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MONSANTO COMPANY

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs.

MONSANTO COMPANY,

Defendant.

Case No. CGC-16-550128

DEFENDANT MONSANTO COMPANY'S TRIAL BRIEF

Trial Date: June 18, 2018
Time: 9:30 a.m.
Department: TBD

I. STATEMENT OF THE CASE

Plaintiff claims that he developed mycosis fungoides, a type of non-Hodgkin's lymphoma ("NHL"), due to exposure to certain Monsanto Glyphosate-based Herbicides ("GBHs"), Ranger PRO®, Roundup PRO Concentrate®, and/or Roundup PROMAX®. Plaintiff allegedly applied the GBHs at various times from approximately June 2012 to late 2015 or early 2016, in the course of his employment at the Benicia Unified School District.[1] In order to prevail on his claims, Plaintiff must establish that some inadequacy in the warnings that accompanied those products was the cause of his cancer or that the products were defectively designed. In addition, he must prove medical causation – both general causation (*i.e.*, that the substance at issue is capable of causing the injury alleged), and specific causation (*i.e.*, that the substance actually caused this specific Plaintiff's injury). *See, e.g.*, *Jones v. Ortho Pharm. Corp.*, 163 Cal. App. 3d 396, 402-04 (1985); *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 318 F. Supp. 2d 879, 890, 922 (C.D. Cal. 2004); *Avila v. Willits Environmental Remediation Trust*, 633 F.3d 828, 836 (9th Cir. 2011); *see also In re Lockheed Litig. Cases*, 115 Cal. App. 4th 558, 561-65 (2004).

Plaintiff's case revolves around the International Agency for Research on Cancer's ("IARC") classification of glyphosate as a "probable carcinogen" in March 2015.[2] At that time, IARC was the first and only scientific body to find that glyphosate is in any way carcinogenic. Indeed, every worldwide regulatory agency conducting its own risk assessment of GBHs has determined they are non-carcinogenic. Importantly, numerous worldwide regulatory agencies, including the U.S. Environmental Protection Agency ("EPA"), have reviewed the carcinogenicity of GBHs *after* the IARC classification. After considering all the studies reviewed by IARC, each agency has reaffirmed its conclusions that GBHs are not carcinogenic.

This consensus of regulatory approval is backed by sound science. Glyphosate is the most

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[1] Evidence establishing the factual statements set forth in this Brief have previously been submitted to this Court in support of or opposition to various motions; for the sake of brevity, citations to that evidence have been omitted.

[2] The IARC Monograph was published in July, 2015, but the IARC meeting was held in March, 2015, and IARC published an abstract on the classifications (four chemicals reviewed at the same meeting) made at the monograph meeting in *The Lancet* shortly thereafter.

tested herbicide in history. Glyphosate was first approved for use in "Roundup" (the primary brand name for most GBHs) in 1974 and has since become the most-used herbicide in the world largely due to its favorable toxicity profile. With respect to carcinogenicity, glyphosate has seven times the number of long-term animal carcinogenicity tests than what is required to register a pesticide, due in large part to the number of glyphosate manufacturers that arose when glyphosate went off patent in 2000. The other two bodies of scientific studies relevant to carcinogenicity, genotoxicity studies and epidemiology studies, have equally robust databases indicating the lack of an association between GBHs and NHL.

Plaintiff will attempt to distract the jury from a scientific inquiry on causation by inflammatory, speculative and unfounded allegations that Monsanto controlled the science and EPA. In resolving the parties' *Sargon* motions, the Court has already curtailed these efforts, ruling that Plaintiff's expert Dr. Benbrook may not make allegations that Monsanto "misled" the EPA. Furthermore, these baseless assertions fall apart when one considers the extent of the worldwide regulatory approvals and the overwhelming body of scientific evidence refuting Plaintiff's allegations.

The most up-to-date science backing glyphosate's safety is likely best demonstrated by the 2018 update to the Agricultural Health Study ("AHS") cohort, which is by far the largest epidemiological study on the potential association between GBHs and NHL.[3] The study was peer-reviewed and published in the Journal of the National Cancer Institute, and its conclusions are unequivocal: "In our study, we observed *no associations* between glyphosate use and NHL overall or any of its subtypes."

Monsanto will introduce evidence from retained expert witnesses, and elicit testimony from Plaintiff's witnesses on cross-examination, demonstrating that the entire body of epidemiology literature shows no causal association between GBHs and NHL and that the animal-study database is most consistent with glyphosate not being a human carcinogen (and is consistently so interpreted by regulatory agencies). Testimony from exposure experts will show

[3] G. Andreotti et al., *Glyphosate Use and Cancer Incidence in the Agricultural Health Study*, 110 J. Nat'l Cancer Inst. (published online Nov. 9, 2017) ("NCI 2018").

that Plaintiff's exposure was minimal due to GBHs' chemical properties as well as the extensive personal protective equipment ("PPE") worn by Plaintiff at all times while mixing or applying GBHs. Testimony from oncologists will show both a lack of evidence that GBHs can cause cancer and that Plaintiff's cancer could not logically be caused by GBH's due to the latency of the disease. Lymphomas such as mycosis fungoides take many years to form, and the short period of time between Plaintiff's first exposure and onset of his disease precludes any possible causal connection here.

