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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

COORDINATION PROCEEDING SPECIAL TITLE (Rule 3.550) ROUNDUP PRODUCTS CASES	JCCP NO. 4953 ASSIGNED FOR ALL PURPOSES TO JUDGE WINIFRED SMITH DEPARTMENT 21
THIS DOCUMENT RELATES TO: PILLIOD, ET AL. v. MONSANTO CO., ET AL., CASE NO. RG17862702	**REPLY BRIEF IN SUPPORT OF DEFENDANT MONSANTO'S MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, SUMMARY ADJUDICATION** Hearing Date: March 7, 2019 Time: 10:00 a.m. Department: 21 Reservation No.: R-2048303

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I. INTRODUCTION

Plaintiffs' Opposition does not meaningfully engage on the merits of Monsanto's Motion for Summary Judgment or, in the Alternative, Summary Adjudication. Rather than come forward with substantive responses to Monsanto's arguments explaining the deficiencies in their claims, Plaintiffs principally offer bluster. But a careful review of Plaintiffs' substantive claims demonstrates that they cannot survive.

With respect to preemption, Plaintiffs concede that FIFRA prohibits Monsanto from independently making the label and design changes Plaintiffs seek without first obtaining EPA approval. This concession confirms that their claims are preempted because Monsanto cannot both provide the warnings Plaintiffs seek and comply with FIFRA. Likewise, Plaintiffs cannot come forward with evidence upon which a jury could find that, at the relevant time period prior to Plaintiffs' injuries, it was "generally accepted" that Roundup causes cancer. Nor have they come forward with evidence from which a reasonable jury could find Monsanto acted "despicably" given the uncontroverted regulatory consensus, held to this day, that glyphosate does not cause cancer in humans.

II. ARGUMENT

A. Plaintiffs' Warnings Claims Are Expressly Preempted.

Plaintiffs argue that summary judgment is inappropriate because their warnings claims do not impose requirements in addition to or different from FIFRA. But not a single one of the cases cited by Plaintiffs addresses the express preemption argument Monsanto is making here. There can be no doubt that California law imposes on manufacturers significantly broader labeling requirements related to foreseeable use than FIFRA. These are not merely inconsistent, nominally equivalent "parallel requirements" of the sort discussed in *Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc.*, 617 F.3d 207 (3d Cir. 2010) and *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005).[1] Rather, California law substantively expands label warnings requirements from FIFRA's

[1] Plaintiffs' discussion of *In re Protexall* is also misleading, as they do not understand the significance of that opinion, which is to demonstrate that FIFRA's "widespread and commonly recognized practice" standard is different than California law. *See* FIFRA Docket Nos. 625, et al., 2 E.A.D. 854 (E.P.A.), 1989 WL 550929, at *3 (July 26, 1989).

"widespread and common uses" to risks associated with ***any*** reasonably foreseeable use or misuse. Accordingly, Plaintiffs' warnings claims are expressly preempted by FIFRA.

B. Plaintiffs Do Not Dispute That It Is Impossible for Monsanto to Both Comply with FIFRA and Provide the Warnings Plaintiffs Seek.

Plaintiffs do not contest that FIFRA, its regulations, and EPA guidance documents prohibit Monsanto from independently making the design and label changes Plaintiffs seek without first obtaining EPA's approval. (Opp. at 15-17). Because Plaintiffs concede that Monsanto cannot independently comply with both FIFRA and their tort claims, they do not contest the fundamental basis of Monsanto's impossibility preemption argument. Instead, they argue that (1) Congress did not intend to impliedly preempt their tort claims; and (2) there is no clear evidence that EPA would have rejected a change to the Roundup labeling. Neither argument is valid, and in any event, neither argument would prevent impossibility preemption where, as here, Plaintiffs concede Monsanto cannot make the label and design changes they seek without EPA's prior approval. Moreover, none of the FIFRA preemption cases Plaintiffs cited that supposedly reject Monsanto's preemption argument dealt with the impossibility preemption argument Monsanto presents here.

