
Case No. 09-1827

**In The United States Court of Appeals
for the Sixth Circuit**

In re: SETTLEMENT FACILITY DOW CORNING TRUST

DOW CORNING CORPORATION,

Interested Party - Appellant,

v.

CLAIMANTS' ADVISORY COMMITTEE,

Interested Party - Appellee.

**On Appeal From The United States District
Court For The Eastern District of Michigan**

BRIEF OF APPELLANT DOW CORNING CORPORATION

Deborah Greenspan
DICKSTEIN SHAPIRO LLP
1825 Eye Street, N.W.
Washington, DC 20006
(202) 420-3100

John Donley
Douglas G. Smith
David Mathues
KIRKLAND & ELLIS LLP
300 North LaSalle Street
Chicago, IL 60654
(312) 862-2000

Counsel for Appellant Dow Corning Corporation

**STATEMENT OF CORPORATE AFFILIATIONS
AND FINANCIAL INTEREST**

Pursuant to 6th Cir. R. 26.1, Dow Corning Corporation makes the following disclosure:

1. Is said party a subsidiary or affiliate of a publicly owned corporation? **YES.**

If the answer is YES, list below the identity of the parent corporation or affiliate and the relationship between it and the named party:

SEE ANSWER TO NO. 2 BELOW.

2. Is there a publicly owned corporation, not a party to the appeal, that has a financial interest in the outcome? **YES.**

If the answer is YES, list the identity of such corporation and the nature of the financial interest:

Dow Corning Corporation is 50% owned by Corning Incorporated, and 50% owned by Dow Holdings, Inc., a wholly owned subsidiary of The Dow Chemical Company. Further, various publicly-owned corporations may be creditors of Dow Corning's Chapter 11 bankruptcy estate, but Dow Corning believes their interests are too attenuated to present any conflict issues here.

/s/ Douglas G. Smith

Douglas G. Smith

KIRKLAND & ELLIS LLP

300 North LaSalle Street

Tel: (312) 862-2000

Fax: (312) 862-2200

douglas.smith@kirkland.com

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STATEMENT IN SUPPORT OF ORAL ARGUMENT

Oral argument is requested. Oral argument will allow the attorneys for the parties to address any outstanding factual or legal issues that the Court deems relevant and will assist the Court in its decision.

INTRODUCTION

This case involves a district court ruling that is contrary to the plain language of Dow Corning's Amended Joint Plan of Reorganization and would result in the payment of numerous ineligible claims from the limited and capped settlement fund created by the Plan. Specifically, the district court held that tort claims arising from the use of "tissue expander" devices are eligible to receive a distribution from the settlement fund created for breast implants under Dow Corning's Plan, even though the Plan provisions discussing which Dow Corning devices are eligible for the settlement option make no reference to "tissue expanders" and specifically limit eligibility to "Breast Implants," which are defined to require that the patient actually had breast implants, as opposed to some other medical device.

The record establishes that medical practitioners do not consider "tissue expanders" to be "breast implants" and that Dow Corning marketed tissue expanders as unique products with designs, functions and uses distinct from breast implants. Unlike breast implants, which serve the long-term function of augmenting the breast or replacing portions of a surgically removed breast, tissue expanders have an entirely different function: temporary insertion to propagate skin and tissue growth before reconstructive surgery. They are thus used in all areas of the body, not just the breast, to create sufficient surrounding tissue for

surgical placement of a long-term implant or surgical repair of a burn or skin wound. Accordingly, the FDA classifies and regulates tissue expanders separately from breast implants.

The district court disregarded both the Plan definition and this well-established usage and asserted that individuals treated with “tissue expanders” are nonetheless entitled to participate in the Plan’s settlement program for individuals with qualified “Breast Implants.” The district court’s ruling was plainly wrong and should be reversed.

STATEMENT OF JURISDICTION

The district court exercised jurisdiction pursuant to 28 U.S.C. § 1334. This Court has jurisdiction to review the district court’s June 10, 2009 final order pursuant to 28 U.S.C. § 1291. (*See* Record Entry No. 673, 6/10/09 Opinion.) Dow Corning filed a timely notice of appeal on June 19, 2009. (*See* Record Entry No. 674, 6/19/09 Notice of Appeal.)

STATEMENT OF THE ISSUE FOR REVIEW

Whether the district court erred in holding that “tissue expanders” used in the breast are “Breast Implants” for purposes of distributing assets of the settlement program for Dow Corning breast implants established in Dow Corning’s Amended Joint Plan of Reorganization, given that the Plan language governing that program does not mention or provide any eligibility criteria for “tissue

expanders,” and the district court acknowledged that the medical community does not consider tissue expanders to be breast implants.

STATEMENT OF THE CASE AND THE FACTS

I. Background

This Court has previously discussed the history of Dow Corning’s bankruptcy proceedings and Amended Joint Plan of Reorganization. *See, e.g., In re Dow Corning Corp.*, 280 F.3d 648 (6th Cir. 2002); *In re Dow Corning Corp.*, 86 F.3d 482 (6th Cir. 1996). Accordingly, only the relevant portions of that history are summarized here.

A. Breast Implants

Dow Corning began selling silicone-gel-filled breast implants in the early 1960s. *See In re Dow Corning Corp.*, 211 B.R. 545, 550 (Bankr. E.D. Mich. 1997); Record Entry No. 51 Ex. A, Jakubczak Aff. ¶ 5. Breast implants were intended for long-term implantation in the breast for cosmetic and reconstructive purposes. (Record Entry No. 51 Ex. A, Jakubczak Aff. ¶ 5.) Their function was to permanently augment or replace natural breast tissue. They were designed to be natural looking, and thus did not contain any “fill valves” that would be seen or felt through the skin. (*Id.*)

In the 1980s, concerns began to emerge regarding a hypothesized relationship between silicone breast implants and various auto-immune diseases, such as lupus, scleroderma, and rheumatoid arthritis. *See In re Dow Corning*, 280

F.3d at 653. In 1992, the FDA requested that manufacturers voluntarily halt the sale of breast implants, and the manufacturers complied except for limited, FDA-sanctioned uses. *See In re Dow Corning*, 280 F.3d at 653; Institute of Medicine, *Safety of Silicone Breast Implants* 30-31 (S. Bondurant et al. eds. 1999), available at http://www.nap.edu/catalog.php?record_id=9602 (last accessed October 12, 2009) (“IOM Report”).

This suggested, but unproven, link between breast implants and disease led to tens of thousands of personal injury claims in the early 1990s, ultimately forcing Dow Corning to file for Chapter 11 bankruptcy protection to resolve the breast implant suits. *See In re Dow Corning Corp.*, 280 F.3d at 653; *In re Dow Corning*, 86 F.3d at 485. While the link between breast implants and disease was subsequently disproven and the scientific consensus today is that there is “no elevated relative risk or odds ratio for an association of implants with disease,”¹

¹ (IOM Report at ES-7.) In 1997, Congress asked the Department of Health and Human Services to sponsor a study of the safety of silicone breast implants by the Institute of Medicine of the National Academy of Sciences. The IOM found that “there is no convincing evidence to support clinically significant immunologic effects of silicone or silicone breast implants.” (*Id.* at 197.) The “Independent Review Group” commissioned by the United Kingdom’s Chief Medical Officer likewise found that “[t]here is no epidemiological evidence for any link between silicone gel breast implants and any established connective tissue disease.” (Silicone Gel Breast Implants, The Report of the Independent Review Group 6 (July 1998), available at <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Breastimplants/Siliconegelbreastimplants/IndependentReviewGroup-siliconegel>

(Continued...)

given the overwhelming number of breast implant claims, Dow Corning had no option in 1995 but to seek relief under Chapter 11. *See In re Dow Corning*, 211 B.R. at 553.

