

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

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

**OPINION
Dow Chemical and Corning, Inc. Summary Judgment**

On December 2, 1993, this court entered an interlocutory order granting summary judgment in favor of Dow Chemical and Corning, Inc. The court expressly declined to certify that decision as final under Fed. R. Civ. P. 54(b). Now pending are plaintiffs' motions to vacate this Order, and motions by these defendants to certify the Order as final. For the reasons stated below, the court concludes that, with respect to Corning, Inc., the Order should be confirmed and certified as a final judgment. With respect to Dow Chemical, the Order should be vacated as to the direct liability claims.¹

In its 1993 Order, the court, after reviewing the potential evidence then shown to be available, concluded that Dow Chemical and Corning could not be held liable under "corporate control" theories, that Dow Corning was not a joint venture or partnership, and that its parent corporations had no legal responsibility to plaintiffs with respect to controlling the operations of Dow Corning. Plaintiffs are not actively challenging those conclusions.

Rather, they assert that evidence obtained in 1994, supplementing that previously known, shows Dow Chemical engaged in conduct making it directly liable to plaintiffs under various tort theories. This new evidence, they say, demonstrates that Dow Chemical was significantly involved with Dow Corning's breast implants — indeed, in virtually all testing of silicone from the 1940s until the early 1970s upon

¹ Plaintiffs have also filed a Motion for sanctions regarding the "Hancock affidavit." Dow Chemical's general counsel signed and distributed affidavits stating "that the Dow Chemical Company (including its divisions and subsidiaries) is not and never has been in the business of manufacturing, designing, testing, distributing, selling and/or promoting silicone mammary implants." (Emphasis supplied.) This statement is now known to be untrue. Although the affidavit is technically incorrect, the court declines to issue sanctions. The affidavit was never presented to this or any court. In addition, no actual harm resulted. Plaintiffs continued to file suits against Dow Chemical and eventually discovered all relevant information. Although the court agrees that the affidavits should not have been presented, it does not find that Dow Chemical acted in bad faith.

which Dow Corning relied. They also contend that Dow Chemical was involved in the distribution of breast implants through its foreign subsidiary, Lepetit. Plaintiffs' theories include negligence, strict liability, concert of action, corporate conspiracy, aiding and abetting, fraud, and fraudulent concealment. Plaintiffs also contend that, although Corning did not research, design, produce, promote, test, or sell breast implants, the actions of Dow Chemical should be attributed to Corning, thereby making Corning liable to plaintiffs to the same extent as Dow Chemical.

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

II. CHOICE OF LAW

In federal multidistrict proceedings, the transferee court applies the substantive law of the transferor courts. *See, e.g., In re San Juan Dupont Plaza Hotel Fire Litigation*, 745 F.Supp. 79, 81 (D.P.R. 1990) (quoting *Ferens v. John Deere Co.*, 494 U.S. 516 (1990) and MANUAL FOR COMPLEX LITIGATION, SECOND § 31.122 n. 25 (1985)). The transferor courts in diversity cases would be bound to apply the law of the forum state, including its choice of law rules. *Klaxon Co. v. Stentor Electric Mfg. Co.*, 313 U.S. 487 (1941). *See also* MANUAL FOR COMPLEX LITIGATION, SECOND § 33.23 n. 36 (1985).

This MDL proceeding involves diversity-jurisdiction cases filed in, or removed to, federal courts in 90 of the 94 districts, located in virtually every state, the District of Columbia, Puerto Rico, and the Virgin Islands. This court must therefore look to the laws of the several states to determine whether Dow Chemical and Corning should be granted summary judgment. When addressing direct liability issues under choice of law rules, this court may be obliged to apply the laws of many different states. Because of variations in applicable state law, summary judgment could be proper in some cases while not warranted in others.

III. FACTS

In evaluating whether summary judgment should be granted in favor of Dow Chemical and Corning, 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.

In 1942, Corning and Dow Chemical agreed to create a corporation in which they would each be 50% shareholders, with Corning supplying silicon technology and Dow Chemical supplying chemical processing and manufacturing know-how. Dow Corning was incorporated in Michigan in February of 1943, and Dow Chemical and Corning have each remained 50% shareholders since its inception. Although Dow Corning is a corporation and its affairs have been conducted in compliance with standards for corporate governance, Dow Chemical and Corning have at times in non-legal statements referred to Dow Corning as a partnership or joint venture.