1. Congressional Intent Is Not Relevant to Impossibility Preemption.

Plaintiffs argue, first, that impossibility preemption is inapplicable because the express preemption clause in FIFRA demonstrates that Congress did not intend to preempt Plaintiffs' claims. Congressional intent, however, is not the touchstone for impossibility preemption.

Unlike express, field, and obstacle preemption that turn on the intent or objectives of Congress, *Arizona v. United States*, 567 U.S. 387, 399 (2012), impossibility preemption "requires no inquiry into congressional design." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963) ("A holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce." (citations omitted)). Rather, impossibility preemption flows from the Constitution's Supremacy Clause and occurs anytime "compliance with both state and federal law is impossible." *Oneok, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591, 1595 (2015) (citation omitted). Accordingly, the absence of statutory language evincing a

congressional intent to preempt state law has no bearing on impossibility preemption. *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 480 (2013) ("Even in the absence of an express pre-emption provision, the Court has found state law to be impliedly pre-empted where it is 'impossible for a private party to comply with both state and federal requirements.'"); *see also Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000) (holding that savings clause did not "bar the ordinary working of conflict pre-emption principles").

2. *Mensing* and *Bartlett* Apply When a Private Party Cannot Comply with State Law Without First Obtaining The Approval of a Federal Regulatory Agency.

Plaintiffs next argue that Monsanto has failed to meet its burden of producing "clear evidence" that the EPA would have rejected a change to the Roundup labeling. (Opp. at 16). This argument relies on the assumption, which Plaintiffs have made without any legal justification, that *Wyeth*'s "clear evidence" standard and not *Bartlett* and *Mensing*'s[2] "prior agency approval" standard applies. This assumption is plainly wrong—the clear evidence standard does not apply.

Wyeth's "clear evidence" standard arose in the context of FDCA's "changes being effected" ("CBE") regulation, 21 C.F.R. § 314.70(c), which authorized the drug maker to ***unilaterally*** add warnings to their drug label subject to FDA's authority to rescind or modify the label change. *Wyeth v. Levine*, 555 U.S. 555, 568 (2009). Under that type of regulation, the Court required the defendant to show "clear evidence" that FDA would have rejected a proposed warning submitted under that mechanism. *Id.* at 568–71. *Bartlett* and *Mensing*, however, apply when the applicable regulation requires the manufacturer to seek regulatory approval ***prior*** to making the label or design change. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015) ("The line *Wyeth* and [*Mensing*] thus draw between changes that can be independently made using the CBE regulation and changes that require prior FDA approval also makes some pragmatic sense."). As the First Circuit observed, *Wyeth*, *Mensing*, and *Bartlett* read in concert means that "[i]f a private party . . . cannot comply with state law without first

[2] *Pliva, Inc. v. Mensing*, 564 U.S. 604 (2011).

obtaining the approval of a federal regulatory agency, then the application of that law to that private party is preempted." *Gustavsen v. Alcon Labs., Inc.*, 903 F.3d 1, 9 (1st Cir. 2018).

Plaintiffs, here, do not dispute that under FIFRA, its regulations, and EPA guidance documents, Monsanto cannot amend its Roundup label to add a cancer warning to the "Precautionary Statements" of the label or change the Roundup formulation without prior EPA approval. Accordingly, *Wyeth*'s "clear evidence" standard for impossibility preemption does not apply and *Mensing* and *Bartlett* should apply. Because prior approval was required for Monsanto to change the label or change the formulation, all of Plaintiffs' claims are preempted here as a matter of law even in absence of evidence as to whether EPA would have rejected any proposed changes.

3. Even Under *Wyeth*'s Clear Evidence Standard Plaintiffs Failed to Controvert Evidence that EPA Has Consistently Rejected That Glyphosate is Carcinogenic to Humans.

