

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ALABAMA  
Southern Division**

In re:	)	Master File No.
SILICONE GEL BREAST IMPLANTS	)	CV 92-P-10000-S
PRODUCTS LIABILITY LITIGATION	)	
(MDL 926)	)	This document applies to all cases

**ORDER No. 37**

**(Final Judgment under Rule 54(b) in favor of Union Carbide Corporation on certain claims)**

For the reasons stated in the accompanying opinion, the Motion for Partial Summary Judgment filed by defendant Union Carbide Corporation is GRANTED. All claims against Union Carbide Corporation and Union Carbide Chemicals and Plastics Company, Inc.—other than those based on Union Carbide's 1990-1992 ownership of McGhan NuSil Corporation—are hereby SEVERED under Fed. R. Civ. P. 42 from other issues and claims remaining in this litigation and are DISMISSED WITH PREJUDICE.

Under Fed. R. Civ. P. 54(b), the court expressly determines that there is no just reason for delay and expressly directs entry of final judgment dismissing such claims against these companies in all cases that are pending or may be later opened in this court under the master file number CV 92-P-10000-S. The Clerk will docket and file a copy of this Order and the accompanying opinion in CV 92-P-10000-S.

The Clerk will also make a docket entry, cross-referencing such Order and opinion, in each breast implant case currently pending in which Union Carbide Corporation or Union Carbide Chemicals and Plastics Company, Inc., remains as a party. Upon opening a new case later filed in, removed to, or transferred to this court in which either of such companies is a defendant, the Clerk will make a similar docket entry in such case under Rules 42 and 54(b), and the time for post-judgment motions or appeal will commence on the date of such entry.

This the 22nd day of August, 1997.

/s/ Sam C. Pointer, Jr.  
Chief Judge Sam C. Pointer, Jr.

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ALABAMA  
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SILICONE GEL BREAST IMPLANTS ) CV 92-P-10000-S  
PRODUCTS LIABILITY LITIGATION )  
(MDL 926) ) This document applies to all cases

**Memorandum of Opinion**  
**(Granting Motion by Union Carbide Corporation for Partial Summary Judgment)**

Under submission after extensive discovery, briefing, and oral argument is a motion for partial summary judgment filed by defendant Union Carbide Corporation.<sup>1</sup> It seeks summary judgment with respect to certain claims that are or may be made against Union Carbide in any breast implant case, whether currently pending in or later filed in, removed to, or transferred to this court. Union Carbide asserts that—leaving aside claims made against it based its two-year ownership of McGhan NuSil Corporation, an issue on which it is not now seeking summary judgment—it cannot be held liable for alleged injuries to breast implant recipients inasmuch as it was merely a bulk supplier of raw materials to sophisticated purchasers and had no duty to provide warnings to implant manufacturers or to breast implant recipients or their physicians. For the reasons stated below, Union Carbide's motion is due to be granted.<sup>2</sup>

**I. STANDARD OF REVIEW**

The basic principles governing summary judgment under Fed. R. Civ. P. 56 were clarified in the trilogy of cases decided by the Supreme Court in 1986: *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986). Summary judgment is proper if, based on the admissible evidence that would be available and the applicable burdens of production and persuasion, a party would be entitled at trial to judgment as a matter of law because of material facts that either are not in substantial controversy or lack

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<sup>1</sup> For several years, Union Carbide owned all stock of Union Carbide Chemicals and Plastics Company, Inc., which produced and sold silicones. Many plaintiffs in this litigation named either or both of these companies as defendants. On May 1, 1994, the two companies merged, with the surviving entity bearing the name Union Carbide Corporation. Union Carbide acknowledges its responsibility for any liabilities of Union Carbide Chemicals and Plastics Company, Inc, and this motion is made on behalf of both of these companies. For convenience, both companies are referred to in this opinion as Union Carbide.

