Case No. 13-2456

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

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UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Disclosure of Corporate Affiliations and Financial Interest

Sixth Circuit
Case Number: 13-2456 Case Name: In re Settlement Facility Dow Corning

Name of counsel: Douglas G. Smith

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

1. Is said party a subsidiary or affiliate of a publicly owned corporation? If Yes, list below the identity of the parent corporation or affiliate and the relationship between it and the named party:

Yes.

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? If yes, list the identity of such corporation and the nature of the financial interest:

Yes.

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.

CERTIFICATE OF SERVICE

I certify that on January 9, 2014 the foregoing document was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by placing a true and correct copy in the United States mail, postage prepaid, to their address of record.

s/ Douglas G. Smith
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This statement is filed twice: when the appeal is initially opened and later, in the principal briefs, immediately preceding the table of contents. See 6th Cir. R. 26.1 on page 2 of this form.

6th Cir. R. 26.1
DISCLOSURE OF CORPORATE AFFILIATIONS AND FINANCIAL INTEREST

(a) **Parties Required to Make Disclosure**. With the exception of the United States government or agencies thereof or a state government or agencies or political subdivisions thereof, all parties and amici curiae to a civil or bankruptcy case, agency review proceeding, or original proceedings, and all corporate defendants in a criminal case shall file a corporate affiliate/financial interest disclosure statement. A negative report is required except in the case of individual criminal defendants.

(b) **Financial Interest to Be Disclosed**.

(1) Whenever a corporation that is a party to an appeal, or which appears as amicus curiae, is a subsidiary or affiliate of any publicly owned corporation not named in the appeal, counsel for the corporation that is a party or amicus shall advise the clerk in the manner provided by subdivision (c) of this rule of the identity of the parent corporation or affiliate and the relationship between it and the corporation that is a party or amicus to the appeal. A corporation shall be considered an affiliate of a publicly owned corporation for purposes of this rule if it controls, is controlled by, or is under common control with a publicly owned corporation.

(2) Whenever, by reason of insurance, a franchise agreement, or indemnity agreement, a publicly owned corporation or its affiliate, not a party to the appeal, nor an amicus, has a substantial financial interest in the outcome of litigation, counsel for the party or amicus whose interest is aligned with that of the publicly owned corporation or its affiliate shall advise the clerk in the manner provided by subdivision (c) of this rule of the identity of the publicly owned corporation and the nature of its or its affiliate's substantial financial interest in the outcome of the litigation.

(c) Form and Time of Disclosure. The disclosure statement shall be made on a form provided by the clerk and filed with the brief of a party or amicus or upon filing a motion, response, petition, or answer in this Court, whichever first occurs.

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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 the Court deems relevant and will assist the Court in its decision. Oral argument is particularly important here, where this Court specifically directed the district court on remand to analyze what this Court described as a "formidable dump" of extrinsic evidence regarding the meaning of the term "Breast Implant" as used in Dow Corning's Plan of Reorganization. *See In re Settlement Facility Dow Corning Trust*, 628 F.3d 769, 772 (6th Cir. 2010).

INTRODUCTION

This Court previously reversed and remanded this matter, which concerns the district court's interpretation of the term "breast implant" as used in Section 1.17 of Dow Corning's Amended Joint Plan of Reorganization (defining "Breast Implant"), and whether that term encompasses "tissue expander" products. *See In re Settlement Facility Dow Corning Trust*, 628 F.3d 769 (6th Cir. 2010). This Court concluded that the district court (Hood, J.) erred in finding that the definition of breast implant was unambiguous and disregarding extrinsic evidence as to its meaning. Accordingly, the Court set aside the district court's conclusion that the term "breast implant" covered "tissue expanders" and remanded the case to the district court with instructions to "assess the relevant extrinsic evidence" regarding the meaning of the term "breast implant." A separate concurring and dissenting opinion agreed that the district court erred in refusing to consider such evidence, but concluded that remand would be futile, given the undisputed extrinsic evidence demonstrating that no reasonable person could conclude that tissue expanders were "breast implants."