Dow Chemical scientists performed the initial testing on silicone products and published their results in 1948. The article has been cited as spawning interest in the use of silicones in medical products. The article stated "silicones . . . as a class are very low in toxicity" and "finished silicone resins are physiologically inert and present no hazards." The article actually related to handling of commercial silicones. No evidence has been presented to indicate that the statement regarding the inertness of silicone resins is inaccurate. In addition, it is undisputed that over 100,000 kinds of silicone compounds exist, only some of which are bioactive.

Dow Chemical, primarily through one of its scientists, V. K. Rowe, performed toxicological tests on certain silicone compounds, arranged and directed outside research on behalf of Dow Corning, analyzed outside research results, and for many years made recommendations to Dow Corning regarding future testing. In 1970, after Dow Corning had been marketing breast implants for six years, the only toxicology tests on file at Dow Corning's library regarding the fluid contained in breast implants were ones that had been conducted by Dow Chemical. Dow Corning, however, did consult with other outside consultants, not just Dow Chemical.

Tests conducted by both Dow Chemical and Dow Corning on silicones prior to and after the introduction of breast implants in 1964 revealed that some silicones, including some used in breast implants, were not wholly inert, but had some biologically active properties. These studies specifically revealed that low molecular weight silicones could affect the immune system and that certain silicone fluids, including the gel making up about 80% of breast implants, had estrogenic effects. Despite finding these reactions to silicones, Dow Chemical scientists continually notified Dow Corning that the adverse reactions were due to other forces and that no further testing needed to be conducted. Some, but not all, of these studies were published in journals or disclosed to the FDA. Dow Chemical and Dow Corning also conducted joint research regarding the use of organosilicon compounds for pharmaceutical applications and agricultural purposes such as pesticides.

From its creation in 1965 and until 1970, Dow Corning's Bioscience Research Department was housed in the Dow Chemical building where Dow Chemical's toxicology and biochemical research labs were located. Dow Corning apparently did not pay rent for the use of this space.

Until the early 1970s, Dow Corning did not have its own toxicology lab and instead relied on outside consultants, such as Dow Chemical, for information regarding silicone toxicological studies. Dow Corning and its scientists frequently sought input from Rowe and other Dow Chemical scientists on their silicone research. Rowe recommended that Dow Corning create its own toxicology lab and made

specific suggestions regarding what types of tests should be conducted in that facility and who should run it. At Rowe's recommendation, Dow Corning hired Ken Olson, a Dow Chemical scientist, to head its toxicology lab. Olson stated that, during his tenure at Dow Corning, his toxicology lab was housed in the same facility as Dow Chemical's and that he had access to and used Dow Chemical's equipment, facilities, lab animals, and personnel in conducting Dow Corning toxicology tests.

Several additional Dow Chemical scientists transferred to Dow Corning for this start-up period, but, like Olson, later returned to Dow Chemical. Although none of them ever, while working at Dow Chemical, specifically opined on breast implant safety or the safety of silicones for use in breast implants, some researched and tested breast implants while at Dow Corning, knew which silicones were contained in breast implants, and knew what hazards were associated with the silicones contained in breast implants. For example, when Olson returned to Dow Chemical in 1973, he had specific knowledge of toxicological studies on breast implants and their components, including knowledge of potential estrogenic effects and gel migration to tissues and organs.

In its 1959 annual report, Dow Chemical stated that "[b]ecause of their chemical inertness and lack of toxicity silicones are rapidly finding use in medical research." Dow Chemical cited Dow Corning's use of silicones in heart and brain valves, tubes, and coatings. In 1973, Dow Chemical reported to its shareholders in its annual report that Dow Corning breast implants were "the standard of the industry."²

On May 5, 1975, Dow Chemical and Dow Corning entered into a Trade Name and Trademark Agreement allowing Dow Corning to continue to use Dow Chemical's corporate name as a part of its name. The agreement required that Dow Corning's products using Dow Chemical's name be "of a nature and quality that is acceptable to Dow Company and shall not damage or reflect adversely on the reputation or goodwill associated with the name and mark 'Dow'" and that Dow Corning, if requested, submit specimens of its products to Dow Chemical and permit inspection of its premises to examine the quality of Dow Corning's products. Dow Chemical maintained the right to withdraw its consent to Dow Corning's use of its name.

Over a period of years, Dow Chemical purchased interests in an Italian pharmaceutical company, Lepetit,³ and eventually came to own over 99% of the company. Lepetit promoted, sold, and distributed Dow Corning's breast implants throughout Europe, Central and South America, Mexico, and Australia. For several years, Lepetit was Dow Corning's largest European and Australian distributor, sole South American distributor, and had an exclusive license to sell breast implants in several countries. By 1976 it ceased distributing implants in all countries other than Spain, Portugal, and Italy; by 1983 it ceased distributions in Spain and Portugal, and by 1992, it ceased all distribution of implants.

