HELMS v. SPORICIDIN INTL.

871 F. Supp. 837 (1994) | Cited 0 times | E.D. North Carolina | September 7, 1994

MEMORANDUM AND RECOMMENDATION

This matter is before the court on the defendant's motions for summary judgment. The plaintiffs, Dorothy and William C. Helms, seek damages for injuries that allegedly resulted from Dorothy Helms' exposure to Sporicidin Cold Sterilizing Solution (SCSS), which is manufactured by Sporicidin International (Sporicidin). Sporicidin contends that all of the Helms' claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 et seq. (FIFRA). The motion for summary judgment should be granted as to all claim premised on Sporicidin's failure to warn and denied as to the claims based on defective testing, design, and manufacturing.

STATEMENT OF THE CASE

Helms filed the complaint on 9 January 1992, alleging personal injuries arising out of the use of SCSS. An amended complaint was filed to add Helms' husband, William C. Helms, III, alleging a claim for loss of consortium. Sporicidin served its answer on 23 March 1992, which substantially denied the substantive allegations of the amended complaint.

On 9 December 1993, Sporicidin moved for summary judgment on the grounds that the FIFRA preempts the four causes of action set forth in the amended complaint. Helms then sought leave to file a second amended complaint. The second amended complaint adds a cause of action based upon the alleged failure of Sporicidin to comply with certain federal laws, deletes two causes of action based on breach of warranty, and adds a failure to warn claim based on Sporicidin's failure to update certain material safety data sheets (MSDS's). Specifically, Helms contends that Sporicidin caused her injuries when it "negligently and recklessly designed ..., manufactured and produced ... Sporicidin[;] ... failed to inspect or monitor levels of glutaraldehyde emission[;] ... [and] failed to provide adequate and proper warnings with respect to ... Sporicidin." (Amended Complaint, §§ 7(a)-(d)).

This court granted the plaintiffs leave to file their second amended complaint on 12 May 1994. The second amended complaint was served on 7 June 1994. Sporicidin filed a supplemental motion for summary judgment on 29 June 1994. The court will now consider both motions.

PROPOSED FINDINGS OF FACTS

Dorothy Helms worked at Craven regional Medical Center as a respiratory technician from 1976 to June 1989. Beginning in 1988, her job duties included cleaning equipment and maintaining and

delivering equipment and supplies. Helms began using SCSS to sterilize and disinfect medical equipment. In March, 1989, Helms began experiencing health problems as a result of her use of SCSS. During the period that Helms used SCSS, SCSS was registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). It was sold and distributed by Sporicidin International with EPA approved product labeling.

Sporicidin contains and emits glutaraldehyde, a toxic chemical manufactured by Union Carbide Corporation. Union Carbide literature describes Glutaraldehyde as toxic to humans whether contact occurs topically or through ingestion or inhalation. (Union Carbide Corporation, Ucarcide Antimicrobial Bulk Storage and Handling Facility Design pp. 6-7, 13 (1986)). The American Conference of Governmental Industrial Hygienists (ACGIH) and the Occupational Safety and Health Administration (OSHA) set a Threshold Limit Value (TLV) of .2ppm for Glutaraldehyde. (Affidavit Robert K. McLellan, M.D., MPH). The TLV is the maximum permissible exposure to a hazardous substance. Id.

Ucarcide is an aqueous solution that contains 25% glutaraldehyde. Id. Union Carbide provided specific instructions for handling Ucarcide. (1986 Union Carbide brochure). If vapors are strong enough to irritate the eyes or nose, the TLV is probably being exceeded and special ventilation and/or respiratory protection may be necessary. Id. The brochure gave other specific instructions concerning respiratory protection, ventilation, and other precautions.

Ucarcide was a component of SCSS. SCSS was delivered to purchasers in two bottles, one containing the 25% aqueous solution of glutaraldehyde and one containing a buffer. (Deposition of Robert Schattner, D.D.S.). The purchaser would buffer the solution by mixing the contents of the two bottles and diluting the mixture with water. The MSDS's accompanying SCSS did not contain the warnings provided to Sporicidin by Union Carbide.

Testing of SCSS would have revealed that glutaraldehyde exposure in excess of .2ppm could occur in certain circumstances. (McLellan Affidavit). This excess exposure would depend upon room size, ventilation, the solution's concentration of glutaraldehyde, and how the product was used. Id. The key factor in assessing the respiratory health risks posed to individuals working with SCSS is the airborne concentration of glutaraldehyde. Id.

