

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

In Re:

**DOW CORNING CORPORATION,

Reorganized Debtor.**

**Civil Action No. 00-X-00001-DT
Litigation Facility Matters**

Honorable Denise Page Hood

**Raw Material Supplier Claims as to
Certain Class 7 Claimants:**

**Rosalyn Chasin (05-30551)
Patricia Ann Cresswell (05-30603)
Beverly J. Ezra (05-30469)
Kathy Jean Gatzka (05-30496)
Linda D. Hays-Gibbs (05-30106)
Barbara Amber Howe (05-30326)
Victoria A. Kuvaas (05-30025)
Lanta K. Smith (05-30094)
Pamela D. Sutherland (05-30276)
Margie Jane Theibert (05-30092)**

MEMORANDUM OPINION

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I. BACKGROUND/FACTS¹

The DCC Litigation Facility, Inc. (“Litigation Facility”) moves for summary judgment on the Class 7 Raw Material Supplier Breast Implant Claims filed by ten Claimants. The DCC raises two arguments in support of its motion. The first is that the Claimants’ claims are barred by the bulk supplier and sophisticated purchaser defense because the breast implant manufacturers altered and incorporated those materials into their own unique implant designs. The second argument is that the claims are barred because the silicone breast implants ruptured, a condition for which Dow Corning Corporation (“Dow Corning”), as the raw material supplier, cannot be held liable since such claims can only be asserted against the manufacturer. The Litigation Facility claims Dow Corning played no role in the design, manufacture or marketing of the finished implants.

The Plaintiffs’ Liaison Counsel submitted a response arguing in opposition that there is a genuine issue of material fact as to whether the commercial gel kits Dow Corning sold to other breast implant manufacturers were defective due to Dow Corning’s superior knowledge of the bio-reactivity of the silicones in its gel, resulting in Dow Corning’s failure to adequately warn purchasers of the known hazards. The Liaison Counsel also argues that summary judgment is inappropriate on Class 7 claims arising from the rupture of implants made by manufacturers other than Dow Corning because it was reasonably foreseeable to Dow Corning that breast implants made by those companies would rupture, resulting in injuries caused by the exposure to the silicone gel provided by Dow Corning.

¹ The following published opinions provide a detailed history of this bankruptcy action: *In re Dow Corning Corp.*, 255 B.R. 445 (E.D. Mich. 2000), 86 F.3d 482 (6th Cir. 1996), 113 F.3d 565 (6th Cir. 1997), 280 F.3d 648 (6th Cir. 2002), and 456 F.3d 668 (6th Cir. 2006).

The Effective Date for the confirmed Joint Amended Plan of Reorganization (“Plan”) in the Dow Corning bankruptcy action was June 1, 2004. (April 2, 2004 Order Establishing Effective Date, Bankruptcy Case No. 95-20512) The Plan provided that claimants who chose not to settle their claims before the Settlement Facility-Dow Corning Trust (“SF-DCT”) could instead proceed against the Litigation Facility.

The ten Class 7 Claimants subject to this motion opted out of the SF-DCT and instead filed a claim against the Litigation Facility. The ten Class 7 Claimants at issue are categorized under the Plan as Class 7 Claimants, which include “Raw Material Implant Claims.” Class 7 Claimants do not have Dow Corning breast implants but instead had implants manufactured by either Heyer-Schulte/Mentor or Medical Engineering Corporation (“MEC”) (which made Surgitek brand implants). (Plan, Art. 1.146) Eight of the ten Class 7 Claimants at issue further assert that their breast implants were ruptured.

The ten Class 7 Claimants subject to this motion are:

- 1) Rosalyn Chasin (05-30551): Heyer-Schulte implants; alleges rupture
- 2) Patricia Cresswell (05-30603): Mentor implants
- 3) Beverly Ezra (05-30469): MEC/Surgitek; Cox Uphoff; alleges rupture
- 4) Kathy Gatzka (05-30496): MEC/Surgitek; Mentor; Unknown; alleges rupture
- 5) Linda Hays-Gibbs (05-30106): Heyer-Schulte with saline filling; alleges rupture
- 6) Barbara Howe (05-30326): Heyer-Schulte, MEC/Surgitek; McGhan; Mentor; alleges rupture
- 7) Victoria Kuvaas (05-30025): Heyer-Schulte; alleges rupture
- 8) Lanta Smith (05-30094): MEC/Surgitek; McGhan; Heyer-Schulte; MEC/Surgitek
- 9) Pamela Sutherland (05-30276): MEC/Surgitek; alleges rupture
- 10) Margie Theibert (05-30092): MEC/Surgitek; McGhan; alleges rupture

