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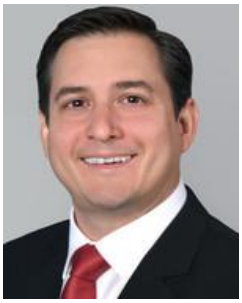
Roundup Case Shows State Law Can Top Preemption Defense

By **Thomas Manakides and Joseph Edmonds** (June 1, 2021, 5:01 PM EDT)



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The U.S. Court of Appeals for the Ninth Circuit recently affirmed a $25 million verdict in Hardeman v. Monsanto Co., the bellwether trial of a cancer case involving the herbicide Roundup.[1] The court rejected the defendant's argument that federal law preempted the plaintiff's state law failure-to-warn claims because the U.S. Environmental Protection Agency had registered Roundup and approved its label.

The court's refusal to recognize a federal preemption defense underscores that in some cases, state statutes, rather than federal ones, may provide a better defense. California, where the case arose, is not one of the growing number of states that has passed a law creating a state law tort defense based on compliance with federal standards. But had the case arisen in a state that recognizes such a defense, the outcome may have been different.

The plaintiff in the case, Edward Hardeman, claimed that his exposure to the chemical glyphosate in Roundup caused him to develop non-Hodgkin's lymphoma.[2] The Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA, requires pesticide manufacturers to register their products with the EPA.[3] Since 1974, the agency has registered pesticides containing glyphosate, the active ingredient in Roundup, and it approved the warning label on Roundup.[4]

Despite classifying glyphosate as a possible human carcinogen in 1985, the court noted that the "EPA has repeatedly approved the use of glyphosate as a pesticide, each time concluding that it is not likely to be carcinogenic to humans."[5] Departing from the EPA's position, the state of California in 2017 designated glyphosate as a chemical known to the state to cause cancer under Proposition 65 — which triggered a mandatory warning label under California law for glyphosate-containing products.

However, the EPA challenged this designation, and issued a letter to all glyphosate registrants instructing them to remove any Proposition 65 warning labels, because the EPA considers the Proposition 65 warning language that glyphosate is carcinogenic to constitute a false and misleading statement, in violation of FIFRA's prohibition against misbranded substances.[6]

Hardeman sued Monsanto in California, alleging that Monsanto failed to warn him of the risk of cancer

from using Roundup. He ultimately won a $25 million jury verdict, including a substantial punitive damages award, and Monsanto appealed.

Monsanto argued that Hardeman's failure-to-warn claim under state law was preempted by FIFRA, because the EPA had registered glyphosate and approved the Roundup warning label. The Ninth Circuit disagreed, and affirmed the verdict.

Under FIFRA, the Ninth Circuit noted, "states cannot 'impose any requirements for labeling or packaging in addition to or different from' the requirements in FIFRA itself."[7] However, the court held that FIFRA did not expressly preempt Hardeman's claims, because "FIFRA's requirement that a pesticide not be misbranded is consistent with, if not broader than, California's common law duty to warn."[8]

The court based its holding on statutory language suggesting that the EPA approval of a label "is not conclusive of FIFRA compliance," and noted that "mere inconsistency" between a state law duty and a manufacturer's label is not sufficient to show preemption.[9]

And even though the EPA had expressly considered the claim that glyphosate causes cancer, and had (1) continued to register the product, (2) continued to approve Roundup's label omitting a cancer warning, and (3) issued a letter directing manufacturers to not warn of cancer, the court held that those actions "do not carry the force of law" and could not establish preemption.[10]

The court also held that there was no implied preemption, reasoning that Monsanto failed to show clear evidence of an "irreconcilable conflict" in complying with both FIFRA and California law, and that "it is not impossible for Monsanto to add a cancer warning to Roundup's label."[11] Again, the court largely relied on its finding that the EPA's actions on glyphosate do not have the force of law.[12]

The end result of the court's ruling is that even though Monsanto was selling a federally registered product, sold under a label that the EPA approved, it was allowed to be found liable by a lay jury in California and subjected to punitive damages for failing to warn of a risk that the EPA had instructed it — albeit after the fact — to omit from its warning label.