Monsanto also disputes that GBH warnings were inadequate based on what was known or knowable in light of the generally accepted scientific and medical knowledge at the time. Monsanto did not intentionally fail to warn Plaintiff about NHL, as evidenced by EPA and other worldwide regulatory agencies' repeated approvals and determinations – both before and after IARC – that GBHs are not carcinogenic.

II. FACTUAL STATEMENT

A. The History and Benefits of Glyphosate-based Herbicides

Glyphosate is "the most important herbicide" developed in the post-World War II era. GBHs first became commercially available in 1974 when, after four years of testing by its research scientists, Monsanto introduced Roundup®, a mixture of glyphosate and surfactants (chemical compounds commonly found in products such as soaps that allow glyphosate to travel on the surface of the weed to growing areas). Farmers apply Roundup® before crops are planted or, where glyphosate resistant seed is used, during the growing process.

Glyphosate works by inhibiting a growth-stimulating enzyme that is specific to plants. However, as documented in numerous scientific analyses, glyphosate is not toxic to humans or animals. The bioavailability of glyphosate is extremely low, meaning that even the heaviest users of GBHs absorb relatively small systemic doses from all possible routes of exposure.

B. Non-Hodgkin Lymphoma

NHL is the seventh most common cancer and adults have approximately a 2.1% chance of developing NHL during their lifetimes. The cause of 70% of NHL cases is unknown. There are, however, several risk factors that may increase a person's likelihood of developing the disease,

one of which is farming even prior to the availability of GBHs.

C. IARC's Classification of Glyphosate

Plaintiff relies almost entirely on IARC's 2015 "cancer hazard" listing of glyphosate as a "probable carcinogen." IARC is located in Lyon, France; it is not a regulatory agency, and none of its determinations are binding on any country. IARC does not take into account levels of exposure, methods of exposure, or other factors central to a determination of whether a substance is a carcinogen. Thus, IARC "may identify cancer hazards even when risks are very low with known patterns of use or exposure." Based on this same methodology, IARC has classified a wide variety of commonly-used substances and exposures as "probable" or "known" carcinogens, including bacon, hot dogs, and red meat; alcoholic beverages; salted fish; shiftwork; frying food; and dry cleaning.

The IARC working group classification of glyphosate has been the subject of intense scrutiny. This working group: (1) was chaired by Plaintiff's expert, Dr. Blair, who admits to hiding epidemiology data that shows no increased risk of NHL attributable to GBHs; (2) included Dr. Portier, who at the time worked for an environmental activist group opposed to the use of pesticides, and who already was engaged by Plaintiffs' counsel in other litigation connected to an IARC review; and (3) conducted its evaluation over a matter of days, without its members reviewing published primary long-term rodent bioassay data or regulatory mechanistic studies.

D. Repeated Determinations that Glyphosate-based Herbicides are Non-Carcinogenic by EPA and Worldwide Regulators

IARC's classification of glyphosate stands in stark contrast to decisions repeatedly and consistently reached over a period of 40 years by regulatory agencies worldwide – including the December 2017 finding by EPA and those similarly tasked with human health and environmental protection throughout the world, including European Food Safety Authority ("EFSA"), the European Chemicals Agency ("ECHA"), the Health Canada Pest Management Regulatory Agency, the German Federal Institute for Risk Assessment ("BfR"), the Australian Pesticides and Veterinary Medicines Authority ("APVMA"), the New Zealand Environmental Protection Authority European Union and several others. *Every* major regulatory agency charged with

answering the question has, with the benefit of all the available primary data, concluded that glyphosate is *not* likely to pose risks of carcinogenicity, including NHL, in humans – *both before and after the IARC classification*. In 2016, the World Health Organization ("WHO") and United Nations Food and Agricultural Organization did so as well. IARC is part of the WHO, so this WHO finding regarding glyphosate's non-carcinogenicity is noteworthy.

E. Glyphosate-based Herbicides Are the Most Studied Pesticide in the World

As numerous regulatory bodies have noted over the years, the toxicology database on glyphosate-based herbicides is extensive. Indeed, Plaintiff's experts have testified the glyphosate toxicology database is exceptionally large, and perhaps unprecedented. While the original studies backing glyphosate's registration were conducted by Monsanto or its contractors, the number of studies conducted by companies other than Monsanto or academics and interested third-parties, including government agencies, is substantial.

