[PUBLISH]

In the United States Court of Appeals

For the Eleventh Circuit

No. 21-10994

JOHN D. CARSON,

Plaintiff-Appellant,

versus

MONSANTO COMPANY,

Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of Georgia
D.C. Docket No. 4:17-cv-00237-RSB-CLR

Before ROSENBAUM, TJOFLAT, Circuit Judges, and MOODY, District Judge.

TJOFLAT, Circuit Judge:

Federal preemption is a bitter pill. We should administer it carefully. And, applying such care to the present case, we hold that John Carson's Georgia failure to warn claim is not preempted by the federal requirements under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") or the Environmental Protection Agency's ("EPA") actions pursuant to it.

I.

John Carson regularly used Roundup® on his lawn for about 30 years until 2016. Around 2016, Carson was diagnosed with malignant fibrous histiocytoma, which he believes was linked to the compound glyphosate, the main chemical ingredient in Roundup®.

Carson filed suit against Monsanto, the manufacturer of Roundup®, on December 5, 2017. In his four-count complaint, Carson alleged strict liability for a design defect under Georgia law (Count I); strict liability for failure to warn under Georgia law

(Count II); negligence under Georgia law (Count III); and breach of implied warranties under Georgia law (Count IV).[1]

Monsanto filed an answer to the Complaint and subsequently moved for judgment on the pleadings.[2] The District Court partially granted the motion. The District Court ruled that Carson's Count II failure to warn claim was preempted under FIFRA because the EPA had classified glyphosate as not likely to be carcinogenic to humans and ruled that Carson's Count IV breach of implied warranties claim under Georgia law was preempted for the same reason. The District Court also dismissed Counts I and III for the strict liability design defect and negligence to the extent that those claims related to how Roundup® was labeled or packaged. Carson moved to amend his complaint to dismiss Counts I and III of the complaint pursuant to a settlement agreement with Monsanto but preserved his right to appeal Count II, the failure to warn claim. The District Court granted that motion, thereby eliminating Counts I and III from the Complaint. Carson timely appealed the District Court's judgment on the pleadings as to Count II.

On appeal, we are essentially tasked with deciding whether the District Court erred in concluding that Carson's failure to warn

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[1] Carson did not specify that his cause of action was under Georgia law in his Complaint, but the District Court determined that his common law claims fell under Georgia law, and Carson does not challenge that determination.

[2] The judgment on the pleadings challenged the legal sufficiency of the Complaint based on federal preemption grounds.

claim was preempted under FIFRA because the EPA had classified glyphosate as not likely to be carcinogenic to humans and approved the Roundup® label. We conclude it did, reverse the District Court's ruling, and remand for further proceedings.

II.

"Judgment on the pleadings is proper when no issues of material fact exist, and the movant is entitled to judgment as a matter of law." *Ortega v. Christian*, 85 F.3d 1521, 1524 (11th Cir. 1996). We review de novo a district court's order granting a judgment on the pleadings, treating the facts alleged in the complaint as true, viewing the record in the light most favorable to the nonmovant, and evaluating any affirmative defenses raised by the moving party (including preemption).[3] *Horsley v. Feldt*, 304 F.3d 1125, 1131 (11th Cir. 2002); *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 767 (11th Cir. 1998).

III.

Starting at the beginning of the EPA's work in a pesticide case like this one, FIFRA requires all pesticide manufacturers to go through a registration process with the EPA before selling a

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[3] In this case, any evidence submitted by Monsanto to support its defense of federal preemption turns out not to be probative because the EPA has not acted with the force of law such as to meet the threshold inquiry for federal preemption, as discussed *infra* Part IV.

particular pesticide. *See* 7 U.S.C. § 136a; 40 C.F.R. § 155.58. As part of that process, the manufacturer submits a proposed label and relevant data for registration to the EPA. 7 U.S.C. §§ 136a(c)(1)(C), (F). In turn, the EPA reviews the efficacy of the pesticide, the adverse health consequences or environmental effects of the pesticide, and the labels on the pesticide for compliance with FIFRA's labeling requirements. *Id.* § 136a(c)(5).

FIFRA prohibits pesticide manufacturers from selling a pesticide that is "misbranded." *Id.* § 136j(a)(1)(E). Misbranding could mean that a pesticide label contains information that is "false or misleading in any particular."[4] *Id.* § 136(q)(1)(A). A pesticide can also be misbranded if the label does not "contain directions for use" or "a warning or caution statement" that is "adequate to protect health and the environment." *Id.* § 136(q)(1)(F), (G).