Without addressing the merits of the court's preemption analysis, this outcome highlights the patchwork of state law tort regimes that currently governs product defect claims. Unlike California, where the Hardeman case arose, several states' tort laws create a defense to product defect suits based on compliance with federal standards that is more expansive than the federal preemption standard.

A common format for a federal compliance defense is found in Texas. There, the Legislature found that "manufacturers and sellers were being held liable in products liability cases even though the products at issue complied with all applicable federal safety standards."[13]

This prompted the Legislature to enact a statute creating two possible avenues for a manufacturer to obtain a rebuttable presumption that it is not liable. First, a manufacturer can establish that: "(1) the product complied with mandatory federal safety standards or regulations, (2) the standards or regulations were applicable to the product at the time of manufacture, and (3) the standards or regulations governed the product risk that allegedly caused the harm."[14]

Second, a manufacturer can prove that:

the product was subject to pre-market licensing or approval by the federal government, or an agency of the federal government, that the manufacturer complied with all of the government's or agency's

procedures and requirements with respect to pre-market licensing or approval, and that after full consideration of the product's risks and benefits the product was approved or licensed for sale by the government or agency.[15]

As but one example, applying this Texas statute, the Texas Court of Appeal in 2010 affirmed summary judgment for the maker of a guardrail end terminal that complied with federal crash testing standards, in Shaw v. Trinity Highway Products LLC.[16]

It is notable in this decision that the key summary judgment evidence the court relied on was "two letters from the Federal Highway Administration, U.S. Department of Transportation, noting that the [product] satisfied the appropriate [federal] standards."[17] In contrast to the federal preemption case law, Texas law lacks any requirement that these approval letters carry the force of law — the issue that doomed the preemption defense in Hardeman.

Like Texas, many states have passed laws creating a complete or partial defense to product liability suits based on compliance with federal standards.[18] These laws take various forms, but they generally provide a rebuttable presumption of no liability where a product manufacturer shows that it has complied with federal standards in designing, manufacturing or labeling a product, or where the product has been approved by federal regulators.[19]

Others state laws are more limited, and provide a defense only as to certain types of products — e.g., drugs[20] — or as to a certain type of damages — e.g., punitive damages.[21] The outcome in Hardeman underscores the importance of this patchwork of state law.

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[1] Hardeman v. Monsanto Co., --- F.3d ---, 2021 WL 1940550 (9th Cir. May 14, 2021).

[2] Id.

[3] Id. at *3.

[4] Id.

[5] Id.

[6] Id.

[7] Id. at *6 (quoting 7 U.S.C. § 136v(b)).

[8] Id. at 6.

[9] Id. at 7 (discussing Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005) and quoting Indian Brand Farms Inc. v. Novartis Crop Prot. Inc., 617 F.3d 207, 222 (3d Cir. 2010)).

[10] Id. at 8.

[11] Id. at 9-10.

[12] Id.

[13] Kia Motors Corp. v. Ruiz, 432 S.W.3d 865, 869 (Tex. 2014).

[14] Id. at 870.

[15] Tex. Civ. Prac, and Remedies Code sec. 82.008(c).

[16] Shaw v. Trinity Highway Prod. LLC, 329 S.W.3d 914, 918 (Tex. App. 2010).

[17] Id.

[18] See, e.g., Indiana Code § 34-20-5-1; N.D. Code § 28-01.3-09; Tenn. Code Ann. § 29-28-104; Mich. Comp. Laws Ann. § 600.2946 (4); Colo. Rev. Stat. Ann. § 13-21-403; Fla. Stat. Ann. § 768.1256; Kan. Stat. Ann. § 60-3304; Utah Code Ann. § 78B-6-703; Wis. Stat. Ann. § 895.047.

[19] See, e.g., Indiana Code § 34-20-5-1.

[20] See, e.g., Mich. Comp. Laws Ann. § 600.2946 (5).

[21] See, e.g., N.D. Cent. Code Ann. § 32-03.2-11 ("Exemplary damages may not be awarded against a manufacturer or seller if the product's manufacture, design, formulation, inspection, testing, packaging, labeling, and warning complied with ... Federal statutes existing at the time the product was produced[;] Administrative regulations ... or Premarket approval or certification by an agency of the federal government").