Lepetit's ads represented that breast implants were inert. During the period in which it distributed implants, Lepetit received many complaints from physicians and breast-implant recipients regarding rupture and adverse reactions. Lepetit did not take any action with regard to these complaints other than to forward them to Dow Corning.

Shortly after Dow Chemical acquired a substantial interest in Lepetit, Dow Chemical "transferred" Charles Hinman, the director of research for Dow Chemical's subsidiary Pitman-Moore, to

² In 1992, responding to the pending silicone-gel breast implant controversy, Dow Chemical's CEO reported to the public that Dow Corning breast implants were "beyond reproach."

³ The court will refer to all related entities as Lepetit. These include Gruppo Lepetit, Ledoga, and all Lepetit subsidiaries.

Lepetit to act as Lepetit's technical advisor. From 1964-66, he worked for Lepetit but his salary and moving expenses were paid by Dow Chemical.

After Dow Chemical acquired a majority interest in Lepetit in 1967, R. William Caldwell, Assistant Director of Dow Chemical's Bioproducts Division, became the "Administratore Delegato" of Lepetit. This position gave him the right to buy, sell, or trade the company. He reported to the head of Dow Chemical's Life Sciences Department and its CEO. Although he held this position at Lepetit, he stated that he always viewed himself to be a Dow Chemical employee.

Many of Lepetit's directors were Dow Chemical officers or directors. Scientists from Lepetit and Dow Chemical freely exchanged research and information, as well as personnel. In 1972, Dow Chemical incorporated the Life Sciences and Consumer Products Departments as the short-lived Delaware corporation Dow-Lepetit.

IV. ANALYSIS

A. Dow Chemical

Plaintiffs allege that Dow Chemical can be found directly liable for negligence, strict liability, corporate conspiracy, concert of action, aiding and abetting, fraud, and fraudulent concealment. Since this court's 1993 order granting summary judgment for Dow Chemical, several other courts entered summary judgment for Dow Chemical based on the evidence then available. However, all but one court considering the supplemental evidence obtained during 1994 have denied Dow Chemical's motion on at least some of plaintiffs' direct liability theories. Judge Colombo denied Dow Chemical's motion on plaintiffs' conspiracy, aiding and abetting, negligence, and fraudulent concealment claims in a toe implant case. *Emert v. Dow Corning Corp.*, No. 91-127-061-NP (Cir. Ct. Mich. Mar. 31, 1995). Judge Andrews of Dallas County, Texas, and Judge Schneider of Harris County, Texas, have denied Dow Chemical's motion on some of the direct liability theories.⁴ Judge Magnuson in the TMJ implant MDL, however, granted summary judgment for Dow Chemical, apparently on the same evidence presently before this court. *In re TMJ Implants Products Liability Litigation*, No. 94-MD-1001 (D. Minn., Mar. 31, 1995).

1. Negligent Undertaking

Restatement (Second) of Torts § 324A states:

One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things,

⁴ A jury in Harris County, Texas, returned a verdict against Dow Chemical on an aiding and abetting theory. Although Judge Schneider set aside the jury's decision, it appears he may have done so because of an inconsistency in the special findings of the jury rather than because the evidence would not support any finding of liability by Dow Chemical.

is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to [perform]⁵ his undertakings, if--

- (a) his failure to exercise reasonable care increases the risk of harm; or
- (b) he has undertaken to perform a duty owed by the other to the third person; or
- (c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

Under this theory, frequently applied in connection with safety inspections by insurers or with third-party repairs to equipment or premises, a duty that would not otherwise have existed can arise when an individual or company nevertheless undertakes to perform some action. *Glanzer v. Shepard*, 135 N.E. 275 (1922). The potential liability for failure to use reasonable care in such circumstances extends to persons who may reasonably be expected to suffer harm from that negligence. Doctrinally, a cause of action under § 324A does not involve an assertion of derivative liability but one of direct liability, since it is based on the actions of the defendant itself.

Plaintiffs allege that Dow Chemical should be held liable under this theory for negligently testing and researching silicones for toxicity, biological activity, and safety. They contend that Dow Chemical failed to exercise reasonable care in performing its research and testing on Dow Corning silicones and therefore Dow Corning did not conduct additional research on the safety of silicones for use in breast implants before marketing silicone-gel breast implants. Plaintiffs assert that this negligence continued into the early 1970s. They also say that Dow Corning's use of "Dow" in its name and Dow Chemical's public statements regarding breast implants led individuals to rely on Dow Chemical's approval and support of breast implants.