III. LEGAL DISCUSSION

Plaintiff asserts several causes of action, including (1) strict liability and negligence for an alleged design defect, and (2) strict liability and negligence for an alleged failure to warn. Plaintiff will be unable to bear his burden at trial on these issues, and Monsanto should be entitled to a judgment of nonsuit or directed verdict because Plaintiff is not entitled to recover as a matter of law.

A. Plaintiff's Case

Plaintiff's theories require him to prove that Monsanto failed to warn Plaintiff, that Monsanto negligently designed Roundup PRO® and Ranger PRO® herbicides, and that his use of these herbicides caused his claimed injury, mycosis fungoides. He cannot make his showing for multiple reasons.

1. Plaintiff Cannot Establish Causation for Any Claim

Under California law, causation is an essential element of all of Plaintiff's claims and requires him to prove that his use of Roundup PRO® and Ranger PRO® caused his mycosis fungoides. *Cf. Rutherford v. Owens-Illinois, Inc.*, 16 Cal. 4th 953, 968–69 (1997); Judicial Council of California Civil Jury Instructions No. 430 ("CACI"); Restatement (Second) of Torts §

431(a) (1965). In a product liability case like this where the plaintiff is claiming that the defendant's product was a substantial factor in causing his harm, the plaintiff must prove his case to a reasonable medical probability based upon competent expert testimony. *See Bockrath v. Aldrich Chem. Co.*, 21 Cal. 4th 71, 79–80 (1999). A reasonable medical probability exists only if it is more likely than not that the defendant's conduct contributed to the plaintiff's injury. *See Saelzler v. Advanced Grp. 400*, 25 Cal. 4th 763, 775–76 (2001).

Plaintiff cannot meet this burden. While Plaintiff's experts purport to conclude that GBHs can cause NHL *generally*, no expert will competently testify that it is more likely than not that Roundup PRO® and Ranger PRO® caused Plaintiff's mycosis fungoides, given the complete absence of a scientific link between mycosis fungoides and GBHs. Plaintiff has no competent evidence that GBHs *can* cause mycosis fungoides (general causation) much less that they actually caused Plaintiff's disease (specific causation). The expert testimony will be insufficient because "evidence of causation 'must rise to the level of *a reasonable probability based upon competent testimony*.'" *Bowman v. Wyatt*, 186 Cal. App. 4th 286, 312 (2010) (emphasis in original); *id.* ("A possible cause only becomes 'probable' when, in the absence of other reasonable causal explanations, it becomes more likely than not that the injury was a result of its action. The defendant's conduct is not the cause in fact of harm where the evidence indicates that there is less than a probability, i.e., a 50–50 possibility or a mere chance, that the harm would have ensued.")

2. Plaintiff Cannot Prevail on His Design Defect Claims

To prove a claim for an alleged design defect, Plaintiff must prove that Roundup® and Ranger PRO® herbicides are defectively designed. *See Lambert v. General Motors*, 67 Cal. App. 4th 1179, 1185 (1998). While Plaintiff has claimed that the jury should be instructed under the "consumer expectations" test for a product defect, Plaintiff is wrong as a matter of law. RangerPRO® is a professional herbicide sold in the specialized Industrial Turf & Ornamental market for licensed or certified applicators in commercial or municipal settings. Plaintiff was required to undergo extensive training and testing to obtain his Qualified Applicators Certificate before he was certified to apply RangerPRO®. Plaintiff is a certified pesticide applicator, and therefore a "sophisticated user." *Johnson v. Honeywell Int'l Inc.*, 179 Cal. App. 4th 549, 558 n.4

(2009). Sophisticated users are not ordinary consumers and not entitled to an instruction based on ordinary consumer expectations. *Id.* (EPA-certified HVAC technician may not claim a product defect under consumer expectations test). Rather, demonstrating a design defect requires weighing the risks and benefits of glyphosate and a showing that the benefits of the GBHs' design outweigh the risks of the design. *See Morson v. Superior Court*, 90 Cal. App. 4th 775, 785 (2001) ("A product is defective if its design embodies excessive preventable danger, unless the benefits of the design outweigh the risk of danger inherent in such design") (quotations and citation omitted); CACI No. 1204. Because the evidence will show that the benefits of GBHs' design outweigh any supposed risks, Plaintiff's claims should fail as a matter of law.