<sup>2</sup> Union Carbide's motion for partial summary judgment has been considered in conjunction with a motion by General Electric Company ("GE") for reconsideration of this court's prior opinion and order that had denied GE's motion for summary judgment. Like Union Carbide, GE asserts the bulk supplier/sophisticated purchaser and raw materials supplier doctrines to absolve itself from potential tort liability.

sufficient evidentiary support. Facts in genuine dispute are evaluated in the light most favorable to the party against whom summary judgment would be entered.

## II. CHOICE OF LAW

In federal multidistrict proceedings under 28 U.S.C. § 1407, the transferee court is obliged to apply the substantive law of the transferor court, as in transfers under 28 U.S.C. § 1404(a). *Van Dusen v. Barrack*, 376 U.S. 612, 639 (1964); *Ferens v. John Deere Co.*, 494 U.S. 516 (1990); and MANUAL FOR COMPLEX LITIGATION, THIRD § 31.132 n. 803 (1995). Transferor courts in diversity cases are bound to apply the substantive law of the forum state, including its choice of law rules. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941).

This MDL proceeding involves diversity-jurisdiction cases filed in, or removed to, federal courts in 93 of the 94 districts.<sup>3</sup> As of the date of its motion, Union Carbide was named as a defendant in one or more cases transferred from 43 states and from the District of Columbia. As the transferee court, bound to apply the choice of law principles of numerous transferor courts, this court cannot grant the requested "global" summary judgment unless under none of these state rules would a genuine dispute as to a material fact exist.

## III. FACTS<sup>4</sup>

### **A. Background**

Union Carbide has been one of the leading manufacturers of silicone fluids and compounds. These materials, sold by it in drums labeled "For Industry Use Only," have a wide range of admittedly safe applications in various industrial uses, such as in waxes and polishes, brake fluids, cosmetics, insulation, lubricants, food additives, and electronic equipment. While warranting through "Product Quality Reports" that its products met certain specifications for chemical composition, density, and viscosity, Union Carbide also cautioned, through "Material Safety Data Sheets," that customers were responsible for determining the safety of their own products and for notifying users of the product and downstream customers of the information on the MSDS "and any other information regarding hazards or safety."

These claims arise out of the fact that, during the years 1976 to 1991 (or possibly into 1992), some of

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<sup>3</sup> The district for the Northern Mariana Islands has had no such cases as of the latest report.

<sup>4</sup> In evaluating whether summary judgment should be granted in favor of Union Carbide, the court treats the following facts as established, either because they are not in genuine dispute or because they are supported by evidence viewed in the light most favorable to the plaintiffs. The court has not recited all evidentiary matters discussed by the parties but has, since the opinion is favorable to the defendant, attempted to cover the items on which the plaintiffs have placed particular emphasis.

Union Carbide's silicone products—albeit a small percentage of its total production, less than 0.1% on average during the period—were subsequently incorporated into silicone-gel breast implants manufactured by an unrelated company, McGhan Medical Corporation,<sup>5</sup> and perhaps, though to an insignificant degree, by a second manufacturer.<sup>6</sup> Initially—from 1976 to 1984—these raw materials were sold by Union Carbide directly to McGhan Medical, which designed, manufactured, and distributed the implants. After 1984, the products were sold by Union Carbide to McGhan NuSil Corporation ("NuSil"),<sup>7</sup> which, after some processing<sup>8</sup> and accompanied by certain warnings and disclaimers,<sup>9</sup> then resold them in bulk to McGhan Medical for still further processing before incorporation into breast implants.

### B. McGhan Medical

After obtaining silicone compounds from Union Carbide and others, McGhan Medical performed various physical, biological, and chemical tests to confirm that each incoming lot of materials met its own specifications and requirements.<sup>10</sup> McGhan then processed the chemicals in a series of steps to create intermediate materials ultimately used in finished breast implants. First, it dispersed the shell materials

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5 McGhan Medical was formed in 1972 by, among others, Donald K. McGhan and Richard Compton, both of whom during the 1960s had worked for Dow Corning (the developer and major producer of silicone-gel implants) and later for Heyer-Schulte (one of Dow Corning's first competitors). In 1977 the company was acquired by Minnesota Mining and Manufacturing Company ("3M") and in August 1984 it was reacquired from 3M by the founders.

