CASE 5.4

Mutual Pharmaceutical Co., Inc. v Bartlett
133 S.Ct. 2466 (2013)

An Anti-Inflammatory Drug and an Inflammatory Decision

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FACTS

In 1978, the FDA approved an anti-inflammatory pain reliever called "sulindac" under the brand name of "Clinoril." When the patent expired, the FDA approved several generic versions of sulindac for sale, including one developed by Mutual Pharmaceutical (Petitioner). The warnings for Clinoril included the possibility of developing toxic epidermal necrolysis. Karen Bartlett (respondent) took a generic form of sulindac in December 2004 and developed an acute case of toxic epidermal necrolysis. Sixty to 65 percent of Ms. Bartlett's body deteriorated, was burned off, or turned into an open wound. She spent months in a medically induced coma, underwent 12 eye surgeries, and was tube-fed for a year. She is now severely disfigured, has a number of physical disabilities, and is nearly blind.

At the time Ms. Bartlett got her sulindac prescription, the label did not refer to toxic epidermal necrolysis but warned that the drug could cause "severe skin reactions" and "fatalities." Toxic epidermal necrolysis was listed as a side effect in the package insert. After Ms. Bartlett was suffering from toxic epidermal necrolysis, the FDA did a comprehensive study and recommended that the product label include more explicit warnings about toxic epidermal necrolysis.

Ms. Bartlett sued Mutual in New Hampshire state court, and Mutual removed the case to federal court. Ms. Bartlett initially asserted both failure-to-warn and design-defect claims, but the District Court dismissed her failure-to-warn claim based on her doctor's "admi[ssion] that he had not read the box label or insert." After a two-week trial on a design-defect claim, a jury found Mutual liable and awarded Ms. Bartlett over $21 million in damages. The Court of Appeals affirmed, and Mutual appealed. The U.S. Supreme Court granted *certiorari.*

JUDICIAL OPINION

ALITO, Justice

We must decide whether federal law pre-empts the New Hampshire design-defect claim.

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]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."

Federal law prevents generic drug manufacturers from changing their labels. When federal law forbids an action that state law requires, the state law is "without effect." 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.

The Court of Appeals reasoned that Mutual could escape the impossibility of complying with both its federal- and state-law duties by "choos[ing] not to make [sulindac] at all." We reject this "stop-selling" rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be "all but meaningless."

The dreadful injuries from which products liabilities cases arise often engender passionate responses. But sympathy for respondent does not relieve us of the responsibility of following the law.

The dissent accuses us of incorrectly assuming "that federal law gives pharmaceutical companies a right to sell a federally approved drug free from common-law liability." But we make no such assumption. Rather, we hold that state-law design-defect claims like New Hampshire's 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. The dissent is quite correct that federal law establishes no safe-harbor for drug companies—but it does prevent them from taking certain remedial measures. Where state law imposes a duty to take such remedial measures, it "actual[ly] conflict[s] with federal law" by making it "'impossible for a private party to comply with both state and federal requirements.'"

Finally, the dissent laments that we have ignored "Congress' explicit efforts to preserve state

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common-law liability." We have not. Suffice to say, the Court would welcome Congress' "explicit" resolution of the difficult pre-emption questions that arise in the prescription drug context. That issue has repeatedly vexed the Court—and produced widely divergent views—in recent years.

As the dissent concedes, however, the [federal law's] treatment of prescription drugs includes neither an express pre-emption clause nor an express non-pre-emption clause. In the absence of that sort of "explicit" expression of congressional intent, we are left to divine Congress' will from the duties the statute imposes. That federal law forbids Mutual to take actions required of it by state tort law evinces an intent to pre-empt.

Congress [has made the] 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. Respondent's situation is tragic and evokes deep sympathy, but a straightforward application of pre-emption law requires that the judgment below be reversed.

CASE QUESTIONS

1. Explain why the extra labeling could not be placed on the generic version of the drug that Ms. Bartlett purchased.
2. Discuss the relationship between state product liability laws and the duty of manufacturers and federal regulation of generic labels.
3. How does the court address the issue of the tragedy of the case?

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Samantha T. Reckis was seven years old in late 2003, when she developed toxic epidermal necrolysis (TEN), a rare but life-threatening skin disorder, after receiving multiple doses of Children's Motrin. Children's Motrin is an over-the-counter (OTC) medication with ibuprofen as its active ingredient that is manufactured and sold by the McNeil–PPC, Inc., whose parent company is Johnson & Johnson.

Lisa and Richard Reckis, Samantha's parents, claim that Samantha developed TEN as a result of being exposed to the ibuprofen in the Children's Motrin. They brought suit alleging that the warning label failed to warn consumers adequately about the serious risk of developing TEN, a life-threatening disease. After a lengthy jury trial, the trial court found for the Reckis family and awarded $63 million in damages to them. Johnson & Johnson (McNeil) appealed on the grounds that the state suit was preempted because the FDA has exclusive authority over drug labels and the Motrin label complied with the FDA requirements. In fact, the FDA had prohibited McNeil from adding any discussion of possible risk of TEN because it was rare and would confuse consumers. What should the court do? [*Reckis v Johnson & Johnson*, 28 N.E.3d 445 (Mass. 2015)]

Ethical Issues

Evaluate the ethics of a generic drug manufacturer using the same label instead of asking for updates when they are aware of risks and harms from usage of the drug.