A155940 & A156706

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT, DIVISION ONE

DEWAYNE JOHNSON,
Plaintiff and Appellant,

v.

MONSANTO COMPANY,
Defendant and Appellant.

APPEAL FROM SAN FRANCISCO COUNTY SUPERIOR COURT
SUZANNE R. BOLANOS, JUDGE • CASE NO. CGC-16-550128

APPELLANT'S SUPPLEMENTAL BRIEF

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INTRODUCTION

This court has requested supplemental briefing on three questions related to whether Plaintiff Dewayne Lee Johnson's claims against Monsanto Company are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA): (1) whether the impossibility preemption standard articulated by the United States Supreme Court in *Wyeth v. Levine* (2009) 555 U.S. 555 [129 S.Ct. 1187, 173 L.Ed.2d 51] (*Wyeth*) applies to cases involving pesticide label warnings regulated under FIFRA; (2) whether, assuming the *Wyeth* "clear evidence" standard applies, this court should determine in the first instance whether there is "clear evidence" EPA would not have approved a cancer warning on the labels of Monsanto's glyphosate-based products, and if so, how the court should resolve that issue; and (3) whether and how the jury verdict would be affected if the court were to determine that Plaintiff's failure-to-warn claims are preempted, but his design-defect claim is not.

As explained below: (1) Wyeth's impossibility preemption standard governs this case. (2) This court should itself resolve whether Plaintiff's claims are barred by impossibility preemption, and in turn hold that Plaintiff's claims are preempted because EPA is and was "fully informed" of the available evidence bearing on whether glyphosate is carcinogenic, and has repeatedly and consistently determined that no cancer warning is warranted or would be approved on glyphosate-based herbicides. (3) If this court concludes that Plaintiff's design defect claim is not equally preempted, it should at the very least order a new trial because the warning and design defect claims were intertwined.

LEGAL AND FACTUAL BACKGROUND

FIFRA establishes a comprehensive statutory scheme regulating the use, sale, and labeling of pesticides. (*Bates v. Dow Agrosciences LLC* (2005) 544 U.S. 431, 437-438 [125 S.Ct. 1788, 161 L.Ed.2d 687] (*Bates*).) Under FIFRA, EPA may not register a pesticide unless it "determine[s] that the pesticide will not cause 'unreasonable adverse effects on the environment' " (*Ruckelshaus v. Monsanto Co.* (1984) 467 U.S. 986, 992 [104 S.Ct. 2862, 81 L.Ed.2d 815]), including an unreasonable adverse effect on human health (see 7 U.S.C. § 136(bb)). EPA approves registrations only after considering voluminous scientific data regarding human health risks (see 7 U.S.C. §§ 136a(c)(1)(F), (c)(2)(A), 136c(a)), *including specifically whether the pesticide poses a risk of cancer to humans* (see 40 C.F.R. § 158.500 (2019) [discussing required toxicology data, including "Carcinogenicity—two rodent species" for pesticides used on food or likely to result in significant human exposure over a considerable portion of the human life span]). EPA's approval of a label in the course of registering a product compels the use of that approved label, without deviation. (See 7 U.S.C. § 136j(a); 40 C.F.R. § 152.44 (2019).)

In addition, FIFRA specifically delineates—and limits—the role of states in pesticide regulation. In a subsection entitled "Uniformity," FIFRA prohibits states from "impos[ing] . . . any requirements for labeling or packaging in addition to or different from those required under [FIFRA]." (7 U.S.C. § 136v(b).) EPA is tasked with making specific judgments about the safety of each pesticide as part of the FIFRA process, and it can approve FIFRA labels for pesticide use only if they properly address risks to human health with appropriate health warnings, directions for use, and mandates for personal protective equipment. (7 U.S.C. § 136a(c)(5)(B), (C); 40 C.F.R. § 152.112 (2019).)

In connection with dozens of FIFRA registration decisions over multiple decades, beginning long before Plaintiff was first exposed to Roundup in 2012, EPA has repeatedly evaluated the potential human health risks of glyphosate, the active ingredient in Roundup, and many other FIFRA-registered pesticides.[1] Each time, after reviewing the available scientific studies, EPA has concluded that glyphosate does not pose a risk of cancer to humans, classifying glyphosate in EPA's lowest risk category since at least 1991. (See pp. 22-23, *post*.) Pursuant to the unique provisions of FIFRA, EPA *must* reevaluate these same safety issues for every pesticide *every 15 years*. (7 U.S.C. § 136a(g)(1)(A)(iv).) It has recently done so for glyphosate, reaching the same conclusions it has for decades under five different presidential administrations. (See EPA, Glyphosate Interim Registration Review Decision, Case No. 0178 (Jan. 2020) p. 10 <https://bit.ly/2uqQDTu> [as of Feb. 11, 2020] (hereafter EPA, Jan. 2020 Glyphosate Interim Registration Review Decision).)

