UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

In Re:

Settlement Facility Dow Corning Trust.

Case No. 00-00005
Honorable Denise Page Hood

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MEMORANDUM OPINION AND ORDER
REGARDING TISSUE EXPANDER ISSUE

I. BACKGROUND

On June 1, 2004, the Amended Joint Plan of Reorganization ("Plan") became effective governing the Dow Corning Corporation bankruptcy matter. The Court retains jurisdiction over the Plan "to resolve controversies and disputes regarding interpretation and implementation of the Plan and the Plan Documents" and "to allow, disallow, estimate, liquidate or determine any Claim, including Claims of a Non-Settling Personal Injury Claimant, against the Debtor and to enter or enforce any order requiring the filing of any such Claim before a particular date." (Plan, §§ 8.7.3, 8.7.4, 8.7.5)

The Settlement Facility-Dow Corning Trust ("SF-DCT") implements the claims of those claimants who elected to settle their claims under the Settlement Program of the Plan. (Plan, § 1.131) The SF-DCT was established to resolve Settling Personal Injury Claims in accordance with the Plan. (Plan, § 2.01) The Settlement Facility and Fund Distribution Agreement ("SFA") and Annex A to the SFA establish the exclusive criteria by which such claims are evaluated, liquidated, allowed and paid. (SFA, § 5.01) The process for resolution of claims is set forth under the SFA and corresponding claims resolution procedures in Annex A. (SFA, § 4.01)

Section 5.05 of the SFA provides that the Debtor's Representatives and the Claimants Advisory Committee ("CAC") may submit joint interpretations and clarifications regarding submissions of claims to the Claims Administrator. The CAC and the Debtor entered into a June 11, 2004 Stipulation and Order Establishing Procedures for Resolution of Disputes Regarding Interpretation of the Amended Joint Plan ("Procedures"). If there is a dispute between the Debtor's Representatives and the CAC, the Claims Administrator may resolve the issue or the issue may be raised before the Court by way of a motion pursuant to the June 11, 2004 Procedures. Section 2.01 of the Procedures provides that "these procedures will apply to disputes arising out of the interpretation or application of the Claims Resolution Procedures–Annex A to the Settlement Facility Agreement–and any claims operations functions set out in the Settlement Facility Agreement." (Plan Interpretation Procedures, § 2.01(a)) After a meet and confer period and submitting the issue before the Claims Administrator, either party may bring the matter before this Court. (Plan Interpretation Procedures, § 2.01(c) and (d)) The SFA and the Procedures authorize only the Debtor's Representatives and the CAC to file a motion to interpret a matter under the SFA. There is no provision under the SFA or the Procedures which allows a claimant to submit an issue to be interpreted before the Court.

The need for this Plan interpretation arose in 1999 at the request of the Claims Administrator of the SF-DCT for advice on whether tissue expanders were breast implants as defined in the Plan. Pursuant to the Procedures, Section 5.05, the CAC submitted its position statement to the Claims Administrator on September 19, 2003 and DCC submitted its response on October 3, 2003. The Claims Administrator held a conference with the CAC and DCC on June 22, 2004 and on June 28, 2004, issued a written statement declining to decide the issue, pursuant to Section 2.01(c)(4) of the

Stipulation. The CAC and DCC then filed these cross-motions pursuant to Section 2.01(d)(2) of the Stipulation.

The CAC filed a Motion to Interpret the Amended Joint Plan Section 1.17 Regarding the Definition of "Breast Implant." Dow Corning Corporation ("DCC") thereafter filed a Motion for A Determination that Tissue Expanders Do Not Constitute Breast Implants for Purposes of Eligibility for Settlement Benefits Under the Dow Corning Amended Joint Plan of Reorganization. Each party filed a Response. These motions were filed pursuant to the June 11, 2004 Procedures seeking an interpretation of the language of Section 1.17 of the Plan, specifically whether tissue expanders implanted in the breast meet the definition of "Breast Implants."

II. ANALYSIS

A. Plan Interpretation

Generally, the provisions of a confirmed plan bind the debtor and any creditor. 11 U.S.C. § 1141(a). In interpreting a confirmed plan, courts use contract principles, since the plan is effectively a new contract between the debtor and its creditors. *In re Dow Corning Corporation,* 456 F.3d 668, 676 (6th Cir. 2006); *see, Hillis Motors, Inc. v. Hawaii Auto. Dealers' Ass'n,* 997 F.2d 581, 588 (9th Cir.1993). State law governs those interpretations, and under long-settled contract law principles, if a plan term is unambiguous, it is to be enforced as written, regardless of whether it is in line with parties' prior obligations. *In re Dow Corning,* 456 F.3d at 676. A term is deemed ambiguous when it is "capable of more than one reasonable interpretation." *Id.* The Court has no authority to modify this language. Although bankruptcy courts have broad equitable powers that extend to approving plans of reorganization, these equitable powers are limited by the role of the bankruptcy court, which is to "guide the division of a pie that is too small to allow each creditor to