(LF Br., Ex. A)

Dow Corning admittedly began supplying silicone raw materials to other breast implant manufacturers, including two types of silicone precursors that Dow Corning supplied to Heyer-

Schulte/Mentor or MEC. One type of material is referred to as “Gel Raw Materials” consisting of precursor silicone fluids that could be processed to make silicone gel. Dow Corning claims the manufacturer determined the combinations of Gel Raw Materials, formulated and mixed them, processed them at the manufacturer-specified temperature for a specified time, and marketed these implants. (LF Br., pp. 5-6)

The second type of silicone raw material provided by Dow Corning was a precursor of silicone elastomer (a rubbery solid) solid in the form of either viscous “slurry” or a gum, referred to as “Elastomer Raw Materials.” The manufacturer would mill the gum, mix it with a solvent, and stir the mixture using a propeller-type mixing machine until it formed a silicone “dispersion” or “slurry.” The manufacturer would form the envelope by dipping a mandrel shaped like breast implant into the viscous dispersion, increasing the number of dips, depending on what the manufacturers’ specifications were as to the thickness of the envelope. The coated mandrel would then be heated to form a solid, finished silicone elastomer for the implant’s outer envelope. (LF Br., pp. 6-7)

The materials were provided by Dow Corning to the purchasers and manufacturers of these materials with a statement that Dow Corning was not responsible for the end-product since Dow Corning could not test and determine the suitability and safety of these materials for use in the purchaser’s intended applications. (Ex. B to LF’s Br., ¶ 19)

Heyer-Schulte was founded by individuals with experience in medical devices, including silicone materials, initially using silicone rubber to improve hydrocephalus shunts. Heyer-Schulte began manufacturing silicone breast implants in 1969 or 1970 (Ex. B to LF’s Br., ¶¶ 11, 13, 18) In 1974, Heyer-Schulte was acquired by American Hospital Supply Company (“AHS”), a supplier and

manufacturer of medical products. Mentor Corporation purchased AHS's plastic surgery business assets, including Heyer-Schulte. Heyer-Schulte went to Dow Corning to supply some of its silicone gel raw materials after General Electric withdrew from supplying silicone materials. (Ex. B to LF's Br., ¶¶ 35-36) Heyer-Schulte used its own composition of the Dow Corning Gel Raw Materials describing the gel as "Dow Corning gel formulation as manufactured here at Heyer-Schulte." (Ex. B to LF's Br., ¶ 37) Heyer-Schulte principals testified that Heyer-Schulte conducted its own safety testing on both the purchased raw materials and the finished breast-implant products. (Ex. B to LF's Br., ¶¶ 39, 46-47)

Wilfred Lynch founded MEC in 1969 to make medical devices and components of implantable devices made from silicone, such as endotracheal tubes and parts for cardiac pacemakers. Mr. Lynch possessed extensive knowledge of silicone technology and wrote two textbooks on silicone. (Ex. B to LF's Br., ¶¶ 1-3) MEC began producing silicone breast implants in 1970. MEC's founder testified that MEC designed its silicone breast implants without input from or reliance on Dow Corning. (Ex. B to LF's Br., ¶ 10) MEC conducted extensive safety tests on raw materials supplied by other companies, including silicone materials supplied by GE and later by Dow Corning. (Ex. B to LF's Br., ¶¶ 14-15) MEC acknowledged its responsibility to ensure the safety of the breast implants it designed and manufactured. (Ex. B to LF's Br., ¶¶ 12-13) Dow Corning told MEC that responsibility for safety of the end-product belonged to MEC as the manufacturer, not Dow Corning. (Ex. B to LF's Br., ¶ 19)