6 Union Carbide also sold a total of 1,290 pounds of its silicone compound A-40 to Heyer-Schulte in the years 1976, 1978, and 1979. It is unclear whether the material was only for experimental use rather than actual use in the manufacture of breast implants. Heyer-Schulte, like McGhan Medical, was totally independent of Union Carbide.

7 In 1984 McGhan Medical leased its equipment and process used in producing intermediate silicone chemicals to NuSil, which became a "secondary processor" of the silicone compounds. On November 30, 1990, Union Carbide purchased the stock of NuSil. NuSil remained a wholly-owned subsidiary of Union Carbide until October 14, 1992, when it was sold to an unrelated company. As earlier mentioned in this opinion, some plaintiffs have asserted claims against Union Carbide based on its 1990-1992 ownership of NuSil—these claims are not addressed in the present motion for partial summary judgment as discovery on these issues is continuing.

8 Although neither party has presented substantial evidence on this issue, plaintiffs claim that NuSil employed the same manufacturing processes, techniques, and specifications previously used by McGhan Medical.

9 NuSil apprised its customers of their responsibility to establish the suitability of the materials for their end uses, informed its customers that it had not performed testing as to the safety and suitability of the materials for use in implants, and warned its customers that the safety of the customer's final product was the customer's responsibility. NuSil's products were delivered with NuSil's own disclaimers, material safety data sheets, and labels.

10 As indicated, after NuSil became a "secondary processor," some of the steps described in this portion of the Opinion may have been performed by NuSil rather than McGhan Medical. Since the question of which company did what is not critical to resolution of the pending motion, the opinion, for simplicity, describes the steps as performed by McGhan Medical.

into a solvent, mixed the shell materials in a ratio it determined,<sup>11</sup> and dipped molds or mandrels into the shell mixture to achieve the desired thickness for each shell. Then McGhan baked the mandrels to cure the shell mixture and cause cross-linking to occur. The shells were removed from the molds by cutting holes in the shells and peeling them off the molds by hand. The shells were inspected, tested, and washed with isopropyl alcohol. Holes in the shells were patched with heat-vulcanizing patches. The patched shells were inspected and tested. The gel material to fill the interior of the implant was created by combining two silicone compounds in a ratio it selected. To create the finished breast implants, McGhan injected the gel mixture into the shells by pumping the gel through a filter and then into the shells through a needle. The filled implants were placed in a vacuum chamber to remove any entrapped air bubbles, and the injection holes and valve were patched with a vulcanizing sealant. To cure the gel and cause cross-linking to occur, the implants were then baked at a temperature and for a duration it determined. Finally, McGhan added accessories such as suture loops and fixation patches, washed the implants in alcohol, and then inspected, sterilized, and individually packaged the implants for sale to physicians.

McGhan Medical, particularly through its principals, had considerable expertise and knowledge regarding the design and manufacture of implants, including the selection of silicone materials—not all of which were obtained from Union Carbide—for integration into its products. McGhan—but not Union Carbide—was subject to various FDA regulations relating to the manufacture and distribution of implants. Nor was McGhan ignorant of the risks potentially posed by the selection of inappropriate materials or by its finished products if defectively designed or manufactured. Information and warnings relating to use and potential health hazards of its implants were provided by McGhan Medical to the purchasing physicians before actual implantation. McGhan Medical also had a sales force that regularly consulted with physicians concerning the implants, and it received and responded to product complaints from physicians.

#### B. Union Carbide<sup>12</sup>

Union Carbide performed tests in the 1970s and early 1980s on the toxicity of some of its commercial silicones, primarily to assess the environmental effects of inhalation in the workplace. One of the

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<sup>11</sup> Unlike their contentions with respect to GE, plaintiffs do not challenge Union Carbide's assertion that the ratios for combining the shell materials and the gel materials were determined by the implant manufacturer.