B. Tissue Expanders

The term “tissue expander” defines a category of products quite separate and distinct from breast implants, with different characteristics, uses, and functions. (Record Entry No. 51 Ex. A, Jakubczak Aff. ¶¶ 11, 12.) Since their first sale by Dow Corning in 1982, tissue expanders were marketed and sold as a completely different product. (*Id.* ¶¶ 6, 10-13.) They are short-term devices, designed to be used for a few weeks or months only. They are not intended to augment or replace breast tissue. Rather, their sole function is to facilitate the short-term growth of skin and other tissue in preparation for surgical placement of an implant or surgical repair of a burn or skin wound. (*Id.* ¶ 6.) This function is qualitatively different

breastimplants/index.htm (last accessed October 12, 2009).) Given this scientific consensus, the FDA reversed its prior moratorium on silicone gel breast implants, finding that “no cause and effect relationship has been established between breast implants and these conditions,” and permitted widespread sales to resume. (FDA, Summary of Safety & Effectiveness Data, Silicone Gel-Filled Breast Implants (Notice of Approval to Mentor re Mentor MemoryGel Silicone Gel-Filled Breast Implants PMA No. P030053) 3 (Nov. 17, 2006), available at http://www.accessdata.fda.gov/cdrh_docs/pdf3/p030053a.pdf (last accessed October 12, 2009).)

from that of breast implants, which are intended to remain in the body for years, serving permanent space-filling and aesthetic functions. (*Id.* ¶¶ 5, 12.)

Unlike breast implants, tissue expanders were not designed exclusively, or primarily, for use in the breast area. Dow Corning made over 250 types, sizes and styles of tissue expanders for short-term use before reconstructive surgery around the body. Only three of these types could be used in the breast region, and indeed, many shapes and sizes of tissue expanders (*e.g.*, rectangle, square, crescent, and round) are incompatible with use in the breast region. (*Id.* ¶ 7.) Because tissue expanders' design was fundamentally different from breast implants, the American Society for Testing and Materials had separate and unique standards for the manufacture of, respectively, tissue expanders and breast implants.²

Surgeons would place a tissue expander under the skin in the appropriate location and then gradually, over a period of weeks, add saline filler hypodermically to expand the device's volume, thus stretching the overlying skin. (*Id.* ¶¶ 6, 8, 9.) Tissue expanders had a metal fill valve that was accessible through

² Compare ASTM, *Standard Specification for Implantable Breast Prostheses* 1997, at 1 (ASTM F703-96) (describing requirements for manufacturer of "breast prostheses") with ASTM, *Standard Specification for Soft-Tissue Expander Devices* 1993, at 1 (ASTM F1441-92) (describing requirements for manufacture of "tissue expansion devices to be used intraoperatively or implanted for typically less than 6 months and then removed").

the skin and could be seen and felt when inserted. (*Id.* ¶ 9.) Dow Corning tissue expanders were not filled with silicone gel. (*Id.* ¶ 8.)

After serving their temporary function of facilitating skin growth, tissue expanders were surgically removed. Consistent with their distinct design and function, Dow Corning product literature marketed its tissue expander products as short-term devices (not long-term implants) whose sole purpose was to prepare the area for reconstructive surgery. (*Id.* ¶ 10.) Dow Corning’s product literature described the products as “tissue expanders” or “percutaneous skin expanders” – not “breast implants.” (*Id.* ¶¶ 11, 14; *see also* Record Entry No. 40 Ex. 1, Dow Corning Wright Silastic Tissue Expander H.P. at 1.)

Medical professionals and the FDA consider breast implants and tissue expanders to be distinct products. (Record Entry No. 51 Ex. A, Jakubczak Aff. ¶¶ 12-13.) Since it began regulating medical devices in 1976, the FDA has treated breast implants as at least a Class II regulated device.³ In 1988, the FDA raised the classification for breast implants to Class III, a category that requires the highest

³ Products are placed in Class II when the FDA concludes that measures beyond labeling and regulation of the manufacturing process are necessary to control product risks. *See* 21 U.S.C. § 360c(a)(1)(B). These additional measures, called special controls, may include performance standards, postmarket studies, user education, or other measures. The 1976 Medical Device Amendments empowered the FDA for the first time to regulate medical devices. (Record Entry No. 51 Ex. A, Jakubczak Aff. ¶ 13.)

level of premarket approval. (*Id.* ¶ 13.) In contrast, the FDA has always categorized tissue expanders as “unclassified medical devices.” (*Id.*)⁴

Myriad FDA publications make clear that tissue expanders and breast implants are separate and distinct products with different functions. In a 1998 Informational Update, for example, the FDA described tissue expanders as products used on a temporary basis *before* surgical placement of breast implants to facilitate the growth of chest tissues surrounding a pocket into which, once the expander is removed, the implant is then inserted.⁵ In a 2000 “Breast Implant Consumer Handbook,” the FDA cautioned that tissue expanders “are not to be

⁴ In 2008, the FDA proposed placing tissue expanders in Class II. *See* 73 Fed. Reg. 78239 (Dec. 22, 2008). However, to date, it has not done so. It did, however, issue a draft Guidance Document that, once again, stated that tissue expanders were not breast implants: “This guidance document is not intended for a breast implant device. For information regarding breast implants, please refer to the guidance entitled Saline, Silicone Gel, and Alternative Breast Implants.” (USDHS, Class II Special Controls Guidance Document: Tissue Expander 3 (2008), available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070819.htm> (last accessed October 12, 2009).)

⁵ *See* FDA, Breast Implants: An Informational Update 11-12 (1998), available at <http://web.archive.org/web/20000815080652/www.fda.gov/cdrh/breastimplants/in dexbip.html> (last accessed October 12, 2009) (two-stage procedure for breast reconstruction “start[s] with the placement of a breast tissue expander, which is replaced several months later with a breast implant”); *see also* FDA, Breast Implants: An Informational Update 10 (2000), available at <http://purl.access.gpo.gov/GPO/LPS40385> (reconstruction “typically involves placement of a tissue expander, which will eventually be replaced with a breast implant.”).

confused” with breast implants because they have different “design specifications” and function, and are “regulated by FDA in a different way than breast implants”:

It should be noted that tissue expanders, which are silicone shells filled with saline, are regulated by FDA in a different way than breast implants. This is because tissue expanders are intended for general tissue expansion for a maximum of 6 months, after which, they are to be removed. Because of this, the design specifications (*e.g.*, thinner shell) and preclinical testing recommendations are different for tissue expanders than for breast implants.⁶

Because tissue expanders are fundamentally different from breast implants, they were not subject to the FDA moratorium on breast implant sales that spawned the litigation against Dow Corning. As the FDA told women at the height of the controversy, the moratorium did not impact women “who have temporary tissue expanders in place and who are waiting for a permanent implant,” (FDA Press Release (April 16, 1992), *available at* <http://web.archive.org/web/19970225092623/http://www.fda.gov/bbs/topics/NEWS/NEW00273> (last accessed October 12, 2009).) Accordingly, Dow Corning faced relatively few tissue expander claims before it filed for protection under Chapter 11 and did not regard

⁶ Record Entry No. 51, Jakubczak Aff. ¶ 13, *quoting* FDA, Breast Implant Consumer Handbook 10 (2004), *available at* <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064263.pdf> (last accessed October 12, 2009). The FDA likewise explained in its February 11, 2003 guidance document that it did not address tissue expanders because they were “unclassified devices for temporary use.” (*See* Record Entry No. 51 Ex. A, Jakubczak Aff. ¶ 13.)

them as significant enough to merit a settlement option in the Plan. (*See* Record Entry No. 51 Ex. A, F. Dunbar, Analysis of Other Product Claims (June 23, 1999).)

II. The Amended Joint Plan of Reorganization

Dow Corning's Amended Joint Plan of Reorganization had nothing to do with tissue expanders. Its purpose was to resolve the massive wave of breast implant claims that led to Dow Corning's bankruptcy, which this Court has described as "one of the world's largest mass tort litigations." *See In re Dow Corning*, 86 F.3d at 485. The Plan released Dow Corning and others from liability for breast implant claims (and a relatively small number of other claims), which were channeled to one of two capped funds: a Litigation Facility for claimants who opted to litigate in court, and a settlement facility (the "Settlement Facility-Dow Corning Trust" or "SF-DCT") for those who opted to settle their claims pursuant to heavily-negotiated, detailed criteria and procedures for determining eligible claims and corresponding payment amounts.⁷ The settlement procedures were set forth in the Settlement Facility Agreement and Fund Distribution Agreement ("SFA") and other Plan documents.