Three years later, the district court issued a decision simply reaffirming its prior ruling and again disregarding the undisputed extrinsic evidence demonstrating that, as the district court itself acknowledged, tissue expanders are *not* "breast implants." The district court expressly found that "[t]here is no dispute

that 'Breast Implant' and 'Tissue Expander' mean different things." (RE #924, 10/08/13 Opinion, Page ID #15732.) The undisputed – albeit utterly ignored – record shows that the medical community, the FDA, and the general public all understood that the term "breast implant" does not include tissue expanders, which are entirely different products created for entirely different purposes. It is precisely because of this difference that, as the district court found, tissue expander claims were *not* included, during the confirmation hearing for Dow Corning's Plan of Reorganization, in the estimation of unliquidated tort claims that would receive compensation under the Plan. Rather, they were treated as non-covered "Other Products" not entitled to compensation.

Nonetheless, the district court ignored both the undisputed evidence regarding the ordinary and technical meaning of these terms and the undisputed record of the bankruptcy proceedings, relying instead on purported "evidence" regarding the practice under a settlement agreement in a *different* proceeding before a *different* court involving claims against *other* manufacturers to which Dow Corning was not a party – the Revised Settlement Program ("RSP") approved by the U.S. District Court for the Northern District of Alabama, which presided over the MDL-926 silicone breast implant litigation. The only support the district court cited for its decision to ignore the undisputed record regarding the Dow Corning Plan in favor of the purported practice under the RSP was a single

reference in a provision of the Settlement Facility Agreement for the Dow Corning Trust, which the district court acknowledged relates solely to "the protocols and procedures developed in connection with the Revised Settlement Program" – *not* substantive determinations about which claims would be paid under Dow Corning's Plan. (*Id.* Page ID #15736.)

Moreover, while the district court asserted on remand that the practice under the RSP supported the position of Appellee, the Claimants' Advisory Committee ("CAC"), the district court previously found *just the opposite*, concluding that the RSP criteria "len[t] credibility to *DCC's claim* that even under the RSP tissue expanders were *not* considered 'Breast Implants.'" (RE #673, 6/10/09 Opinion, Page ID #8749 (emphasis added).) While the RSP applied a "multiple manufacturer" discount where a claimant received more than one set of "breast implants" from different manufacturers, no such reduction was applied where claimants received both another manufacturer's breast implants and Dow Corning tissue expander products, which were not considered "breast implants." (*Id.*) Thus, not only did the district court err as a matter of law by ignoring the undisputed extrinsic evidence regarding the ordinary and technical meaning of the term "Breast Implant" and the undisputed record in the Dow Corning bankruptcy proceedings, but its ruling is premised on inconsistent fact finding regarding the practice under the RSP, constituting clear error. *See United States v. City of*

Warren, Mich., 138 F.3d 1083, 1092-93 (6th Cir. 1998) (district court decision "inconsistent with its own [prior] findings" is "clearly erroneous").

In sum, the district court's order not only repeats the prior errors that this Court previously held warranted reversal, but compounds them with a series of new errors. The district court's errors include (1) ignoring the undisputed evidence regarding the ordinary and technical meaning of the term "breast implant" that this Court directed the district court to consider, (2) disregarding the undisputed evidence from the bankruptcy proceedings that tissue expanders were *not* treated as "breast implants" and were expressly excluded from the estimation of claims that would receive compensation under the Plan, and (3) looking instead to proceedings other than the Dow Corning chapter 11 case and then ignoring its own prior finding that Dow Corning tissue expanders were *not* treated as breast implants in those proceedings either. This Court should reverse and enter judgment for Dow Corning.

STATEMENT OF JURISDICTION

The district court exercised jurisdiction pursuant to 28 U.S.C. § 1334 ("bankruptcy cases and proceedings"). This Court has jurisdiction to review the district court's October 8, 2013 final order pursuant to 28 U.S.C. § 1291. (*See* RE #924, 10/08/13 Opinion.) Dow Corning filed a timely notice of appeal on October 22, 2013. (*See* RE #927, 10/22/13 Notice of Appeal.)