Monsanto submitted an overwhelming evidentiary record showing that EPA has repeatedly determined that glyphosate is not carcinogenic, including on at least five occasions since IARC's classification. Just a few weeks ago, for the sixth time since IARC's classification, EPA reiterated that "it is confident" that "glyphosate is not likely to be carcinogenic" and that its conclusion is consistent with Canadian, European Union, German, and Japanese regulators. (UMF 28). EPA has also approved labels for glyphosate-based herbicides without cancer warnings both before IARC's classification, as well as after learning of IARC's position concerning glyphosate as shown by EPA approval letters issued in October 2016 for Roundup Custom® Herbicide and February 2018 for Roundup QuikPRO®. (RJN Exs. 12-16) Plaintiffs do not dispute that EPA has consistently rejected the proposition that glyphosate causes cancer in humans—the essential claim in this litigation.

Plaintiffs instead contend that Monsanto's failure to propose to EPA a cancer warning for Roundup somehow precludes a finding of "clear evidence" that EPA would have rejected such a proposed warning. But, as another California court recognized, "[*Wyeth v.*] *Levine* does not premise clear evidence on manufacturer submission of a proposed warning to" EPA. *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1169 (S.D. Cal. 2016) ("The relevant inquiry

in each conflict preemption case since *Levine* is stated as whether the FDA would have rejected a proposed labeling change, not whether the FDA did in fact issue an explicit rejection."). A party can also meet the "clear evidence" evidence standard by showing the regulatory agency disagrees that a warning is scientifically supportable. *Id.* at 1170.

Courts have held that a regulatory agency's repeated and consistent conclusion that a particular product does not pose a particular risk constitutes "clear evidence" that the regulatory agency would have rejected a proposed warning related to that risk. *See id.* at 1174 ("The FDA's repeated conclusion that scientific data did not support warning of pancreatic cancer risk coupled with the FDA's statement that product labeling was adequate amounts to clear evidence that the FDA would have rejected a pancreatic cancer labeling change."); *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1276–77 (W.D. Okla. 2011) (the FDA's "repeated conclusions . . . that there was no scientific evidence to support a causal connection between [selective serotonin reuptake inhibitors] and suicidality in adult patients" constituted "clear evidence that the FDA would have rejected" an expanded warning for suicide). EPA's repeated conclusions that glyphosate is not carcinogenic therefore constitute "clear evidence" that EPA would have rejected a warning related to carcinogenicity. Because Plaintiffs have not disputed this clear evidence, summary judgment is appropriate. *See id.* at 1268, 1280 (granting summary judgment where the plaintiff did not dispute the FDA's repeated conclusions).

C. Plaintiffs Have Not Come Forward With Evidence that it was "Generally Accepted" in the Scientific Community at the Time of Plaintiffs' Relevant Exposure that Roundup Causes Cancer.

To prove their warnings claim, Plaintiffs must show that, at the time when the product that allegedly caused their harm was distributed, it was "known or knowable in light of the scientific knowledge that was ***generally accepted*** in the scientific community" that Roundup can cause cancer. CACI 1205 (emphasis added). To satisfy California law, that risk must be generally accepted—not merely a minority view. *Id.*, Directions for Use ("A risk may be 'generally recognized' as a view (knowledge) advanced by one body of scientific thought and experiment, but it may not be the 'prevailing' or 'best' scientific view; that is, it may be a minority view. The committee believes that when a risk is (1) generally recognized (2) as prevailing in the relevant

scientific community, and (3) represents the best scholarship available, it is sufficient to say that the risk is knowable in light of 'the generally accepted' scientific knowledge."). Plaintiffs, who were diagnosed with NHL in 2011 and early 2015, respectively, failed to produce any evidence showing that it was "generally accepted in the scientific community" that Roundup caused cancer as of the time of the exposure that allegedly caused their disease. (Opp. at 18). Nor have Plaintiffs controverted Monsanto's evidence showing the inverse—that it was "generally accepted" by EPA and other worldwide regulatory agencies that Roundup did *not* cause cancer in humans.