In 1976, both Heyer-Schulte and MEC began purchasing silicone gel from Dow Corning as a two-part "gel kit." (Condra Aff., Ex. 2, ¶¶ 7, 8) The product information bulletin described the gel kit as the "Dow Corning Q7-2167/Q7-2168 Silicone Gel System," a "two-part system designed

for producing a responsive silicone gel.” (Condra Aff., Ex. 19) Nothing was added to the two-part system by either MEC or Heyer-Schulte. (Condra Aff., Ex. 18, ¶ 10) Dow Corning’s recommendation was to mix three (3) parts of Q7-2167 and one (1) part Q7-2168, cook it at 320°F for three hours and twenty minutes to obtain a gel with “optimum properties.” (Condra Aff., Ex. 19) Dow Corning used the same ratio, time and temperature in its own silicone gel breast implants. (Condra Aff., Ex. 20) Heyer-Schulte and MEC generally followed Dow Corning’s recommendations for the gel. (Condra Aff., Exs. 21-24) The manufacturing operation did not chemically alter the silicone, and the finished gel contained 80-90% liquid silicone. (Condra Aff., Exs. 25-26)

The chemical details of Dow Corning’s gel was not shared with Heyer Schulte or MEC, other than describing the gel as a “polydimethylsiloxane composition.” (Condra Aff., Ex. 11) Dow Corning knew that MEC and Heyer-Schulte were using Dow Corning’s gel kits to make silicone gel breast implants. (Condra Aff., Ex. 28) The brochure distributed by Dow Corning represented that Dow Corning was the leading authority on the medical/silicone subject, that the silicone materials were tested more thoroughly by Dow Corning than others, that no one could match Dow Corning’s years of controlled studies history on the implantation of silicones and, by purchasing silicone products such as gel from Dow Corning, manufacturers could reduce the need for time consuming inspection and testing, indicating that “We’ve already done it for you.” (Condra Aff., Ex. 11) The brochure further states “Quality” is “the comforting knowledge that Dow Corning silicones will meet the requirements you would specify if the device were used in your own body.” (Condra Aff., Ex. 11) “Also, in a litigious society, the quality of raw materials, and the confidence that the company supplying them will stand behind them, are value-added benefits worth your

consideration.” (Condra Aff., Ex. 32) Dow Corning encouraged its customers not to conduct their own testing on Dow Corning’s “medical grade” silicone gel, but rather to rely on the safety testing already performed by Dow Corning. (Condra Aff., Ex. 12) Both Heyer-Schulte and MEC were under the impression that Dow Corning had valid data to support the long-term safety of its silicone gel. (Condra Aff., Exs. 12, 31)

In a September 23, 1983 memorandum, a Dow Corning scientist indicated that the gel being supplied to the other manufacturers (Q7-2167/2168) had never been specifically tested for long-term safety and that Dow Corning had no such data. (Condra Aff., Ex. 32) The scientist expressed concern that Dow Corning was misrepresenting to its silicone gel customers that the “safety testing to qualify [silicone gels] as implant materials does exist and can be obtained readily from Dow Corning.” (Condra Aff., Ex. 33) Other than very limited short-term testing on Dow Corning’s silicone gel, neither MEC nor Heyer-Schulte conducted any further testing, acknowledging that they relied heavily on Dow Corning for the safety and biocompatibility of the silicone gel used in their breast implants. (Condra Aff., Exs. 34-35) A Dow Corning scientist proposed that an in depth study of Dow Corning’s gel, envelope and bleed phenomenon was further required and that capsule contracture was not the only problem. (Condra Aff., Ex. 36)

In 1965, Dow Corning received permission from the Food and Drug Administration (“FDA”) to begin clinical trials for the injection of silicone fluid for various cosmetic uses under an Investigational New Drug (“IND”) Application. The FDA notified Dow Corning that its IND request did not contain sufficient data to support a conclusion that it was “reasonably safe” to continue clinical investigation. Dow Corning supplied additional data but the FDA again notified Dow Corning that its submission was inadequate. The IND was terminated in 1976. (Condra Aff.,

Ex. 38) Investigators discovered that the fluid, even when injected under the controlled conditions of a study, could trigger a chronic inflammatory response and edema with swelling and that the fluid could migrate and accumulate and could not be removed totally by surgery. (Condra Aff., Exs. 41-42)

The silicone gel used in breast implants are up to 90% liquid silicone fluid contained within a matrix of cross-linked polymers. (Condra Aff., Ex. 56) It is generally referred to as polydimethylsiloxane but the fluid contained thousands of different polydimethylsiloxanes, including low molecular weight cyclics D₄, D₅, D₆, D₇ and linear versions of the cyclic polymers. The silicone elastomer shell is more cross-linked and contains a larger percentage of higher molecular weight components, with up to 30% of the shell consisting of silica (SiO₂).

