

**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
)	
)	

**ORDER
Bristol-Myers Squibb Summary Judgment**

For the reasons stated in the accompanying opinion, defendant Bristol-Myers Squibb's Motion for summary judgment is hereby DENIED.

This the 25th day of April, 1995.

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

Service:
Plaintiffs' Liaison Counsel
Defendants' Liaison Counsel

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**OPINION
Bristol-Myers Squibb Summary Judgment**

Under submission after appropriate discovery, extensive briefing, and oral argument is the motion for summary judgment filed by defendant Bristol-Myers Squibb Co. Bristol is the sole shareholder of Medical Engineering Corporation, a major supplier of breast implants, but has never itself manufactured or distributed breast implants. Bristol asserts that the evidence is insufficient for the plaintiffs' claims to proceed against it, whether through piercing the corporate veil or under a theory of direct liability. The parties agree that, with discovery substantially complete, this motion is ripe for decision. For the reasons stated below, the court concludes that Bristol is not entitled to summary judgment.

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, because of facts shown not to be in genuine dispute, a party is entitled to judgment as a matter of law. Material facts in genuine dispute are assumed to be favorable to the party against whom summary judgment would be entered. In deciding whether a party is entitled to a judgment as a matter of law, the court uses the same standards and burdens of production and persuasion that would apply at a jury trial.

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 Bristol's motion should be granted. Many states would call for this court, when addressing "alter ego" and other "veil piercing" issues, to apply the law of Delaware, where Bristol and MEC are incorporated. But, under choice-of-law rules in other jurisdictions, 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

For purposes of Bristol's summary judgment motion, 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.

MEC was incorporated in Wisconsin in 1969, with its principal place of business in Racine. It was an independent, privately-held corporation manufacturing a variety of medical and plastic surgery devices, including breast implants.

In 1982, after an extensive due diligence review that included information regarding capsular contracture, rupture, and gel bleed, Bristol, a Delaware corporation, purchased MEC's stock for \$28 million through a series of mergers and corporate reorganizations. Bristol created a wholly-owned subsidiary, Lakeside Engineering, Inc., a Delaware corporation, which created MEC Acquisition Corporation, a Wisconsin corporation. After MEC merged into MEC Acquisition (extinguishing MEC Acquisition), it then merged into Lakeside, and the surviving corporation changed its name to Medical Engineering Corporation. Since this series of transactions in 1982, MEC, a Delaware corporation with a principal place of business in Racine, Wisconsin, has been a wholly-owned subsidiary of Bristol, operated by Bristol as part of its Health Care Group.

In 1988 Bristol expanded its breast implant business by purchasing from the Cooper Companies two other breast-implant manufacturers, Natural Y Surgical Specialties, Inc. and Aesthetech Corporation. Though executed in the name of MEC and the Cooper Companies, the purchase was negotiated between Bristol and the Cooper Companies, and the purchase price of \$8.7 million was paid from a Bristol account (though charged to MEC). The due diligence review, which indicated potential hazards and possible liability relating to polyurethane-coated breast implants, was conducted jointly by MEC and Bristol.

Documents reflect that MEC has had, at least in form, a board of three directors, generally consisting of the Bristol Vice President then serving as President of Bristol's Health Care Group, another Bristol executive, and MEC's president. Bristol's Health Care Group President, who reported to Bristol's president or chairman, could not be outvoted by the other two MEC board members. Several of the former MEC presidents did not recall that MEC had a board, let alone that they were members; and one of these stated that he did not attend, call, or receive notice of board meetings in his five years of service because he had a designated Bristol officer to contact. The few resolutions that were adopted by MEC's board were apparently prepared by Bristol officials.

MEC prepared "significant event" reports for Bristol's Corporate Policy Committee. These reports included information on breast implant production, such as publicity, testing, expenses, lawsuit settlements, and backorders caused by sterilization difficulties. Neither Bristol managers nor MEC Presidents recall any orders or recommendations being issued by Bristol as a result of these reviews. Bristol also required MEC to prepare and submit a five-year plan for its review.

MEC submitted budgets for approval by Bristol's senior management. For this submission, MEC filled out a series of standard Bristol forms that included information on projected sales, profits and losses, cash flow, balance sheets, and capital requirements. Bristol had the authority to modify this budget, though it rarely, if ever, actually did so.