Plaintiffs direct the court to a couple rodent studies from the 1980s that EPA ultimately concluded did not establish glyphosate was carcinogenetic, Dr. Parry's reports from late the 1990s concerning potential genotoxicity of glyphosate,[3] and a single epidemiology paper. (Opp. at 18). This is nothing but a tiny fraction of the glyphosate science. (UMF 15, OPP Report at 10 ("An extensive database exists for evaluating the carcinogenic potential of glyphosate, including 63 epidemiological studies, 14 animal carcinogenicity studies, and nearly 90 genotoxicity studies.")). Pointing to a few studies taken out of context cannot establish general acceptance. EPA and other agencies have regularly reviewed the entire body of science related to glyphosate and concluded again and again that glyphosate is not carcinogenic. (UMF 22). Summary judgment is appropriate on Plaintiffs' warnings claims because undisputed facts show that "at the time of distribution" to Plaintiffs, Roundup's supposed capacity to cause cancer was not "known or knowable in light of the scientific knowledge that was ***generally accepted*** in the scientific community."

D. <u>Plaintiffs Have No Evidence That Roundup Caused Their Cancers.</u>

Plaintiffs' Opposition makes clear that their causation case relies entirely on the faulty opinions of their specific-causation experts. For the reasons discussed in Monsanto's concurrently

[3] Genotoxicity studies have only marginal relevance because they cannot establish that a substance is carcinogenic. Genotoxicity is type of mechanistic data that, at most, is supplemental to more substantial epidemiology or toxicology evidence. *In re Roundup Prods. Liab. Litig.*, No. 16-md-02741-VC, 2018 WL 3368534, at *17 (N.D. Cal. July 10, 2018).

pending *Sargon* motions, those opinions are unreliable. Plaintiffs thus have no admissible evidence to prove that Roundup caused their NHL, and for this reason alone, Monsanto is entitled to summary judgment on all causes of action.

E. Plaintiffs' Punitive Damage Claims Fail Because They Did Not Produce Evidence of "Despicable" Conduct By Monsanto.

Plaintiffs vaguely claim they are entitled to punitive damages because Monsanto sold Roundup while failing to warn consumers of a "known risk of NHL"; did not conduct certain studies; marketed products with a POEA surfactant; withheld information from EPA; and "ghostwrote" articles.[4] (Opp. at 20). Because all reasonable factual inferences inure to the non-movant at summary judgment, Monsanto will not dispute in detail these purported "facts" now. But, as a threshold matter, Plaintiffs' reliance on Monsanto's conduct after the onset of their NHL is improper because due process requires punitive damages to be derived "from the acts upon which liability was premised." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422–23 (2003). The remaining evidence, even when afforded all favorable inferences,[5] is not sufficient for a jury to find Monsanto acted "despicably," especially when that evidence is weighed against a worldwide regulatory consensus that glyphosate is not carcinogenic and epidemiology showing no causal association. Moreover, none of the evidence involves persons who were directors, officers, or managing agents of Monsanto.

1. Monsanto Cannot Be Punished For Conduct That Could Not Have Caused Plaintiffs' NHL.

A punitive damage award cannot be premised on "conduct that bore no relation to the [Plaintiffs'] harm" without violating federal due process. *State Farm*, 538 U.S. at 422–23 ("A defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages."); *see also Willis v. Buffalo Pumps Inc.*, No. 12cv744 BTM (DHB), 2014 WL 1028437, at *5 (S.D. Cal. Mar. 17, 2014) ("Punitive damages are not

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[5] Notably, Plaintiffs' punitive damages case is largely based on Dr. Parry's review of genotoxicity papers and three articles concerning genotoxicity. Genotoxicity studies, however, do not prove that something is a carcinogen. *See supra*, n. 7.

simply recoverable in the abstract. They must be tied to oppression, fraud or malice in the conduct which gave rise to liability in the case."). None of the of the evidence cited by Plaintiffs that occurred after their respective diagnoses—*e.g.*, the Williams (2016) article, Monsanto's response to IARC's classification, and the ATSDR review—could have been related to the cause of Plaintiffs' NHL and, therefore, is not competent to oppose summary judgment on punitive damages.