STATEMENT OF THE ISSUES FOR REVIEW

1. Whether the district court erred in ignoring extrinsic evidence regarding the plain meaning of the term "Breast Implant."

2. Whether the district court erred in holding that tissue expander claims qualify for compensation as "Breast Implants" under Dow Corning's Amended Joint Plan of Reorganization, where the evidence from the Plan confirmation proceedings demonstrates that tissue expanders were not considered Breast Implants.

3. Whether the district court erred by basing its decision on the alleged practice under a settlement agreement in another proceeding before a different court involving different parties, and under which the district court previously found Dow Corning's tissue expander products were not treated as breast implants.

STATEMENT OF THE CASE AND THE FACTS

I. Background

This Court has previously discussed the history of Dow Corning Corporation's ("Dow Corning" or "DCC") bankruptcy proceedings and Amended Joint Plan of Reorganization. *See, e.g.*, *In re Settlement Facility Dow Corning Trust*, 628 F.3d 769 (6th Cir. 2010); *In re Dow Corning Corp.*, 280 F.3d 648 (6th Cir. 2002); *In re Dow Corning Corp.*, 86 F.3d 482 (6th Cir. 1996). 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). Breast implants were intended for long-term implantation in the breast for cosmetic and reconstructive purposes. (RE #51, Jakubczak Aff., Page ID #178, ¶ 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 id.*

This suggested, but unproven, link between breast implants and disease led to tens of thousands of personal injury lawsuits in the early 1990s, ultimately forcing Dow Corning to file for chapter 11 bankruptcy protection to resolve the breast implant suits. *See* 628 F.3d at 771; 280 F.3d at 653-54; 86 F.3d at 485. While independent scientists subsequently disproved the hypothesized link between breast implants and disease, and the scientific consensus today is that

there is "no elevated relative risk or odds ratios for an association of implants with disease" (IOM Report at ES-7),[1] 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 separate and distinct from breast implants, with different characteristics, uses, and functions. (RE #51, Jakubczak Aff., Page ID #180, ¶¶ 11, 12.) They are short-term devices,

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[1] 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. (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 1/2/14) ("IOM Report") (All websites cited in this brief were previously cited in Dow Corning's briefs before this Court (10/14/09 DCC App. Br. and/or 11/30/09 DCC App. Reply Br.), and those briefs were included in the Agreed Joint Index submitted to the district court on remand (RE #781, Agreed Joint Index at 6).) The IOM found that "there is no convincing evidence to support clinically significant immunologic effects of silicone or silicone breast implants." (IOM Report at 197.) Similarly, the "Independent Review Group" commissioned by the United Kingdom's Chief Medical Officer found that "[t]here is no epidemiological evidence for any link between silicone gel breast implants and any established connective tissue disease." (Report of the Independent Review Group 6 (July 1998), *available at* http://www.mhra.gov.uk/home/groups/dts-bi/documents/websiteresources/con2032510.pdf (last accessed 1/2/14).) Given this scientific consensus, in 2006 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 3 (Nov. 17, 2006), *available at* http://www.accessdata.fda.gov/cdrh_docs/pdf3/p030053b.pdf (last accessed 1/2/14).)

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.* Page ID #179, ¶ 6.) This function is qualitatively different from that of breast implants, which are intended to remain in the body for years, serving permanent space-filling and aesthetic functions. (*Id.* Page ID #178, 180, ¶¶ 5, 12.) Dow Corning marketed and sold tissue expanders as a completely different product. (*Id.* Page ID #179-81, ¶¶ 6, 10-13.)