3. Plaintiff Cannot Prevail on His Failure to Warn Claims

Plaintiff's failure-to-warn claims require a showing that Monsanto failed to adequately warn of risks associated with GBHs. *See Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 1002–03 (1991). Monsanto had no duty to warn Plaintiff about a non-existent cancer risk for GBHs. *See T.H. v. Novartis Pharm. Corp.*, 245 Cal. App. 4th 589 (2016) ("A manufacturer is not required to warn about speculative harm."), *aff'd*, 4 Cal. 5th 145 (2017); *Rosburg v. Minnesota Mining & Mfg. Co.*, 181 Cal. App. 3d 726, 735 (1986) ("There is no requirement that a manufacturer must give a warning which could not possibly be effective in lessening the Plaintiff's risk of harm.") (citations omitted); *Cf. Finn v. G. D. Searle & Co.*, 35 Cal. 3d 691, 701 (1984) ("'[B]oth common sense and experience suggest that if every report of a possible risk, no matter how speculative, conjectural, or tentative, imposed an affirmative duty to give some warning, a manufacturer would be required to inundate [the public] indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given.") (citations omitted). Plaintiff will be unable to prove that generally accepted scientific knowledge established a causal relationship between GBHs and mycosis fungoides in 2012 to 2016 (the dates Plaintiff applied GBHs), in light of the overwhelming conclusions of the scientific literature and world's regulatory bodies.

Moreover, in the failure-to-warn context, Plaintiff bears the additional burden of proving that a different warning or instruction on Roundup PRO® and Ranger PRO® would have resulted

in Plaintiff not suffering from mycosis fungoides. *See Huitt v. S. California Gas Co.*, 188 Cal. App. 4th 1586, 1604 (2010) ("[A] defendant is not liable to a Plaintiff if the injury would have occurred even if the defendant had issued adequate warnings."); *Cf. Motus v. Pfizer Inc.,* 196 F. Supp. 2d 984, 999 (C.D. Cal. 2001), *aff'd,* 358 F.3d 659 (9th Cir. 2004) (granting summary judgment because the Plaintiff failed to identify any "evidence establishing that Dr. Trostler would have acted differently had Pfizer provided an adequate warning about the alleged risk .... [and] [ ] is therefore unable to create a genuine issue as to whether [the defendant's] [ ] alleged failure to provide an adequate warning caused her injuries"). Because no expert will competently testify that it is more likely than not that Roundup Pro® and Ranger Pro® caused Plaintiff's mycosis fungoides, Plaintiff cannot prove that a different warning would have caused a different result.

4. Plaintiff is Not Entitled to Punitive Damages

Finally, Plaintiff is making a demand for punitive damages. To receive punitive damages, Plaintiff must prove by clear and convincing evidence that an officer, director, or managing agent of Monsanto committed, authorized, or knew of malicious or oppressive conduct that caused Plaintiff's injuries. *See* CACI No. 3945. This is a showing that Plaintiff has not, and cannot, make at trial.

B. <u>Monsanto's Expected Case</u>

1. Motion for Nonsuit/Directed Verdict

For the reasons set forth above, Monsanto should be entitled to a judgment of nonsuit or directed verdict because it will show that Plaintiff is not entitled to recover as a matter of law. *See* Cal. Code of Civ. Proc. § 581c; *see also Baker v. Am. Horticulture Supply, Inc.*, 186 Cal. App. 4th 1059, 1072 (2010) ("A defendant is entitled to a nonsuit [or directed verdict] if the trial court determines that, as a matter of law, the evidence presented by Plaintiff is insufficient to permit a jury to find in his favor."). At the close of Plaintiff's evidence, "the only reasonable inference which can be drawn from the evidence is that the proximate cause of Plaintiff's condition remains unknown and unproved," "that Plaintiff did not establish a prima facie case," and that a "motion for nonsuit w[ill be] properly granted." *Jones*, 163 Cal. App. 3d at 404; *Cf. In re Lockheed*, 115 Cal. App. 4th at 565 (affirming judgment to the defendant where there was no reasonable basis for

an expert's opinion that chemicals in the workplace caused increased risk of cancer).

2. Presentation of Evidence

In the event that the Court does not grant Monsanto's nonsuit or directed verdict motions, Monsanto intends to present evidence in its defense against Plaintiff's failure-to-warn and design defect claims. To present its defense and rebut Plaintiff's claims, Monsanto expects to call multiple scientific experts to discuss the results of epidemiology, animal, and genotoxicity studies conducted regarding glyphosate and to evaluate Plaintiff's lack of exposure to glyphosate. Monsanto expects to call expert witnesses to testify about glyphosate's unique properties and strong safety profile in comparison to other herbicides, and the body of regulatory review concluding that glyphosate is not carcinogenic to humans.

In addition to the presentation of expert witnesses, Monsanto anticipates calling an oncologist and former consultant involved in Plaintiff's care to discuss Plaintiff's medical condition, prognosis, and treatment and to testify as to the lack of any known cause of mycosis fungoides. Monsanto expects to call Plaintiff's former coworkers at Benicia Unified School District to discuss the training and education received by BUSD employees related to pesticide application and their knowledge of Plaintiff's alleged exposure.

Dated: June 1, 2018

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