Defense Lawyers' Wake-Up Call

Can FIFRA Preemption Be Revived?

By Lawrence S. Ebner

Pesticide tort preemption needs to be revitalized, not resurrected. And the author explains how to do it.

During the past decade, most of the high-profile case law concerning federal preemption of product liability suits has focused on FDA-regulated drugs and medical devices. *See, e.g., Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (generic drugs); *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (generic drugs); *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011) (vaccines); *Wyeth v. Levine*, 555 U.S. 555 (2009) (brand-name drugs); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (medical devices). But what about pesticides? The plaintiffs' bar and environmental activists have targeted pesticides since the early 1970s. Pesticides include thousands of widely used, potentially hazardous industrial and consumer products ranging from agricultural insecticides, herbicides, and fungicides, to industrial biocides and wood preservatives, to structural termiticides and rodenticides, to household disinfectants and bug sprays.

Similar to drugs and medical devices, pesticides are subject to extensive federal regulation, especially in connection with product labeling and warnings. The significant, federal, safety-related interest in regulating drugs, medical devices, and pesticides in a nationally uniform manner compels preemption of many types of state-law tort claims, particularly for inadequate labeling and/or failure to warn.

Between 1991 and 2005, no fewer than nine federal circuits and appellate courts in 27 states concluded that pesticide-related failure-to-warn and inadequate-labeling claims, and in some cases, breach-of-warranty and design-defect claims, were preempted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the principal pesticide regulatory statute. Then the Supreme Court decided *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), and inexplicably, the FIFRA preemption defense seemed to disappear almost overnight.

The Court held in *Bates* that FIFRA's express preemption provision, 7 U.S.C. §136v(b), which prohibits states from regulating pesticide labeling, *can preempt* pesticide-related damages claims for inadequate labeling or failure to warn. Anti-pesticide groups and their plaintiffs' bar allies, however, seized upon the Court's

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holding that such claims are not *categorically* preempted. They immediately—and erroneously—proclaimed that *Bates* rang the death knell for federal preemption of any and all pesticide toxic tort or product liability claims. Their hyperbole about *Bates* was virtually unrestrained. For example, according to a leading public interest law firm, *Bates* rejected "corporate wrongdoer" arguments that "they can't be sued, even if they acted outrageously… [that] they're immune from suit, and are free to do harm, and their victims have no remedy at all." Arthur H. Bryant, *Power Unchecked: Access to Justice at Risk,* 20 BNA Toxics Law Rptr. 635 (July 7, 2005). *See also* Leslie A. Brueckner, *Why Bates Matters: A Response to the Critique of the U.S. Supreme Court's Holding In Bates v. Dow AgroSciences*, 20 BNA Toxics Law Rptr. 784 (Aug. 25, 2005) (*Bates* is "a devastating loss for the pesticide industry"). Another anti-pesticide group declared that the *Bates* decision was "critical… huge"; it was a "'landmark' decision… affirming 'a moral value that life is more precious than chemical company profits.'" Carmel Sileo, *Supreme Court Preemption Decision Bugs Pesticide Makers*, 41 Trial, Ass'n of Trial Lawyers of America 90 (July 2005) (quoting Jay Feldman, Exec. Dir., Beyond Pesticides); Pesticide & Toxic Chem. News, Vol. 33, No. 28, at 20 (May 2, 2005) (quoting Jay Feldman).

Unfortunately, many defense attorneys representing pesticide manufacturers in toxic tort suits also overreacted to *Bates*. They should have embraced *Bates* by taking advantage of the case-by-case FIFRA preemption defense that the Supreme Court both recognized and delineated in *Bates*. Instead, industry attorneys, confronted with the loss of what most lower courts had viewed as the *categorical* preemption of pesticide-related failure-to-warn and inadequate-labeling claims, abruptly and unnecessarily abandoned the defense altogether. As a result, a robust body of post-*Bates* FIFRA preemption case law never developed, and the FIFRA preemption defense has languished in a somnambulant state for the past decade. In the author's view, the FIFRA tort preemption defense can and should be revived, especially in light of the still-developing jurisprudence on medical device and drug preemption.