So, the EPA checks for these possible misbranding violations on labels when completing the registration process for pesticide manufacturers. *Id.* § 136a(c)(5)(B). But, even with EPA oversight at the initial registration process,[5] pesticide manufacturers have a perpetual duty to adhere to FIFRA's labeling requirements and to

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[4] "The term 'label' means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." 7 U.S.C. § 136(p)(1).

[5] The EPA must reconsider a pesticide's registration every fifteen years. 7 U.S.C. § 136a(g)(1)(A)(iv).

report any new adverse effects to the EPA. *Id.* § 136j(a)(1)(E); § 136a(f)(1); § 136d(a)(2); 40 C.F.R. § 159.184. And, sometimes, the EPA might just miss a misbranded label in the registration process. FIFRA accounts for that possibility by explaining that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter." 7 U.S.C. § 136a(f)(2). In other words, a pesticide manufacturer can't point to EPA registration as a defense to a misbranding violation under FIFRA.

In sum, we have two things going on here: 1) we have the EPA's registration process for pesticide manufacturers seeking to market their pesticides; and 2) we have FIFRA's statutory labeling requirements and consequences for failing to properly label. These two components underlie the preemption analysis.

IV.

Sometimes, FIFRA or the EPA's actions pursuant to FIFRA may preempt state law. But only federal action with the force of law has the capacity to preempt state law.[6] *See Wyeth v. Levine*,

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[6] Congress created wide latitude for state regulation in the context of FIFRA. *See* 7 U.S.C. § 136v(a) ("A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter."); *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 446, 125 S. Ct. 1788, 1799 (2005) ("Under § 136v(a), a state agency may ban the sale of a pesticide if it finds, for instance, that one of the pesticide's label-approved uses is unsafe.

555 U.S. 555, 576, 580, 129 S. Ct. 1187, 1200 (2009). So, any preemption analysis in the FIFRA context first requires us to do a *Mead* analysis.[7] *United States v. Mead Corp.*, 533 U.S. 218, 230–31, 121 S. Ct. 2164, 2172–73 (2001). If, and only if, the EPA has acted with the force of law, may we move on to a preemption analysis.

In the universe where there is either an applicable FIFRA statute or the EPA has acted with the force of law, we turn to FIFRA's uniformity statute, which says that no state shall "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b). So, a state rule, including a common-law cause of action like Georgia's failure-to-warn claim, is preempted by FIFRA if two conditions are met: 1) the state requirement must be "for labeling or packaging" under the language of the statute; and

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This ban might well induce the manufacturer to change its label to warn against this questioned use.").

[7] The Supremacy Clause, the source of federal preemption, only applies to agency action that constitutes "federal law." *Marrache v. Bacardi U.S.A., Inc.*, 17 F.4th 1084, 1094 (11th Cir. 2021); *cf. Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015) ("In both *Chevron* and preemption contexts, a central inquiry is whether an agency has validly created federal law pursuant to the gap-filling power delegated to it by Congress. In the former situation, we decide whether *Chevron*-level deference is due because Congress intended for the agency's pronouncement to carry the force of law; in the latter, we decide whether state law is preempted because Congress intended for the agency's pronouncement to carry the binding and exclusive force of federal law. Creation of federal law should demand at least the same formality for purposes of preemption as it does for purposes of *Chevron* deference.").

2) the state requirement is "in addition to or different from" requirements derived from FIFRA. *Id.*; *see also Bates*, 544 U.S. at 444, 125 S. Ct. at 1798. Straightforward in recitation. A bit complicated in practice.

Since Carson's failure to warn claim under Georgia law hinges on whether Georgia's cause of action is different from or in addition to the federal law imposed on Monsanto for its marketing of Roundup®, we must first look to the EPA's registration process and then FIFRA's misbranding statutes.

The EPA registered Roundup®, whose main chemical ingredient is glyphosate, for distribution, sale, and manufacture in the United States. Even with that approval, Carson argues that Roundup's® label failed to adequately warn of the harmful nature of glyphosate under Georgia law. So, the question under FIFRA is whether Georgia common law failure to warn would be different from or in addition to any action the EPA has taken that has the force of law. 7 U.S.C. § 136v(b). Connecting the dots, the only way that we could have a preemption problem in the registration process is if the EPA registration process itself carries with it the force of law. Otherwise, the threshold step for preemption—the force of law—is not met, and we can't even continue to the *Bates* analysis for preemption of state law under FIFRA.