Cash received by MEC was transferred to an account maintained by Bristol. This money was credited to MEC, but the interest earned was credited to Bristol. Bristol was MEC's banker, providing such loans as it determined MEC needed. Bristol required MEC to obtain its approval for capital appropriations,¹ though most, if not all, of these requests were approved.

Bristol set the employment policies and wage scales that applied to MEC's employees. Before hiring a top executive or negotiating the salary, MEC was required to seek Bristol's approval. Before hiring a vice president of MEC, MEC's president and his superior at Bristol interviewed the candidate. Key executive employees were rated on the Bristol schedule. Bristol set a target for salary increases below the key executive level and approved those for employees above that level. Key executives of MEC received stock options for Bristol stock. MEC employees could participate in Bristol's pension and savings plans.

Bristol provided various services to MEC. Zimmer International, another Bristol subsidiary, distributed MEC breast implants but did not receive any benefit for doing so. Bristol's corporate development group assisted MEC in seeking out new product lines. Bristol's scientific experts researched the hazards of breast implants and polyurethane foam. Bristol provided funds for MEC to conduct sales contests. Bristol funded tests on breast implants. Another Bristol subsidiary, ConvaTec, assisted MEC in developing its premarket approval application (PMAA) regarding breast implants for the FDA. In addition to this assistance, Bristol hired an outside laboratory to verify ConvaTec's analysis. Bristol also conducted post-market surveillance at the request of the FDA.

¹ The evidence reflects, for example, that MEC sought this approval before purchasing a laboratory sink costing \$4600.

Some of Bristol's in-house counsel acted as MEC attorneys. These attorneys advised MEC on virtually every aspect of its business including budgets, price increases, new product development, package inserts, liability, compliance with FDA regulations, and negotiated settlements with individuals claiming damages from breast implants. They also developed the system for handling complaints about MEC products. They reviewed all breast implant promotional materials and responses to allegations of harm and liability.

Bristol's Technical Evaluation and Service Department ("TESD") performed auditing and review functions for MEC once or twice a year. They performed all Good Manufacturing Practices (GMP) audits at MEC. These audits were designed to ensure consistent quality of MEC's products. Bristol expected MEC to comply with any manufacturing deficiencies TESD found. A number of the conditions listed as needing corrective action regarded breast implants. TESD also audited MEC's sterilization and lab companies.

Bristol's public relations department issued statements regarding the allegations of TDA production and cancer in rats implanted with polyurethane implants. Bristol's corporate communication department prepared question and answer scripts for MEC employees for use in responding to questions about breast implant safety. Bristol's public affairs department developed a strategic plan to address concerns about the MEME implant and to respond to questions and concerns about the safety of breast implants in general. Bristol's press releases consistently represented that Bristol was researching breast implant safety. For example, in a release dated July 9, 1991, Bristol stated that tests underway would "confirm the well-established safety profile of polyurethane coated breast implants" and that Bristol completed testing which showed that earlier findings concerning the production of TDA from the breakdown of polyurethane were the result of inappropriate testing conditions. In a statement dated July 24, 1991, Bristol represented that numerous other studies were being undertaken to assure the public and the FDA of the safety of polyurethane coated breast implants.

Bristol's name and logo were contained in the package inserts and promotional products regarding breast implants, apparently as a marketing tool to increase confidence in the product. Bristol's name was used in all sales and promotional communications with physicians.

MEC posted a profit every year between 1983 and 1990. Total sales increased from approximately \$14 million in 1983 to \$65 million in 1990. Bristol never received dividends from MEC. Bristol prepared consolidated federal income tax returns but MEC prepared its own Wisconsin tax forms. Bristol also purchased insurance for MEC under its policy. This insurance has a face value of over \$2 billion.

Bristol's executive vice president suspended MEC's sales of polyurethane coated breast implants on April 17, 1991, and determined not to submit a PMAA for the implants to the FDA. MEC ceased its breast implant business in 1991 and later that year MEC ceased all operations by selling its urology division. This sale could not have occurred without Bristol's approval, and proceeds from the sale were turned over to Bristol, which then executed a low-interest demand note for \$57,518,888 payable to MEC. MEC's only assets at this time are this demand note and its indemnity insurance.