get the slice for which he originally contracted." *Id.* at 677-78 (quoting *In re Chicago*, 791 F.2d 524, 528 (7th Cir.1986)). "A bankruptcy court's exercise of its equitable powers is cabined by the provisions of the Bankruptcy Code." *Id.* at 678 (citing *In re Highland Superstores, Inc.*, 154 F.3d 573, 578-79 (6th Cir.1998)). New York law governs the interpretation of the Plan. (Plan, § 6.13) Under New York law, a court must first decide whether the contract is ambiguous. *B.F. Goodrich Co. v. U.S. Filter Corp.*, 245 F.3d 587, 595 (6th Cir. 2001).

The CAC asserts that the proper standard of review is *de novo*, even though nothing in the Stipulation specifies the standard of review when the Claims Administrator declines to issue a decision. The Court agrees.

B. Tissue Expander

1. "Breast Implant" Definition

The language of the Plan provides that to receive benefits under Classes 5, 6.1 or 6.2, claimants must have been implanted with a Breast Implant. Section 1.17 of the Plan defines Breast Implant:

> **"Breast Implant"** means all silicone gel and saline-filled breast implants with silicone elastomer envelopes manufactured and either sold or otherwise distributed by the Debtor.

(Plan, § 1.17). The CAC argues that DCC's tissue expander meets all four of the criteria listed in the definition: 1) the breast design tissue expander is filled with saline; 2) the breast design tissue expanders were intended to and in fact were implanted in the breast; 3) the tissue expanders have a silicone envelope; and 4) the tissue expander is manufactured and either sold or otherwise distributed by the Debtor, DCC. (CAC Motion to Interpret, p. 3) The CAC argues that the product information supports its contentions. The Dow Corning Wright Silastic Tissue Expander H.P.

information states:

> The SILASTIC© Percutaneous Tissue Expander is an inflatable envelope made of high performance medical grade silicone elastomer. It is designed for temporary subcutaneous implantation. After wound healing, the implant is slowly inflated by a series of percutaneous injections of sterile, isotonic saline.

(CAC Motion to Interpret, Exhibit 1). The product literature notes the tissue expander is produced by "DCC & DCW." The product label describes the product as "Tissue Expander Implant." (CAC Motion to Interpret, Exhibit 2)

2. Silicone Envelope and Manufactured by DCC

There is no dispute as to parts 3 and 4 of the definition. The tissue expanders produced by DCC have a silicone envelope. DCC manufactured, marketed and distributed three styles of tissue expanders with a breast design. (CAC Motion to Interpret, Exhibits 1 and 2; Jakubczak Affidavit, ¶¶ 6-8, 13)

3. Saline Filled

There is also no dispute that at some point in its use the tissue expander is filled with saline. DCC states that the tissue expanders were intended for short term use only. They were placed under the skin and inflated over a period of weeks with saline filler, expanding its volume and stretching the overlying skin. (Jakubczak Affidavit, ¶¶ 6, 8, 9) Some tissue expanders were filled with saline more quickly. The tissue expanders have a fill valve, accessible though the skin that could be seen and felt, unlike a breast implant with smooth, natural looking surfaces. (Jakubczak Affidavit, ¶¶ 5, 9)

DCC notes that the tissue expanders were also sold without the saline filling. As such, a tissue expander does not qualify as a "Breast Implant" under the definition in the Plan. The CAC

claims that the definition does not indicate when the implant must be filled with saline, therefore, this does not disqualify the tissue expander under the definition. The CAC also notes that some saline breast implants are not filled with saline at the time of manufacture, but filled at the time of implantation, like the tissue expanders. (CAC Response, p.3, n. 1). DCC, however, asserts that the Dow Corning breast implants were filled with silicone gel or saline before implantation.

The Plan definition of "Breast Implant" makes no mention of when the implant is filled with saline. The Court finds that the tissue expanders meet the definition requiring that the product be saline-filled.

4. Implanted in the Breast

The CAC submits the product literature indicates that the tissue expander is designed to be implanted in the breast, albeit for a temporary period. Only three styles of the tissue expanders were designed for implantation in the breast. (CAC Motion to Interpret, Exhibit 2) To the extent that a tissue expander was not implanted in the breast and was not designed to be implanted in the breast, it does not meet the definition of "Breast Implant" under the Plan. Although DCC suggests a testicular tissue expander might be implanted in the breast for some reason, the Court finds this unlikely and agrees that a testicular tissue expander even if implanted in the breast would not meet the definition of "Breast Implant."