Dow Corning discovered extreme biological activity in a silicone compound called 2,6-cis, a compound related to D₄ except that it contains a phenyl component. Dow Corning thereafter intended to develop commercial products exploiting the biologic activity of the whole range of silicone compounds. Dow Corning's Bioscience Research Department found various silicones, including some of the polydimethylsiloxanes used in its silicone gel, to have unexpected effects suggesting biological activity and mobility in the human body. (Condra Aff., Ex. 46). By the early 1970's, Dow Corning was focusing on the effectiveness of various polydimethylsiloxanes, including D₄, as adjuvants, which is a substance that causes the body's immune system to attack itself. (Condra Aff., Ex. 49) Researches concluded in 1974 that the data indicated that organosilicon compounds can stimulate the immune response. (Condra Aff., Ex. 51) By January 1975, researchers found that various organosilicon fluids, including polydimethylsiloxane fluids contained in breast implants potentiated the formation of humoral antibody, modulated cell mediated immunity

and promoted the induction of interferon by stimulation of the immune system. (Condra Aff., Ex. 53) Later testing revealed that some of the polydimethylsiloxanes in breast implants also produced eosinophilia, which is considered indicative of an allergic response and that low molecular weight silicones impaired the phagocytic ability of macrophages. (Condra Aff., Ex. 53) The macrophages, the cells that engulf foreign substances in the body, were impaired in their ability to secrete the foreign substances from the body. (Condra Aff., Ex. 54) Dow Corning did not disclose these results to MEC or Heyer-Schulte when Dow Corning began supplying its silicone gel to both these companies in 1976. Dr. Donald Bennett of Dow Corning, recommended to executives in 1974 the establishment of a patient registry for breast implants because of the concern about silicone's local and systemic biological activity and its ability to migrate in the body. (Condra Aff., Ex. 46)

In 1972, Dow Corning began a long-term clinical study, conducted during the years it sold silicone gel kits, among fifty women with silicone breast implants, following the women for ten years. The results were never published or disclosed to Heyer-Schulte or MEC or to the FDA. (Condra Aff., Ex. 55) The results revealed that nine out of forty-two women followed developed problems with pain and/or inflammation. (Condra Aff., Ex. 55)

Various other studies were performed in the 1970's and 1980's by Dow Corning. Some studies found depolymerization, the conversion of high molecular weight polydimethylsiloxanes to potentially more dangerous low molecular weight polydimethylsiloxanes, metabolism to silanols through a hydrolysis reaction. (Condra Aff., Exs. 64-66) In 1985, Dow Corning conducted a follow-up thirty-day test to investigate the possibility of immunological sensitization to a component of the gel formulation and found increased numbers of eosinophils were evident at the gel implant site, indicative of an allergic response. (Condra Aff., Ex. 69) This study was not published or

disclosed to Dow Corning's silicone gel customers.

Another extensive program study was performed in 1985 to study the effects of the components of silicone gel breast implants in the immune system. Dow Corning scientists conceded that the animal studies suggest that silicone materials may be able to modify the immune system. (Condra Aff., Ex. 71) This information was not conveyed to its silicone gel customers.