FIFRA's Express Preemption Provision

FIFRA is the comprehensive federal regulatory statute governing registration, sale, labeling, and use of pesticides. *See* 7 U.S.C. §§136-136y. The U.S. Environmental Protection Agency (EPA), through its Office of Pesticide Programs, is responsible for administering FIFRA.

Since 1972, FIFRA has contained an express preemption provision, which vests EPA with sole and exclusive authority over pesticide labeling: A "State shall not impose or continue in effect *any requirements for labeling* or packaging *in addition to or different from* those required under [FIFRA]." *Id.* §136v(b) (emphasis added). States retain authority to regulate "the sale or use of any federally registered pesticide." *Id.* §136v(a). *See generally Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597 (1991) (holding that FIFRA does not preempt local governments from regulating pesticide use). But under §136v(b), *only EPA* can regulate the scope, content, and format of a pesticide's labeling, including the warnings and other precautionary statements that accompany a pesticide product through the chain of manufacture, distribution, sale, and use. As the Supreme Court explained in *Bates*, §136v(b), which is entitled "Uniformity," serves an "important role": It "pre-empts competing state labeling standards—imagine 50 different labeling regimes prescribing the color, font size, and wording of warnings." 544 U.S. at 452. *See also* Br. for the United States as Amicus Curiae Supporting Respondent, *Bates v. Dow AgroSciences LLC*, No. 03-388 (U.S. Nov. 24, 2004), at 1 ("The United States… has a strong interest in preserving Congress's express delineation of federal and state authority, which ensures that the federal government can establish and maintain nationally uniform requirements for labeling and packaging.").

EPA-Approved Product Labeling Is the Key to Federal Preemption

The need for every FIFRA-registered pesticide to be accompanied by its own, nationally uniform, EPA-regulated product labeling is critical. Labeling is EPA's principal risk-management tool for protecting pesticide users and the public, along with their property, from potential harm by communicating essential warnings and other precautionary information. *See* 70 Fed. Reg. 12,276, 12,281 (Mar. 11, 2005) (EPA notice explaining that "[a] pesticide label is the user's direction for using pesticides safely and effectively. It contains important information about where to use, or not to use, the product, health and safety information that should be read and understood before using a pesticide product, and how to dispose of that product."). Indeed, because adherence to the safety-related information provided on a pesticide's label is so vital, FIFRA makes it unlawful "to use any registered pesticide in a manner inconsistent with its labeling." 7 U.S.C. §136j(a)(2)(G). Further, and important for preemption purposes, the statute *prohibits* manufacturers from adding or modifying label warnings without EPA's preapproval. *See id.* §136j(a)(2)(A). *See also* 40 C.F.R. §152.130(a) (pesticide products may be distributed or sold only with the "labeling currently approved by the Agency"). 40 C.F.R. §156.70(c) ("Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency.").

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Because there are a multitude of pesticide products differing in composition, uses, and potential risks, EPA views its pesticide labeling regulations, 40 C.F.R. Part 156, as the baseline for regulating labeling on a product-by-product basis. To regulate labeling, EPA requires a pesticide's manufacturer to submit specific types of product chemistry, toxicology, environmental, and other data, which the agency then reviews in conjunction with

draft labeling to determine exactly what warnings should appear on the label and precisely how they should be worded. *See* 40 C.F.R. pt. 158 ("Data Requirements for Pesticides"). Equally important, EPA endeavors to avoid inclusion of scientifically unwarranted warnings that can distract pesticide users from focusing on the warnings that the agency determines are necessary. The goal of EPA's regulation of pesticide labeling is to ensure that a use of a product "will not generally cause unreasonable adverse effects on the environment," which the statute defines as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. §§136a(c)(5)(D), 136(bb).