Dow Chemical responds that, because the research and testing was not specifically performed on breast implants, Dow Chemical did not assume a duty to these plaintiffs and therefore Dow Chemical cannot be held liable for negligent undertaking. Dow Chemical also argues that the trademark agreement

⁵ Section 324A uses the word "protect" instead of "perform." This appears to be a typographical error. See *Hill v. United States Fidelity and Guaranty Co.*, 428 F.2d 112, 115 n.5 (5th Cir. 1970), *cert. denied*, 400 U.S. 1008 (1971).

did not create a duty to breast implant recipients.

Dow Chemical's reading of § 324A is too restrictive. That section provides that one who undertakes services on behalf of another assumes a duty to use due care. The proper focus of the inquiry is whether Dow Chemical undertook to perform services to Dow Corning that Dow Chemical should have recognized were necessary for the protection of third persons. The undertaking creates a duty that would not otherwise exist. Dow Chemical's argument that liability for negligent undertaking can arise only as to a specific final product takes too narrow a view of negligent undertaking analysis. Liability can arise when it is reasonably foreseeable that another will be harmed by the failure to exercise reasonable care in performing such an undertaking.

Dow Chemical performed tests on breast implant components. Dow Chemical knew that Dow Corning did not have a toxicology lab until the 1970s and was relying on the information it had provided. Eventually Dow Chemical became aware of which silicones were contained in breast implants and aware of possible problems associated with such silicones. Dow Chemical acquired this knowledge no later than Ken Olson's return to Dow Chemical from Dow Corning in 1973. Because of the relationship and proximity of the two companies, their scientific departments, and their research staffs, a jury could determine that Dow Chemical had this knowledge much earlier.

The fact that much of the testing plaintiffs refer to occurred prior to the introduction of breast implants does not prevent liability of Dow Chemical with regard to negligent undertaking. The duty is measured in terms of reasonable foreseeability. If Dow Chemical knew that its testing was being relied upon to develop products that would be implanted in humans, Dow Chemical had a duty to use due care in providing reasonably accurate and complete information even if it did not specifically know in which part of the body the products would be implanted.

Dow Chemical knew that its research was being used to promote medical uses of silicones and that Dow Corning was using silicones for human implantation. Dow Chemical stated in their annual reports that silicones were being used by Dow Corning in implanted devices. In addition, Dow Chemical publicly stated in 1973 that Dow Corning breast implants were "the standard of the industry."

Dow Chemical's subsidiary, Lepetit, was a major distributor of Dow Corning's breast implants.

The degree of control over Lepetit possessed by Dow Chemical would, under American law, be unusual in that, although Dow Chemical did not own all of Lepetit's stock, one of its officers had the power to buy, sell, or trade the company. The court need not, however, go through a "piercing the veil" analysis with regard to Lepetit to determine whether Dow Chemical is responsible for its distribution of implants. Regardless of that determination, Lepetit's distribution of implants can be considered as a factor in assessing Dow Chemical's involvement and knowledge concerning breast implants.

A standard trademark agreement does not, in and of itself, create an affirmative duty to inspect which could result in tort liability to third persons. *See e.g. Mini Maid Services Co. v. Maid Brigade Systems, Inc.*, 967 F.2d 1516, 1520 (11th Cir. 1992). Standard quality control provisions exist to protect the integrity of the trademark under the Lanham Act. These provisions do not alone operate as the affirmative undertaking of a service required under § 324A. A trademark agreement evidencing more control than standard protection, however, could constitute at least part of the evidence demonstrating an affirmative undertaking. The court need not determine whether the agreement evidences such control, but its existence is one factor in assessing Dow Chemical's knowledge and involvement in Dow Corning's breast implant activities.

Evidence exists upon which a jury could determine that Dow Chemical knew that its research would be and was being used to market additional products for human implantation, that the research would be relied upon by Dow Corning and implant recipients or their physicians, that the research was necessary for the protection of recipients of Dow Corning medical devices, and that harm could result if that research was improperly conducted or reported. A jury could also determine that women and their physicians reasonably relied to their detriment on Dow Chemical's statements regarding breast implants.

In addition to presenting evidence demonstrating an affirmative undertaking to render services that might be needed for the protection of third persons, plaintiffs must present evidence regarding an increase in the risk of harm, the undertaking by Dow Chemical of a duty owed by Dow Corning, or reliance of Dow Corning or others upon Dow Chemical's undertaking. There is evidence that Dow Corning relied on Dow Chemical's silicone testing, research, and recommendations and therefore did not perform other tests on silicone prior to its distribution of breast implants. There is evidence that Dow

Corning continued to rely on Dow Chemical's research into the 1970s. There is evidence that Dow Corning relied on Dow Chemical's toxicology testing in not performing any additional toxicological tests before marketing breast implants. This is sufficient to create a jury question regarding whether Dow Chemical undertook Dow Corning's duty to adequately test and research silicones for human implantation or whether Dow Corning relied on Dow Chemical's research and testing of silicones.