Notwithstanding decades of consistent scientific determinations by EPA, and like determinations by a host of expert government regulators in national and supranational agencies, including the European Union, Germany, Canada, and Australia (see *Nat. Association of Wheat Growers v. Zeise* (E.D.Cal. 2018) 309 F.Supp.3d 842, 852 [citing these regulatory findings]; AOB 24-25, 71-72), a working group at the International Agency for Research on Cancer (IARC) in 2015 classified glyphosate as "probably carcinogenic to humans" (5 AA 5591-5592). In the wake of that classification, EPA fully considered IARC's report, the data relied upon by IARC, and a significant number of additional studies that IARC did not

[1] In addition to considering and registering each active ingredient that can be included in a pesticide product, EPA also considers and approves the formulated product. (See, e.g., 7 U.S.C. § 136a(e)-(f); 40 C.F.R. § 152.43 (2019).)

review—and in three separate instances reaffirmed its previous determinations that glyphosate was "not likely to be carcinogenic to humans." (5 AA 5574-5575; 7 AA 7159, 7287; EPA, Jan. 2020 Glyphosate Interim Registration Review Decision, *supra*, at p. 10.) In an August 2019 letter to all glyphosate registrants, the agency unequivocally stated that "[g]iven EPA's determination that glyphosate is 'not likely to be carcinogenic to humans,' " EPA considers a warning that glyphosate *is* carcinogenic "to constitute a *false and misleading* statement" that would cause a pesticide product to be illegally *misbranded* under FIFRA. (EPA Registration Div. Director Michael L. Goodis, EPA Office of Pesticide Programs, Letter to EPA Registrants, Aug. 7, 2019, p. 1 <https://tinyurl.com/y552m94m> [as of Feb. 11, 2020] (hereafter EPA Aug. 2019 Letter), emphasis added.)

At trial, Plaintiff asserted claims for strict liability and negligent failure to warn, and design defect based on the consumer expectations theory. All three of these theories relied on the lack of a cancer warning as a basis for liability.

Monsanto argued to the trial court that FIFRA expressly preempts Plaintiff's claims because those claims seek to impose state-law "requirements for labeling or packaging in addition to or different from those required under this subchapter." (7 U.S.C. § 136v(b); see 9/13/19 Opposition to Motion to Strike Monsanto's Notice of Supplemental Authority 10 (Opp. to Motion to Strike).) The label warnings "required under this subchapter" are the warnings with regard to human health that EPA has determined are warranted based on its comprehensive scientific reviews—including its repeated determinations that no cancer warning is warranted for glyphosate-based herbicides and consequent approval of the sale of myriad glyphosate products *without* Plaintiff's desired cancer warning on the product labels. (See Brief for United States as Amicus Curiae in Support of Monsanto,

Monsanto Co. v. Hardeman, No. 19-16636 (9th Cir. Dec. 20, 2019) (hereafter U.S. Brief), attached as exh. A to Declaration of David M. Axelrad in Support of Motion for Judicial Notice, pp. 18-19 ["EPA approved the label for . . . Roundup[ ] through a registration process that did not require a cancer warning. In fact, EPA has never required a labeling warning of a cancer risk posed by Roundup, and such a warning would be inconsistent with the agency's scientific assessments of the carcinogenic potential of the product"].)[2]

Because Plaintiff's claims are based on a supposed state-law duty to include a cancer warning on the labeling of these products, Monsanto has argued from the outset of this case that Plaintiff's claims would impose state-law labeling requirements in addition to and different from what is required by EPA for glyphosate pesticide labels under FIFRA. (See U.S. Brief, *supra*, pp. 18-19.)[3] The trial court nonetheless ruled that Plaintiff's claims were not expressly preempted. (4 AA 3208-3209.)

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[2] The court granted Monsanto's request to take judicial notice of EPA's amicus curiae brief in the *Hardeman* case. When citing to this amicus brief, we cite to the Bates-stamped numbers rather than the page numbers of the amicus brief.

[3] EPA's labeling requirements establish what is "required under [FIFRA]" for express preemption purposes in circumstances where EPA has exercised its discretion under the statute to impose such requirements. EPA extensively evaluates carcinogenicity and other human health and safety concerns, and requires "under [FIFRA]" (7 U.S.C. § 136v(b)) those health and safety warnings that are necessary to avoid misbranding (U.S. Brief, *supra*, at pp. 28-29). EPA's determinations regarding what health and safety warnings are required on pesticide labels leave no room for additional or differing state-law requirements. (Compare *Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312, 322-325 [128 S.Ct. 999, 169 L.Ed.2d 892] [state-law claims expressly preempted because agency *had* approved the safety and efficacy of the product at issue, which by statute could not be modified without the agency's further approval] with *Bates*, *supra*, 544 U.S. at p. 440 [state-law claims not necessarily preempted where, in registering the pesticide, EPA had explicitly declined to review the manufacturer's claims of efficacy, which were the focus of the suit].)

Monsanto also argued that Plaintiff's claims are impliedly preempted by FIFRA because it would have been "impossible" for Monsanto to comply with both federal law and the state-law duty upon which the jury verdict rests. (See 1 AA 232-234.) That is so because EPA's repeated determinations under FIFRA over a period of decades that glyphosate does not cause cancer—combined with its recent express confirmation that a cancer warning on glyphosate-based products would render the products misbranded in violation of FIFRA—constitute "clear evidence" that Monsanto would not have been permitted to add such a warning to Roundup's label. (See AOB 64-66, citing *Wyeth*, *supra*, 555 U.S. at pp. 571-572; ARB/X-RB 53-54; Opp. to Motion to Strike 10-11.) In other words, the "clear evidence" of what EPA would do is what EPA did, over and over again for decades, with respect to Roundup and other glyphosate-based pesticides. But the trial court rejected this argument, ruling that "*Wyeth* and its progeny do not apply" in the context of FIFRA because states retain the authority to ban pesticides approved by EPA. (4 AA 3209-3211.)