⁷ The SF-DCT Settlement Facility was capped at \$1.95 billion, Net Present Value as of the June 2004 Effective Date. *In re Dow Corning Corp.*, 244 B.R. 721, 726 (Bankr. E.D. Mich. 1999), *rev'd on other grounds*, 255 B.R. 445 (E.D. Mich. 2000).

The Plan's Breast Implant Settlement Option provides various levels of settlement benefits to Class 5, 6.1 and 6.2 claimants, whose claims arose from their use of "Breast Implants." The Plan, in turn, defines "Breast Implant" as "all silicone gel and saline-filled breast implants with silicone elastomer envelopes manufactured and either sold or otherwise distributed by the Debtor." (Record Entry No. 700 Ex. B, Plan § 1.17.)

The Plan's Breast Implant Settlement Option does not mention "tissue expanders" or offer any settlement option whatsoever for claims arising from the use of such products. Under the "Breast Implant" definition, a qualifying claimant is required (1) first and foremost, to have been implanted with a "breast implant," and in addition her breast implants must have been (2) filled with silicone gel or saline, (3) covered with a silicone elastomer shell, and (4) manufactured and sold or distributed by the debtor, Dow Corning. (Record Entry No. 700 Ex. B, Plan § 1.17.) Breast implants manufactured by other parties are excluded, as are breast implants that lack silicone gel or saline filling or a silicone elastomer shell. Most importantly, products that are not breast implants at all are excluded – even if they were made by Dow Corning, contained silicone gel or saline filling, or had a silicone elastomer shell.

Schedule I to the Plan's Claims Resolution Procedures (Annex A to the SFA) lists the product identification requirements for eligible Breast Implant

products, including model and brand names and unique design features or characteristics referred to as “unique product identifiers” that distinguish Dow Corning breast implants from those of its competitors. (Record Entry No. 700 Ex. D, SFA Annex A, Schedule I, Part I.D.) To meet the identification requirements, the device in question must be a breast implant *and* must satisfy these identifier criteria as well. (*Id.*)

At no stage in Plan drafting or the confirmation hearing did any party, including the Official Committee of Tort Claimants, ever assert that they believed that tissue expanders were “Breast Implants” entitled to compensation under the Plan’s Breast Implant Settlement Option. It would have been inconceivable for anyone to so assert, given the substantial benefits ascribed to Breast Implant recipients – up to \$300,000 – and the utter lack of any suggestion linking temporary tissue expander devices to disease. (*See* Record Entry No. 700 Ex. D, SFA Annex A, at A-14, A-15.) Accordingly, tissue expanders were not included in the estimates of the total cost of the settlement program placed into evidence at the confirmation hearing to demonstrate Plan feasibility.

This evidence was offered by the Plan’s proponents, Dow Corning *and* the Tort Claimants’ Committee, was relied on by the Bankruptcy Court in finding that the Plan was feasible and that creditors would be paid in full, and was prominently featured in the testimony and analysis of mass-tort specialist and economist Dr.

Frederick Dunbar. (*See* Record Entry No. 673, 6/10/09 Opinion at 10-11; Record Entry No. 51 Ex. A, F. Dunbar, Analysis of Other Product Claims (June 23, 1999); *In re Dow Corning*, 244 B.R. at 732-33.) Dr. Dunbar specifically listed “tissue expanders” among the non-Breast Implant “Other Products” that would not be covered under the Plan’s Settlement Option for Breast Implants, but that would be addressed only through the litigation option. (Record Entry No. 51 Ex. A, F. Dunbar, Analysis of Other Product Claims (June 23, 1999); *see also In re Dow Corning*, 244 B.R. at 730-31 (relying on Dr. Dunbar’s testimony that “claims stemming from products other than breast implants” would be resolved by the Litigation Facility).)

III. The Present Dispute and the District Court’s Ruling

Despite the plain language of the Plan and this history, several claimants asserted claims against the SF-DCT based on their exposure to tissue expanders. The SF-DCT Claims Administrator initially sought the opinion of Dow Corning and the Tort Claimants’ Committee regarding whether claimants with tissue expanders were eligible for the payment grid provided for claimants with Breast Implants. Pursuant to SFA Section 5.05, the Tort Claimants’ Committee then sought a determination from the Claims Administrator. But after convening a proceeding at which Dow Corning and the Tort Claimants’ Committee expressed their views, on June 28, 2004 the Claims Administrator declined to render any

ruling. Pursuant to Section 5.05 of the SFA, Dow Corning and the Claimants' Advisory Committee filed "cross motions" on July 19, 2004 seeking a determination from the district court. Five years later, the district court issued its ruling.

As the district court observed, "[t]he 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." (Record Entry No. 673, 6/10/09 Opinion at 4.) The district court did not dispute that medical professionals did not "refer to tissue expanders as breast implants" and that Dow Corning "did not refer to tissue expanders as breast implants in the product literature." (*Id.* at 7.) The court further acknowledged that the FDA classified tissue expanders as a separate and distinct product, noting 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." (*Id.* at 8.) Finally, it acknowledged that tissue expanders had a completely different function from breast implants – *i.e.*, to "stretch the skin to accommodate a long term implant device or for other reconstructive surgery" and "to repair skin defects or to facilitate wound closure." (*Id.* at 7.)

In addition, the district court found that the parties agreed that the vast majority of tissue expander products were physically incapable of being

“implanted in the breast and [were] not designed to be implanted in the breast.” (*Id.* at 6.) As the district court recognized, a “variety of shapes, rectangle, square, crescent, were incompatible with use as breast implants and were used in other parts of the body.” (*Id.* at 7.) The court found that out of the approximately 250 tissue expander products, only three styles (which it did not identify) were capable of use in the breast. (*Id.* at 6, 9.)

Nevertheless, Judge Hood held that tissue expander products are “Breast Implants” and qualify for the “Breast Implant” settlement grid if they happen to be used in the breast. (*Id.* at 11-12.) The district court did not reconcile its ruling with the well-settled meaning of “breast implant.” Nor did it reconcile it with the fact that tissue expanders were excluded from the product identification guidelines set forth in Schedule I of Annex A to the Plan’s SFA. Rather, the court simply asserted that “there is no requirement that the product must be designated by DCC and others as [a] ‘breast implant’ in order to meet the ‘Breast Implant’ Plan definition” – before contradicting itself in the very next phrase by conceding that the express language of the Plan’s definition of Breast Implant “does use the term ‘breast implant’.” (*Id.* at 7.)

SUMMARY OF ARGUMENT

The district court erred in holding that a tissue expander used in the breast is a “Breast Implant” for purposes of the Breast Implant Settlement Option under

Dow Corning's Amended Joint Plan of Reorganization. The Plan does not mention the term "tissue expander" in describing which Dow Corning devices are settlement-eligible, much less state that claimants with Dow Corning tissue expanders – but no Dow Corning breast implant – are eligible to participate in the settlement program for Classes 5, 6.1 and 6.2 (the classes for claimants with Dow Corning breast implants). Rather, the Plan's definition of "Breast Implant" authorizes such settlement benefits solely for claimants who actually have Dow Corning breast implants, a term that has a well-established meaning that excludes "tissue expanders." As the district court noted, medical practitioners do not consider "tissue expanders" to be "breast implants." Nor does the FDA, which treats "tissue expanders" as a distinct category of products with a distinct purpose, function and regulatory classification.

Tissue expanders were not theorized to cause disease and were not subject to the FDA moratorium that spawned the breast implant litigation. Accordingly, at no time during negotiation of the Plan or during the confirmation proceedings did the Plan Proponents or claimants suggest that tissue expanders would be eligible for compensation as "Breast Implants." Nor did any of the estimates of settlement payments presented by the Plan Proponents during the confirmation hearing contemplate expenditure of settlement funds for tissue expander claims. A host of Plan provisions, such as enhanced payouts for breast implant claimants whose

implants rupture or are surgically explanted, do not apply to tissue expanders (which, by design, do not remain in the body after fulfilling their temporary function and thus are not available to be either ruptured or explanted). Therefore it would be nonsensical to import “tissue expanders” into the definition of “Breast Implants.”