<sup>12</sup> To reiterate (see footnote 4, *supra*), the court here treats as "fact" the evidence viewed in the light most favorable to the plaintiffs.

products tested was the silicone fluid "VS-7207," which was promoted by Union Carbide primarily for use in cosmetics but was also described as having potential medical and health care applications, and which was one of the products sold by Union Carbide to McGhan Medical. A July 1972 report noted that, after six rats were exposed to eight hours of inhalation of VS-7207, two died and the test animals suffered from "salivation, breathing difficulties, coordination loss, tonic spasms, prostration, and death." A June 1974 report cautioned that prolonged inhalation of VS-7207 should be avoided because it might result in severe loss of coordination, respiratory difficulties, prostration, and death. In a 1982 inhalation study of VS-7207, however, after exposing test animals to an atmosphere of vapor from VS-7207 for six hours, Union Carbide found no signs of death or toxicity. Authors of the study concluded that there should be no short-term adverse effects from inhaling VS-7207 vapor, but they noted the contradictory findings in the 1972 study.

A Union Carbide 1980 sales brochure, entitled "Union Carbide Silicones for the Drug and Pharmaceutical Industry," stated that certain of its silicone products "are chemically inert under most conditions [and] may be of specific value in the formulation of certain ointment bases and medical devices," and "[are] of extreme value in the manufacture of silicone rubber implants and other medical devices." It cautioned, however, that "nothing in this booklet is to be taken as a warranty or representation" and that "no chemical should be used in a food, feed, drug, or cosmetic, or in a product or process in which it may contact a food, feed, drug, or cosmetic, until you have determined the safety and legality of the use." In this brochure, Union Carbide's A-40—its brand name for a dimethylsiloxane D4 chemical that was sold to McGhan Medical and many others—was represented as being of particular value in the manufacture of silicone rubber implants and other medical devices.

Union Carbide does not appear to have conducted its own tests on A-40. Instead, it apparently relied on information regarding D4 publicly available or obtained by it through the Silicones Health Council<sup>13</sup> and the Global Silicone Producers Association.<sup>14</sup> At the April 1988 meeting of the GSPA, members received a report on the status of D4 studies, one item being a 28-day D4 inhalation study performed on

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13 Union Carbide, along with Dow Corning and GE, was a founding member of the Silicones Health Council ("SHC"), established in the mid-1970s to address issues related to the health and safety of silicones.

14 The Global Silicone Producers Association ("GSPA") was organized in 1985 to examine the toxicity of various silicone compounds, including the low molecular weight silicone known as D4. Union Carbide was one of the founders. The GSPA was reorganized in May of 1992 as a task force of the Silicones Health Council.

rats by a Japanese company. The members agreed that the study should be submitted to the EPA, which had earlier requested environmental effect studies on D4. At an October 1988 meeting, the GSPA decided to conduct a 90-day inhalation study. This study, when completed, showed a biological response—increased liver weights—after D4 inhalation.

In February 1991, Dr. Bryan Ballantyne, Union Carbide's Director of Applied Toxicology, circulated an internal memorandum about the implications of recent studies on D4. Ballantyne recommended that Union Carbide label its D4 product "May Cause Liver Injury," and he proposed amendments to the company's Medical Safety Data Sheets. That same month, Union Carbide sent a letter to its customers whose products contained one percent or more of D4 or D5, informing them of three toxicology studies showing liver damage after exposure to D4 or D5. In the following month, Union Carbide's Material Safety Data Sheets were amended to indicate the potential for increased liver weight after exposures to D4.