I. Question 1: *Wyeth*'s clear evidence standard applies in determining whether Plaintiff's claims are preempted.

In *Wyeth*, the Court applied well-established impossibility preemption precedent when it held that a plaintiff's state-law claim alleging that a drug label contained an inadequate warning is preempted if there is "clear evidence" the Food and Drug Administration (FDA) would have rejected the proposed warnings. (*Wyeth*, *supra*, 555 U.S. at pp. 571-573.) *Wyeth* did not invent a new conflict preemption rule that applies only under the Federal Food, Drug, and Cosmetic Act (FDCA). Instead, it applied longstanding preemption principles to the case before it, and those same principles control in this case. There is no reason for this court to deviate from applying that "clear evidence" standard to cases alleging deficiencies in warnings approved by EPA. As is the case with FDA's authority under FDCA, FIFRA

mandates that EPA approve both the product registration and all labeling before any product may be sold or used.

"[I]t has long been settled that state laws that conflict with federal law are 'without effect.' " (*Mutual Pharmaceutical Co. v. Bartlett* (2013) 570 U.S. 472, 479-480 [133 S.Ct. 2466, 186 L.Ed.2d 607] (*Bartlett*), quoting *Maryland v. Louisiana* (1981) 451 U.S. 725, 746 [101 S.Ct. 2114, 68 L.Ed.2d 576].) The Supreme Court has deployed various formulations of this standard in cases raising issues of impossibility preemption. (See, e.g., *English v. General Electric Co.* (1990) 496 U.S. 72, 79 [110 S.Ct. 2270, 110 L.Ed.2d 65] [state law preempted when it was "impossible for a private party to comply with both state and federal requirements"]; *Geier v. American Honda Motor Co.* (2000) 529 U.S. 861, 873 [120 S.Ct. 1913, 146 L.Ed.2d 914] (*Geier*) [state law preempted when "state law penalizes what federal law requires"]; *Florida Avocado Growers v. Paul* (1963) 373 U.S. 132, 142-143 [83 S.Ct. 1210, 10 L.Ed.2d 248] [state law preempted when "compliance with both federal and state regulations is a physical impossibility"].) But in all instances, the fundamental principle remains the same: A state-law obligation is barred by impossibility preemption when it requires something that federal law prohibits.

In *Wyeth*, the Supreme Court applied that principle in the context of the FDCA. FDCA allowed brand-name drug manufacturers to unilaterally add a new warning under the Changes Being Effected (CBE) regulation, subject to FDA's authority "to reject [such] labeling changes." (*Wyeth, supra*, 555 U.S. at p. 571.) The *Wyeth* Court concluded that the plaintiff's claims of inadequate warning on a product label would have been preempted had there been "clear evidence" that FDA would have rejected the proposed warnings. Because such evidence was lacking (*id.* at pp. 571-572), the Court concluded that it was not "impossible" for the manufacturer to fulfill the state-law requirement without violating federal law (*id.* at p. 573).

Wyeth's analytical framework governs here, even if the result is different. The jury concluded that Monsanto should be held liable under state tort law for failing to include a cancer warning on its product labeling. FIFRA makes it more difficult than FDCA to provide such a warning. Unlike in *Wyeth* where the manufacturer could have unilaterally added a warning subject to FDA possibly rejecting it (see *Wyeth*, *supra*, 555 U.S. at p. 568), Monsanto could not lawfully add a cancer warning to Roundup's label at all without prior EPA approval (see 40 C.F.R. § 152.44(a) (2019)). Given that agency approval is essential under FIFRA to add such a warning, if there is "clear evidence" EPA would not have approved that warning (see *Wyeth*, at p. 571), then it would have been "impossible for [Monsanto] to comply with both state and federal law," and Plaintiff's claims are impliedly preempted (*Crosby v. Nat'l Foreign Trade Council* (2000) 530 U.S. 363, 372-373 [120 S.Ct. 2288, 147 L.Ed.2d 352]). Although *Wyeth* arose in the context of FDCA, nothing in the Supreme Court's decision suggests that its articulation of the "clear evidence" showing is limited only to that particular statute. The Court did not so state, and reading *Wyeth* so narrowly would ignore the Court's application of a general impossibility preemption jurisprudence, which, at its core, applies across statutory contexts.