Accordingly, the district court’s ruling is contrary to the text, history and purpose of the Plan and the heavily negotiated Settlement Option, and will deplete limited funds otherwise available to pay eligible Breast Implant claims. It should be reversed.

STANDARD OF REVIEW

A bankruptcy court’s order interpreting a confirmed plan is normally reviewed for an abuse of discretion. *In re Dow Corning Corp.*, 456 F.3d 668, 675-76 (6th Cir. 2006).⁸ However, this standard does not apply where, as here, the district court found that the Plan was unambiguous and the appeal relates to the lower court’s legal conclusions: in such cases, this Court “review[s] ‘the bankruptcy court’s legal conclusions *de novo*.’” *In re Eagle-Picher Indus., Inc.*,

⁸ A court abuses its discretion when, among other things, it relies on clearly erroneous findings of fact, improperly applies the law, or uses an erroneous legal standard. *Hamad v. Woodcrest Condo. Ass’n*, 328 F.3d 224, 237 (6th Cir. 2003); *Performance Unlimited, Inc. v. Questar Publishers, Inc.*, 52 F.3d 1373, 1378 (6th Cir. 1995).

447 F.3d 461, 464 (6th Cir. 2006). *See also In re Shenango Group, Inc.*, 501 F.3d 338, 346 (3d Cir. 2007) (review of plan interpretation decision is *de novo* “if the issue being reviewed presents only a question of law”); *In re National Gypsum Co.*, 219 F.3d 478, 484, 489 (5th Cir. 2000) (appellate court “review[s] *de novo* . . . purely legal issues” decided by bankruptcy court interpreting a plan, and accordingly court will “not defer to the bankruptcy court’s interpretation of . . . unambiguous text [in plan and confirmation order]”).⁹

More generally, the rationale for applying the abuse of discretion standard is inapplicable here. The district court in this case was not interpreting its “own order.” *In re Weber*, 25 F.3d 413, 416 (7th Cir. 1994). Judge Hood did not sit as the bankruptcy court during the Plan confirmation hearings and did not issue the confirmation order (Judge Spector did, with Judge Hood withdrawing the reference

⁹ *See also generally Performance Unlimited*, 52 F.3d at 1378 (in applying abuse of discretion standard “legal conclusions are given *de novo* review”); *Vision Information Servs., LLC. v. C.I.R.*, 419 F.3d 554, 558 (6th Cir. 2005) (reviewing Tax Court’s interpretation of agreement *de novo* where language found to be unambiguous); *Heights Driving School, Inc. v. Top Driver, Inc.*, 51 Fed. Appx. 932, 935 (6th Cir. 2002) (review of district court’s interpretation of contract governed by New York law was “*de novo*, as long as the contract is ‘plain and unambiguous’” because, under New York law, “‘the construction of a plain and unambiguous contract is for the court to pass on,’” *quoting West, Weir & Bartel, Inc. v. Mary Carter Paint Co.*, 255 N.E.2d 709, 711 (N.Y. 1969)); *Bunch v. Hodel*, 793 F.2d 129, 132 (6th Cir. 1986) (“whether the terms of the lease are ambiguous is a question of law for this Court to determine . . . , and a *de novo* standard of review will apply to the district court’s holding concerning the unambiguous nature of the lease”).

at a later date). As this Court recently held, while a bankruptcy court's interpretation of its own plan and confirmation order may be reviewed for an abuse of discretion, "[i]n a bankruptcy case on appeal from a district court, [the Court] owe[s] no special deference to the district court's decision." *See In re Eagle-Picher*, 447 F.3d at 463.¹⁰

ARGUMENT

I. The Plain Language of the Plan Makes Clear That Tissue Expander Claims Are Not Eligible for Settlement Payments

In interpreting a confirmed plan, courts apply contract principles, since the plan is effectively a contract between the debtor and its creditors. *In re Dow Corning Corp.*, 456 F.3d 668, 676 (6th Cir. 2006); *see also Hillis Motors, Inc. v. Hawaii Auto. Dealers' Ass'n*, 997 F.2d 581, 588 (9th Cir. 1993). State law governs those interpretations, and the Plan must be enforced as written. *In re Dow Corning*, 456 F.3d at 676.¹¹

Accordingly, under established principles of contract interpretation, the terms of a confirmed plan must be construed according to their "plain, ordinary

¹⁰ This holding is even more applicable here, where the district court applied *de novo* review to a decision of the SF-DCT Claims Administrator. (*See* Record Entry No. 673, 6/10/09 Opinion at 4 ("The CAC asserts that the proper standard of review is *de novo* . . . The Court agrees."))

¹¹ Here, the Plan and related documents "shall be governed by and construed in accordance with the laws of the State of New York and applicable federal law."

(Continued...)

meaning,” *Constr. Interior Sys., Inc. v. Marriott Family Restaurants, Inc.*, 984 F.2d 749, 756 (6th Cir. 1993), and “commonly accepted” definitions are controlling, *Bridgeport Music, Inc. v. Dimension Films*, 410 F.3d 792, 798 (6th Cir. 2005) (adopting “the definition commonly accepted within the industry”). Here, the text, structure, history and purpose of Dow Corning’s Plan all demonstrate that “tissue expanders” are not breast implants and tissue expander claims are not eligible to participate in the settlement program for breast implant claims.

A. As Defined by the Plan, the Breast Implant Settlement Option Is Open Only to Claimants With “Breast Implants,” Not Claimants With “Tissue Expanders”

Dow Corning’s Plan is unambiguous: nowhere does the Plan provide that “tissue expanders” are eligible for the breast implant settlement payments provided for Classes 5, 6.1, 6.2. Rather, eligibility is limited to claimants who received a Dow Corning “Breast Implant,” defined by the Plan as follows:

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

(Record Entry No. 700 Ex. B, Plan § 1.17 (emphasis added).) While claimants attempt to argue that “tissue expanders” are “breast implants,” the term “breast implant” has a well-accepted meaning that specifically excludes tissue expanders. The record is undisputed that the medical community recognized that tissue

(Record Entry No. 700 Ex. B, Plan § 6.13.)

expanders were separate and distinct products with distinct designs and functions, and that Dow Corning marketed tissue expanders as such. (*See* Record Entry No. 673, 6/10/09 Opinion at 7; Record Entry No. 51 Ex. A, Jakubczak Aff. ¶¶ 11-13.) As the district court noted, unlike breast implants, tissue expanders were designed for “temporary use” to “stretch the skin to accommodate a long term implant device or for other reconstructive surgery.” (Record Entry No. 673, 6/10/09 Opinion at 7.) They were *not* designed for long-term use or for cosmetic purposes.

The FDA recognized this distinction in its regulation of these products, cautioning that tissue expanders “are not to be confused” with breast implants because they have different “design specifications” and function, and are “regulated by FDA in a different way than breast implants.” (FDA Breast Implant Consumer Handbook 10 (2004), *quoted in* Record Entry No. 51 Ex. A, Jakubczak Aff. ¶ 13.)

Under well-established principles of construction, such common usages govern. *See, e.g., Bridgeport Music*, 410 F.3d at 798; *Constr. Interior Sys.*, 984 F.2d at 756. Indeed, the very nature of the definition provided in Section 1.17 of the Plan demonstrates that the parties intended to adopt this well-settled meaning of the term “breast implant.” As the district court observed, “[t]here is no definition within the ‘Breast Implant’ definition as to the meaning of the term ‘breast implant’ in lower case.” (Record Entry No. 673, 6/10/09 Opinion at 7-8.)