***Bates* held** that §136v(b) expressly preempts failure-to-warn, inadequate-labeling, and fraud claims provided they are based on state-law labeling requirements that are "in addition to or different from" federal labeling requirements, not state-law requirements that are "*genuinely* equivalent to" federal labeling requirements.

What *Bates* Actually Held

Bates was an agricultural crop-damage suit. Texas farmers alleged that their peanut crops, planted in soils with high-pH levels, were damaged by a herbicide distributed with an EPA-approved label that, during the relevant time period, recommended use "in all areas where peanuts are grown," rather than warning against use in high-pH soil areas. *Bates*, 544 U.S. at 440. A federal district court held that §136v(b) of FIFRA expressly preempted all of the farmers' state law claims, which included breach of express warranty, fraud, strict liability (defective design and defective manufacture), negligent testing, and negligent failure to warn. The Fifth Circuit affirmed, and the Supreme Court granted certiorari.

In a sometimes murky opinion authored by Justice Stevens, the Court held that

the prohibition against imposition of state labeling requirements in §136v(b) "reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties," 544 U.S. at 443. The Court further held that to be preempted by §136v(b), a state tort claim must satisfy two conditions set forth in that preemption provision's text. *Id.* at 444.

The *first* of those conditions is that a preempted claim must be premised on common-law rules that qualify as "requirements for labeling" in that they "set a standard for a product's labeling." *Id.* at 446. Defining "requirement," Justice Stevens wrote that "[a] requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision"—such as a manufacturer's decision to seek EPA approval to add particular warnings to a label—"is not a requirement." *Id.* at 445. According to the Court, a tort claim that, if successful, merely would "induce" a manufacturer to change its label to avoid future liability is not necessarily premised on a "requirement" for labeling. *Id.*

The Court indicated that the *Bates* plaintiffs' fraud and negligent-failure-to-warn claims met this first condition for express preemption: Those claims were premised on common-law rules that impose "requirements for labeling" because they "set a standard" that the labeling of the herbicide at issue was "alleged to have violated by containing false statements and inadequate warnings." *Id.* at 446. But the Court ruled that the *Bates* plaintiffs' claims for defective design, defective manufacture, negligent testing, and breach of express warranty, were not preempted because none of the common-law rules on which those claims were premised "require[d] that manufacturers label… their products in any particular way." *Id.* at 444.

The *second* condition that the Court identified for preemption under §136v(b) is that a state-law labeling requirement must be "in addition to or different from"—not "equivalent" or "parallel" to—federal labeling requirements. *Id.* at 447. Thus, §136v(b) "pre-empts any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations." *Id.* at 452. Section 136v(b) does not preempt, however, "a state-law labeling requirement if it is equivalent to, and fully consistent with, FIFRA's misbranding provision." *Id.* at 447. That provision makes it unlawful to distribute or to sell a pesticide that is "misbranded." 7 U.S.C. §136j(a)(1)(E).

Under FIFRA's broad definition of misbranding, a pesticide is misbranded if, for example, its label does not contain "a warning or caution statement which… is adequate to protect health and the environment," or if its labeling "bears any statement… which is false or misleading in any particular." 7 U.S.C. §§136(q)(1)(G), 136(q)(1)(F), 136(q)(1)(A). *Bates* explains that if a pesticide product is not misbranded under FIFRA, then a failure-to-warn or inadequate-labeling claim would be preempted because it necessarily would impose state law labeling requirements that are "in addition to or different from," and not equivalent or parallel to, federal labeling requirements. *See Bates*, 544 U.S. at 454. *See also id.* at 456 (Thomas, J., concurring in the judgment in part and dissenting in part) ("A state-law cause of action, even if not specific to labeling, nevertheless imposes a labeling requirement 'in addition to or different from' FIFRA's when it attaches liability to statements on the label that do not produce liability under FIFRA.").

In short, *Bates* held that §136v(b) expressly preempts failure-to-warn, inadequate- labeling, and fraud claims provided they are based on state-law labeling requirements that are "in addition to or different from" federal labeling requirements, not state-law requirements that are

"*genuinely* equivalent to" federal labeling requirements. *Id.* at 454. *See also* Lawrence S. Ebner, *FIFRA Preemption After Bates v. Dow AgroSciences*, 20 BNA Toxics Law Rptr. 541 (June 9, 2005).