Many similar features of the FDCA and FIFRA regulatory schemes reinforce the conclusion that *Wyeth*'s "clear evidence" standard for impossibility preemption applies to this case. (See *Merck Sharp & Dohme Corp. v. Albrecht* (2019) 587 U.S. __ [139 S.Ct. 1668, 1678, 203 L.Ed.2d 822] (*Albrecht*) [explaining that its holding "flow[s] from our precedents on impossibility pre-emption and the statutory and regulatory scheme"].) Both FDA and EPA must approve proposed labeling before approving a new drug application or registering a new pesticide. (21 U.S.C. § 355(a) [FDCA]; 21 C.F.R. § 314.105(b) (2019); 7 U.S.C. § 136a(c)(1)(C) [FIFRA]; 40 C.F.R. § 152.112(f) (2019).) Both FDA and EPA maintain comprehensive

regulations governing the content of the relevant labels, including safety information. (See 21 C.F.R. § 201.57 (2019) [FDA]; 40 C.F.R. §§ 156.10, 156.60 (2019) [EPA].) And both FDA and EPA possess express authority to reject products on the basis of labeling that is false, misleading, or otherwise insufficient. (21 U.S.C. § 355(c) & (d) [FDCA]; 7 U.S.C. §§ 136(q)(1)(A), 136j(a)(1)(E) [FIFRA].) The bottom line is that under both regimes, a manufacturer is *prohibited* from complying with a state-law warning requirement that the relevant federal agency would not approve. Indeed, while EPA's amicus brief in *Hardeman* argued primarily that plaintiff's claims were expressly preempted, EPA cited *Wyeth*'s "implied preemption standard" in noting the Government's agreement that impossibility preemption would also bar Hardeman's labeling claims. (U.S. Brief, *supra*, at p. 23, fn. 14.) This court should thus apply the "clear evidence" standard to determine whether federal law prohibits a *pesticide* manufacturer from adding a warning required by state law, just as the Supreme Court applied the standard when determining whether federal law prohibited a *drug* manufacturer from adding a warning required by state law.

In addition to these similarities, the *differences* between the regulatory schemes confirm that, to the extent the statutes and underlying regulations differ, the FIFRA framework provides even greater indication of whether EPA would reject the label warning given decades of EPA label approvals for glyphosate under this statutory scheme. Under FDCA, a manufacturer can make provisional changes to its drug label—including, in certain circumstances, adding a warning—without waiting to obtain FDA approval. (*Wyeth*, *supra*, 555 U.S. at p. 568; 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2019).) For that reason, "a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both." (*Albrecht*, *supra*, 139 S.Ct. at p. 1679.) Under FIFRA, however, a pesticide registrant must obtain EPA

approval before making *any* changes to the label concerning human health (40 C.F.R. §§ 152.44(a), 152.46 (2019))—authority that EPA repeatedly exercises when conducting its registration review function under FIFRA (7 U.S.C. § 136a(g)). A pesticide registrant's inability to unilaterally alter its label confirms that state-law failure-to-warn claims must be preempted where there is "clear evidence" that EPA would not have approved the warning purportedly required by state law.[4]

Nonetheless, the trial court held, and Plaintiff argues, that impossibility preemption is unavailable here. According to both, states must be able to impose whatever labeling warnings they wish because, under 7 U.S.C. § 136v(a), states can within their borders ban particular pesticides altogether. (See RB/X-AOB 95; accord, 4 AA 3210-3211.) But this argument does not track Congress's actual statutory text. That states may ban the *sale* or *use* of pesticides registered by EPA under section 136v(a) does not mean that, for those pesticides they do allow, they can impose *labeling* requirements that EPA would prohibit. To the contrary, the primacy of EPA on matters *of labeling* is confirmed by section 136a, which prohibits the sale of products with labeling that has not been approved by EPA, and by section 136v(b), entitled "Uniformity," which prohibits a state from imposing labeling requirements in addition to or different from the federal requirements. (See *Bates*, *supra*, 544 U.S. at p. 452, fn. 26 [citing " 'the industry's need for uniformity' " in labeling pesticides in a nationwide

[4] To the extent that differences between FIFRA and FDCA modify how preemption principles apply under FIFRA, it is in the opposite direction of what the trial court found. As the First Circuit has concluded, where a registrant "cannot comply with state law without first obtaining the approval of a federal regulatory agency," "the application of that law to [the registrant] is preempted" irrespective of whether the federal agency might consent to the change required by state law. (*Gustavsen v. Alcon Laboratories, Inc.* (1st Cir. 2018) 903 F.3d 1, 9; see AOB 64.) Because there is plainly clear evidence that EPA would not have approved a cancer warning on Roundup, the court should not need to reach that issue.

market as impetus for this provision]; see also *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 485 [116 S.Ct. 2240, 135 L.Ed.2d 700] [" '[T]he purpose of Congress is the ultimate touchstone' in every pre-emption case"].) In sum, states' authority to regulate sale or use under section 136v(a) cannot reasonably be read to negate Congress's express provision in section 136v(b) that EPA retains primacy over labeling.

In addition, the Supreme Court has expressly rejected the theory that a manufacturer could comply with conflicting state and federal laws simply by "ceas[ing] to act" at all. (See *Bartlett*, *supra*, 570 U.S. at p. 488.) Such a theory, the Court explained, is "incoheren[t] . . . when viewed through the lens of" the Court's impossibility preemption decisions. (*Ibid.*) If accepted, it would mean that "the vast majority—if not all—of" those cases were wrongly decided, and impossibility preemption would become "a dead letter." (*Id.* at pp. 475, 489.) The fact that Monsanto could simply stop selling Roundup in California, consistent with FIFRA, thus "is irrelevant" to the analysis. (*Id.* at p. 490.)