Dow Corning conducted a comprehensive review of all internally conducted safety studies of silicone gel implants in late 1986 and noted that silicone gel contained within a silicone elastomer shell induces a chronic inflammatory reaction with the same characteristics as noted for free gel. Resolution is never entirely achieved because the permeation of fluid through the shell is very slow and constitutes a rate-limiting process, that is, the contained gel functions as an infinite sink. (Condra Aff., Ex. 72) Dow Corning acknowledged that the gel from an implant was not contained within the fibrous capsule and that released polydimethylsiloxane would be phagocytized at least in part by macrophages and giant cells. The phagocytic cells transport engulfed silicone to at least regional lymph nodes. (Condra Aff., Ex. 72) Dow Corning scientists postulated that phagocytized silicone will accumulate in draining lymph nodes, followed by slow transport to the liver, and will cycle to other tissues of the reticuloendothelial system. Elimination is postulated to occur at a slow rate via the lung alveolar phagocyte migration up the respiratory tree to the esophagus. (Condra Aff., Ex. 92) Dow Corning summarized the deficiencies in the safety studies performed up to 1986, noting that the histopathology of the reticuloendothelial system has not been adequately assessed in any long-term study including determination of the organ distribution of silicone materials and that none of the existing studies critically assess possible systemic effects arising from the local inflammatory reaction or from material transport. These issues are relevant to the claims and

suspicious of autoimmune-like disorders linked to silicone fluid and gel and to synovitis and lymphadenopathy associated with elastomer abrasion particles. (Condra Aff., Ex. 92) The report was not disclosed to Dow Corning's silicone gel customers.

Although not cited in its initial brief, the Litigation Facility submitted with its reply brief various reports and documents to support its motion. The first report is the Rule 706 Science Panel Report which was ordered in the MDL-926 Breast Implant Litigation in 1996. The November 1998 Report by the Panel concluded that “[t]here was no association between silicone gel-filled implants and any of the definite connective tissue diseases (including Sjogren’s Syndrome) or other autoimmune rheumatic conditions.” (LF’s Reply Br., Ex. A) The Panel also found no association between atypical connective tissue diseases or any distinctive constellation of symptoms observed in women with breast implants. (*Id.*) The second report is the 1999 Institute of Medicine Report which found no convincing evidence to support clinically significant immunologic effects of silicone or silicone breast implants. (LF’s Reply Br., Ex. B) The third report is the 1998 Britain Independent Review Group Report which concluded that there was no histopathological or conclusive immunological evidence for an abnormal immune response to silicone from breast implants in tissue nor any epidemiological evidence for any link between silicone gel breast implants and any established connective tissue disease. (LF’s Reply Br., Ex. C) The fourth document is the FDA Summary of Safety & Effectiveness Data, Silicone Gel-Filled Breast Implants (Notice of Approval to Mentor re Mentor Memory Gel Silicone Gel-Filled Breast Implants PMA No. P030053) (Nov. 17, 2006) which approved the commercial sale of silicone-gel-filled implants after the FDA considered various reports, finding that “no cause and effect relationship has been established between breast implants and these conditions.” (LF’s Reply Br., Ex. D)

The parties have submitted arguments to support their positions. The Liaison Counsel, Ms. Ezra, Ms. Gatza, Ms. Hays-Gibbs, Ms. Howe, Ms. Smith and Ms. Sutherland filed responses. A hearing was held on the matter.

II. ANALYSIS

A. Summary Judgment Standard of Review

Rule 56(c) provides that summary judgment should be entered only where "the pleadings, depositions, answers to the interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." The presence of factual disputes will preclude granting of summary judgment only if the disputes are genuine and concern material facts. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute about a material fact is "genuine" only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* Although the Court must view the motion in the light most favorable to the nonmoving party, where "the moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986). Summary judgment must be entered against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be "no genuine issue as to any material fact," since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial. *Celotex Corp.*, 477 U.S. at 322-23. A court must look to the substantive law to identify which facts are material. *Anderson*, 477 U.S. at 248.

B. Applicable Law

The Litigation Facility argues that the Court apply the sophisticated purchaser/bulk supplier doctrine but the Liaison Counsel responds by directing the Court to the test articulated in the Restatement (Third) of Torts: Products Liability (1998). The Litigation Facility claims that the Restatement is merely a restatement of the law on a particular subject. Whether referenced as the “bulk supplier,” “raw material supplier,” or “sophisticated purchaser” doctrine, the Litigation Facility argues that courts have universally adopted the core components of the doctrine, which are also articulated in the Restatement (Third) of Torts: Products Liability § 5 (2007). The Litigation Facility claims that there is essentially no conflict between the Third Restatement and the four-factor test articulated by the Honorable Sam Pointer in *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 996 F.Supp. 1110 (N.D. Ala. 1997). The Litigation Facility points to Judge Pointer’s opinion which cites section 5 of the then-proposed final draft of the Restatement as recognizing and restating the defense as it exists in the case law. 996 F.Supp. at 1114.