Scope of Post-*Bates* FIFRA Preemption

One indisputable aspect of *Bates* is that §136v(b) applies not only to labeling requirements imposed by state statutes and regulations, but also to labeling requirements imposed through state common-law claims. Indeed, three years after *Bates*, in *Riegel v. Medtronic, Inc.*, a medical device preemption case, the Supreme Court explicitly placed Congress on notice that "[a]bsent other indication, reference [in a federal statute] to a State's 'requirements' includes its common-law duties." 552 U.S. at 324 (citing *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 521–22 (1992)). The Court explained that it held in *Cipollone*, and also in *Bates*, "that a provision pre-empting state 'requirements' pre-empted common-law duties." *Id.* Along the same lines, in *Northwest, Inc. v. Ginsberg*, 134 S. Ct. 1422 (2014), a tort suit involving the Airline Deregulation Act, the Court squarely rejected the plaintiff's contention that the statute's preemption provision "applies only to legislation enacted by a state legislature and regulations issued by a state administrative agency but not to a common-law rule." *Id.* at 1429. Writing for a unanimous Court, Justice Alito explained that "there surely can be no doubt" that a preemption provision's use of terms such as "rules," "standards," or "requirements" encompasses common- law claims. *Id.* The Court further explained that a federal statute's "aim can be undermined just as surely by a state common-law rule as it can by a state statute or regulation." *Id.* at 1430.

A major part of *Bates* that is debatable, however, is the Court's seemingly broad-brush holding that claims for defective design, inadequate testing, and breach of express warranty are excluded from §136v(b)'s preemptive scope. *See, e.g.*, *Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 887 (8th Cir. 2005) (holding in light if *Bates* that claims for defective design, breach of implied warranties of fitness for a particular use and merchantability, and recklessness, as pleaded, were not preempted because "the rules underlying them do not require anything in the way of labeling"). At the least, plaintiffs should not be allowed to evade FIFRA preemption by attempting to disguise failure-to-warn or inadequate-labeling claims as claims for defective design, breach of warranty, or inadequate testing. *See generally Aetna Health Inc. v. Davila*, 542 U.S. 200, 214 (2004) ("[D]istinguishing between pre-empted and non-pre-empted claims based on the particular label affixed to them would 'elevate form over substance and allow parties to evade' the pre-emptive scope of [a statute] simply 'by relabeling' their… claims.") (citation omitted).

Although Supreme Court clarification or reconsideration about what constitutes "requirements for labeling" will have to await a future case, *Bates* left intact, and indeed affirmed, the most important FIFRA tort preemption principle—that pesticide-related failure-to-warn and inadequate-labeling claims are encompassed by §136v(b). Persuading a jury that a pesticide manufacturer failed to provide adequate warnings about the personal injury, crop damage, or environmental harm allegedly caused by a pesticide is generally much easier to accomplish than proving that a FIFRA-registered pesticide was defectively designed or inadequately tested. For this reason, a holding that a plaintiff's labeling and warning claims are preempted should go a long way in achieving dismissal or settlement of a pesticide suit.

Meaning of "Parallel" State Requirements

The principal questions that *Bates* left to the lower courts to resolve are the precise meaning and practical application of the "parallel requirements" exclusion from express preemption under §136v(b). The Supreme Court has identified essentially the same exclusion under the Federal Food, Drug, and Cosmetic Act's Medical Device Amendments, which expressly prohibit a state from establishing "any requirement—which is different from, or in addition to, any requirement applicable [to a medical] device." 21 U.S.C. §360k(a)(1). *See Riegel,* 552 U.S. at 322; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). In the medical device arena too, however, the Court has declined to elaborate on the parameters of the parallel requirements exclusion from preemption, including in connection with misbranding and failure-to-warn claims. *See* Michael A. Walsh, *Parallel Claims: Who, What, When, Where, and Why*, For The Defense, DRI—The Voice of the Defense Bar at 24 (Sept. 2014).