The trial court and Plaintiff also err in contending that the existence of an express preemption clause in FIFRA precludes, or creates a presumption against, conflict preemption. (See 4 AA 3210-3211; RB/X-AOB 94-95.) The Supreme Court has made clear that "neither an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.' " (*Buckman Co. v. Plaintiffs' Legal Comm.* (2001) 531 U.S. 341, 352 [121 S.Ct. 1012, 148 L.Ed.2d 854], quoting *Geier*, 529 U.S. at p. 869.) And it has made equally clear that the existence of an express preemption provision does not "impose a 'special burden' that would make it more difficult to establish the preemption of laws

falling outside the clause." (*Arizona v. United States* (2012) 567 U.S. 387, 406 [132 S.Ct. 2492, 183 L.Ed.2d 351].)[5]

II. Question 2: This court should hold in the first instance that "clear evidence" exists showing Plaintiff's claims are barred by impossibility preemption.

There is no need for a remand here. The "clear evidence" question is a purely legal one subject to de novo review " ' "independent of the trial court's ruling or reasoning." ' " (*Alameda County Deputy Sheriff's Assn. v. Alameda County Employees' Retirement Assn.* (2018) 19 Cal.App.5th 61, 89, review granted Mar. 28, 2018, S247095, quoting *Redevelopment Agency of the City of Long Beach v. County of Los Angeles* (1999) 75 Cal.App.4th 68, 74; see *People v. Salcido* (2019) 42 Cal.App.5th 529, 537.) The record contains undisputed factual information from which this court can determine that EPA was "fully informed" about Roundup's alleged carcinogenicity risk during Plaintiff's period of use (2012-2015) and that EPA communicated its rejection of that risk. This court should decide conflict preemption rather than remand the question for a decision by the superior court that would be entitled to no deference in a subsequent appeal. And because there is clear evidence that EPA would not have approved such a warning, it should hold that Plaintiff's claims are impliedly preempted.

A. This court should resolve the impossibility preemption question.

The U.S. Supreme Court decided in *Albrecht* that the "clear evidence" question "is a legal one for the judge, not a jury." (*Albrecht*, *supra*, 139 S.Ct.

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[5] Plaintiff is wrong to suggest that the "implied preemption question was specifically before the [C]ourt in *Bates*." (RB/X-AOB 94.) The scope of FIFRA's express preemption provision was the only question resolved by the Supreme Court, which did not cite or rely on principles of conflict preemption. (See *Bates*, *supra*, 544 U.S. at pp. 440-441.)

at pp. 1679-1680.) This is because "judges, rather than lay juries, are better equipped to evaluate the nature and scope of an agency's determination" and "[d]oing so should produce greater uniformity among courts . . . concerning the scope and effect of federal agency action." (*Id.* at p. 1680.) Like here, "[t]he question [of clear evidence] often involves the use of legal skills to determine whether agency disapproval fits facts that are not in dispute." (*Id.* at p. 1679.)

Moreover, because the meaning and effect of EPA's decisions is clear, this court should review the "clear evidence" question independently without any deference to the superior court. (*Ghirardo v. Antonioli* (1994) 8 Cal.4th 791, 799 ["When the decisive facts are undisputed, we are confronted with a question of law and are not bound by the findings of the trial court."]; accord, *City of Santa Cruz v. Patel* (2007) 155 Cal.App.4th 234, 243.) The Supreme Court in *Ghirardo* instructed the Court of Appeal to independently review questions requiring application of fact to law like the "clear evidence" question, because "[i]f such questions were effectively removed from the consideration of the appellate courts, the development and clarification of the important issues affecting commerce would be impeded." (*Ghirardo*, at pp. 800-801 [independent review of whether debt restructuring violated usury law].)

EPA's repeated actions concerning glyphosate—i.e., the historical facts of what happened—are not in dispute. EPA registered Roundup in 1974, reregistered Roundup in 1991, recently issued an Interim Registration Review Decision, and has consistently classified Roundup as not likely to be carcinogenic—before, during, and since Plaintiff used Roundup. Although Plaintiff has attempted to manufacture trivial factual disputes concerning the completeness and credibility of EPA's classification of glyphosate as non-carcinogenic (see, e.g., ARB/X-RB 53-54, fn. 14; X-ARB 13), EPA's reports and decisions explain precisely the scope and methods supporting the

agency's decision (see pp. 22-23, *post*). Moreover, this court is required to presume that EPA properly discharged its duties under FIFRA when classifying glyphosate as non-carcinogenic and determining that a cancer warning on glyphosate labeling is unlawful. (See *U.S. Postal Service v. Gregory* (2001) 534 U.S. 1, 10 [122 S.Ct. 431, 151 L.Ed.2d 323] ["a presumption of regularity attaches to the actions of Government agencies . . . and . . . some deference to agency disciplinary actions is appropriate" (citation omitted)]; *Albrecht, supra*, 139 S.Ct. at p. 1684 (conc. opn. of Alito, J.) [presuming that FDA's decision to not require a warning after receiving new data was based on determination that a warning was unjustified].) To the extent Plaintiff suggests this case presents "subsidiary factual questions" that require resolution, the preemption issue remains a question of law for this court to decide itself, just as the Supreme Court itself resolved the application of impossibility preemption in *Wyeth*. (*Wyeth*, *supra*, 555 U.S. at p. 573.)

The "clear evidence" question presented here is thus a "tightly circumscribed legal analysis" that this court should independently review. Remand to the superior court to first decide the "clear evidence" question is an unnecessary use of judicial resources when the superior's court decision on remand would be entitled to no deference by this court in a subsequent appeal. Accordingly, this court should resolve the "clear evidence" question as part of this appeal.