2. Plaintiffs Failed to Produce Evidence Showing Monsanto's Scientists Directed Roundup Corporate Policy.

As further discussed in Monsanto's Motion, to defeat summary adjudication on punitive damages, Plaintiffs must produce evidence that the conduct at issue was performed by an "officer, director, or managing agent of" Monsanto. Cal. Civ. Code § 3294(b). Plaintiffs' opposition entirely fails to address this argument. In any event, they have produced *no* evidence that the individuals identified in their brief were "managing agents" that directed Monsanto's corporate policy on Roundup.

3. Monsanto Reasonably Relied on the Best Scientific Data Available and a Worldwide Regulatory Consensus.

Plaintiffs claim that they are entitled to punitive damages because Monsanto continued to market and sell Roundup while failing to warn consumers of a known risk. (Opp. at 20). But, as discussed, the science does not support a "known risk" of NHL associated with Roundup. In contrast to the handful of cherry-picked papers and emails Plaintiffs rely on to support punitive damages, Monsanto relied on the best scientific data available and the undisputed global regulatory consensus that glyphosate is not a human carcinogen.[6] Relying on strong epidemiological evidence and consistent regulatory approval of glyphosate is not "despicable"

[6] Although Plaintiff purports to "dispute" this fact, they do so only on the basis of California's Prop 65 classification of glyphosate, which was a ministerial action that was not based on any independent evaluation of the science. *See* Monsanto's Evidentiary Objection No. 8. Indeed, in *Johnson*, Judge Bolanos ruled that any mention of California's classification of glyphosate under Prop 65 was inadmissible. There is thus no "genuine" dispute: the fact is that regulators worldwide have concurred that glyphosate is not likely to be carcinogenic.

conduct; rather, it is reasonable corporate conduct that merits dismissal of Plaintiffs' punitive damages claims.

4. Monsanto's Response to Dr. Parry's Genotoxicity Review Was Not Improper, Let Alone Despicable.

Plaintiffs claim Monsanto acted despicably by not volunteering Dr. Parry's report about a handful of published genotoxicity papers to EPA and by failing to conduct certain studies. (Opp. 20). Plaintiffs provide no evidence, however, that Monsanto's failure to share the Parry report altered EPA's evaluation about glyphosate's carcinogenicity. Every piece of evidence cuts against such an inference. Monsanto performed the tests recommended by Dr. Parry concerning genotoxicity and published the results in a 2008 paper. (UMF 48). Moreover, EPA has considered nearly 90 published genotoxicity studies for the active ingredient glyphosate, in addition to numerous epidemiology and toxicology studies relating glyphosate, in reaching its unequivocal conclusion that glyphosate is not carcinogenic. (UMF 15). EPA reiterated just one month ago that it "is confident in its conclusion that glyphosate is not likely to be carcinogenic to humans." (UMF 28).

5. Monsanto's Involvement with Williams (2000), Williams (2012), and Kier & Kirkland (2013) Was Not Improper, Let Alone Despicable.

