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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	MDL No. 2741 Case No. 3:16-md-02741-VC
This document relates to: *Hardeman v. Monsanto,* 3:16-cv-00525 - VC	**PLAINTIFF'S RESPONSE TO PTO 115**

Introduction

The Court decided this issue at the pleading stage. Mr. Hardeman has always alleged that Roundup® is inherently and unavoidably unsafe. Not surprisingly, when Monsanto moved to dismiss Plaintiff's design defect claim, it did so pursuant to comment k of the Restatement (Second) of Torts. Then, the Court correctly rejected Monsanto's argument because the protections of comment k do not extend outside of the medical context. *See Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037, 1040 (N.D. Cal. 2016). There are no facts or evidence necessitating a different result now and unavoidably unsafe products are still subject to strict liability in tort under a defective design theory where the protections of comment k are inapplicable.

I. Monsanto Waived Any Summary Judgment Argument on Plaintiff's Design Defect Claim.

As a threshold matter, Monsanto did not move for summary judgment on Plaintiff's design defect claim. Federal Rule of Civil Procedure 56 is clear: "unless a different time is set by local rule or the court orders otherwise, a party may file a motion for summary judgment at any time until 30 days after the close of all discovery." Fed. R. Civ. P. 56. It is now March 17, 2019 and discovery closed well over 30 days ago. In fact, the parties have been in trial since February 25, 2019. The Court did not issue any new deadline or otherwise invite Monsanto to present argument under Rule 56. In fact, Monsanto concedes that there is no authority to support its position and it has not offered any explanation that could constitute good cause for the delay. *See* Tr. 2117:22-23. Accordingly, Monsanto waived any claim for summary judgment on Plaintiff's design defect claim by raising the argument for the first time nearly 90 days after the close of discovery and over 60 days past the Court's own deadline for summary judgment briefing. *See* PTO 53.

II. Monsanto's comment k affirmative defense demonstrates that design defect claims are cognizable even with unavoidably unsafe products.

First, Unavoidably unsafe products like Roundup® are nonetheless subject to design defect claims sounding in strict liability when comment k does not apply. Comment k of the Restatement (Second) of Torts § 402A addresses inherently dangerous products, stating that

"[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs." Restatement (Second) of Torts § 402A, comment k. Under the comment, "[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous." *Id.* Courts in California have interpreted comment k as prohibiting design defect claims involving prescription drugs and medical devices. *See Brown v. Superior Court*, 44 Cal. 3d 1049, 1065, 751 P.2d 470, 480 (Cal. 1988); *Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 360, 13 Cal. Rptr. 2d 811, 818 (Ct. App. 1992).

Monsanto has asserted comment k as an affirmative defense, but implicit in that defense is the tacit and necessary concession that design defect claims are cognizable when a product is incapable of being made safe and is unavoidably dangerous. Otherwise there would be no need for comment k at all since *any* claim sounding in design defect would necessarily fail where, as here, a plaintiff alleges that a product was inherently and unavoidably unsafe.

Accordingly, although comment k can, for example, preclude liability for some medical products, it does not confer immunity for products like Roundup® which are only designed to aid productivity. *See Hardeman*, 216 F. Supp. 3d at 1040 ("Monsanto does not cite—and the Court cannot find—a California case applying comment k outside the medical context[.]"); *Giglio v. Monsanto Co.*, 15CV2279 BTM(NLS), 2016 WL 1722859, at *4 (S.D. Cal. Apr. 29, 2016) ("California courts have applied comment k to prescription drugs and medical devices only."); *Wilkinson v. Bay Shore Lumber Co.*, 182 Cal. App. 3d 594, 601, 227 Cal. Rptr. 327, 331 (Ct. App. 1986) ("[D]ecisions in this jurisdiction which refer to comment k overwhelmingly involve products such as prescription drugs, vaccines, blood, and medical devices[.]"). In *Brown*, the California Supreme Court drew "an important distinction between prescription drugs and other products."[1] For products "necessary to alleviate pain and suffering or to sustain life," strong policy considerations weigh against the imposition of strict design-defect liability. 751

[1] Under *Brown*, Courts have extended the application of comment k to other medical products, reasoning that "[s]uch products are commonly crucial to the well-being of the patient. Some devices are so important that, as is the case with prescription drugs, the patient faces death without them." *Hufft v. Horowitz*, 4 Cal. App. 4th 8, 18, 5 Cal. Rptr. 2d 377, 383 (1992), *modified* (Mar. 17, 1992).

P.2d at 478. However, for products "used to make work easier or to provide pleasure" the California Supreme Court has refused to apply comment k because those same policy considerations do not apply. *Id; See also Arkansas-Platte & Gulf Partn. v. Dow Chem. Co.*, 886 F. Supp. 762, 767 (D. Colo. 1995) ("For the rule precluding liability for unavoidably unsafe products to apply to a given product, the product's utility must greatly outweigh the risk created by its use, the risk must be a known one, the product's benefit must not be achievable in another manner, and the risk must be unavoidable under the state of knowledge existing at the time of manufacture."). Roundup does not alleviate pain or suffering and it does not sustain life. It was used by Mr. Hardeman to kill poison oak and other weeds, it is not an indispensible life-saving medication.