B. This court should determine Plaintiff's claims are impliedly preempted by FIFRA.

Plaintiff's state-law failure-to-warn claims are preempted because there is "clear evidence" that EPA, having been fully informed, would have rejected Monsanto's request to add the label warning that state law here purportedly requires and, accordingly, that it would be "impossible" for

Monsanto to comply with both federal law and the state-law duty to warn theory on which the verdict rests.

Albrecht elaborated on *Wyeth*'s "clear evidence" standard, explaining that a manufacturer can establish "impossibility preemption" by showing that the agency (1) was "fully informed" of the "justifications for the warning" the plaintiff demands, and (2) has communicated its rejection of the warning. (*Albrecht*, 139 S.Ct. at p. 1678.) Both of those conditions are met here.

First, EPA was "fully informed" regarding "the justifications for the warning required by state law"—*i.e.*, the supposed evidence that glyphosate is carcinogenic—when determining that no cancer warning was warranted. (See *Albrecht*, *supra*, 139 S.Ct. at p. 1678.) EPA has repeatedly undertaken in-depth scientific reviews of the evidence on glyphosate's safety across five presidential administrations, and repeatedly concluded that it is non-carcinogenic. The record shows EPA has classified glyphosate as non-carcinogenic for humans since 1991:

- **1991:** EPA classified glyphosate as non-carcinogenic " 'based on a lack of convincing evidence of carcinogenicity in adequate studies.' " (5 AA 5704; accord, 7 AA 7603, 7634.)
- **1993**: EPA's Reregistration Eligibility Decision confirms glyphosate as non-carcinogenic for humans "based on a lack of convincing evidence of carcinogenicity in adequate studies." (7 AA 7634; see 7 AA 7619-7620.)
- **2015:** EPA's Cancer Assessment Review Committee (CARC) classified glyphosate as " 'not likely to be carcinogenic to humans' " after the IARC classification. (5 AA 5574-5575; 7 AA 7060, 7069.)
- **2016:** EPA concluded that "the strongest support is for 'not likely to be carcinogenic to humans' at doses relevant to human health risk assessment." (7 AA 7147, 7287.)
- **2017:** EPA evaluated 63 epidemiological studies, 14 animal carcinogenicity studies, and nearly 90 genotoxicity studies (4 AA 4429)

and concluded "[t]he strongest support is for 'not likely to be carcinogenic to humans' " (4 AA 4428).

- **2019:** EPA sent a letter to all glyphosate registrants reaffirming that "glyphosate is 'not likely to be carcinogenic to humans,' " and that any cancer warning on a glyphosate product label would be a "false and misleading statement" rendering that product "misbranded" under FIFRA. (EPA Aug. 2019 Letter, *supra*, at p. 1.)
- **2020:** EPA stated that it "has thoroughly evaluated potential human health risk associated with exposure to glyphosate and determined that there are no risks to human health . . . and that glyphosate is not likely to be carcinogenic to humans." (EPA, Jan. 2020 Glyphosate Interim Registration Review Decision, *supra*, at p. 10.)

Several of EPA's most recent determinations—including a 2019 review of "[a]ll studies of adequate scientific caliber that [EPA] was aware of" and a reaffirmation of glyphosate's noncarcinogenicity in 2020—were made *after* all of the supposed "evidence" of glyphosate's carcinogenicity cited in Plaintiff's complaint became public. (EPA, Glyphosate Proposed Interim Registration Review Decision, Case No. 0178 (Apr. 2019) p. 10 <https://bit.ly/2xQ7Cwe> [as of Feb. 11, 2020] (hereafter, EPA Apr. 2019 PID); EPA, Jan. 2020 Glyphosate Interim Registration Review Decision, *supra*, at pp. 4-5, 10.) Indeed, as part of EPA's registration review process, the agency thoroughly evaluated every study on which Plaintiff's experts relied, including the IARC report, and legions of public comments, expert panel deliberations, and other materials over decades of time. (See *ante*, pp. 22-23; EPA Apr. 2019 PID, *supra*, at p. 7 [EPA noting that its review of the scientific literature was more robust than IARC's because "IARC only

considered a subset of the studies included in the EPA's evaluation"].) Beyond question, EPA was "fully informed."[6]

Second, EPA has repeatedly made clear that it would not approve changing Roundup's label to include a cancer warning. (See *Albrecht*, *supra*, 139 S. Ct. at p. 1678.) Conclusive evidence of what EPA would have done, had Monsanto proposed to amend the label with a cancer warning, is provided by what EPA has *already* done. The record of EPA's actions here demonstrates that—before, during, and after Plaintiff's period of use—EPA has determined that glyphosate is not a carcinogen, that it views a cancer warning on Roundup labeling as false and misleading, and that it "would not approve changing the [product's] label to include" a cancer warning. (See *Albrecht*, at p. 1678.) Given EPA's repeated exercise of its lawfully delegated authority under FIFRA to reject a cancer warning on glyphosate labels,[7] Monsanto could not have been required to go through the pointless

