defect claim, reasoning that the defendant could not have tweaked the drug's molecule to make it safer:

> [S]tate-law design defect claims… that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling.… *Creating an alternative design would require changing the composition of an FDA-approved drug, which is prohibited by federal law.*

*Id.* at 1041 (emphasis added). *See also Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 808 F.3d. 281, 299 (6th Cir. 2015) (finding the plaintiff's argument that the defendants should have altered the formulation of their brand-name prescription drug by lowering the dosage after the FDA had approved it was clearly preempted); *Barcal v. EMD Serono, Inc.*, No. 5:14-CV-01709-MHH, 2016 WL 1086028 (N.D. Ala. Mar. 21, 2016) (holding that an Alabama design-defect claim requiring the redesign of a brand-name drug was "precisely the kind of impossibility in which the Supreme Court has found preemption," and "any approved drug… cannot be altered without the FDA's prior permission, rendering compliance with both state and federal law impossible.").

Recent case law has also rejected the premise advanced in the *Hunt* and *Brown* decisions that impossibility preemption was irrelevant to non-prescription drugs. In *Batoh v. McNeil-PPC, Inc.*, the manufacturer of a brand-name, OTC medication argued that impossibility preemption barred the plaintiff's claim that the medication had a defectively designed chemical composition. No. 3:14-CV-01462 (MPS), 2016 WL 922779 (D. Conn. Mar. 10, 2016). Under Connecticut law, cases involving complex product design employ a modified consumer-expectation test for which a jury may consider risk-utility factors such as "the feasibility of an alternative design." In *Batoh*, the defendant could only have avoided state liability by "choosing a safer design for the drug" or "by strengthening the drug's warning label."

Absent a warning-based claim, the *Batoh* court found that federal law preempted the plaintiff's claim that the defendants could have altered the chemical composition of their drug. And, when the plaintiff offered an alternative product to support the allegation that the "defendants never switched to an alternatively designed drug…, despite indications that it would have been safer," the court found that the plaintiff had "submitted *no evidence that the FDA has ever approved [that drug]* for consumer use." *Id* at *17 (emphasis added). Changing the active ingredient in an FDA-approved product, the court reasoned, would qualify as a "major change" under 21 C.F.R. §314.70(b)(2)(i), and it would require prior approval from the FDA. The defendants could not have unilaterally changed the active ingredient in their drug to satisfy their state law duty. If they had, they would have violated federal law. *But cf. In re Tylenol (Acetaminophen) Marketing*, No. 2436, 2015 WL 7075949, at *22–23 (E.D. Pa. Nov. 13, 2015) (holding that federal preemption did not apply to a brand-name, OTC product operating under a tentative final monograph because, among other reasons, the FDA had already approved an alternative design that the defendants did not implement).

## Expansion of *Bartlett* to Pre-FDA Approval Cases

Pharmaceutical manufacturers should also be optimistic about recent cases holding that a defendant's ability to alter the chem-

ical composition of a drug *prior* to FDA approval is incompatible with *Bartlett*. In *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, the Sixth Circuit applied impossibility preemption to a plaintiff's claim that she experienced a stroke while using a birth control patch. 808 F.3d. at 299. Rejecting the plaintiff's pre-approval design-defect theory, the court held that the defendants owed the plaintiff no duty to design the FDA-approved drug differently in the first instance. The court found the plaintiff's argument "too attenuated," making it impossible for the defendants to simultaneously comply with state and federal law.

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Applying the jurisdiction's "risk-utility" test, the Sixth Circuit found that the defendants could only have avoided state law liability by choosing a safer design for their birth control patch. The court explained why the proposed *pre*-approval duty to alter the medication would be too speculative:

> To imagine such a pre-approval duty exists, we would have to speculate that had defendants designed [their birth control patch] differently, the FDA would have approved the alternate design. Next, we would have to assume that [the plaintiff] would have selected this method of birth control. Further yet, we would have to suppose that this alternate design would not have caused [the plaintiff] to suffer a stroke. This is several steps too far. Even if New York law requires defendants to produce and market a different design, the ultimate availability to [the plaintiff] is contingent upon whether the FDA would approve the alternate design in the first place.

Accordingly, impossibility preemption applied in *Yates* because the "[d]efendants could not have complied with whatever pre-approval duty might exist without ultimately seeking the FDA's approval prior to marketing" their drug.

Other courts have adopted *Yates's* reasoning and shut down pre-approval, design-defect theories. In *Wardell Fleming v. Janssen Pharm., Inc.*, the plaintiff alleged a brand-name diabetes drug was defectively designed and caused him to suffer serious kidney injuries. No. 215CV02799JPMDKV, 2016 WL 3180299 (W.D. Tenn. May 6, 2016). In that case, the U.S. District Court for the Western District of Tennessee applied impossibility preemption because the defendants had no duty to design their drug differently before FDA approval. *Id* at *5. Citing *Yates*, the court recognized that a pre-approval argument was too attenuated and speculative "because it requires several assumptions as to FDA approval and a patient's selection of and medical reaction to the alternative design." *Id*.

## Application to Future Cases

The rapid, recent evolution of pharmaceutical design-defect cases suggests that impossibility preemption should apply to all design-defect claims against the manufacturers of FDA-approved drugs—whether brand-name, generic, OTC, or prescription. Manufacturers cannot simultaneously comply with (1) state laws requiring that they alter the design of their products and (2) federal regulations prohibiting "major changes" to the formulation of FDA-approved drugs. Although failure-to-warn claims may survive in many instances, allegations framed in terms of a manufacturer's obligation to market safer, alternatively designed products should not survive a properly stated federal preemption argument. FD