The Supreme Court has discussed “the settled principle that ‘[c]reditors’ entitlements in bankruptcy rise in the first instance from the underlying substantive law creating the debtor’s obligation, subject to any qualifying or contrary provisions of the Bankruptcy Code.’ That principle requires bankruptcy courts to consult state law in determining the validity of most claims.” *Travelers Casualty & Surety Co. of America v. Pacific Gas & Electric Co.*, 127 S.Ct. 1199, 1204-05 (2007) (citations omitted). Courts have long recognized that the basic federal rule in bankruptcy is that state law governs the substance of claims, Congress having generally left the determination of property rights in the assets of a bankrupt’s estate to state law. *Id.* at 1205. When considering questions of state law, a federal court must apply the state law that would have applied to the

individual cases had they not been transferred for consolidation. *See TMJ Implants Prod. Liab. Lit. v. E.I. Du Pont De Nemours and Co.*, 97 F.3d 1050, 1055 (8th Cir. 1996). Products liability claims are state law actions. *Id.*

As noted by Judge Pointer in his opinion, the raw material/bulk supplier doctrine has been expressly adopted by a large number of jurisdictions. *In re Silicone Gel Breast Implant Lit.*, 996 F.Supp at 1113. The doctrine has been applied in 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. *Id.* For the purposes of this motion, the Court finds that there is essentially no difference between the Restatement elements as to the raw materials/bulk supplier doctrine and the test set forth in Judge Pointer's opinion, especially since Judge Pointer cited the Restatement in his opinion.

The Court notes that since there have been no Complaints filed in any of these cases, the Court is not ruling on the merits of any of the Class 7 Claimants' potential claims against the Litigation Facility. The Court will only address the defense raised by the Litigation Facility. Although the Litigation Facility did not address the specific state law applicable to each of the ten Class 7 Claimants, the Court will proceed as if the defense applies to each of the Class 7 Claimants at issue, for the purposes of this motion only.

B. The Bulk Supplier/Raw Material Supplier/Sophisticated Purchaser Defense

1. Four-Factor Test

This Court applies the four-factor test to establish a sophisticated purchaser/raw material and bulk supplier defense: 1) whether the materials supplied in bulk were not themselves inherently

dangerous; 2) whether the manufacturers who purchased the materials were sophisticated buyers; 3) whether the raw materials underwent substantial changes in the process of the manufacturer's incorporation of them into the finished end-product; and 4) whether the supplier substantially participated in design of the component into the design of the product. *Id.* at 1114-17.

2. Inherently Defective or Dangerous

The Litigation Facility argues that a supplier of raw materials is not legally responsible for ensuring that its materials are incorporated into a product that is safe for all conceivable uses. The Litigation Facility claims that there is no evidence that the silicone materials supplied by Dow Corning to MEC and Heyer-Schulte are inherently dangerous or defective. The Litigation Facility cites the report of the National Science Panel which found no association between the silicone gel-filled implants and disease or any distinctive constellation of symptoms. (National Science Panel Report at 4-5) The Litigation Facility argues that Judge Pointer found that the silicone supplied by General Electric was not inherently defective or unreasonably dangerous. *In re Silicone Gel Breast Implants*, 996 F.Supp. at 1114. The Litigation Facility claims that the Dow Corning silicone at issue was essentially identical to the General Electric silicone material. (Ex. B to LF's Br., ¶ 36)

The Liaison Counsel notes that the component at issue is the silicone liquid/gel kit, which can be defective if it is designed defectively or fails to have adequate warnings. The Liaison Counsel argues that the gel kits were defective. The components contained a mixing kit to make silicone gel (Q7-2167 and 2168). The Liaison Counsel claims that Dow Corning knew that the silicone fluids were dangerous.