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[6] Plaintiff briefly suggests that Monsanto did not " 'fully inform' " EPA of the justifications for the state-law warning because it did not share with EPA one review of several genotoxicity studies published in the 1990s. (RB/X-AOB 96.) But EPA's comprehensive review of glyphosate as part of its registration review omitted nothing of scientific substance, and included review of the genotoxicity studies underlying the Parry report. (See ARB/X-RB 53-54, fn. 14; 4 AA 4407-4413; 6 AA 6308-6314.) Moreover, *Albrecht*'s requirement that EPA be "fully informed" does not mean Monsanto itself had to supply EPA with *every* conceivable opinion of any outside observer of every study involving glyphosate that is and was publicly available. Equally irrelevant to the preemption question are Monsanto's supposed "refusal" to conduct a particular study or the company's alleged "confounding of important scientific information." (1/29/20 Respondent/ Cross-Appellant's Motion for Judicial Notice 43.) Nothing in *Albrecht* suggests Monsanto bears the burden to prove that it furnished EPA with data from studies that were *not* conducted. And the record contains no evidence that any alleged efforts by Monsanto to "confound[ ] . . . scientific information" (*ibid.*), hindered EPA, with its own vast and independent scientific resources, from accessing and weighing the import of the available glyphosate-related studies.

[7] EPA's labeling decisions "carry[ ] the force of law." (*Albrecht*, *supra*, 139 S.Ct. at p. 1679.) In *Albrecht*, the Court emphasized that FDA's drug-

(continued...)

exercise of actually submitting to EPA a label containing warnings EPA had made clear it would not accept.[8] (See *Seufert v. Merck Sharp & Dohme Corp.* (S.D.Cal. 2016) 187 F.Supp.3d 1163, 1169, 1174 [explaining that *Wyeth* "does not premise clear evidence on manufacturer submission of a proposed warning" to the agency, and that the agency's "repeated conclusion that scientific data did not support warning of [a] cancer risk" satisfies the "clear evidence" threshold].) No "clear[er] evidence" (*Wyeth*, *supra*, 555 U.S. at p. 571) could be required.[9]

In short, Monsanto has done exactly what the Supreme Court described in *Wyeth* and *Albrecht*: It has proffered clear evidence that, had it

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specific labeling decisions pursuant to its regulations have substantive legal effect. (See *id.* at p. 1679 [citing 21 C.F.R. § 314.125(b)(6), which instructs that FDA may withhold approval of a new drug application if "the proposed labeling is false or misleading in any particular"].) So too here: EPA's fully-informed exercise of its congressionally delegated authority to interpret FIFRA's misbranding provision carries the force of law. (See *Albrecht*, at p. 1679; *Reckitt Benckiser, Inc. v. E.P.A.* (D.C. Cir. 2010) 613 F.3d 1131, 1138 ["EPA, which is charged with administering FIFRA, has made an authoritative interpretation of its FIFRA misbranding authority that has practical and significant legal effects"].)

[8] EPA's oversight in approving two glyphosate labels that contained California Proposition 65 cancer warnings in an inapplicable section of the label titled "Optional Marketing Statements" (U.S. Brief, *supra*, at p. 15) does not alter this conclusion. EPA has explained that these prior approvals "did not receive" the appropriate level of review because they were "framed as a statement about California's assessment"; were "implementation mistakes"; "were erroneous because the proposed edits warned of a cancer risk that, according to EPA's assessment, does not exist;" and that these "mistakenly approved" warnings have now been corrected. (*Id.* at pp. 15, 22, 23-24, fn. 14.) The possibility that an agency might mistakenly and temporarily grant an approval—because of the erroneous way a private party framed its request—is not sufficient to defeat impossibility preemption.

[9] This case bears little resemblance to the situation in *Wyeth*, where the record contained "no evidence . . . that either the FDA or the manufacturer gave more than passing attention" to the dangers giving rise to the plaintiff's desired warning. (*Wyeth*, *supra*, 555 U.S. at p. 572; *Albrecht*, *supra*, 139 S.Ct. at p. 1678.) Here, as previously described, EPA time and again considered the carcinogenicity of glyphosate based on a massive record. There is no ambiguity about what EPA thought, and no guesswork involved.

sought EPA approval to change Roundup's label to accommodate state law, the agency would have rejected its request. Because it would therefore have been impossible for Monsanto to comply with both federal and state law, under the Supremacy Clause state law must give way.

III. Question 3: If the court determines that Plaintiff's failure-to-warn claims are preempted, but his design-defect claim is not, then a new trial is required.

The jury found Monsanto liable on claims for design defect, strict liability failure to warn, and negligent failure to warn. (5 AA 5499-5502.) Plaintiff premised all three claims, including the design defect claim, on the contention that Monsanto's warning labels were deficient. Because failure to include a cancer warning was the only design defect Plaintiff presented to the jury, all three claims should be preempted. (See, e.g., 29A RT 5119:17-23 [Plaintiff's counsel explaining to the jury that an ordinary consumer can form a reasonable safety expectation about Roundup because "the label specifically says it doesn't have any risk" of cancer], 5120:1-11 [Plaintiff's counsel explaining to the jury that Roundup failed to perform as safely as an ordinary consumer would have expected because "[t]he label is in evidence" and "[t]here is nothing about cancer"].) And even if Plaintiff had not tied his design defect claim to the content of Roundup's label, any other design defect claims would be preempted in any event because a pesticide registrant like Monsanto is not free to alter the composition of the approved pesticide without EPA's express preapproval. (See 40 C.F.R. §§ 152.44, 152.46 (2019) [requiring registrant to submit amended registration to EPA for approval of proposed formulation change]; *Bartlett*, *supra*, 570 U.S. at pp. 480-487 [holding that design defect claim premised on change of formulation of product that must be pre-approved by federal agency is preempted].) As such, this court should direct the trial court to enter judgment in favor of Monsanto. (See AOB 64-67; ARB 48, fn. 13.)