Also during 1991, Union Carbide personnel engaged in a series of discussions and analyses arising from particular concerns as to the safety of silicone breast implants. In September 1991, Union Carbide completed an "Analysis of Breast Implants for McGhan NuSil and McGhan Medical Corporation," which analyzed compounds extracted from implant gel and envelope materials. In March 1992 Union Carbide ceased all sales of A-40 to customers intending to use the product in manufacturing breast implant devices.<sup>15</sup>

#### IV. ANALYSIS

Union Carbide has moved for partial summary judgment on all claims in which it has been sued for supplying raw materials to other companies for use in the manufacture of breast implants. It contends that it was merely a bulk supplier to sophisticated purchasers of raw materials, not inherently dangerous, that underwent substantial changes before resale, and that it had no duty to provide warnings to McGhan Medical or to breast implant recipients or their physicians. The plaintiffs argue that the motion should be denied because there are triable issues of material fact as to claims against Union Carbide under the principles of Sections 402A and 388 of the Restatement (Second) of Torts (1965), as well as for common law negligence claims.

Plaintiffs assert that Union Carbide is—or, at least for purposes of summary judgment, may be—

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<sup>15</sup> In May 1992, Union Carbide divested itself of NuSil, which it had owned since 1990.

liable to them under the principles of § 402A of The Restatement (Second) of Torts. Section 402A states:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
  - (a) the seller is engaged in the business of selling such a product, and
  - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
  - (a) the seller has exercised all possible care in the preparation and sale of his product, and
  - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Plaintiffs also contend that there is a genuine issue of material fact as to whether Union Carbide failed to provide appropriate warnings of dangers posed by the use of silicone compounds in breast implants under § 388 of the Restatement (Second) of Torts. According to Section 388:

- One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier
- (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
  - (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
  - (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Comment *n* to Section 388 lists six factors that should be considered in determining whether a supplier has a duty warn an intermediate manufacturer: (1) the dangerous condition of the product; (2) the purpose for which the product is used; (3) the form of any warnings given; (4) the reliability of the third party as a conduit of necessary information about the product; (5) the magnitude of the risk involved; and (6) the burdens imposed on the supplier by requiring that he directly warn all users.

Finally, the plaintiffs assert that Union Carbide is—or, at least for purposes of summary judgment may be—liable to them under general principles of tort law and common law negligence.

Each of these causes of action is, however, as Union Carbide correctly contends, subject to what has been characterized as the "raw material supplier defense" or the "bulk sales/sophisticated purchaser rule." These two doctrines, though conceptually distinct, overlap and tend to merge, as is recognized in Section 5 of the Proposed Final Draft of the Restatement of the Law of Torts: Products Liability (Third). What divergence exists between the various courts, apart from the labels, is not whether to apply the doctrines, but the significance of various factors—such as whether the raw material is itself inherently dangerous,

whether (or to what extent) the product is changed before integration into the end-product, and whether (or to what extent) the supplier was involved in designing the end-product.

Included as Comment *p* to § 402A of Restatement (Second) of Torts (1965) was the following:

The manufacturer of pigiron, which is capable of a wide variety of uses, is not so likely to be held to strict liability when it turns out to be unsuitable for the child's tricycle into which it is finally made by a remote buyer. The question is essentially one of whether the responsibility for discovery and prevention of the dangerous defect is shifted to the intermediate party who is to make the changes.

Though premised on the fundamental notion that responsibility should generally be placed on the manufacturer that selects a material for incorporation into its own product, this comment recognized in the then existing law two subsidiary principles that, on occasion, have been important in deciding whether to apply the doctrine; namely, the extent to which the materials supplied have safe uses in other applications and the extent to which those materials undergo changes before incorporation into the finished product distributed to the ultimate consumer.