That is because the term “breast implant” had a well-accepted meaning among the medical community, the FDA and the general public. There was no need of further definition; indeed, the fact that no further definition was provided demonstrates that the drafters intended to use the common, accepted meaning. *See, e.g., Fathauer v. U.S.*, 566 F.3d 1352, 1355 (Fed. Cir. 2009) (holding that “Congress’s decision to use the word ‘employee’ in [statutory] definition demonstrates that a special definition was unnecessary because the word was intended to be given its ordinary meaning” and rejecting claim that the term was “ambiguous”); *Grant Thornton, LLP v. Office of Comptroller of the Currency*, 514 F.3d 1328, 1332 (D.C. Cir. 2008) (finding that where a statute “define[d] a ‘bank’ as ‘any national bank and State bank, and any Federal branch and insured branch’” and thus provided a definition that was “in part circular, itself depending on the meaning of the word ‘bank,’ Congress evidently relied on common understanding to fill the gap”); *F.T.C. v. Verity Intern., Ltd.*, 443 F.3d 48, 57-58 (2d Cir. 2006) (holding that the term “common carrier” must be interpreted “according to the ordinary sense of the word when Congress used it,” because “the phrase ‘common carrier’ had an ordinary meaning at the time, explaining why the Interstate Commerce Act left the term undefined and why the Communications Act included only a circular definition”); *Enercon GmbH v. International Trade Com’n*, 151 F.3d 1376, 1381 (Fed. Cir. 1998) (where term “sale” was not defined in statute, court must infer that

“Congress intended to give the term its ordinary meaning, thereby making an explicit definition unnecessary”).

The Plan’s requirement that a settlement-eligible medical device must in fact be a “breast implant” under that term’s well-settled, common meaning is dispositive. Nonetheless, both the CAC’s arguments below and Judge Hood’s opinion ignored it almost entirely. The district court inexplicably read this threshold, fundamental requirement out of the Plan, finding that “[t]here is no requirement that the product must be designated by DCC and others as [a] ‘breast implant’ in order to meet the ‘Breast Implant’ Plan definition” (Record Entry No. 673, 6/10/09 Opinion at 7.) In the very same sentence, however, the court contradicted itself and acknowledged that the definition *does* in fact require that the device be a “breast implant,” stating: “. . . . although the definition does use the term ‘breast implant.’” (*Id.*)

Having excised the fundamental “breast implant” requirement from Section 1.17’s definition of an eligible “Breast Implant,” the district court then focused on additional, ancillary definitional requirements contained within Section 1.17: whether the implant (1) was silicone- or saline-filled, (2) had silicone elastomer, and (3) was manufactured and sold or distributed by the Debtor. While these ancillary definitional elements are *necessary* to satisfy the definition of “Breast Implant,” they are not by themselves *sufficient* if the device in question is not in

fact a breast implant in the first place.¹² They are merely additional requirements for eligibility that must be satisfied, if and only if it is first shown that the claimant in fact had a breast implant. They provide specificity about which *types* of breast implants are covered, namely: (1) implants with silicone or saline filling (as opposed to soybean oil or other fillers not used by Dow Corning); (2) implants with silicone elastomer shells (as opposed to polyurethane foam and other non-silicone shells, which were never used by Dow Corning); and (3) implants manufactured by Dow Corning (as opposed to other manufacturers). Satisfying these three ancillary requirements, however, cannot cure a failure to satisfy the first and most fundamental requirement: that the claimant must have had a breast implant in the first place.

The district court's error in focusing on the three additional requirements while ignoring the first and most fundamental requirement can be illustrated using an everyday example. A recipe for apple pie may specify the use of "red apples

¹² They are not sufficient because there are many Dow Corning products that were filled with saline and contained a silicone elastomer that clearly do not fall within the Plan definition of "Breast Implant" because they are not breast implants. For example, Dow Corning manufactured and sold or distributed testicular implants that were filled with saline and had silicone elastomer. However, no one would claim that they are "breast implants," and indeed the district court noted that "a testicular tissue expander even if implanted in the breast would not meet the definition of 'Breast Implant.'" (Record Entry No. 673, 6/10/09 Opinion at 6.) Likewise, the more than 240 tissue expander products that the district court ruled were *not* breast implants also meet the three ancillary requirements of Section 1.17.

that are sweet and fresh,” thus limiting the universe of apples that may be used and excluding green, tart or stale apples. However, the recipe need not define the term “apple,” because “apple” has a clear, commonly understood meaning that distinguishes it from other fruits such as “blueberries” or “strawberries.” Moreover, a cook who uses red, sweet, and fresh strawberries would not be following the recipe. Such strawberries may be (1) red, (2) sweet, and (3) fresh – and thus comply with the three ancillary requirements in the recipe – but that does not transform them into “apples.” The fact that a strawberry meets three of the four requirements stated in the recipe does not mean that it complies with the recipe as a whole, given that it indisputably fails to meet the initial, *most fundamental*, requirement: you have to use apples.

However, that is precisely the construction of Dow Corning’s Plan that the CAC urged and the district court adopted here in holding that “tissue expanders” were entitled to compensation as Breast Implants because they (1) are silicone or saline-filled, (2) have silicone elastomer, and (3) were manufactured and either sold or otherwise distributed by the Debtor. Meeting three out of four requirements simply is not good enough; tissue expanders fail the definition because they fail to meet the most fundamental requirement of being a breast implant in the first place.

B. The Structure and Terms of the Plan Further Demonstrate That Tissue Expander Claims Are Not “Breast Implants”

Various Plan provisions either exclude tissue expanders from treatment as breast implants or would make no sense if tissue expanders were to be imported into the definition of “Breast Implants.”

First, the Plan’s eligibility criteria to receive a settlement payment as a Breast Implant exclude “tissue expanders.” Specifically, tissue expanders are not listed among the products that are eligible for payment as “Breast Implants” in the schedule of exclusive qualifying product identifiers contained in Annex A to the SFA. (Record Entry No. 700 Ex. D, SFA Annex A, Schedule I.A.) To qualify under this schedule, a claimant’s implants must meet at least two requirements: (1) they must be “Dow Corning Breast Implants,” and (2) they must have been sold under one of the enumerated brand names used by Dow Corning in specified timeframes. Qualifying implants include eight models of breast implants sold by Dow Corning, for example “Cronin” model breast implants sold in 1963-1971, “Silastic” model breast implants, and “Varifil” model breast implants. But there is no mention of tissue expanders anywhere on this qualifying schedule, regardless of whether the tissue expander had a “Silastic” or any other Dow Corning brand name. The mere presence of a brand name, such as “Silastic,” is necessary but not sufficient to satisfy the Breast Implant eligibility schedule, since Dow Corning used the “Silastic” brand name for numerous products other than breast implants.

Indeed, the Plan identifies 54 non-breast-implant products made by Dow Corning for which “Silastic” is an acceptable brand name identifier for specified “Covered Other Products” – *i.e.*, Other Products for which a Plan settlement option is available under Classes 9, 10.1, and 10.2 of the Plan. The eligibility criteria and the payment amounts available for these specified Covered Other Products differ substantially from those applicable to claimants with Breast Implants. (Record Entry No. 700 Ex. D, SFA Annex A, at A-64, A-65, A-75.) To qualify for any settlement grid under the Plan, the claimant must demonstrate the presence of both the appropriate brand name and the type of implant for which payment is allowed. Thus, to qualify for the substantial settlement payments applicable to the Breast Implant Settlement Option, both the correct brand name (whether “Silastic” or one of the other qualifying brands) *and* being a breast implant are required.¹³

Second, the settlement benefits afforded breast implant claimants would make no sense if they were applied to tissue expanders. For example, domestic breast implant claimants are entitled to an explantation benefit under the Plan – *i.e.*, a payment of \$5,000 for those breast implant claimants who elect to undergo

¹³ Moreover, tissue expanders were never mentioned when the SF-DCT staff was trained – in conjunction with Dow Corning and the Tort Claimants’ Committee – in how to use the identifiers contained in SFA Annex A, Schedule I. (Record Entry No. 51 Ex. A, Jakubczak Aff. ¶¶ 15-16.) The product identification materials and training materials referred *only* to breast implants and compensable “Other Products,” not to tissue expanders. (*Id.*)

explant surgery to have their breast implants removed. (SFA Annex A, §§ 6.02(a)(i), (c).) An explantation benefit, however, would make no sense for tissue expanders, which are used on a temporary basis in anticipation of reconstructive surgery and thus are designed to always be removed. An incremental \$5,000 explantation option for tissue expander claimants – relating to a procedure that is intended and necessary for all recipients of that device – would be irrational and nonsensical.

