STAY AHEAD OF THE CURVE

Litigation Advisory
April 1, 2008

THE *NOT-SO-NEW* CASE FOR IMPLIED PREEMPTION OF PESTICIDE FAILURE-TO-WARN CLAIMS

Lawrence S. Ebner, Partner

Seventeen years ago, the U.S. Court of Appeals for the Eleventh Circuit got it right in the case of *Papas v. Upjohn Co.* (commonly known as "*Papas I*"), 926 F.2d 1019 (11th Cir. 1991). The plaintiff, a Florida veterinary worker, sued pesticide manufacturers for health problems that he alleged were caused by his exposure to flea and tick products. He claimed that the products' EPA-approved labeling failed to warn him adequately about the hazards of using the products. Following briefing and oral argument in Atlanta, the court of appeals affirmed dismissal of the case on the ground that FIFRA, the federal pesticide statute, *impliedly* preempts state-law damages claims for inadequate pesticide labeling.

FIFRA Preemption Before *Cipollone*

FIFRA, of course, contains an *express* preemption provision, § 24(b), which prohibits a State from imposing "any requirements for labeling" that are "in addition to or different from" those required under the statute. 7 U.S.C. § 136v(b). But state law can be impliedly preempted too, if it "actually conflicts with federal law." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). "Such a conflict arises when compliance with both federal and state regulations is a physical impossibility . . . or when a state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 605 (1991) (internal quotation marks omitted). The doctrine of implied conflict preemption is derived directly from the U.S. Constitution's Supremacy Clause, under which "state laws that 'interfere with, or are contrary to the laws of congress' are invalid." *Id.* at 604 (quoting U.S. Const., Art. VI, cl. 2).

The Supreme Court has made it clear that the presence of an express preemption provision in a federal statute (e.g., § 136v(b) of FIFRA) "does *not* bar the ordinary working of conflict pre-emption principles." *Geier v. American Honda Motor Co., Inc.*¸ 529 U.S. 861, 869 (2000). In the *Papas I* case, the federal court of appeals applied the doctrine of implied conflict preemption to the plaintiff's state-law damages claims for inadequate labeling and failure to warn. The court held that "a jury determination, via a state common tort judgment, that a pesticide's labeling is inadequate results in a direct conflict with the EPA's determination that the labeling is adequate to protect against health risks." *Papas I*¸ 926 F.2d at 1025. Thus, "FIFRA impliedly preempts state common law tort suits against manufacturers of EPA-registered pesticides *to the extent that* such actions are based on claims of inadequate labeling." *Id.* at 1026.

Early in 1992, the U.S. Court of Appeals for the Tenth Circuit reached the same conclusion. *See Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.* ("*Arkansas-Platte I*"), 959 F.2d 158 (10th Cir. 1992). Among other things, both *Papas I* and *Arkansas-Platte I* recognized that adjudicating pesticide-related product liability claims for inadequate labeling or failure to warn would hinder accomplishment of the full purpose of § 136v(b), which is to ensure that each FIFRA-registered pesticide product is accompanied by nationally uniform product labeling regulated solely by EPA.

Cipollone and Express Preemption

The pesticide industry seemed to be on a roll with the implied preemption defense when, in June 1992, the Supreme Court issued its opinion in *Cipollone v. Liggett Group*, which involved the scope of the federal cigarette statute's express preemption provision. Like § 136v(b) of FIFRA, the cigarette statute expressly bars

States from imposing their own "requirements." The Supreme Court held in *Cipollone* (and repeatedly has reaffirmed) that the term "requirements" in a federal preemption provision is not limited to state statutes and regulations, but also encompasses common-law duties (i.e., requirements) underlying product liability claims.

Rather than reviewing the implied preemption decisions in *Arkansas-Platte I* and *Papas I*, the Supreme Court sent those cases back to the courts of appeals for further consideration in light of *Cipollone.* On remand, the Tenth and Eleventh Circuits held in 1993 that § 136v(b) *expressly* preempts pesticide-related claims for inadequate labeling or failure to warn. Those rulings triggered an avalanche of federal and state appellate and trial court decisions which, based on express preemption under § 136v(b), virtually wiped out pesticide-related failure-to-warn claims for the next 12 years.

Bates

Then, in 2005 the Supreme Court decided *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005). *Bates* is the Court's first and only decision on the applicability of § 136v(b) to pesticide product liability claims. The Court held that § 136v(b) does expressly preempt failure-to-warn claims, but only those that would impose a labeling requirement which "diverges from"—not one which is "equivalent" or "parallel" to, or "fully consistent with"—federal labeling requirements. *Id*. at 447, 452. In the wake of *Bates*, "victims' rights" lawyers, and some courts, have transformed *Bates*' fuzzy "parallel requirements" exclusion into a gaping loophole that authorizes trial of failure-to-warn claims which, as virtually all failure-to-warn claims do, purport to be based on general state-law duties to provide adequate warnings.

Bates was limited to the scope of § 136v(b) and did not address *implied* preemption of failure-to-warn claims. Justice Thomas, joined by Justice Scalia, asserted in his separate opinion that the *Bates* majority decision "comports with this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption." 544 U.S. at 459 (Thomas, J., concurring in the judgment in part and dissenting in part). But that statement does not, and cannot, alter the Supremacy Clause, which as discussed above, underlies the doctrine of implied conflict preemption, and as the Court held in *Geier*, operates independently of express preemption.