Based upon the submission of the parties, the Court finds there is a genuine issue of material fact as to whether the silicone gel kits provided by Dow Corning to Heyer-Schulte and MEC were

inherently defective or unreasonably dangerous. Dow Corning performed numerous tests where results appeared to show that the silicone fluids were defective or unreasonably dangerous, including the immunological effects its own scientists studied between the 1970s to the 1980s. (Condra Aff., Exs. 46, 49, 51, 53-55, 64-66, 69, 71-72, 92) There is also sufficient evidence to show a question of fact as to whether Heyer-Schulte and MEC relied on Dow Corning's superior knowledge, as advertised by Dow Corning, regarding the safety of the silicone fluids. (Condra Aff., Exs. 34-35) Although Dow Corning submits the findings of the National Science Panel, the results and reports issued by Dow Corning create a question of fact as to whether the silicone fluids are defective or unreasonably dangerous.

As to Judge Pointer's findings regarding GE silicone, Judge Pointer noted that GE had done no testing to determine whether the substances were safe for use in implants. Judge Pointer further noted that GE did not promote its silicone materials as safe for use in implants and GE's product data sheets cautioned that the users were responsible for determining the safety, compatibility and approval necessary for use in any medical application. 996 F.Supp. at 1115. In Dow Corning's case, Dow Corning advertised in its brochures its role as the pioneer and the leader in the industry. (Condra Aff., Exs. 11-12) Dow Corning performed numerous testing on liquid silicones that comprised up to 90% of the gel implant and finished gel itself but Dow Corning also observed adverse results, without notifying its customers as to any adverse results. (Condra Aff., Exs. 46, 49, 51, 53-55, 64-66, 69, 71-72, 92) Its brochures actively promoted that silicone gel was safe for implantation in the body. (Condra Aff., Ex. 11) Dow Corning further notified its customers that they did not need to further test the silicone gel because Dow Corning had already done the testing. (Condra Aff., Exs. 34-35) Judge Pointer found that GE did not possess knowledge of any danger

in the product. *Id.* at 1114. Here, there is sufficient evidence to show that Dow Corning possessed knowledge that the product was dangerous or defective. Although the Litigation Facility argues that the GE gel and the Dow Corning gel were essentially identical, a closer reading of the submitted testimony shows that this statement was based on the molecular weight data and chemical tests which measures the angle that light is bent, not from testimony that specifically identified the chemical and molecular makeup of both the GE gel and the Dow Corning gel. (Ex. B to LF's Br., ¶ 36)

There may be safe uses for the silicone gel or liquids but, with regards to implantation in the body, there is a genuine issue of material fact whether the product is inherently dangerous or defective based upon the submissions submitted by the parties.

3. Sophisticated Buyers

The Litigation Facility argues that there is no dispute that Heyer-Schulte and MEC are sophisticated buyers as noted by Judge Pointer in his opinion. *Id.* at 1115. The Liaison Counsel argues that Heyer-Schulte and MEC, although competitors of Dow Corning in the breast implant product, relied on Dow Corning regarding the safety of the silicone fluids supplied by Dow Corning.

The Liaison Counsel submitted evidence to create a genuine issue of material fact that although Heyer-Schulte and MEC may have been sophisticated buyers, they relied on Dow Corning's representations as to the safety of the silicone fluids supplied by Dow Corning. (Condra Aff., Exs. 34-35) The Liaison Counsel submitted evidence that since the 1960s through the 1980s, Dow Corning developed and tested various forms of silicone fluids. (Condra Aff., Exs. 46, 49, 51, 53-55, 64-66, 69, 71-72, 92) There is sufficient evidence submitted to create a genuine issue of material fact that Dow Corning told Heyer-Schulte and MEC not to perform further testing but to

rely on Dow Corning's research on the safety of the silicone fluids.

4. Substantially Altered Materials

The Litigation Facility argues that Heyer-Schulte and MEC substantially altered the materials so that Dow Corning was not liable for any injuries from the breast implants. The Liaison Counsel argues that Heyer-Schulte and MEC simply took the two parts they received from Dow Corning, mixed them together, as instructed by Dow Corning, injected them into a shell and cooked the implants in an oven.