Over the years, the raw material/bulk supplier doctrines have been expressly adopted by a large number of jurisdictions. See *In re Silicone Gel Breast Implants Prod. Liab. Lit.*, 887 F. Supp. 1463, 1467 (N.D. Ala. 1995); *In re TMJ Implants Prod. Liab. Lit.*, 872 F. Supp. 1019, 1029 (D.Minn. 1995) (quoting American Law of Products Liability 3d § 5.23 (Matthew J. Canavan, ed. 1994)). These opinions cite decisions applying the doctrines under the law of Alabama, California, Connecticut, Florida, Georgia, Hawaii, Illinois, Kansas, Louisiana, Michigan, Minnesota, Missouri, New Jersey, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin. Additionally, in the DuPont cases involving implantation of temporomandibular jaw (TMJ) implants, each federal circuit confronted with the issue has likewise applied the doctrines. See *Kealoha v. E.I. DuPont de Nemours & Co.*, 82 F.3d 894 (9th Cir. 1996) (applying Hawaii law); *LaMontagne v. E.I. DuPont de Nemours & Co.*, 41 F.3d 846 (2d Cir. 1994) (applying Connecticut law); *Apperson v. E.I. DuPont de Nemours & Co.*, 41 F.3d 1103 (7th Cir. 1994) (applying Illinois law); *Klem v. E.I. DuPont de Nemours & Co.*, 19 F.3d 997 (5th Cir. 1994) (applying Louisiana law). Indeed, the doctrine has apparently been adopted in all states in which the question has been presented, and this court must conclude that—albeit with some variations regarding the burden of proof, the effect of inherent dangers of the raw materials, or the extent of changes that must be made in the materials—the doctrines must be considered a part of the products liability law of each jurisdiction.

Sometimes a supplier has been sued when it was unaware that its product had been subsequently

incorporated by intermediate manufacturers into other products.<sup>16</sup> However, given the underlying rationale—that the supplier of nondefective and reasonably safe products should not be responsible for determining the safety of such products when transformed by another company into other goods—the supplier is not liable merely because the end use is foreseeable or even known. As the district court in *Kealoha* stated:

[t]he alleged foreseeability of the risk of the finished product is irrelevant to determining the liability of the component part manufacturer because imposing such a duty would force the supplier to retain an expert in every finished product manufacturer's line of business and second-guess the finished product manufacturer whenever any of its employees received any information about any potential problems.

*Kealoha v. E.I. DuPont de Nemours & Co.*, 844 F. Supp 590, 594 (D.Haw. 1994) (citing *Childress v. Gresen Mfg. Co.*, 888 F.2d 45, 49 (6th Cir. 1989)), *aff'd* 82 F.3d 894 (9th Cir. 1996).

The expected development of the bulk/raw materials supplier doctrine, as presaged in the 1965 Restatement (Second) has been recognized in the Proposed Final Draft of the Restatement of the Law of Torts: Products Liability (Third), which, including the Reporters' proposed Amendment 9, was approved at the May 20, 1997, meeting of the American Law Institute. Section 5, entitled "Liability of Commercial Seller or Distributor of Product Components for Harm Caused by Products Into Which Components Are Integrated," addresses the liability of component sellers whose products are incorporated into another's final product. Comment *a* to Section 5 concisely states one aspect of the doctrine that is of particular significance with respect to claims against Union Carbide: "component sellers who do not participate in the integration of the component into the design of the product should not be liable merely because the integration of the component causes the product to become dangerously defective." Comment *c* further notes: [R]aw materials sellers are not subject to liability for harm caused by defective design of the end-product. To impose a duty to warn would require the seller to develop expertise regarding a multitude of different end-products and to investigate the actual use of raw materials by manufacturers over whom the supplier has no control. Courts uniformly refuse to impose such an onerous duty to warn.

The rationale for the rule, absolving the supplier from liability to ultimate users of the end-product, is strongest when the supplier sells to a knowledgeable manufacturer raw materials in bulk, which are not themselves inherently dangerous and which are substantially changed during the manufacturing process

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<sup>16</sup> In an earlier decision granting summary judgment in favor of another supplier, this court noted that Scotfoam was unaware its products were being incorporated into implants. *In re Silicone Gel Breast Implants Prod. Liab. Lit. (MDL 926)*, 887 F. Supp. 1463 (N.D. Ala. 1995).

before resale to consumers, and when the supplier has little or no role in the design of the product. Each of these elements supports Union Carbide's motion for summary judgment.