The problem for Monsanto is that the EPA's registration process is not sufficiently formal to carry with it the force of law under *Mead*. *See Mead Corp.*, 533 U.S. at 230, 121 S. Ct. at 2172

("It is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force."); *id.* at 234, 121 S. Ct. at 2175 ("[P]olicy statements, agency manuals, and enforcement guidelines" are insufficient to carry the force of law.). Congress itself undermined the formality of EPA registration when it explained that EPA registration served only as prima facie evidence of compliance with the registration requirements of FIFRA.[8] 7 U.S.C. § 136a(f)(2). In short, we can only take EPA registration for what it's worth. And it doesn't amount to a sufficiently formal proceeding to carry the force of law since it at most creates a rebuttable presumption of compliance with FIFRA's registration process and nothing more.[9] *See Hardeman v. Monsanto Co.*, 997 F.3d 941, 956 (9th Cir. 2021) ("So even

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[8] We note that compliance with the registration process does not even serve as evidence of compliance with the labeling provisions of FIFRA. *See* 7 U.S.C. § 136a(f)(2) ("In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter.").

[9] And, even if this were a close case on whether the EPA has acted with the force of law, which it isn't, "[t]he long history of tort litigation against manufacturers of poisonous substances adds force to the [existing] presumption against pre-emption, for Congress surely would have expressed its intention more clearly if it had meant to deprive injured parties of a long available form of compensation." *Bates*, 544 U.S. at 432–33, 125 S. Ct. at 1792.

though EPA approved Roundup's® label, a judge or jury could disagree and find that same label violates FIFRA.").

Next, we turn to the FIFRA labeling provisions, which obviously carry the force of law, to determine whether Georgia's failure to warn claims are different from or in addition to those federal statutes.[10] FIFRA requires that pesticide labels "contain a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment." 7 U.S.C. § 136(q)(1)(G). Georgia law subjects a manufacturer to liability for failure to warn when the manufacturer "(a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition and (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous." *Greenway*, 294 S.E.2d at 545–46 (quoting Restatement (Second) of Torts § 388). Matching up FIFRA's labeling requirement with the Georgia cause of action for failure to warn, we see that the Georgia law failure to warn claim, if anything, imposes less of a duty on Monsanto than the FIFRA statute does because under Georgia law Monsanto is only required to warn when those who

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[10] We note that the first step of the *Bates* test is met as to the FIFRA statutes. Georgia's common law cause of action for failure to warn is clearly an imposition of a labeling or packaging requirement. *See Greenway v. Peabody Int'l Corp.*, 294 S.E.2d 541, 545–46 (Ga. 1982) (quoting Restatement (Second) of Torts § 388). We need not analyze this step any further.

will be using the product do not realize the dangerous condition of the product. On the other hand, FIFRA imposes a blanket duty, regardless of the knowledge of the consumer, when the warning is necessary to protect health and the environment. In practice, the Georgia failure to warn claim simply enforces the FIFRA cause of action, so it is not expressly preempted. *Bates*, 544 U.S. at 447–48, 125 S. Ct. at 1800.[11]

In its final effort to have Georgia law preempted, Monsanto points to various EPA documents to suggest that the EPA has acted with the force of law, such that Monsanto could not label Roundup® as carcinogenic without consequences from the EPA. In its brief, Monsanto points to the following actions as having the force of law:

- The EPA's Label Registration, and subsequent interim registration reviews and re-registration eligibility decisions of glyphosate pesticides. EPA,

[11] Monsanto also makes a separate argument that Georgia's failure to warn claim is impliedly preempted because Monsanto cannot comply with both state and federal requirements. *See Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472, 480, 133 S. Ct. 2466, 2473 (2013). Because an implied preemption analysis turns on whether a federal agency has indicated through some action carrying the force of law that it would not accept a label mandated by state law, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678–79 (2019), and we have already determined that the EPA has not acted with the force of law and that FIFRA statutes are consistent with Georgia law, we do not address this argument further.

Reregistration Eligibility Decision (RED) – Glyphosate (Sept. 1993); EPA, Glyphosate: Interim Registration Review Decision Case No. 0178 (Jan. 2020) (1993 reregistration); The EPA's response to comments on the glyphosate proposed interim decision. EPA, Response from the Pesticide Re-evaluation Division (PRD) to Comments on the Glyphosate Proposed Interim Decision (Jan. 2020).

- An EPA Paper written about the EPA Scientific Advisory Panel's independent review of the effects of glyphosate. EPA, Revised Glyphosate Issue Paper (Dec. 12, 2017).

- A letter issued by the EPA in August 2019. EPA, Office of Pesticide Programs, Letter to Glyphosate Registrants Regarding Labeling Requirements (Aug. 7, 2019) ("Letter to Registrants").