IV. ANALYSIS

The various theories of recovery made by plaintiffs against Bristol can be generally divided

between those involving "corporate control" and those asserting direct liability. The corporate control claims deal with piercing the corporate veil to abrogate limited liability and hold Bristol responsible for actions of MEC. The direct liability theories include strict products liability, negligence, negligent failure to warn, negligence per se for not complying with FDA regulations, misrepresentation, fraud, and participation.

A. "Corporate Control" Claims

The potential for abuse of the corporate form is greatest when, as here, the corporation is owned by a single shareholder. The evaluation of corporate control claims cannot, however, disregard the fact that, no different from other stockholders, a parent corporation is expected — indeed, required — to exert some control over its subsidiary. Limited liability is the rule, not the exception. *Anderson v. Abbott*, 321 U.S. 349, 362 (1944). However, when a corporation is so controlled as to be the alter ego or mere instrumentality of its stockholder, the corporate form may be disregarded in the interests of justice. So far as this court has been able to determine, some variation of this theory of liability is recognized in all jurisdictions.

An initial question is whether veil-piercing may ever be resolved by summary judgment. Ordinarily the fact-intensive nature of the issue will require that it be resolved only through a trial. Summary judgment, however, can be proper if, as occurred earlier in this litigation with respect to claims against Dow Chemical and Corning, the evidence presented could lead to but one result. Because the court concludes that a jury (or in some jurisdictions, the judge acting in equity) could — and, under the laws of many states, probably should — find that MEC was but the alter ego of Bristol, summary judgment must be denied.

The totality of circumstances must be evaluated in determining whether a subsidiary may be found to be the alter ego or mere instrumentality of the parent corporation. Although the standards are not identical in each state, all jurisdictions require a showing of substantial domination. Among the factors to be considered are whether:

- the parent and the subsidiary have common directors or officers
- the parent and the subsidiary have common business departments
- the parent and the subsidiary file consolidated financial statements and tax returns

- the parent finances the subsidiary
 - the parent caused the incorporation of the subsidiary
 - the subsidiary operates with grossly inadequate capital
 - the parent pays the salaries and other expenses of the subsidiary
 - the subsidiary receives no business except that given to it by the parent
 - the parent uses the subsidiary's property as its own
 - the daily operations of the two corporations are not kept separate
- the subsidiary does not observe the basic corporate formalities, such as keeping separate books and records and holding shareholder and board meetings.

United States v. Jon-T Chemicals, Inc., 768 F.2d 686, 691-92 (5th Cir. 1985), *cert. denied* 475 U.S. 1014 (1986).

The fact-finder at a trial could find that the evidence supports the conclusion that many of these factors have been proven: two of MEC's three directors were Bristol directors; MEC was part of Bristol's Health Care group and used Bristol's legal, auditing, and communications departments; MEC and Bristol filed consolidated federal tax returns and Bristol prepared consolidated financial reports; Bristol operated as MEC's finance company, providing loans for the purchase of Aesthetech and Natural Y, receiving interest on MEC's funds, and requiring MEC to make requests for capital appropriations; Bristol effectively used MEC's resources as its own by obtaining interest on MEC's money and requiring MEC to make requests for capital appropriations to obtain its own funds; some members of MEC's board were not aware that MEC had a board of directors, let alone that they were members; and the senior Bristol member of MEC's board could not be out-voted by the other two directors. These facts, even apart from evidence that might establish some of the other factors listed above, would provide significant support for a finding at trial that MEC is Bristol's alter ego.

Bristol contends that a finding of fraud or like misconduct is necessary to pierce the corporate veil. Despite Bristol's contentions to the contrary, Delaware courts — to which Bristol would have this court look — do not necessarily require a showing of fraud if a subsidiary is found to be the mere

instrumentality or alter ego of its sole stockholder. See *Geyer v. Ingersoll Publications Co.*, 621 A.2d 784, 793 (Del.Ch. 1992), *Mabon, Nugent & Co. v. Texas American Energy Corp.*, 16 Del. J. Corp. L 829, 838 (Del.Ch. 1990), and *Skouras v. Admiralty Enterprises, Inc.*, 386 A.2d 674, 681 (Del.Ch. 1978). In addition, many jurisdictions that require a showing of fraud, injustice, or inequity in a contract case do not in a tort situation. See *Jon-T Chemicals*, 693 F.2d at 692. A rational distinction can be drawn between tort and contract cases. In actions based on contract, "the creditor has willingly transacted business with the subsidiary" although it could have insisted on assurances that would make the parent also responsible. *Id.* at 693. In a tort situation, however, the injured party had no such choice; the limitations on corporate liability were, from its standpoint, fortuitous and non-consensual.