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 the 250 types of tissue expanders could be used in the breast. (*Id.* Page ID #179, ¶ 7.) Indeed, many shapes and sizes of tissue expanders (*e.g.*, rectangle, square) are incompatible with use in the breast. (*Id.*) Because tissue expanders were fundamentally different from breast implants, the American Society for Testing and Materials had separate and unique standards for the manufacture of tissue expanders and breast implants.[2]

[2] *Compare* ASTM, Standard Specification for Implantable Breast Prostheses 1997, at 1 (ASTM F703-96) (describing requirements for manufacture of "breast prostheses"), *available at* http://www.astm.org/DATABASE.CART/

Tissue expanders had a metal fill valve that was accessible through the skin and could be seen and felt when inserted. (*Id.* Page ID #180, ¶ 9.) 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 through the valve to expand the device's volume, thus stretching the overlying skin. (*Id.* Page ID #179-80, ¶¶ 6, 8-9.) Unlike breast implants, Dow Corning tissue expanders were never filled with silicone gel. (*Id.* Page ID #179-80, ¶ 8.)

After serving their temporary function of facilitating skin growth, tissue expanders were surgically removed. Consistent with tissue expanders' distinct design and function, Dow Corning product literature marketed them as short-term devices (not long-term implants) whose sole purpose was to prepare the area for reconstructive surgery. (*Id.* Page ID #180, ¶ 10.) Dow Corning's product literature described the products as "tissue expanders" or "percutaneous skin expanders" – not "breast implants." (*Id.* Page ID #180-82, ¶¶ 11, 14; *see also* RE #40 Ex. 1, Dow Corning Wright Silastic Tissue Expander H.P., at 1.)

HISTORICAL/F703-96.htm (last accessed 1/2/14), *with* ASTM, Standard Specification for Soft-Tissue Expander Devices 1993 (Reapproved 1998), at Section 1, page 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"), *available at* ftp://65.198.187.10/project/ASTM_pdf/44/R9EONDE_.PDF (last accessed 1/2/14).

Medical professionals and the FDA consider breast implants and tissue expanders distinct products. (RE #51, Jakubczak Aff., Page ID #180-81, ¶¶ 12-13.)[3] 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.[4] In its 2004 "Breast Implant Consumer Handbook," the FDA cautioned that tissue expanders "are not to be

[3] A breast implant is commonly understood to be "[a]n implant for cosmetic purposes to replace a breast that has been surgically removed." (Webster's Dictionary, *available at* http://www.websters-online-dictionary.org/br/breast_implant.html (last accessed 1/2/14).) Tissue expanders are not implanted for "cosmetic purposes"; they contain valves and other design aspects that prohibit them from serving in this role. Nor do they "replace a breast that has been surgically removed." They are altogether different, used on a temporary basis to "stretch the skin" for reconstructive surgery or to "repair skin defects or to facilitate wound closure." (*See* RE #673, 6/10/09 Opinion, Page ID #8746.)

[4] *See* FDA, Breast Implants: An Informational Update 11-12 (1998), *available at* http://web.archive.org/web/20000815080652/www.fda.gov/cdrh/breastimplants/indexbip.html (cited in 10/14/09 DCC App. Br. at page 8 fn. 5) (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://permanent.access.gpo.gov/lps40385/indexbip.pdf (last accessed 1/2/14) (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 functions, 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.

(RE #51, Jakubczak Aff., Page ID #180-81, ¶ 13, *quoting* FDA, Breast Implant Consumer Handbook 10 (2004).)

Accordingly, the FDA has always categorized breast implants and tissue expanders in separate regulatory classes. Since it began regulating medical devices in 1976, the FDA treated breast implants as at least a Class II regulated device.[5] In 1998, the FDA raised the classification for breast implants to Class III, a category that requires the highest level of premarket approval. (*Id.* Page ID #180-81, ¶ 13.)

In contrast, the FDA always categorized tissue expanders as "unclassified medical devices." (*Id.*) In 2008, the FDA proposed placing tissue expanders in Class II, 73 Fed. Reg. 78239-01 (Dec. 22, 2008), but did not do so then or since.

[5] Products are placed in Class II when the FDA concludes that "special controls" beyond labeling and regulation of the manufacturing process are necessary to control product risks. *See* 21 U.S.C. § 360c(a)(1)(B). The 1976 Medical Device Amendments empowered the FDA for the first time to regulate medical devices. (RE #51, Jakubczak Aff., Page ID #180-81, ¶ 13.)