- Various papers involving scientific analysis where the EPA concluded that glyphosate does not cause cancer. EPA, Health Effects Division, Second Peer Review of Glyphosate (Oct. 30, 1991); EPA, Report of the Hazard Identification Assessment Review Committee at 6-7 (Apr. 20, 1998), https://tinyurl.com/b95mdvja; Final Rule: Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,935-43 (Sept.

27, 2002); Final Rule: Glyphosate, Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008); EPA, Office of Pesticide Programs, Glyphosate Issue Paper: Evaluation of Carcinogenic Potential at 141 (Sept. 12, 2016), https://tinyurl.com/4d6us439; EPA, Office of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017); EPA, Glyphosate – Proposed Interim Registration Review Decision Case Number 0178 (Apr. 2019).

The problem for Monsanto is again that none of these documents have the indicia of formality to pass the *Mead* standard. Monsanto cannot wave the "formality" wand on EPA actions to accomplish compliance with the *Mead* standard. None of them are the product of "notice-and-comment rulemaking"[12] or "formal adjudication." *Mead*, 533 U.S. at 230. Nor do the EPA letters Monsanto points to "bespeak the legislative type of activity that would naturally bind" Monsanto. *Id.* at 232. So, we find Monsanto's arguments on this front unpersuasive.

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[12] As Monsanto correctly notes, there is something akin to a notice and comment requirement in the registration process. 40 C.F.R. § 155.58. But, because the registration itself does not lead to any formal agency action, like a rule produced from notice-and-comment rulemaking, the fact that the EPA takes comments on its registration decision does not change our analysis.

V.

For the foregoing reasons, we reverse the District Court's ruling on Carson's failure to warn claim and remand for further proceedings.

REVERSED AND REMANDED.

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

ELBERT PARR TUTTLE COURT OF APPEALS BUILDING
56 Forsyth Street, N.W.
Atlanta, Georgia 30303

David J. Smith
Clerk of Court

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July 12, 2022

MEMORANDUM TO COUNSEL OR PARTIES

Appeal Number: 21-10994-BB
Case Style: John Carson v. Monsanto Company
District Court Docket No: 4:17-cv-00237-RSB-CLR

Electronic Filing
All counsel must file documents electronically using the Electronic Case Files ("ECF") system, unless exempted for good cause. Although not required, non-incarcerated pro se parties are permitted to use the ECF system by registering for an account at www.pacer.gov. Information and training materials related to electronic filing are available on the Court's website. Enclosed is a copy of the court's decision filed today in this appeal. Judgment has this day been entered pursuant to FRAP 36. The court's mandate will issue at a later date in accordance with FRAP 41(b).

The time for filing a petition for rehearing is governed by 11th Cir. R. 40-3, and the time for filing a petition for rehearing en banc is governed by 11th Cir. R. 35-2. Except as otherwise provided by FRAP 25(a) for inmate filings, a petition for rehearing or for rehearing en banc is timely only if received in the clerk's office within the time specified in the rules. Costs are governed by FRAP 39 and 11th Cir.R. 39-1. The timing, format, and content of a motion for attorney's fees and an objection thereto is governed by 11th Cir. R. 39-2 and 39-3.

Please note that a petition for rehearing en banc must include in the Certificate of Interested Persons a complete list of all persons and entities listed on all certificates previously filed by any party in the appeal. See 11th Cir. R. 26.1-1. In addition, a copy of the opinion sought to be reheard must be included in any petition for rehearing or petition for rehearing en banc. See 11th Cir. R. 35-5(k) and 40-1 .

Counsel appointed under the Criminal Justice Act (CJA) must submit a voucher claiming compensation for time spent on the appeal no later than 60 days after either issuance of mandate or filing with the U.S. Supreme Court of a petition for writ of certiorari (whichever is later) via the eVoucher system. Please contact the CJA Team at (404) 335-6167 or cja_evoucher@ca11.uscourts.gov for questions regarding CJA vouchers or the eVoucher system.

Pursuant to Fed.R.App.P. 39, costs taxed against appellee.

Please use the most recent version of the Bill of Costs form available on the court's website at www.ca11.uscourts.gov.

For questions concerning the issuance of the decision of this court, please call the number referenced in the signature block below. For all other questions, please call Tonya L. Richardson, BB at (404) 335-6174.

Sincerely,

DAVID J. SMITH, Clerk of Court

Reply to: Jeff R. Patch
Phone #: 404-335-6151

OPIN-1A Issuance of Opinion With Costs