Even if Plaintiff's design defect claim could somehow escape preemption, the appropriate remedy is still to reverse with directions to enter judgment in favor of Monsanto because the consumer expectations theory has no application in a case like this involving complex expert testimony required to establish the nature of the defect. (AOB 48-56.) Alternatively, at the very least, if the court finds the warnings claims preempted and the consumer expectations claims valid, the court should not affirm the judgment based solely on Plaintiff's overlapping design claim. A new trial requiring Plaintiff to prove a design defect unrelated to whether Roundup's labeling should have contained a cancer warning would be necessary. (Code Civ. Proc., §§ 43, 906.) Affirming the judgment solely on the design defect claim would amount to a denial of a fair trial to Monsanto.

Claims that are substantially "interwoven" at trial cannot be severed to affirm a judgment where doing so would result in an unfair trial. (*Hamasaki v. Flotho* (1952) 39 Cal.2d 602, 608 ["the issues are so interwoven that a partial retrial would be unfair to the other party"]; *Carson Citizens for Reform v. Kawagoe* (2009) 178 Cal.App.4th 357, 371 [collecting cases].) Here, Plaintiff presented his warning and design defect claims to the jury in an inseparable manner. His counsel and experts argued to the jury that liability should be premised on Monsanto's failure to warn that Roundup caused cancer. (See 9 RT 1429:11-22 [Plaintiff's counsel: "Nobody here is saying—and we're not going to present evidence—that glyphosate or Roundup should be banned. Nobody is saying that. . . . We are saying, however—and we plan to prove with evidence, that you should just warn; right?"]; 21A RT 3601:14-21 [Plaintiff's expert Sawyer testified he did *not* believe that Roundup should be taken off the market, and that it "could be used" "[i]f there were proper warnings"].) Plaintiff did not submit a design defect claim premised on a risk-benefit theory that contemplates an alternative product design, and he expressly rejected any claim that Roundup

should be removed from the market. The result of Plaintiff's trial strategy is that the jury found Roundup to be defectively designed under the consumer expectations test because the product did not bear a cancer warning. (29A RT 5119-5120.)

Plaintiff conceded during this appeal that his design claim is "interwoven" with and inseparable from his failure-to-warn claims, arguing: "Contrary to Monsanto's assertion, the absence of warnings regarding the safety of Roundup is relevant to whether the product performed as safely as an ordinary consumer would have expected it to perform." (RB/X-AOB 68, citing *West v. Johnson & Johnson Prods., Inc*. (1985) 174 Cal.App.3d 831, 866-867, *Mariscal v. Graco, Inc.* (N.D.Cal. 2014) 52 F.Supp.3d 973, 986, *Ford Motor Co. v. Trejo* (Nev. 2017) 402 P.3d 649, 656.) Plaintiff is asking this court to affirm liability on his design defect claim on the basis that Roundup lacked a cancer warning.

Given the linkage between the warning and design defect claims, an affirmance of the judgment based on the design defect claim alone would be a miscarriage of justice. A fair trial not including the failure to warn claims would necessarily involve different evidence, argument, and jury instructions than the one that took place here. Even putting aside the interwoven nature of the liability claims, there can be little doubt that the punitive damage award was predicated on preempted warning liability theories and evidence. It would of course be wholly unfair to affirm a punitive damage award based on conduct that this court found should have been excluded from the case as a matter of law. For all of these reasons, if this court does not direct that judgment be entered in favor of Monsanto, it should at least grant a new trial.

CONCLUSION

The court should reverse with directions that judgment be entered in favor of Monsanto because Plaintiffs' claims are preempted by FIFRA. If, however, the court concludes that Plaintiff's design defect claim is not preempted or otherwise invalid as a matter of law, the court should reverse the judgment and remand the case for a new trial on all issues.

February 11, 2020

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CERTIFICATE OF WORD COUNT
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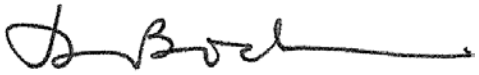
The text of this brief consists of 6,746 words as counted by the Microsoft Word version 2016 word processing program used to generate the brief.

Dated: February 11, 2020



Dean A. Bochner

PROOF OF SERVICE

Johnson v. Monsanto Company
Case No. A155940 & A156706

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

At the time of service, I was over 18 years of age and not a party to this action. I am employed in the County of Los Angeles, State of California. My business address is 3601 West Olive Avenue, 8th Floor, Burbank, CA 91505-4681.

On February 11, 2020, I served true copies of the following document(s) described as **APPELLANT'S SUPPLEMENTAL BRIEF** on the interested parties in this action as follows:

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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

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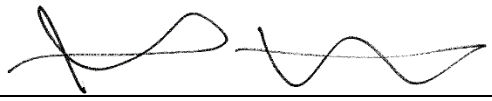

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Case No. A155940 & A156706

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