Back To The Future

Recent Supreme Court developments seem to bode well for the reemergence of implied preemption as a viable defense to pesticide failure-to-warn claims. *Riegel v. Medtronic¸ Inc.*, 128 S. Ct. 999 (2008), an 8-1 decision, involved the federal medical device statute's express preemption provision (which the Court noted in *Bates* is similar to § 136v(b) of FIFRA). Justice Scalia, writing for the majority, explained that "[s]tate tort law that requires a manufacturer's [product] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme." *Riegel*, 128 S. Ct. at 1008. Along the same lines, during the Supreme Court's recent hearing in *Warner-Lambert, Co., LLC v. Kent*, No. 06-1498, in which an evenly divided Court subsequently affirmed a lower court's ruling that certain "fraud on the FDA" claims are not impliedly preempted, 128 S. Ct. 1168 (Mem) (2008), Justice Breyer commented as follows:

> Now, who would you rather have make the decision as to whether this drug is, on balance, going to save people or, on balance, going to hurt people? An expert agency, on the one hand, or 12 people pulled randomly for a jury role who see before them only the people whom the drug hurt and don't see those who need the drug to cure them?
>
> Now, that it seems to me is Congress's fundamental choice, and Congress has opted for the agency.

Tr: at 30-31 (Feb. 25, 2008).

This *crucial* point—that product liability claims can conflict with an expert federal regulatory agency's balancing of risks and benefits—is strikingly similar to the Eleventh Circuit's implied preemption reasoning in *Papas I*. Discussing the FIFRA scheme for regulating pesticides, the federal court of appeals explained "Congress recognized that the control of pesticides required a careful balancing of benefit against risk" and

that "[t]he EPA Administrator was designated as the entity to conduct the balancing analysis." *Papas I*¸ 926 F.2d at 1022. "[A] jury determination . . . that a pesticide's labeling is inadequate [is] in direct conflict with the Congressional intent that *the EPA Administrator* determine the reasonableness of the risks to man and the environment posed by pesticides, at least with respect to the labeling of pesticides." *Id.* at 1025.

Next Fall, the Supreme Court will be hearing *Wyeth v. Levine*, No. 06-1249, which squarely presents the question of whether the Food, Drug, and Cosmetic Act, which contains no express preemption provision applicable to prescription drugs, impliedly preempts failure-to-warn claims. That decision may bolster the case for implied preemption of pesticide-related failure-to-warn claims.

What Pesticide Manufacturers and Distributors Should Do Now

Meanwhile, pesticide manufacturers or distributors confronted with product liability suits alleging inadequate labeling or failure to warn, should vigorously pursue the FIFRA implied preemption defense. Even Justice Ginsburg, one of the most liberal members of the Supreme Court, noted in her *Riegel* dissent that although a claim may not be expressly preempted, a "manufacturer may have a dispositive defense if it can identify an actual conflict between the plaintiff's theory of the case and the [federal agency's] premarket approval of the [product] in question." *Riegel*, 128 S. Ct. at 1019-20 (Ginsburg, J., dissenting).

Why should a court find that a pesticide-related failure-to-warn claim is *impliedly* preempted even if it appears to fall into the *Bates* "parallel requirements" express preemption loophole? The answer is based on congressional intent, which is the "ultimate touchstone of pre-emption analysis." *Cipollone*, 505 U.S. at 516 (internal quotation marks omitted). As the court of appeals explained in *Papas I*, in order to achieve "an effective pesticide program," Congress intended "to completely preempt State authority in regard to labeling." 926 F.2d at 1023 (quoting H.R. Rep. No. 92-511 (1971) at 16). "[S]uch claims would be barred under principles of implied preemption" because "a State's imposition of common-law duties that are nominally similar to FIFRA's misbranding prohibition would nevertheless result, as a practical matter, in subjecting pesticide manufacturers to inconsistent labeling obligations that would stand as an obstacle to Congress's manifest goal of imposing a uniform body of federal labeling requirements." U.S. Br. at 27 n.14 in *Bates*.

To present a strong implied preemption argument, a pesticide manufacturer or distributor should explain, based on carefully maintained correspondence with EPA, why a particular claim would conflict with EPA's regulation of a product's labeling. For example, a claim may challenge the absence of a human health warning or precautionary measure that EPA determined need not be included on the label. Or, a claim may challenge particular label language that EPA required. Regardless of whether these and similar types of claims for inadequate labeling or warnings are expressly preempted by § 136v(b), pesticide manufacturers and distributors should argue that they are impliedly preempted because they undermine EPA's regulation of labeling.

About Us

McKenna Long & Aldridge LLP is an international law firm composed of lawyers and public-policy advisors with offices in Albany, Atlanta, Brussels, Denver, Los Angeles, New York, Philadelphia, San Diego, San Francisco, and Washington, D.C. The firm provides business solutions in the areas of corporate law, government contracts, intellectual property and technology, complex litigation, public policy and regulatory affairs, international law, real estate, environmental, energy, and finance.

Larry Ebner, Partner

Larry has been representing manufacturers, distributors, and their trade associations in pesticide-related litigation for almost 35 years. In January 2005 CropLife America and RISE honored Larry for his advocacy of FIFRA preemption on behalf the pesticide industry. Larry can be reached at lebner@mckennalong.com or (202) 496-7727 Please click to view bio.

*This Advisory is for informational purposes only and does not constitute specific legal advice or opinions. Such advice and opinions are provided by the firm only upon engagement with respect to specific factual situations. This communication is considered Attorney Advertising.

© Copyright 2008, McKenna Long & Aldridge LLP, 1900 K Street, NW, Washington DC, 20006