Plaintiffs suggest Monsanto acted "despicably" in supposedly "ghostwriting" three genotoxicity papers: Williams (2000), Williams (2012), and Kier & Kirkland (2013). (Opp. at 20). But Plaintiffs do not claim there is anything false or misleading about the data or statements contained in these articles. Nor is there any evidence that any of the data and statements in these articles had any type of negative impact on Plaintiffs. And Monsanto cannot be punished for participating in scientific debate about glyphosate. *See Board of Trs. of Leland Stanford Jr. Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991) ("It is . . . settled . . . that the First Amendment protects scientific expression and debate . . . ."); *Senart v. Mobay Chem. Corp.*, 597 F. Supp. 502, 505-06 (D. Minn. 1984) ("[P]laintiffs assail defendants for taking a particular view in a scientific debate and for trying to retain a regulatory standard which defendants preferred. Not only do these actions not constitute torts, they are protected by the first amendment.").

Furthermore, as detailed in Monsanto's motion and supporting evidence, these review articles transparently reflect Monsanto's involvement, which means they were not nefariously ghostwritten in any sense relevant to punitive damages. (Mot. at 19; UMFs 45-47). Even afforded all inferences, no jury can find that Monsanto's participation in these three review articles "is so vile, base, [or] contemptible . . . that it would be looked down on and despised by ordinary decent people." *Mock v. Michigan Millers Mut. Ins. Co.*, 4 Cal. App. 4th 306, 331 (1992).

6. Monsanto's Testing of Surfactants Was Not Improper, Let Alone Despicable.

Plaintiffs' insinuation that Monsanto did not perform chronic carcinogenicity testing on the surfactants used in Roundup is wrong. (Opp. at 20). Monsanto performed chronic carcinogenicity tests on the surfactants used in Roundup and submitted those tests to EPA for approval. (Monsanto's Reply to Plaintiff's Separate Statement of Facts, No. 48). Monsanto simply did not perform chronic carcinogenicity tests on the formulated Roundup product as a whole, nor did EPA require that testing. Plaintiffs also fail to tie their allegations about POEA and a European regulator's inquiry into tallow amine to anything that is remotely related causally to Plaintiffs' cancer. *State Farm*, 538 U.S. at 423 ("A defendant should [only] be punished for the conduct that harmed the plaintiff . . . ."). Plaintiffs produced no evidence they were even exposed to POEA, let alone evidence that suggests any exposure increased their risk of NHL compared to other glyphosate-based herbicides.

III. CONCLUSION

In sum, Monsanto is entitled to summary judgment because Plaintiffs' claims are preempted by federal law and because Plaintiffs cannot produce evidence to prove that their NHL was caused by Roundup. At the very least, Monsanto is entitled to summary adjudication on Plaintiffs' warnings and punitive damages claims because, as explained herein and in Monsanto's motion, Plaintiffs have failed to meet their burden of producing evidence to support those claims.

Dated February 26, 2019.

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PROOF OF ELECTRONIC SERVICE

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I am employed in the County of San Francisco, State of California. I am over the age of 18 and not a party to the within action. My business address is One California Street, 18th Floor, San Francisco, California 94111.

On February 26, 2019, I served a true and correct copy of the documents described as

REPLY BRIEF IN SUPPORT OF DEFENDANT MONSANTO'S MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, SUMMARY ADJUDICATION;

SUPPLEMENTAL DECLARATION OF EUGENE BROWN IN SUPPORT OF DEFENDANT MONSANTO COMPANY'S MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, SUMMARY ADJUDICATION;

RESPONSE TO PLAINTIFFS' SEPARATE STATEMENT OF MATERIAL FACTS;

EVIDENTIARY OBJECTIONS TO PLAINTIFFS' EVIDENCE IN OPPOSITION TO MOTION FOR SUMMARY JUDGMENT;

[PROPOSED] ORDER REGARDING MONSANTO'S EVIDENTIARY OBJECTIONS TO PLAINTIFFS' EVIDENCE IN OPPOSITION TO MOTION FOR SUMMARY JUDGMENT

on the interested parties by electronic transfer to Case Anywhere via the Internet, pursuant to the Court's Case Management Order No. 2 Authorizing Electronic Service dated March 23, 2018.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this Proof of Electronic Service was executed on February 26, 2019 at San Francisco, California.

_/s/_____

Letha Payne