Shipping SCSS with a 25% glutaraldehyde solution, which would be added to a buffer to create a 2% glutaraldehyde solution, was not essential, because SCSS could have been shipped in a diluted form. Id. Even after dilution to concentrations below 2%, however, risks of over exposure remain under certain conditions. Id. Helms' exposure to glutaraldehyde would have been substantially less, if SCSS had been shipped in a pre-diluted form. Id.

PROPOSED CONCLUSIONS OF LAW

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Sporicidin moves for summary judgment claiming that the FIFRA preempts Helms' claims. Summary judgment must be granted if, after an adequate time for discovery, "there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law." Celotex Corp. v. Catrett, 477 U.S. 317, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986); Fed. R. Civ. P. 56(c). Rule 56(c) requires an examination of the entire record including pleadings, depositions, answers to interrogatories, admissions on file, and affidavits in the light most favorable to the non-moving party. The court must also consider every inference that can be drawn from this evidence. Ross v. Communications Satellite Corp., 759 F.2d 355, 364 (4th Cir. 1985).

The non-moving party, however, cannot "rest on the mere allegations" of the pleadings, but must produce "specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e). "The mere existence of a scintilla of evidence in support of the [non-moving party's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [non-moving party]." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial," and summary judgment is appropriate. Matsushita Electric Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986).

Federal preemption is based upon the Supremacy Clause of the United States Constitution: the laws of the United States "shall be the supreme Law of the Land; ... any Thing in the constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. art. VI, cl.2. State law that conflicts with federal law is "'without effect.'" Cipollone v. Liggett Group, Inc., 120 L. Ed. 2d 407, 112 S. Ct. 2608, 2617 (1992) (quoting Maryland v. Louisiana, 451 U.S. 725, 746, 68 L. Ed. 2d 576, 101 S. Ct. 2114 (1981)). A federal law preempts state law if preemption is the "'clear and manifest purpose of Congress.'" Id. (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 91 L. Ed. 1447, 67 S. Ct. 1146 (1947)). Congressional intent to preempt may be expressly stated by statute or implied by its structure or purpose. Id. Preemption is implied when the state law conflicts with federal law or if federal law occupies the field to the extent that states are left without room to supplement federal law. Id. at 2618. Preemption applies to statutory and common law. Id. at 2620.

FIFRA governs registration, labeling, and use of pesticides. Ruckelshaus v. Monsanto Co., 467 U.S. 986, 991, 81 L. Ed. 2d 815, 104 S. Ct. 2862 (1984). Although FIFRA may be supplemented in certain ways, it expressly controls regulation of labeling. FIFRA's labeling provisions read, in relevant part, as follows: Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter. 7 U.S.C. § 136v.

The FIFRA preempts a plaintiff's state law failure to warn and inadequate labeling claims. Worm v. American Cyanamid, 5 F.3d 744 (4th Cir. 1993). The Fourth Circuit has limited the narrow preemptive overlap of § 136v(b) to cover only a "state common law cause of action that rests on an alleged failure to warn or communicate information about a product through its labeling." Id. at 747. "Claims for negligent testing, manufacturing, and formulation ... are not preempted." Id.

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Failure to Warn

Helms alleges negligence by Sporicidin for its failure to provide an adequate Material Safety Data Sheet (MSDS), which Helms contends is not a label. A manufacturer must obtain or develop a MSDS for each hazardous substance used. 29 C.F.R. 1910.1200(g)(1). The MSDS provided by Sporicidin did not include relevant information included in the MSDS provided by Union Carbide. Had Helms' supervisors known of the dangers revealed by the Ucarcide MSDS, they would have required Helms to use the product under different conditions, as recommended by the Ucarcide MSDS.

Helms' argument that MSDS is not a label under FIFRA is irrelevant. Failure to warn claims based on materials unassociated with the label necessarily challenge the sufficiency of the label. Papas v. Upjohn Co., 985 F.2d 516, 518 (11th Cir. 1993). The court in Worm II specifically held that a plaintiff cannot avoid preemption by basing a failure to warn claim on statements unassociated with the label, if the challenged language questions the sufficiency of the language approved by the EPA pursuant to § 136v. 5 F.3d at 747. By challenging the MSDS provided by Sporicidin, Helms essentially challenges the language that was approved by the EPA under the FIFRA. This claim is preempted, and summary judgment should be allowed. Id.