Tellingly, the FDA's contemporaneous draft Guidance Document confirmed that tissue expanders are 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."[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."[7]

II. Dow Corning's Amended Joint Plan Of Reorganization And Confirmation Proceedings

Dow Corning's chapter 11 case 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, "one of the world's largest mass tort litigations." *See In re*

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[6] USDHHS, Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Tissue Expander, § 3 (2008), *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070819.htm (last accessed 1/2/14). The FDA likewise explained in its February 11, 2003 guidance document for breast implants that it did not address tissue expanders because they were "unclassified devices for temporary use." (RE #51, Jakubczak Aff., Page ID #180-81, ¶ 13, *quoting* FDA, Breast Implant Consumer Handbook 10 (2004).)

[7] 4/16/92 FDA Press Release, *available at* http://web.archive.org/web/19970225092623/http:/www.fda.gov/bbs/topics/NEWS/NEW00273 (last accessed 1/2/14).

Dow Corning, 86 F.3d at 485-86. The Amended Joint Plan of Reorganization released Dow Corning and others from liability for breast implant claims providing such claimants with two options: file suit against a Litigation Facility (which has a capped Litigation Fund) or file an administrative claim with a Settlement Facility (the "Settlement Facility Dow Corning Trust" or "SF-DCT", which has a capped Settlement Fund) pursuant to heavily-negotiated, detailed criteria and procedures for determining eligible claims and payment amounts, which are set forth in a Settlement Facility Agreement and Fund Distribution Agreement ("SFA") and other Plan documents.

The Plan provides various levels of settlement benefits to claimants (in Classes 5, 6.1 and 6.2) 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." (RE #700 Ex. B, Plan, Page ID #10073, § 1.17.)

The Plan does not mention "tissue expanders" in the definition of "Breast Implant" or offer any settlement option whatsoever for claims arising from the use of a tissue expander. 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. (RE #700 Ex. B, Plan, Page ID #10073, § 1.17.) Under the first criterion, 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.[8]

The Plan also provides settlement options for certain specifically-enumerated non-Breast Implant products (called "Covered Other Products"), albeit at much lower amounts than Breast Implant Claims. (*See* RE #700 Ex. D, SFA Annex A, Page ID #10240-41, 10256, at A-14, A-15, A-30 (base payments for Breast Implant claims range up to $300,000, while payments for Covered Other Products range up to $10,000); *see also* RE #700 Ex. D, SFA Annex A, Page ID #10246, 10289-305, § 6.03(a) & Schedule I, Part II; RE #700 Ex. B, Plan, Page ID #10079, 10108, §§ 1.40, 5.4.1.2.) The Plan's exhaustive list of compensable Covered Other Products includes 42 models of hip and knee implants; 15 chin, nose or jaw implants or materials; and 16 testicular or penile implants. (*See* RE

[8] 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 other manufacturers. (RE #700 Ex. D, SFA Annex A, Schedule I, Part I.D., Page ID #10286-88.) To meet the identification requirements, the device in question must be a breast implant and must satisfy these identifier criteria as well. *(Id.*)

#700 Ex. D, SFA Annex A, Page ID # 10240-301, Schedule I, Part II, at A-64 to A-75.)

Claims based on tissue expanders are not included in the exhaustive enumeration of compensable "Covered Other Products," but rather fall into a third category of Dow Corning medical products under the Plan: those for which there is no settlement option, and can be resolved only through litigation against the Litigation Facility. (*Id.* Page ID #10247, § 6.03(b)) Such non-covered "Other Products" include "metal, silicone or silicone-containing products, other than Breast Implants . . . including, but not limited to" a non-exhaustive list of five products. (RE #700 Ex. B, Plan, Page ID #10089-90, § 1.117.)[9]

At no stage in Plan drafting or the confirmation hearing did any party, including individual tissue expander claimants and the Official Committee of Tort Claimants (the "Tort Claimants' Committee"), ever assert that they believed that tissue expanders were "Breast Implants" entitled to compensation under the Plan's settlement options for Breast Implant claims. 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 even a hypothesized link

[9] Additional similarly non-covered Other Products include injectable silicone fluid and certain types of Dow Corning silicone gel raw materials. (*See* RE #700 Ex. D, SFA Annex A, Page ID #100246, at § 6.03(a) (failing to list such materials among "Covered Other Products"); RE #51, Ex. A, F. Dunbar, Analysis of Other Product Claims (June 23, 1999), Page ID #176.)

between temporary tissue expander devices and disease. (*See* RE #700 Ex. D, SFA Annex A, Page ID #10240-41, 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 – which the Bankruptcy Code requires plan proponents to demonstrate in order to confirm a plan of reorganization. *See* 11 U.S.C. § 1129(a)(11).