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In the wake of *Bates*, the plaintiffs' bar quickly advocated an expansive interpretation of "parallel" or "equivalent" state-labeling requirements that would transform this narrow exclusion from §136v(b)'s broad scope into a gaping loophole that would swallow the preemption provision itself. More specifically, plaintiffs' attorneys simplistically argued that claims for inadequate labeling or failure to warn escape preemption merely because the general state tort duties on which they are based are parallel or equivalent to, and consistent with, the broad, general language in FIFRA's misbranding definition. If this superficial comparison actually were the test for exclusion from FIFRA preemption, virtually no pesticide-related claim for inadequate labeling or failure to warn ever would be preempted by §136v(b). That apparently would be fine with the plaintiffs' bar. *See, e.g.*, Leslie A. Brueckner, *Why Bates Matters: A Response to the Critique of the U.S. Supreme Court's Holding In Bates v. Dow AgroSciences*, 20 BNA Tox-

ics Law Rptr. 784 (Aug. 25, 2005) ("[M]ost failure-to-warn… claims will easily pass this test.").

Bates establishes, however, that qualifying for the parallel requirements exclusion from §136v(b) preemption requires considerably more than a cursory comparison between state tort duties and FIFRA's misbranding definition. The Court not only "emphasize[d] that a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive pre-emption," but also that "[s]tate-law requirements must… be *measured against any relevant EPA regulations* that give content to FIFRA's misbranding standards." 544 U.S. at 453 (emphasis added). *See also Id*. at 452 (explaining that §136v(b) "pre-empts any… common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA *and its implementing regulations*") (emphasis added); *Id*. at 454 ("If a case proceeds to trial… a court should instruct the jury on the relevant FIFRA misbranding standards, as well as *any regulations that add content to those standards.*") (emphasis added); *Id*. at 454 (Breyer, J., concurring) (writing "separately to stress the practical importance of the Court's statement that state-law requirements must 'be measured against' relevant [EPA] regulations 'that give content to [FIFRA's] misbranding standards'"). In the amicus brief that it submitted in *Bates*, the United States agreed that labeling-related claims that merely are based on "nominally harmonious state common-law standards" should be preempted "in order to avoid the conflict, uncertainty, cost, and potential misinformation that would inevitably result from simultaneous federal and state labeling prescriptions." U.S. Br., *Bates*, No. 03-388, at 26–27.

Bates left intact, and indeed affirmed, the most important FIFRA tort preemption principle—that pesticide-related failure-to-warn and inadequate-labeling claims are encompassed by §136v(b).

EPA "regulations" that give content to FIFRA's misbranding standards not only are set forth at 40 C.F.R. Part 156, but also are established through EPA's meticulous, product-by-product labeling determinations and requirements. For this reason, a state labeling requirement for a particular pesticide product would be genuinely equivalent or parallel to EPA's labeling requirements for that product *only if* the former required *nothing more* than the latter. For example, if the manufacturer of pesticide product "X" fails to comply with EPA's determination that the product must be distributed with a label that includes warning "Y," a failure-to-warn claim based on breach of a state law duty to provide warning "Y" would be parallel or equivalent to the federal labeling requirement, and thus, *not* expressly preempted by §136v(b).

This is what the Court meant in *Bates* when it stated that "[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA." 544 U.S. at 451. *See also Mortellite v. Novartis Crop Prot., Inc.*, 460 F.3d 483, 491 (3d Cir. 2006) (under the "*Bates* test," failure-to-warn "[c]laims that result in requirements that are consistent with FIFRA requirements and which only provide new remedies are not preempted"). But if a failure-to-warn claim is based on a state-law duty to provide a stronger, more elaborate, or differently worded "Y" warning—or to provide an additional warning, a warning "Z," not required by EPA—that claim would be expressly preempted because *only EPA*, not the states, can determine the content of pesticide labeling, including warnings and precautionary statements.