There should be little doubt that Dow Chemical's activities were provided as a service to Dow Corning. While it is unclear whether Dow Chemical ever received direct compensation from Dow Corning for its testing and recommendations, Dow Chemical, as a 50% stockholder, certainly had an interest in Dow Corning's profits and a reason to render services to Dow Corning. Section 324A does not condition liability upon proof of consideration and, indeed, covers undertakings that are "gratuitously" provided.

The decision that summary judgment cannot be granted as to Dow Chemical with regard to negligent undertaking is based on the court's conclusion that under the substantive law of at least some states — though not necessarily all states — the evidence would create a jury question in federal court. It may, of course, be that at trial a motion by Dow Chemical for judgment as a matter of law should and would be granted.⁶

2. Other Theories

Plaintiffs assert many additional theories of direct liability. Because summary judgment cannot be entered in favor of Dow Chemical on the negligent undertaking claim, the court need not address these other theories, which include strict liability, corporate conspiracy, concert of action, aiding and abetting, fraud, and fraudulent concealment.

B. Corning, Inc.

Plaintiffs concede there is no basis on which to find Corning directly liable. Instead, they contend that Corning should be accountable for the actions of Dow Chemical because of a purported joint venture/partner relationship between Dow Chemical and Corning. According to plaintiffs, Corning and Dow

⁶ Although the standards are the same under Rules 50 and 56, a judge sometimes gains an insight from hearing the actual presentation of evidence at a trial that warrants entry of judgment as a matter of law that was not clear from reviewing the written materials submitted on summary judgment.

Chemical were engaged in a joint venture or partnership with each other that makes Corning vicariously liable to the same extent as Dow Chemical.

This court has previously ruled that Dow Corning is not a joint venture because Dow Chemical and Corning did not agree to share losses, the time period was not limited, and the purpose was not limited. *In re Silicone Breast Implants*, 837 F.Supp. 1128, 1139 (N.D.Ala. 1993). No new evidence has been presented to alter this ruling.

As a general proposition, the fact that an entity is a corporation precludes a finding that it is a partnership or a joint venture or a finding that its stockholders constitute partners or joint venturers. Only in very limited circumstances have courts recognized a continuing relationship among the incorporating stockholders that, as it relates to third persons, has the incidents of partnership or joint venture. In those instances, a partnership or joint venture was only partially incorporated to do a specific act and a written agreement existed demonstrating that the corporation encompassed only a portion of the partnership or joint venture. Certain terms of a partnership or joint venture have also been held to survive incorporation in the context of the stockholders' duties to each other. A joint venture cannot, however, be carried on in corporate form because the two forms of business are mutually exclusive. *See Bevilacqua v. Ford Motor Co.*, 509 N.Y.S.2d 595, 599 (N.Y.App.Div. 1986), *and Weisman v. Awnair Corp.*, 144 N.E.2d 415, 418 (N.Y. 1957).

Dow Corning is not a joint venture, but a corporation. Dow Chemical and Corning agreed only to each become 50% owners of the same corporation. The fact that they have not changed their relationship in fifty years or that they have occasionally used the term joint venture in non-legal situations does not justify a finding that, notwithstanding their incorporation of Dow Corning, they really intended to be partners or joint venturers in a legal sense. Their only connection with one another has been as owners of Dow Corning. There is no evidence that Dow Chemical and Corning intended to have a relationship beyond being shareholders in the corporation, Dow Corning. They did not become partners or joint venturers by agreeing to create a corporation in which they would each hold an equal number of shares. Corning cannot be found liable for Dow Chemical's actions.

V. CONCLUSION

By separate order, the court will vacate its 1993 order granting summary judgment in favor of Dow Chemical with respect to "direct liability" claims. As with other orders denying summary judgment, this decision is interlocutory and does not constitute a holding that Dow Chemical is liable to the plaintiffs. It will also not bar a motion for summary judgment or for judgment as a matter of law filed in a case applying the law of a particular state.

By separate order, the court will confirm its order granting summary judgment in favor of Corning. Plaintiffs' claims against this company will be severed under Fed. R. Civ. P. 42 from other issues and claims remaining in this litigation, and the order, dismissing claims against Corning, will be certified as final under Fed. R. Civ. P. 54(b).

This the 25th day of April, 1995.

/s/ Sam C. Pointer, Jr.
United States District Judge