This evidence was offered jointly by the Plan's proponents, Dow Corning and the Tort Claimants' Committee (the predecessor of Appellee CAC), was relied on by the Bankruptcy Court in finding that the Plan was feasible under 11 U.S.C. § 1129(a)(11), and was prominently featured in the testimony and analysis of mass-tort specialist and economist Dr. Frederick Dunbar who estimated the tort claims on behalf of Dow Corning and the Tort Claimants' Committee. (*See* RE #673, 6/10/09 Opinion, Page ID #8749-50; RE #51 Ex. A, F. Dunbar, Analysis of Other Product Claims (June 23, 1999), Page ID #176; *In re Dow Corning Corp.*, 244 B.R. 721, 731-33 (Bankr. E.D. Mich. 1999).) Dr. Dunbar estimated that there would be 159,577 Breast Implant claims, including settlement amounts estimated at more than $2.027 billion.[10] Dr. Dunbar, however, specifically *excluded* tissue

[10] Dr. Dunbar further estimated that there would be approximately $29,687,964 worth of Covered Other Products that were specifically designated to receive compensation under the Plan. (Dunbar Expert Notebook at 17, 45, 46, 166 (admitted into evidence at 6/29/99 Conf. Hr'g Tr. at 150, 160-61, *In re Dow Corning*, No. 95-20512).)

expanders from his analysis of the number and cost of claims in the Breast Implant category that would receive compensation under the Plan. Rather, he 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 instead would be addressed only through the litigation option. (RE #51 Ex. A, F. Dunbar, Analysis of Other Product Claims (June 23, 1999), Page ID #176; *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).)

The CAC has tried to distance itself from this analysis by suggesting, in appellate briefing more than a decade after-the-fact, that Dr. Dunbar's analysis was presented solely on behalf of Dow Corning. However, as the Bankruptcy Court recognized contemporaneously, Dr. Dunbar's analysis was presented on behalf of *both* Plan Proponents – the Debtor (Dow Corning) *and* the Tort Claimants' Committee. *See In re Dow Corning Corp.*, 237 B.R. 364, 369 n.4 (Bankr. E.D. Mich. 1999) (Dr. Dunbar "was called to testify *by the Proponents* to establish that the $400 million Litigation Facility would be adequate") (emphasis added); *In re Dow Corning Corp.*, 255 B.R. 445, 502 (E.D. Mich. 2000) ("The Bankruptcy Court was very impressed by *the Proponents' witness* on this issue – Mr. Dunbar.") (emphasis added). Moreover, the CAC has never cited any pleading,

brief, objection or other document from the bankruptcy proceedings in which anyone ever objected to Dr. Dunbar's exclusion of tissue expanders from the estimation of compensable tort claims or contemporaneously asserted that tissue expanders were entitled to compensation as "Breast Implants." In November 1999, the Bankruptcy Court entered a series of orders confirming the Plan, none of which suggested that tissue expander claims were eligible for *any* settlement option, much less that they were entitled to settlement compensation reserved for "Breast Implants" under the Plan.[11]

III. Non-Payment Of Tissue Expander Claims By The Settlement Facility

For several years before the Plan became effective in 2004, the Settlement Facility-Dow Corning Trust hired, prepared, and trained staff to process the payment of tort claims. During that time, tissue expanders were never mentioned in the training of the Settlement Facility staff, which was done in conjunction with both Dow Corning and the Tort Claimants' Committee. (RE #51, Jakubczak Aff.,