Reviving FIFRA Preemption

The FIFRA preemption defense is not dead! It needs to be revived, not resurrected. The best way to revitalize the defense is for attorneys representing pesticide manufacturers and distributors, or their insurers, to resume pursuing it. Since FIFRA preemption is an affirmative defense, it should be included in the Answer to a Complaint. In most cases, the FIFRA preemption defense then should be asserted, before trial, through a Rule 56 motion for summary judgment.

At a minimum, defense counsel should support a summary judgment motion with a declaration or other evidence establishing that the pesticide product was distributed with EPA-approved labeling at the time that the plaintiff's cause of action arose. *See* 7 U.S.C. §136(p) (FIFRA definition of label and labeling). To help overcome the parallel requirements exclusion, defense counsel also may want to support summary judgment with additional evidence regarding EPA's consideration of the warning language at issue, or its consideration of the need to include a label warning about the alleged injury or harm involved in the suit. This information may be available in the form of registration correspondence between a manufacturer and EPA. Relevant information about EPA's labeling determinations for pesticide products containing a particular active ingredient or involving a particular type of use also may be found in FIFRA "reregistration," "registration review," or "special review" documents, or in pesticide regulation ("PR") notices, available on the EPA website (www.epa.gov/pesticides). And of course, defense counsel's summary judgment brief should discuss the FIFRA regulatory scheme, particularly regarding preemption of state labeling requirements, and carefully explain what the Supreme Court did—and did not—hold in *Bates*. In addition to invoking express preemption under §136v(b), counsel also make want to discuss implied preemption principles (*i.e.*, "impossibility" or "purposes and objectives" preemption) as alternative grounds for preemption, especially if the plaintiff's claims are broader than failure to warn.

Finally, defense counsel should monitor the continuing development of Supreme Court tort preemption jurisprudence regarding other types of federally regulated products. Although each federal reg-

ulatory scheme differs (*e.g.*, no express preemption provision exists for prescription drugs), preemption case law on other categories of federally regulated products may provide helpful guidance to pesticide litigants and courts. For example, in the *Mutual Pharmaceutical* case, the Supreme Court held in a 5–4 decision that state-law, generic drug, design-defect claims are impliedly preempted if they would impose liability upon a manufacturer for failing to unilaterally add a label warning stronger than the warning that the FDA had approved. The Court's majority opinion explained that "state law imposed a duty on [the manufacturer] *not* to comply with federal law." 133 S. Ct. at 2470 (emphasis in original). Similarly, as discussed above, FIFRA prohibits a pesticide manufacturer from adding or modifying a label warning for any pesticide product without EPA's preapproval.

The Supreme Court's future resolution of still-debated fundamental preemption principles, such as the so-called "presumption against preemption," also may prove to be instructive for further development of FIFRA preemption jurisprudence. For example, as a corollary to the presumption-against-preemption debate, divisions remain within the Court regarding how to interpret express preemption provisions. In *CTS Corp. v. Waldburger*, 134 S. Ct. 2175, 2188 (2014), holding that CERCLA does not preempt state statutes of repose, three Justices cited *Bates* and *Lohr* for the proposition that "when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily accept the reading that disfavors pre-emption" (internal quotation marks and citation omitted). But in a separate opinion in *Waldburger*, three other Justices insisted that the interpretation of express preemption provisions should be governed by "ordinary principles of statutory construction." *Id.* at 2189 (Scalia, J., concurring in judgment in part and dissenting in part).

Conclusion

Many of the Supreme Court's tort preemption cases during the past 25 years are difficult to reconcile. *Bates* is part of that often puzzling body of case law. That decision narrowed, but certainly did not eliminate, the FIFRA preemption defense, and it does not deserve the apocalyptic spin that the plaintiffs' bar and pesticide foes breathlessly assigned to it. Defense lawyers should take another look at *Bates* and consider raising FIFRA preemption the next time they are called upon to defend a pesticide-related toxic tort or product liability case.