Based on the evidence submitted by the Liaison Counsel, as to the silicone fluid/gel received from Dow Corning, there is a genuine issue of material fact that Heyer-Schulte and MEC may not have substantially altered the silicone gel they injected into the breast implant shells they manufactured. There is sufficient evidence submitted that Heyer-Schulte and MEC generally followed Dow Corning's mixing and cooking recommendations for the gel. (Condra Aff., Exs. 21-24). Heyer-Schulte and MEC may have manufactured their own breast implant shells and may have substantially altered the components and materials used for the breast implant shells. However, as to the silicone gel injected into the breast implant shells, the Court finds there is a genuine issue of material fact that the silicone gel from Dow Corning was not substantially altered by Heyer-Schulte and MEC.

5. Substantially Participate

The Litigation Facility claims that Heyer-Schulte and MEC designed and developed their own implants without Dow Corning's participation. The Liaison Counsel argues that while a claim that there is a manufacturing defect in a Heyer-Schulte and MEC implant shell, there is a defect in the gel supplied by Dow Corning and that Heyer-Schulte and MEC relied on Dow Corning as to how

the silicone gel was to be mixed. For the reasons set forth above, the Court finds there is a genuine issue of material fact that Dow Corning substantially participated in the manufacture of the silicone gel which was placed in the Heyer-Schulte and MEC breast implant shells.

The Court finds that the Litigation Facility's Motion for Summary Judgment based upon the bulk supplier, raw material supplier, and/or sophisticated purchaser defense is denied as to the silicone fluid/gel used in the Heyer-Schulte and MEC breast implants.

C. Rupture Claims

Dow Corning claims that eight of the ten Class 7 Claimants allege a sub-category rupture claim. There is no dispute that Heyer-Schulte and MEC developed their own outer shell properties which they advertised as different from and better than the same features in implants made by Dow Corning and other competitors. The Liaison Counsel agrees that these Class 7 Claimants do not have a claim against Dow Corning for the breast implant shells not manufactured by Dow Corning. The Liaison Counsel argues that because Dow Corning had knowledge that the Heyer-Schulte and MEC breast implant shells were susceptible to rupture, Dow Corning should be liable for any injuries caused by the leaked silicone gel.

In order to show a manufacturing defect case, a "plaintiff must show that the defect existed at the time the product left the manufacturer." *Johnson v. Black & Decker (U.S.), Inc.*, 408 F. Supp. 2d 353, 357 (E.D. Mich. 2005). In a design defect case, the focus is on the manufacturer of the finished product. *Prentis v. Yale Manufacturing Co.*, 365 N.W.2d 176, 185 (Mich. 1984). The supplier of component materials or parts has no duty to analyze the design and assembly of the completed product of an unrelated manufacturer to determine if the component is made dangerous by the integration into the finished product. *Citizens Ins. Co. of America v. Sears Roebuck & Co.*,

203 F.Supp.2d 837, 847 (W.D. Mich. 2002).

The Court finds there is no genuine issue of material fact that Heyer-Schulte and MEC manufactured the finished breast implants. Liaison Counsel and the Class 7 Claimants have not submitted sufficient facts to create a genuine issue of material fact that Dow Corning participated in the manufacture and the design of the outer breast implant shell, which the Class 7 Claimants argue ruptured. The Class 7 Claimants have not sufficiently alleged a rupture claim against Dow Corning as to the Heyer-Schulte and MEC breast implants. The rupture claims must be dismissed as to Dow Corning. Any failure to warn claims the Class 7 Claimants may allege regarding the silicone fluid/gel remain as to Dow Corning. However, if a Class 7 Claimant can show that their particular state's manufacturer defect or design defect laws are not the state of the law in that particular state, the Class 7 Claimant is free to file a Motion for Reconsideration within ten (10) days from the entry of this Order.

III. CONCLUSION

For the reasons set forth above, the Litigation Facility's Motion for Summary Judgment is GRANTED IN PART and DENIED IN PART as more fully set forth above. An Order will be entered in each of the cases noted. The remaining Class 7 Claimants are subject to the terms of the Amended Joint Plan of Reorganization, the Litigation Facility Agreement, and the various Case Management Orders entered in Case No. 00-00001 and any related cases.

/s/ Denise Page Hood
DENISE PAGE HOOD
United States District Judge

DATED: October 14, 2008