Second, As the Court previously recognized, "comment k only applies where products 'are properly prepared and marketed, and proper warning is given.'" *Hardeman*, at 1040 (quoting Restatement (Second) of Torts § 402A, comment k). Here, it is undisputed that Monsanto never warned that Roundup could cause cancer, thus "by its own terms—comment k doesn't apply." *Id.*

Third, "[t]o the extent that comment k could be applied to pesticides, the determination of whether the application of comment k is warranted would be based on the particular product in question" and "the trier of fact should determine a pesticide's value to society relative to the harm it causes." *Giglio*, 2016 WL 1722859, at *4 (quoting a *Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wash. 2d 493, 509, 7 P.3d 795, 803, *opinion after certified question answered*, 243 F.3d 549 (9th Cir. 2000)). Accordingly, Plaintiff is entitled to present his design defect claim to the jury should the case proceed to Phase 2.

III. California Law Does Not Require Mr. Hardeman to Prove an Alternative Design.

California's strict product liability law contains no requirement that Mr. Hardeman prove an alternative design. The California Supreme Court has repeatedly described two tests for strict product liability design defect:

> A product design may be found defective if (1) "the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner" (consumer expectations test), or (2) the risk of danger inherent in

the product's design outweighs the design's benefits (risk-benefit test).

Webb v. Special Electric Co., Inc, 63 Cal.4th 167, 180 (2016) (citations omitted). The two tests "provide alternative means for a plaintiff to prove design defect" but importantly "do not serve as defenses to one another." *McCabe v. Am. Honda Motor Co.*, 123 Cal. Rptr. 2d 303, 310 (Cal. App. 2d Dist. 2002)."The tests are not mutually exclusive, and ***a plaintiff may proceed under either or both***." *McCabe v. Am. Honda Motor Co.*, 123 Cal. Rptr. 2d 303, 315 (Cal. App. 2d Dist. 2002) (emphasis added). Thus, "[a] product may be defective under the consumer expectation test even if the benefits of the design outweigh the risks" and vice versa. *McCabe*, 123 Cal. Rptr. 2d at 310.

Here, Plaintiff requested jury instructions for a design defect claim under the consumer expectation test whereas Monsanto requested jury instructions for the risk-benefit test. Under either test, Plaintiff has presented sufficient evidence to submit this claim to the jury. Under either test a Plaintiff is not required to "prove that there was a safer alternative design." *Sparks v. Owens-Illinois, Inc.*, 32 Cal. App. 4th 461 (1995).

If the Court gives Plaintiff's requested consumer expectation jury instruction then Monsanto may not defend a claim under the consumer expectations test by relying on the risk-benefit test. *McCabe*, 123 Cal. Rptr. 2d at 310. Under these circumstances, the benefits of Roundup are not only irrelevant, they are to be excluded:

> …the consumer expectation test applies in 'cases in which the everyday experience of the product's users permits a conclusion that the product's design violated minimum safety assumptions, and is thus defective regardless of expert opinion about the merits of the design.' A plaintiff may show the objective condition of the product, and the fact finder may use its own 'sense of whether the product meets ordinary expectations as to its safety under the circumstances presented by the evidence.' ***A defendant may not rebut such a claim with evidence of the design's relative risks and benefits***…")

Arena v. Owens-Corning Fiberglas Corp. (1998) 63 Cal.App.4th 1178, 1186 (*quoting* Soule 8 Cal 4th at 567, 607) (emphasis added).

Even if the risk-benefit test applies, there is no requirement for Mr. Hardeman to "prove that there was a safer alternative design," Mr. Hardeman must only "demonstrate[] that the product's design proximately caused his injury." *Sparks*, 32 Cal. App. 4th at 472–73. Once a plaintiff produces sufficient evidence for a jury to find that the product caused the injury, the

burden then shifts to the Defendant "to establish, in light of the relevant factors, that, on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design." *Id.* Plaintiff has no requirement to demonstrate an alternative design. Rather it is Defendant's burden to demonstrate that there is no "safer alternative design." *Id.* ("In order to satisfy its burden under this so-called "risk-benefit" theory, the defendant manufacturer may-but is not required to-present evidence of the feasibility of a safer alternative design, the financial cost of an improved design, and any adverse consequences to the product or the consumer from the alternative design.")[2]

As CACI 1204 makes clear "[i]f [name of plaintiff] has proved these three facts, then your decision on this claim must be for [name of plaintiff] unless [name of defendant] proves that the benefits of the [product]'s design outweigh the risks of the design."