Defective Product Claim

Claims based on a defect in the product are not preempted. Id. As the court in Worm II explained, however, "the line between a claim for mislabeling and a claim for defective product may not always be clear." Id. at 747. The court suggested the test is "whether one could reasonably foresee that the manufacturer, in seeking to avoid liability for the error, would choose to alter the product or the label." Id. at 747-48.

Sporicidin responds that these claims are merely failure to warn claims. In support, Sporicidin offers the transcript of an open court ruling in a similar case, in which the court concluded that the negligent testing, design, and manufacture claims were indeed failure to warn claims. Lowes v. Sporicidin International, No. PJM 92-2855 (D. Md. 19 May 1994). This conclusion was based on the fact that "the only evidence that plaintiff has in this case ... essentially is synonymous with failure to warn." The determination requires an examination of the relevant facts.

Dr. Robert I. Schattner, the president and sole shareholder of Sporicidin, designed and prepared manufacturing specifications for SCSS. It was produced by contract manufacturers, pursuant to specifications supplied by Sporicidin. Glutaraldehyde is an active ingredient in Sporicidin. Both the ACGIH and OSHA have established maximum permissible levels of exposure to glutaraldehyde. The maximum permissible exposure is .2ppm. (McLellan Affidavit).

Schattner claims to have done all testing required by the EPA prior to registering SCSS under FIFRA. In support, he produced all documents supplied to the EPA prior to registering SCSS. None of these

documents reveal any tests to determine whether SCSS was capable of off-gassing toxic levels of glutaraldehyde into the working environment of individuals using SCSS. McLellan opines that testing of the product would have revealed that glutaraldehyde exposure in excess of .2ppm could occur in certain circumstances. The circumstances include room size, ventilation, the solution concentration of glutaraldehyde, and how the product is used. Exposure at this level is in excess of the maximum permissible exposure limits as defined by ACGIH and OSHA.

McLellan examined Helms and evaluated her exposure to glutaraldehyde from SCSS. McLellan concluded that Helms was exposed to levels of glutaraldehyde in excess of the maximum permissible exposure limits.

Schattner contends that the design of SCSS was within the limits of OSHA for safety. Using SCSS, however, required individuals such as Helms to dilute a 25% glutaraldehyde solution to create a 2% glutaraldehyde solution. Under these circumstances, SCSS did not necessarily fall within the OSHA .2ppm guidelines. McLellan concludes that Helms' exposure level would have been substantially less if SCSS had been supplied in a pre-diluted form.

Based on these facts, Helms concludes that Sporicidin negligently tested, designed, and manufactured SCSS. Helms specifically attacks Sporicidin's testing of SCSS. She also contends that the product should have been supplied in pre-diluted form. The evidence offered is obviously distinguishable from the situation in Lowe where "the only evidence ... is ... synonymous with a failure to warn." Id. To avoid liability based on Helms' evidence, "one could reasonably foresee that [Sporicidin] ... would choose to alter the product...," instead of the labeling. Worm II, 5 F.3d at 747-48. These claims are not preempted. The motion for summary judgment should be denied on this issue.

To recover for personal injuries resulting from a manufacturer's negligence in North Carolina, the plaintiff must show that the product was defective when it left the plant. Sutton v. Major Products Co., 91 N.C.App. 610, 372 S.E.2d 897 (1988). The product is defective if the defendant failed to act as a reasonably prudent person in designing the product, selecting proper materials as components for the product, and in inspecting the product for hidden defects. Alexander v. Seaboard Air Line Railroad Company, 346 F. Supp. 320, 323 (1971). Although Helms has presented evidence that Sporicidin failed to test SCSS appropriately, the parties memoranda focused on the preemption issue. The court concludes that the claims of a defective product, as presented, are not preempted. This ruling, however, does not preclude the parties from addressing by further motion practice the sufficiency of these claims on the merits.

CONCLUSION

Helms has alleged claims based on theories of negligent testing, design, and manufacturing and failure to warn. The claims based on the failure to warn theory are preempted by the FIFRA. Worm II, 5 F.3d at 747. Helms' claims for defective testing, design, and manufacture are not preempted and

should survive summary judgment. Id.

THIS MEMORANDUM AND RECOMMENDATION ENTERED, this 7th day of September, 1994.

CHARLES K. MCCOTTER, JR.

UNITED STATES MAGISTRATE JUDGE