Third, there likewise is no rationale for tissue expander claimants to receive the \$20,000 rupture payment available to breast implant claimants. (See Record Entry No. 700 Ex. D, SFA Annex A § 6.02(e)(viii).) The rupture settlement option addresses the experience that some silicone gel breast implants may rupture and release silicone gel into the body.¹⁴ Tissue expanders did not contain silicone gel and were not subject to the rupture risk associated with long-term implantation; thus, the rupture payment option makes no sense for them. (See Record Entry No. 51 Ex. A, Jakubczak Aff. ¶ 8.)

Fourth, there would be no rational basis to provide a disease payment option to individuals with tissue expanders. Under the Plan, such payment options for

¹⁴ Individuals with saline-filled implants were not eligible for the additional rupture payment. (See Record Entry No. 700 Ex. D, SFA Annex A § 6.02(e)(i) (limiting definition of “Rupture” to silicone-gel Breast Implants).)

Breast Implant recipients range from \$10,000 to \$300,000. (*See* Record Entry No. 700 Ex. D, SFA Annex A, at A-13 to A-14.) These are extraordinary settlement values. It would not make any sense to provide such settlement values for a product that is nothing more than a short-term mechanism to prepare for surgery, and that was never associated with any disease allegations.

Fifth, the Plan's definition of "Other Products" plainly encompasses tissue expanders, confirming that they are separate and distinct from "Breast Implants" and not eligible for the settlement grid:

"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.)

Tissue expanders are plainly "silicone-containing products" that are distinct from "Breast Implants" and thus fall within the Plan's definition of "Other Products," along with numerous other kinds of silicone-containing products manufactured by Dow Corning.

Significantly, there are two types of “Other Products” under the Plan: “Covered Other Products” which are eligible for settlement, albeit at much lower amounts than Breast Implant claims and “Other Products” that are not covered by any Plan settlement option. (*See* Record Entry No. 700 Ex. D, SFA Annex A, at A-14, A-15, A-30 (showing base payments for breast implant claims ranging up to \$300,000 and payments for Covered Other Products ranging up to \$10,000).)¹⁵ The Plan enumerates an exhaustive list of “Covered Other Products,” including 44 models of hip and knee implants; 15 chin, nose or jaw implants or materials; and 16 testicular or penile implants. (*See* Record Entry No. 700 Ex. D, SFA Annex A, Schedule I, Part II, at A-65 to A-75.) These settlement-eligible Covered Other Products stand in contrast to tissue expanders and other Dow Corning medical materials and devices whose recipients were *not* given any settlement option in the Plan and who retained the right under the Plan to pursue their claims through litigation against the Litigation Facility. (*Id.* § 6.03(b).)¹⁶

¹⁵ *See also* Record Entry No. 700 Ex. D, SFA Annex A, § 6.03(a) & Schedule I, Part II; Record Entry No. 700 Ex. B, Plan §§ 1.40, 5.4.1.2.

¹⁶ Additional similarly non-covered Other Products include injectable silicone fluid and certain types of Dow Corning silicone gel raw materials. (*See* Record Entry No. 700 Ex. D, SFA Annex A § 6.03(a) (failing to list such materials among “Covered Other Products”); Record Entry No. 51 No. A, Frederick Dunbar, Analysis of Other Product Claims (June 23, 1999).)

Finally, the parties have consistently treated tissue expanders as distinct products that are not “breast implants” under other parts of the Plan. For example, claimants have consistently maintained that tissue expanders are not breast implants for purposes of the Plan’s multiple manufacturer reduction. The multiple manufacturer reduction provides that claimants “shall have the Allowed amount of their Claim reduced by fifty (50) percent” where, in addition to a Dow Corning breast implant, they were also implanted with a “a silicone gel breast implant manufactured by or attributed to Bristol, Baxter or 3M.” (Record Entry No. 700 Ex. D, SFA Annex A § 6.02(d)(v), at A-12 to A-13.) This provision is designed to reduce claimants’ recovery where claimants have been exposed to another, non-Dow-Corning “breast implant” that they allege could have caused their disease. However, claimants have consistently maintained that tissue expanders are not “breast implants” for purposes of the multiple manufacturer reduction, and that accordingly their claims should not be reduced by 50% where they have been implanted with another manufacturer’s tissue expander product. Likewise, Dow Corning has not opposed payment of the full amount of such claims based on the parties’ mutual understanding that “tissue expanders” are not “breast implants” and thus do not trigger the 50% reduction. Claimants’ allegation that tissue expanders *are* “breast implants” for purposes of the Class 5, 6.1, and 6.2 payments is flatly inconsistent with this course of performance as well as the plain language of this

Plan provision. At bottom, claimants seek to count “tissue expanders” as “breast implants” where it benefits them under the Plan, while at the same time excluding “tissue expanders” from the definition of “breast implants” where it does not. Such an interpretation is contrary to well-settled principles of construction. *See, e.g., New York v. R.J. Reynolds Tobacco Co.*, 304 A.D.2d 379, 380 (N.Y. App. Div. 2003) (holding that a “phrase should presumptively be given the same meaning” in different portions of a contract); *Finest Investments v. Security Trust Co. of Rochester*, 96 A.D.2d 227, 230 (N.Y. App. Div. 1983) (courts “presume that the same words used in different parts of a writing have the same meaning”); *see also Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007) (“[I]dential words and phrases within the same statute should normally be given the same meaning.”); *Lake Cumberland Trust, Inc. v. U.S. E.P.A.*, 954 F.2d 1218, 1222 (6th Cir. 1992) (“We must presume that words used more than once in the same statute have the same meaning.”).¹⁷

¹⁷ If, however, the district court’s interpretation were to stand and tissue expanders were deemed “breast implants” under the Plan, Dow Corning would be entitled to refund of overpayments from potentially thousands of claimants who received other manufacturers’ tissue expanders before receiving a Dow Corning breast implant.

C. The Purpose and History of the Plan Confirm That Tissue Expander Claims Were Never Intended To Be Treated as Breast Implant Claims

Holding that “tissue expanders” are “Breast Implants” under the Plan is inconsistent with the genesis of the Chapter 11 case and fundamental purpose of the settlement program. As this Court has previously recognized, the entire purpose of the bankruptcy was to resolve Dow Corning’s *breast implant* claims. *See In re Dow Corning*, 456 F.3d at 671; *In re Dow Corning*, 86 F.3d at 485. The Plan, which was jointly proposed by Dow Corning and the Tort Claimants’ Committee and overwhelmingly approved by personal-injury tort creditors, resolved the tens of thousands of breast implant claims asserted against Dow Corning, by creating a capped fund of \$1.95 billion (Net Present Value) to settle those claims – to the exclusion of claims for tissue expanders and other settlement-ineligible devices. There were relatively few pre-petition tissue expander claims. As temporary skin-growth enhancers, tissue expanders simply were not theorized to cause disease. Nor were tissue expanders subject to the FDA moratorium that spawned the litigation.

Accordingly, during the confirmation hearings, the Plan Proponents made clear that tissue expander claims would *not* receive settlement compensation under the settlement option. For example, the Plan Proponents’ claims estimation expert, Dr. Frederick Dunbar, provided a summary of claims that specifically excluded

tissue expander claims from those entitled to settlement compensation, listing tissue expanders as an “Other Product” that was not “covered” by the Breast Implant Settlement Option. (See Record Entry No. 51 Ex. A, Frederick Dunbar, Analysis of Other Product Claims (June 23, 1999).) As the district court noted, “tissue expanders were never included in the evaluation of potential settling claims and the corresponding claims values” under the Plan. (Record Entry No. 673, 6/10/09 Opinion at 10-11.)

In approving the Plan, the bankruptcy court found that “all breast-implant claims, both domestic and foreign, are substantially similar” – a point “upon which there is virtually no disagreement.” See *In re Dow Corning Corp.*, 244 B.R. 634, 658 (Bankr. E.D. Mich. 1999). “All are unsecured, unliquidated and disputed tort claims arising out of the Debtor’s sale and manufacture of *silicone-gel breast implants*.” *Id.* (emphasis added). In addition, “[a]ll of the [breast implant] claimants used the Debtor’s products in the same manner.” *Id.* at 656. These findings could not have been made if “tissue expanders” were included within the “breast implant” claims, given that such products have a fundamentally different purpose, use, and structure.