[11] *See, e.g.*, *In re Dow Corning Corp.* (Amended Opinion on the Classification and Treatment of Claims), 244 B.R. 634 (Bankr. E.D. Mich. 1999); *In re Dow Corning Corp.* (Opinion on Best-Interests-of-Creditors Test, Feasibility, and Whether Plan and the Proponents Comply with the Applicable Provision of Title 11), 244 B.R. 721 (Bankr. E.D. Mich. 1999). Various parties appealed the Bankruptcy Court rulings to the district court, *In re Dow Corning Corp.*, 255 B.R. 445 (E.D. Mich. 2000), and ultimately to this Court, *In re Dow Corning Corp.*, 280 F.3d 648 (6th Cir. 2002). None of these numerous opinions on various aspects of Plan confirmation suggests that tissue expander claims would receive compensation under the Plan's settlement options.

Page ID #182, ¶¶ 15-16.) The product identification materials and training materials referred to Breast Implants and compensable "Other Products," but not to tissue expanders. (*Id.*)

In 2003, certain claimants asserted claims against the Settlement Facility based on their exposure to tissue expander products. After convening a proceeding at which Dow Corning and the Tort Claimants' Committee expressed their views on the matter, on June 28, 2004 the Settlement Facility's Claims Administrator declined to issue a determination that tissue expanders were eligible for compensation as "breast implants." Pursuant to Section 5.05 of the SFA, Dow Corning and the CAC filed "cross motions" seeking a determination from the district court. Five years later, the district court issued its first ruling on this matter. (RE #673, 6/10/09 Opinion.)

IV. The District Court's First Ruling Allowing Compensation For Tissue Expander Claims And This Court's Reversal Of That Ruling

As the district court acknowledged in its first Opinion on this issue, "[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." (*Id.* Page ID #8743.) 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.* Page ID #8746.) 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 FDA while 'breast implants' were classified in Class II and ultimately Class III by the FDA." (*Id.* Page ID #8747.) The court agreed 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.* Page #8746.)

Significantly, the district court found that the CAC's primary argument – that tissue expanders were treated as "breast implants" under the Revised Settlement Program ("RSP") approved by the U.S. District Court for the Northern District of Alabama in the MDL litigation – was refuted by the RSP record, which instead "len[t] credibility to DCC's claim that even under the RSP tissue expanders were *not* considered 'Breast Implants.'" (RE #673, 6/10/09 Opinion, Page ID #8749 (emphasis added).) The RSP, like the Dow Corning Plan, applied a "multiple manufacturer" discount where a claimant received multiple "breast implants" from different manufacturers in order to prevent the claimant from receiving what would amount to a double recovery if she received a 100% settlement payment from each of two or more manufacturers. (*Id.* Page ID #8748-49; RE #40 Ex. 3, 1/25/02 SF-DCT email.) No such reduction was applied in the

RSP for a claimant who received both breast implants made by one manufacturer and a tissue expander made by Dow Corning. (*Id.*)

Nevertheless, the district court refused to consider this extrinsic evidence on the ground that the Plan was purportedly "unambiguous" and that "there is no requirement that the product must be designated or identified by DCC and others as [a] 'breast implant' in order to meet the 'Breast Implant' Plan definition." (RE #673, 6/10/09 Opinion, Page ID #8746, 8750.)

This Court reversed the district court's ruling, holding that "§ 1.17 [of Dow Corning's Plan] is ambiguous" and thus the district court's refusal to consider the parties' extrinsic evidence constituted reversible error. *In re Settlement Facility*, 628 F.3d at 773. The majority remanded with instructions to the district court to "assess the relevant extrinsic evidence" in the first instance to determine whether the term "breast implants" used in Section 1.17 encompassed the tissue expanders at issue here. *Id.* at 773. This included, among other things, evidence concerning both the "technical" and "ordinary" meaning of "the words 'breast implant.'" *Id.*