DCC claims that the tissue expanders are not "Breast Implants" because they are short term devices used to expand body tissue in preparation for reconstructive surgery. (DCC Motion for Determination, p. 3) DCC also argues that the tissue expanders were not designed to function as implants and were marketed as an entirely different product than breast implants. DCC notes that over 250 different types, styles and sizes of tissue expanders were made, marketed and sold by DCC

between 1982 and 1992. Some of the variety of shapes, rectangle, square, crescent, were incompatible with use as breast implants and were used in other parts of the body. (Jakubczak Affidavit, ¶7) The function of the tissue expanders was to stretch the skin to accommodate a long term implant device or for other reconstructive surgery. (Jakubczak Affidavit, ¶6) Tissue expanders were also used to repair skin defects or to facilitate wound closure. The tissue expanders were designed to be inserted into the body for short periods in preparation for breast implantation and were never marketed for permanent use. DCC submits that the Gibney RDL-Xpand, an adjustable mammary prosthesis and the Mentor Becker Expander/Mammary Prosthesis, were products that converted from tissue expander to mammary prosthesis and remained permanently in the breast, unlike the DCC product. (Jakubczak Affidavit, ¶6) DCC seems to suggest that the Gibney product and the Becker product could qualify as "Breast Implants" because of their ability to convert to a permanent breast implant, unlike the Dow Corning tissue expanders. The Dow Corning tissue expanders were intended for temporary use, unlike the Dow Corning breast implants that were designed for long term implantation. (Jakubczak Affidavit, ¶10)

The Court finds that nothing in the "Breast Implant" definition requires that an implant be implanted for a long term period. There is no imposition of any time limitation in the definition.

DCC also argues that in order to be a "Breast Implant," the product must be named and designated as a breast implant, noting that DCC did not refer to tissue expanders as breast implants in the product literature. Nor did medical professionals refer to tissue expanders as breast implants. (Jakubczak Affidavit, ¶¶11, 12) However, there is no requirement that the product must be designated or identified by DCC and others as "breast implant" in order to meet the "Breast Implant" Plan definition, although the definition does use the term "breast implant." There is no definition

within the "Breast Implant" definition as to the meaning of the term "breast implant" in lower case.

DCC further claims that tissue expanders are deemed "unclassified medical devices" by the United States Food and Drug Administration ("FDA") while "breast implants" were classified in Class II and ultimately Class III by the FDA. DCC further argues that the FDA treated tissue expanders differently than breast implants noting that the guidance document for "saline, Silicone Gel and Alternative Breast Implants specifically did not address tissue expanders because of their short term use and because the FDA regulated tissue expanders differently. (Jakubczak Affidavit, ¶13) DCC claims it had unique product identifiers for its breast implants, but not for tissue expanders, consistent with DCC's position that tissue expanders are not breast implants. In preparation for use in Annex A, Schedule I, DCC was not asked to provide such product identifiers for tissue expanders. (Jakubczak Affidavit, ¶15) However, the CAC notes that SILASTIC, the brand under which certain Dow tissue expanders were marketed is an eligible brand name for breast implants under the Plan.

Additionally, DCC claims that if tissue expanders were to be included as "Breast Implants," the language would have expressly so indicated. The fact the tissue expanders are not mentioned as "Breast Implants" belies their inclusion in the Plan definition.

The Court finds that the failure to specifically name tissue expanders within the "Breast Implants" definition does not preclude tissue expanders which meet the criteria listed in Section 1.17. "Tissue Expanders" are not defined under the Plan definitions. The "Other Products" definition also does not specifically include tissue expanders implanted in the breast:

> "**Other Products**" means metal, silicone or silicone-containing products, other than Breast Implants and raw materials used in the manufacture of a Non-Dow Corning Breast Implant or a Non-Dow Corning Implant, manufactured by the Debtor or any of its Joint

> Ventures or Subsidiaries for implant into humans, including, but not limited to: (a) reconstruction and aesthetic surgery products (including custom implants) such as facial components, nasal and chin implants, testicular and penile implants, or medical treatments, (b) orthopedic products such as for use in legs, hips, knees, ankles, wrists, hands, fingers, toes and wrists, (c) silicone temporomandibular joint (TMJ) implants using medical grade or HP sheeting, the Wilkes implant or Silastic Block, (d) medical products for use in the head, heart or eyes, and (e) fluids. The inclusion of fluids among Other Products is not an admission of any Dow Corning responsibility for, or the potential for Allowance of Claims relating to, silicone injections.