Finally, Dow Corning tissue expanders were not considered “breast implants” in the Multi-District Litigation breast implant proceedings before the United States District Court for the Northern District of Alabama. The MDL’s

court-approved Revised Settlement Program (“RSP”) provided that a plaintiff who had multiple sets of breast implants, one pair made by manufacturer A and the other pair made by Dow Corning, would receive a 50% reduction in benefits (the “multiple manufacturer reduction”). The RSP does *not* treat Dow Corning tissue expanders as breast implants for purposes of the multiple manufacturer reduction, even though the companies that entered into the RSP would have benefited from such a classification because it would have reduced their payments whenever a claimant had a Dow Corning tissue expander.¹⁸ As the district court acknowledged: “[T]issue expanders made by Dow Corning did not trigger the 50% reduction in benefits that the breast implants did[,] lending credibility to

¹⁸ While certain other manufacturers’ “tissue expander” products were eligible for compensation in the RSP, in many such instances the products were hybrids intended for long-term implantation, regulated by FDA as breast implants and were expressly designated as being eligible, unlike Dow Corning tissue expanders which had much different characteristics. (See Record Entry No. 51, DCC Motion at 8 (July 19, 2004); Record Entry No. 688, Hearing Tr. 37-38 (June 22, 2004).) Thus, for example, Exhibit G to Annex A of the SFA provides a list of products specifically covered under the RSP. Products such as CUI’s “Tissue Expander” and “Intraoperative Tissue Expander” are expressly listed as compensable. (Record Entry No. 700 Ex. D, SFA Annex A, Ex. G, at A-81 to A-83.) There was no understanding that *all* tissue expanders are breast implants or that *all* tissue expanders were automatically entitled to compensation. Just the opposite, other companies’ tissue expander products were *not* compensable unless expressly designated as such. Moreover, as noted above, it is undisputed that *none* of Dow Corning’s tissue expander products were considered “breast implants” under the RSP. Most importantly, no Dow Corning tissue expander products were specifically designated as compensable products under Schedule I of Annex A to the SFA.

DCC's claim that even under the RSP tissue expanders were not considered 'Breast Implants.'" (Record Entry No. 673, 6/10/09 Opinion at 9-10; *see also* Record Entry No. 40 Ex. 3, 1/25/02 SF-DCT email.)

In sum, the record shows that the parties did not intend tissue expander claims to receive benefits as Breast Implants, as evidenced by (among other things) the omission of such claims from the analyses submitted jointly by the parties regarding the amount of funds necessary to adequately fund the SF-DCT. (*See* Record Entry No. 673, 6/10/09 Opinion at 10-11.) Providing such compensation at this stage would be fundamentally unfair not only to Dow Corning, but also to legitimate Breast Implant claimants who look to the capped, finite settlement fund for payment.

II. The District Court's Ruling Made Fundamental Errors of Law

The district court's ruling disregarded the plain language of Dow Corning's Plan, and was the result of a series of legal errors.¹⁹

First, the district court ignored the plain meaning of the term "breast implant." As noted above, the district court acknowledged and did not dispute the record that the medical community does not consider "tissue expanders" to be

¹⁹ Not only do these errors constitute legal errors reversible under a *de novo* standard, but also constitute an abuse of discretion. *See Hamad*, 328 F.3d at 237; *Performance Unlimited, Inc.*, 52 F.3d at 1378.

“breast implants.” (Record Entry No. 673, 6/10/09 Opinion at 7.) As the authorities above demonstrate, this accepted meaning is dispositive. *See, e.g., Constr. Interior Sys*, 984 F.2d at 756 (such “ordinary meaning[s]” govern).

Second, the district court erred by focusing on subsidiary elements of the Plan’s definition of qualifying “Breast Implants,” while ignoring the fundamental requirement that only claims arising from the use of “breast implants” are eligible for the Breast Implant Settlement Option. (*See* Record Entry No. 700 Ex. B, Plan § 1.17; Record Entry No. 673, 6/10/09 Opinion at 7-8.) In doing so, it violated fundamental principles of construction that required the court to construe the Plan as a whole and give every provision meaning. *See, e.g., Diversified Energy, Inc. v. Tennessee Valley Authority*, 223 F.3d 328, 339 (6th Cir. 2000) (“Under settled principles of construction, this contract must be read as a whole so as to give meaning and effect to all of its provisions.”); *see also In re Celotex Corp.*, 487 F.3d 1320, 1333-34 (11th Cir. 2007) (holding that “[t]he Plan Documents must be construed as a whole, with each provision given reasonable meaning and effect,” and rejecting interpretation that would be “inconsistent” with other provisions).²⁰

²⁰ In reading “breast implant” out of the Plan’s controlling definition of “Breast Implant,” the court also essentially made an impermissible Plan modification by deleting a requirement under the plain language of the Plan.

Section 1.17 is clear that a “Breast Implant” is a “silicone gel and saline-filled *breast implant* with silicone elastomer manufactured and either sold or otherwise distributed by the Debtor.” (Record Entry No. 700 Ex. B, Plan § 1.17 (emphasis added).) Thus, to qualify under the definition, at least four requirements must be met: a product must (1) be a breast implant, (2) be silicone or saline-filled, (3) have silicone elastomer, and (4) be manufactured and either sold or distributed by the Debtor. Illogically and without explanation, the district court dispensed with the first and most fundamental requirement on the ground that other requirements were met. However, the plain language of the Plan makes clear that all four requirements must be satisfied.

Third, the district court failed to reconcile its ruling with the omission of tissue expanders from the Plan’s eligibility criteria in SFA Annex A, Schedule I. While the district court noted the CAC’s argument that “Silastic” brand breast implant models were listed in Schedule I and that “Silastic” was also a brand “under which certain Dow [Corning] tissue expanders were marketed” (Record Entry No. 673, 6/10/09 Opinion at 8), in fact while the brand name Silastic is used in Schedule I with reference to breast implant models, it is not used with reference to any model of tissue expander. (Record Entry No. 700 Ex. D, SFA Annex A, Schedule I, Parts I.A, I.D., II.B, II.C.) Mere use of the word “Silastic” is irrelevant to whether tissue expanders are breast implants, as that word was also used in the

Plan to refer to dozens of Silastic implants that are *not* “Breast Implants,” but rather are Silastic-brand “Covered Other Products,” including bone plugs, chin implants, rhinoplasty implants, testicular prostheses and implants, penile implants, TMJ joint implants, silicone sheeting, toe implants, tendon spacers, and finger joint implants. (See Record Entry No. 700 Ex. D, SFA Annex A, § 6.03(b) & Schedule I, Part II.) In disregarding the plain language of Schedule I, the district court again failed to follow settled principles of construction that require that the Plan be interpreted as a whole and that each provision be given its plain meaning. See, e.g., *Popovich v. Sony Music Entertainment, Inc.*, 508 F.3d 348, 363 (6th Cir. 2007); *Diversified Energy, Inc.*, 223 F.3d at 339.

Fourth, the district court misinterpreted the Plan’s definition of “Other Products,” whose plain meaning demonstrates that tissue expanders are included within the definition “Other Products” (and thereby excluded from the definition of “Breast Implants”). As discussed above, that provision plainly states that “Other Products” means “metal, silicone or silicone-containing products, other than Breast Implants . . . including, but not limited to” a list of five specified products. (Record Entry No. 700 Ex. B, Plan § 1.117.) The district court ruled that tissue expanders must be Breast Implants because “[t]he parties could have expressly included tissue expanders in this definition if the parties intended to exclude tissue expanders designed to be implanted in the breast.” (Record Entry No. 673, 6/10/09

Opinion at 9.) However, there is no dispute – and the district court expressly found – that “tissue expanders produced by DCC have a silicone envelope.” (*Id.* at 5.) They therefore are “silicone-containing products” and fit within the plain language of the “Other Products” definition. The fact that tissue expanders are not expressly listed by name in the “Other Products” definition is irrelevant. The list provided in the definition is not exclusive; to the contrary, it is preceded by the phrase “including but not limited to,” which indicates that the list is merely exemplary. The district court’s ruling violates this well-settled principle of construction. *See, e.g., United States v. Hynes*, 467 F.3d 951, 963 (6th Cir. 2006) (use of “the language ‘including, but not limited to,’ mean[s] that the list” was “not exhaustive”); *In re Alt*, 305 F.3d 413, 419 n.2 (6th Cir. 2002) (“The fact that the statute uses the word ‘including’ demonstrates that the factors listed are not exclusive.”).