There is, however, evidence precluding summary judgment even in jurisdictions that require a finding of fraud, inequity, or injustice. This conclusion is not based merely on the evidence that, even accepting Bristol's contentions regarding the amount of insurance available to MEC, MEC may have insufficient funds to satisfy the potential risks of responding to, and defending against, the numerous existing and potential claims of the plaintiffs. Equally significant is the fact that Bristol permitted its name to appear on breast implant advertisements, packages, and product inserts to improve sales by giving the product additional credibility. Combined with the evidence of potentially insufficient assets, this fact would support a finding that it would be inequitable and unjust to allow Bristol now to avoid liability to those induced to believe Bristol was vouching for this product.

Because the evidence available at a trial could support — if not, under some state laws, perhaps mandate — a finding that the corporate veil should be pierced, Bristol is not entitled through summary judgment to dismissal of the claims against it.

B. Direct Liability Claims

There is an additional reason why Bristol is not entitled to summary judgment. Under the law in most jurisdictions, it may also be subject to liability under at least one of the direct liability claims made by plaintiffs; namely, the theory of negligent undertaking pursuant to Restatement (Second) of Torts § 324A. That section provides:

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, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to [perform]² 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 a 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 defendant itself. The existence of a parent-subsidary relationship, while not required, is obviously no defense to such a claim.

Of the many actions of Bristol asserted by plaintiffs as constituting such undertakings, some involve activities of Bristol's legal staff. In particular, Bristol's in-house counsel reviewed and approved warnings in package inserts and other information given by MEC to physicians. Bristol contends that, because these employees were attorneys, their actions do not represent its undertakings under § 324A. Citing a case involving the parent's hiring of outside counsel for its subsidiary, *Sanders v. Mapco, Inc.*, 1987 WL 5895 (D.Md. Jan. 28, 1987), *aff'd* 829 F.2d 36 (4th Cir. 1987), Bristol argues that an attorney's actions should not be imputed to the parent corporation. Unlike the situation in *Sanders*, however, the attorneys designated by Bristol to assist MEC would have had responsibilities not just to MEC but to their employer, Bristol, as well. Whether there was any failure on their part to use reasonable care in the performance of their responsibilities need not now be assessed; the point rather is that the fact-finder at a

² 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).

trial could consider their actions as undertakings by Bristol.

By allowing its name to be placed on breast implant packages and product inserts, Bristol held itself out as supporting the product, apparently to increase confidence in the product and to increase sales. Bristol also issued press releases stating that polyurethane-coated breast implants were safe. Having engaged in this type of marketing, it cannot now deny its potential responsibility under § 324A.

Bristol attempts to distinguish cases involving claims by employees of an inspected company, arguing that any duty under § 324A should not extend to purchasers and users of another company's products. The duty, however, covers undertakings that should be recognized as necessary for the protection of others, not only by actually increasing the risk of harm but also by being relied upon by such persons. As with many other torts, the duty is measured in terms of reasonable foreseeability. In this case, by both conducting tests relating to MEC implants and making public statements regarding the safety of such implants, Bristol can be held to have assumed a duty of reasonable care towards potential users who might rely upon such tests and statements.

Bristol has probably been named as a defendant in some cases involving implants sold before its acquisition of MEC in 1982 or before it undertook to conduct and publicize tests relating to safety of implants. It may also have been named as a defendant in some cases involving Natural Y and Aesthetech implants sold before acquisition of these companies in 1988. The extent, if any, of Bristol's potential liability under § 324A in such cases will likely depend not only on questions of proximate causation but also on whether the particular jurisdiction imposes any post-sale duty to warn on manufacturers and suppliers of products. This opinion does not attempt to resolve the special issues that may be presented in such cases.

Plaintiffs have asserted various other direct liability claims against Bristol in addition to those under § 324A. Having concluded that, because of genuine disputes relating to corporate control issues and relating to potential liability under § 324A, Bristol is not entitled to summary judgment, the court declines to address such alternative causes of action.

V. CONCLUSION

By separate order, Bristol's motion for summary judgment will be denied. As with other orders

denying summary judgment, this decision is interlocutory and does not constitute a holding that Bristol is liable to the plaintiffs.

This the 25th day of April, 1995.

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