(Plan, § 1.117). The parties could have expressly included tissue expanders in this definition if the parties intended to exclude tissue expanders designed to be implanted in the breasts. Tissue expanders designed to be implanted in the breasts are not included in the "Other Products" definition in contrast to the express language that products for use in other areas of the body are noted in the "Other Products" definition. The "Other Products" definition would exclude from the "Breast Implant" definition a gel-filled testicular implant that was implanted in the breast area, as noted by the DCC. (DCC Motion for Determination, p. 4) However, tissue expanders designed to be implanted in the breasts are not expressly excluded from the "Breast Implant" definition and are not expressly included in the "Other Products" definition.

The Court further finds that those tissue expanders meeting the definition stated above, specifically tissue expanders designed for and implanted in the breast, are within the meaning of "Breast Implant" defined in Section 1.17 of the Plan. As noted by the CAC, there are only three tissue expanders designed for breast implantation, not the 250 or more noted by the DCC.

5. Tissue expanders under the Revised Settlement Plan

The CAC contends that according to information from SF-DCT, tissue expanders were "treated like implants for purposes of disease claims. However, tissue expanders made by Dow

Corning did not trigger the 50% reduction in benefits that the breast implants did." (CAC Motion to Interpret, Exhibit 3, E-mail from vwillard@sfdct.com to Deborah@thefineberggroup.com, dpend440@aol.com and copied to EWHuber@sfdct.com) Claimants with tissue expanders manufactured by Baxter, Bristol and 3M did receive some settlement benefits under the Revised Settlement Program ("RSP") in the MDL-926 breast implant multi-district litigation before the United District Court for the Northern District of Alabama. DCC claims this was an affirmative decision on the part of parties to the RSP with respect to some tissue expanders. However, DCC argues that the Plan Proponents made no such decision with respect to tissue expanders under the Plan because the products would have been otherwise listed as acceptable products. The tissue expanders made by Dow Corning did not trigger the 50% reduction in benefits as did breast implants lending credibility to DCC's claim that even under the RSP tissue expanders were not considered "Breast Implants."

The CAC argues that under Section 4.03(a) of the Settlement Facility and Fund Distribution Agreement ("SFA"), the SF-DCT Claims Administrator is required to follow the RSP processing guidelines and that these guidelines treated tissue expanders as Breast Implants. (CAC Motion to Interpret, Exhibit 3) The CAC further argues that DCC provides no support for a Plan modification of those processing guidelines with respect to tissue expanders. DCC, however, contends that to the extent the Plan sets forth different criteria different from the MDL that SF-DCT must follow the Plan, the Plan having no provision for treating tissue expanders as Breast Implants.

In further support of its argument DCC asserts that testimony regarding tissue expanders was never presented at the estimation hearing before the Bankruptcy Court. As such, tissue expanders were never included in the evaluation of potential settling claims and the corresponding claims

values. (DCC Motion for Determination, p. 6) DCC claims that at this point the inclusion of tissue expanders would be a Plan modification, requiring new product identification manuals and new training sessions, and perhaps reducing the payments to eligible Breast Implant claimants.

Because the Court has determined above, without considering the evidence involving the MDL and post-confirmation proceedings, that tissue expanders designed specifically for and implanted in the breast meet the definition of "Breast Implant" set forth in the Plan at Section 1.17, such evidence is not required to determine whether tissue expanders meet the definition of "Breast Implant." The Court does not agree with DCC's argument that including tissue expanders modifies the Plan, in light of the fact that both parties submitted the issue for the Court's determination under the Procedures agreed to by the DCC and the CAC. The Plan further allows the Court to "remedy any defect or omission or reconcile any inconsistency" in the Plan at the request of the Plan Proponents. (Plan, § 11.4)

III. CONCLUSION

For the reasons set forth above, the Court finds that a tissue expander specifically designed for implantation in the breasts and implanted in the breasts meet the definition of "Breast Implant" under Section 1.17 of the Plan. The CAC notes only three styles of tissue expanders were designed to be implanted in the breasts.

Accordingly,

IT IS ORDERED that the SF-DCT Claims Administrator apply the Court's interpretation as noted above in the review of claims involving tissue expanders.

IT IS FURTHER ORDERED that the Motion of Claimants' Advisory Committee to Interpret the Amended Joint Plan Section 1.17 Regarding the Definition of "Breast Implant" **(Doc. No. 40,**

filed July 19, 2004) is GRANTED as more fully set forth above.

IT IS FURTHER ORDERED that the Motion of Dow Corning Corporation for a Determination that Tissue Expanders Do Not Constitute Breast Implants for Purposes of Eligibility for Settlement Benefits under the Dow Corning Amended Joint Plan of Reorganization **(Doc. No. 51, filed July 19, 2004)** is DENIED as more fully set forth above.

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

DATED: June 10, 2009