Fifth, the district court’s interpretation is at odds with the parties’ understanding of the term “breast implant” as used in other parts of the Plan. Specifically, the district court’s interpretation is at odds with the parties’ consistent treatment of tissue expanders as distinct products that are not “breast implants” for purposes of the multiple manufacturer reduction. (Record Entry No. 700 Ex. D, SFA Annex A § 6.02(d)(v), at A-12 to A-13.) Again, in adopting a construction that is at odds with the parties’ interpretation of the same language in another part

of the Plan, the district court violated well-settled principles of construction. *See, e.g., R.J. Reynolds Tobacco Co.*, 304 A.D.2d at 380 (a “phrase should presumptively be given the same meaning” in different portions of a contract); *Finest Investments*, 96 A.D.2d at 230 (courts “presume that the same words used in different parts of a writing have the same meaning”); *Powerex Corp.*, 551 U.S. at 232 (“[I]dential words and phrases within the same statute should normally be given the same meaning.”).

Finally, the district court did not reconcile its ruling with the fundamental purpose and history of Dow Corning’s Plan, the parties’ understanding in the confirmation proceedings, and the prior MDL proceedings demonstrating that tissue expanders are not “Breast Implants” for purposes of the settlement. Instead, the Court expressly ignored that record, asserting that “such evidence is not required to determine whether tissue expanders meet the definition of ‘Breast Implant.’” (Record Entry No. 673, 6/10/09 Opinion at 11.) Yet, as the district court itself noted, the record reflects (and there is no record to the contrary) that under Dow Corning’s Plan, “tissue expanders were never included in the evaluation of potential settling claims and the corresponding claims values.” (*Id.* at 10-11.) That is because the entire purpose of the Dow Corning Breast Implant Settlement Option was to settle *breast implant* claims – not tissue expanders. Likewise, as the district court found, the treatment of Dow Corning tissue

expanders in the MDL proceedings “lend[s] credibility to DCC’s claim that even under the RSP tissue expanders were not considered ‘Breast Implants.’” (*Id.* at 10.)

The district court erred by ignoring this undisputed purpose and history of the Dow Corning Plan. See *In re Consolidated Pioneer Mortgage Entities*, 264 F.3d 803, 807 (9th Cir. 2001) (plan must be interpreted according to its “language and purpose”); *cf. Winnett v. Caterpillar, Inc.*, 553 F.3d 1000, 1008 (6th Cir. 2009) (in construing a contract, courts must “interpret each provision in question as part of the integrated whole” and “consistently with . . . the relative positions and purposes of the parties”); *Westmoreland Coal Co. v. Entech, Inc.*, 794 N.E.2d 667, 670 (N.Y. 2003) (“A written contract ‘will be read as a whole, and every part will be interpreted with reference to the whole; and if possible it will be so interpreted as to give effect to its general purpose.’”).

CONCLUSION

For the foregoing reasons, Dow Corning respectfully requests that the Court reverse the district court's order.

October 14, 2009

Respectfully submitted,

/s/ Douglas G. Smith

John Donley

Douglas G. Smith

David Mathues

KIRKLAND & ELLIS LLP

300 North LaSalle Street

Chicago, Illinois 60654

Tel: (312) 862-2000

Fax: (312) 862-2200

douglas.smith@kirkland.com

Deborah Greenspan

DICKSTEIN SHAPIRO LLP

1825 Eye Street, N.W.

Washington, DC 20006

Tel: (202) 420-3100

Fax: (202) 420-2201

Attorneys for Appellant

Dow Corning Corporation

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B). According to the word processing program used to prepare this brief (Microsoft Word), this brief contains 10,301 words.

/s/ Douglas G. Smith

Douglas G. Smith

KIRKLAND & ELLIS LLP

300 North LaSalle Street

Chicago, Illinois 60654

Tel: (312) 862-2000

Fax: (312) 862-2200

douglas.smith@kirkland.com

CERTIFICATE OF SERVICE

I certify that on October 14, 2009, I electronically filed a copy of the foregoing Brief of Appellant Dow Corning Corporation with the Clerk of Court through the Court's electronic filing system, which will send notice and a copy of this brief to all registered counsel in this case.

/s/ Douglas G. Smith

Douglas G. Smith
KIRKLAND & ELLIS LLP
300 North LaSalle Street
Chicago, IL 60654
Tel: (312) 862-2000
Fax: (312) 862-2200
douglas.smith@kirkland.com

**ADDENDUM DESIGNATING RELEVANT DOCUMENTS IN THE
DISTRICT COURT DOCKET (00-0005)**

Documents

- Doc 40 7/19/04 MOTION or a determination re tissue expanders filed
by Claimants' Advisory Committee
 EXHIBIT 1 – DCC Wright Silastic Tissue Expander
 Pamphlet
 EXHIBIT 2 – Tissue Expander product label
 EXHIBIT 3 – E-mail from V. Willard at SF-DCT to
 D. Greenspan and D. Pendleton
 EXHIBIT 4 – Excerpt from the Hearing before Claims
 Administrator Trachte-Huber, June 22,
 2004
- Doc 51 7/19/04 MOTION for a Determination that Tissue Expanders do not
Constitute Breast Implants for Purposes of Eligibility for Settlement
Benefits with Attachments by Dow Corning Corporation.
 EXHIBIT A – Dunbar Estimate
 EXHIBIT B – Affidavit of Gene Jakubczak
 EXHIBIT 1 – Mentor tissue expander product
 pamphlet
 EXHIBIT 2 – CUI tissue expander product
 pamphlet
- Doc 55 8/9/04 RESPONSE to Motion to Extend filed by Dow Corning
Corporation
- Doc 57 2/8/05 RESPONSE to Motion for a determination re tissue expanders
filed by Claimants' Advisory Committee
 EXHIBIT 1 – Article “Augmentation Mammoplasty
 Associated with a Severe System illness”
 EXHIBIT 2 – DCC POC Form
- Doc 673 6/10/09 Memorandum Opinion and Order Regarding Tissue Expander
Issue

- Doc 674 6/19/09 NOTICE OF APPEAL by Dow Corning Corporation re Doc 673 Order
EXHIBIT A - Memorandum and Opinion dated 6/10/09
- Doc 676 6/19/09 MOTION to Stay the Court's Rulings on the Disability Level A and Tissue Expander Issues Pending Appeal by Dow Corning Corporation
EXHIBIT A - Affidavit of Deborah Greenspan
- Doc 681 6/30/09 RESPONSE to Motion to Stay the Court's Rulings on the Disability Level A and Tissue Expander Issues Pending Appeal filed by Claimants' Advisory Committee
- Doc 682 7/10/09 REPLY to Response re Motion to Stay the Court's Rulings on the Disability Level A and Tissue Expander Issues Pending Appeal filed by Dow Corning Corporation
EXHIBIT A - IOM Report
EXHIBIT B - FDA Notice
- Doc 683 7/10/09 MOTION for Leave to File Excess Pages by Dow Corning Corporation
- Doc 700 10/13/09 STIPULATED MOTION to Supplement the Record for the Tissue Expander Appeal by Dow Corning Corporation
EXHIBIT A – Amended Joint Disclosure Statement
EXHIBIT B – Amended Joint Plan of Reorganization
EXHIBIT C – Settlement Facility and Fund Distribution Agreement
EXHIBIT D – Annex A to the SFA

Hearing Transcripts

- Doc 688 Hearing before Claims Administrator: June 22, 2004
- Doc 687 Hearing held on 9/9/04 before District Court