IV. A Jury Could Reasonably Conclude that Formulated Roundup is Defective and that Glyphosate Alone is a Safer Alternative Design.

As a fall back position, the jury has already heard sufficient evidence to conclude that Roundup® is defectively designed and considerably more dangerous than glyphosate. Plaintiff has already presented considerable evidence that Roundup® is more dangerous, and particularly genotoxic, than glyphosate alone. *See e.g.,* Tr.1123:9-18; (Dr. Weisenburger explaining that "Roundup® in this study is ten times more genotoxic than glyphosate"); 1124:15-1126:7. Plaintiff intends to introduce even more evidence in Phase 2 that Roundup® is more dangerous than glyphosate because surfactants increase the danger of glyphosate exponentially. For example, Plaintiff will introduce evidence that:

- Evidence that the surfactants causes genotoxicity. (Exh. 1 at 2.)
- Dr. Parry's report demonstrating that formulated Roundup® more genotoxic than glyphosate alone. (Exh. 2.)
- Emails from Monsanto spokesperson and toxicologist Donna Farmer indicating that "[t]he terms glyphosate and Roundup cannot be used interchangeably nor can you use "Roundup" for all glyphosate-based herbicides any more. For example

[2], Monsanto has not offered expert testimony as to the feasibility, the financial costs, or adverse consequences from an alternative design.

you cannot say that Roundup is not a carcinogen." (Exh. 3.)

- Evidence from a ghostwritten review article noting "[t]he fact that test materials identified as Roundup-branded formulations may actually have different compositions should be considered when comparing results of different studies, as should *the possibility that any observed effects may be due to specific GBF components other than the glyphosate active ingredient.*") (emphasis added). (Exh. 4.)

Because there is already evidence that Roundup® is more dangerous than glyphosate, Monsanto bears the burden of showing that glyphosate alone is not a feasible alternative design. *Sparks*, 32 Cal. App. 4th at 73 ("In order to satisfy its burden under this so-called 'risk-benefit' theory, the defendant manufacturer may-but is not required to-present evidence of the feasibility of a safer alternative design, the financial cost of an improved design, and any adverse consequences to the product or the consumer from the alternative design.").

V. Monsanto Misconstrues the Component Parts Doctrine.

Monsanto, relying upon *Webb* and the component parts doctrine espoused in comment c to § 5 of the Restatement (Third) of Torts, argues in its letter brief that "a chemical... cannot by definition be defectively designed." *See* ECF No. 2991 (citing 63 Cal. 4th 167, 184 (2016)). But this argument fundamentally misinterprets comment c. Comment c by its own terms applies to "a *basic* raw material such as sand, gravel, or kerosene." *Webb*, 370 P.3d at 1031-32 (emphasis added) (quoting Restatement (Third) Torts § 5, com. c.). Glyphosate is not naturally occurring nor is it a basic raw material. Instead, it is a synthesized chemical compound which makes comment c inapplicable.[3]

Making matters worse for Monsanto, § 5, which concerns the component parts doctrine, is inapplicable to final products such as Roundup® by its own terms. This defense "protects manufacturers and sellers of component parts from liability to users of finished products

[3] Moreover, the *Webb* holding was expressly limited to warnings claims and did not extend to design defect claims. *See Webb* at 1032, fn. 8 ("The present case concerns only failure to warn, and we express no view on design defect liability.")

incorporating their components." *Webb*, 370 P.3d at 1031-32. But Monsanto is the manufacturer of the finished product and the component parts doctrine is therefore inapplicable. [4]

Poosh v. Philip Morris USA, Inc., does not stand for a different proposition. *See* 904 F. Supp. 2d 1009 (N.D. Ca. 2012). This is because the component part alleged to be defective in *Poosh*, nicotine, is naturally occurring in tobacco. As the court observed in *Poosh*, nicotine is normally present in tobacco." *Id.* By faulting the presence of nicotine in cigarettes, the plaintiffs in *Pooshs* attacked cigarettes as a whole and not their design. Here, Mr. Hardeman alleges that "Roundup is more toxic than glyphosate alone" and that Monsanto "knew or should have known that tests limited to Roundup's active ingredient glyphosate were insufficient to prove the safety of Roundup." Am. Compl. at ¶ 58-59. Accordingly, *Poosh* distinguishable.

Conclusion

In conclusion, Mr. Hardeman has presented a cognizable design defect theory that must be allowed to proceed to the jury.

Dated: March 17, 2019

Respecfully submitted,

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[4] This is because comment 5 is only concerned with limiting liability for component part manufacturers who do not sell finished products because "[i]mposing liability would require the component seller to scrutinize another's product which the component seller has no role in developing." Restatement (Third) of Torts: Prod. Liab. § 5 (1998)

CERTIFICATE OF SERVICE

I certify that on March 17, 2019, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Aimee Wagstaff