First, it is clear that the silicone products sold in bulk by Union Carbide to McGhan Medical (and later to NuSil for processing and resale to McGhan Medical) were not inherently defective or unreasonably dangerous to consumers. These same materials were sold to other companies in a variety of industries, where they were safely incorporated into various products, including waxes and polishes, brake fluids, cosmetics, insulation, lubricants, food additives, stomach medicine, and electronic equipment. These silicone compounds became potentially harmful, if at all, only in particular applications—here, according to plaintiffs, when incorporated into breast implants. Even for such applications, the rat D4 inhalation studies can hardly be viewed as sufficient to create material issues regarding the safety of the raw materials for incorporation into implants.

Second, it is clear that McGhan Medical was a "sophisticated" purchaser. It was aware of—and in a position to evaluate—the potential risks of its products and of their constituent elements. It had an independent duty to warn. Indeed, it was in a far superior position to determine the risks and provide appropriate warnings. *See Kealoha v. E.I. Du Pont de Nemours & Co.*, 82 F.3d 894, 901 (9th Cir. 1996). As earlier indicated, Don McGhan and Richard Compton, who founded McGhan Medical in 1975, were former employees of Dow Corning and Heyer-Schulte, had many years of expertise in the implant business, and were very knowledgeable about the process of manufacturing breast implants. As noted in Comment *b* to Section 5 of the Proposed Final Draft of the Restatement of the Law Torts: Products Liability (Third):

when a sophisticated buyer integrates a component into another product, the component seller owes no duty to warn either the immediate buyer or ultimate consumers of dangers arising because the component is unsuited for the special purpose to which the buyer puts it. To impose a duty to warn in such a circumstance would require that component sellers monitor the development of products and systems into which their components are to be integrated.

Nor should one ignore the virtual impossibility and minimal utility of Union Carbide's being required to provide to ultimate consumers—the physicians and the implant recipients—warnings concerning its limited knowledge of possible hazards from exposure to silicone vapors.

Third, it is clear that the materials sold by Union Carbide underwent "substantial changes" in the process of being incorporated by McGhan Medical into finished implants. Although, as asserted by plaintiffs during oral argument, even more extensive changes may have occurred in the manufacturing

process with respect to materials supplied by GE to its customers, the undeniable fact is that the Union Carbide products were substantially changed when incorporated into McGhan Medical's implants. For details concerning the manufacturing process, see part III.B., *supra*, of this opinion.

Finally, it is clear that Union Carbide did not participate in the integration of its products into the design of the McGhan implants. While Union Carbide was aware of this end use of its products, it did not actively engage in the design and manufacture of those products. The mere foreseeability, or knowledge, of the end use is insufficient to impose liability on the bulk supplier.

## V. CONCLUSION

The Court hereby GRANTS the motion of defendant Union Carbide for partial summary judgment.<sup>17</sup>

By separate order, partial summary judgment will be entered in favor of Union Carbide. The claims against Union Carbide—other than those made against it based upon its two-year ownership of McGhan NuSil Corporation—will be severed under Fed. R. Civ. P. 42 from other issues and claims remaining in this litigation against Union Carbide and against other defendants, and the order dismissing these claims will be made final under Fed. R. Civ. P. 54(b). It is appropriate and desirable to make this determination under Rule 54(b) because this will, if not reversed on appeal, result in the dismissal of all claims against Union Carbide in hundreds of cases and will result in shorter and less confusing trials of claims against

the remaining defendants in those cases.

This the 22nd day of August, 1997.

/s/ Sam C. Pointer, Jr.  
Chief Judge Sam C. Pointer, Jr.

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<sup>17</sup> In reaching this conclusion, the court does not, in accordance with Federal Rule of Evidence 408, consider as evidence of liability the fact that Union Carbide is a participant in a settlement program offered to breast implant recipients. On the other hand, this decision does not relieve Union Carbide of any of its responsibilities under that program.