In a partial concurrence and dissent, Judge Batchelder stated that remand would be futile, given that "the extrinsic evidence … clearly favors Dow Corning's interpretation of the Plan" and "it is unreasonable to conclude that the Plan definition of 'Breast Implants' includes tissue expanders." *Id.* at 777. Judge Batchelder observed that (1) the "undisputed evidence" showed that "the medical

community and the FDA both considered tissue expanders to be an entirely separate product from breast implants"; (2) no "reasonable lay person" would think that a "tissue expander" was a "breast implant"; (3) the "undisputed evidence" from the history of the bankruptcy proceedings demonstrates that the proceedings arose directly from the need to address breast implant, not tissue expander, claims; (4) the confirmation proceedings demonstrate that only breast implant claims were estimated to receive settlement compensation under the Plan; Dr. Dunbar's analysis "expressly excluded all then-existing and predicted lawsuits based on tissue expanders" and "there is no evidence that any party ever objected to his analysis excluding those lawsuits"; (5) the evidence the CAC submitted regarding other proceedings (the RSP) constituted "strong evidence that tissue expanders were *not* intended to be included in the [Dow Corning] Plan definition"; (6) and the provision of the Settlement Facility Agreement referring to the RSP imposes only a "procedural guarantee, not a substantive one." *Id.* at 777-79. Accordingly, Judge Batchelder concluded that "[t]he record in this case is long, but it is not overly complicated, and it simply does not support [the CAC's] preferred interpretation." *Id.* at 779.

V. The District Court's Reaffirmation Of Its Original Ruling In The Face Of This Court's Remand Instructions

On remand, the district court directed the parties to submit supplemental briefs limited to 10 pages per side along with an Agreed Joint Index of Materials.

(*See* RE #777, Briefing Schedule; RE #782, DCC Mem., at n.1.) No additional extrinsic evidence, other than that submitted in the original district court proceedings, was filed and no hearing held. The CAC did not seek to present additional evidence at a hearing; nor did Dow Corning, given that all of the existing record evidence demonstrated that both the ordinary and technical meaning of the term "Breast Implant" excluded tissue expander products. All the record evidence regarding the Plan confirmation proceedings shows that tissue expanders were not treated as Breast Implants: the Dunbar analysis expressly excludes tissue expanders from the estimation of tort claims that would be paid under the Plan's settlement options, and the CAC submitted no contrary evidence (because there is none). (RE #51 Ex. A, F. Dunbar, Analysis of Other Product Claims (June 23, 1999), Page ID #176.) Moreover, all the record evidence regarding contemporaneous meaning within the medical and regulatory community as well as the general population demonstrates that tissue expanders are not breast implants. Specifically, the only affidavit providing extrinsic evidence on the meaning of the terms was a detailed affidavit of Gene Jakubczak, Dow Corning's medical device operations manager, submitted by Dow Corning. (RE #51, Jakubczak Aff.) After all these years, the CAC has never produced an affidavit from a single patient or doctor attesting that they considered tissue expanders to be "breast implants." Instead, the only "evidence" the CAC submitted was from a

separately negotiated settlement in another proceeding among different parties (the RSP) and an assertion – supported nowhere in the record – that the RSP governs the substantive criteria for payment of claims by the Dow Corning Settlement Facility.

Approximately three years after this Court ordered remand, and two and a half years after the parties submitted their supplemental briefs on remand, the district court issued its decision, simply repeating its original ruling that tissue expanders could receive compensation as "breast implants" and again ignoring the extrinsic evidence this Court directed it to consider. The district court conceded that "[t]here is no dispute that the terms 'Breast Implant' and 'Tissue Expander' mean different things." (RE #924, 10/08/13 Opinion, Page ID #15732.) Nonetheless, the court determined that it could disregard all extrinsic evidence regarding the ordinary and technical meaning of these terms in favor of some undocumented, idiosyncratic "intent" of the parties unsupported by any actual evidence. (*Id.*) In doing so, the district court was unable to identify any evidence from the Dow Corning bankruptcy proceedings that supports this interpretation of the term "breast implant." To the contrary, it recognized that "[t]he parties did not expressly include the term 'Tissue Expander' in the 'Breast Implant' definition"; that Dr. Dunbar, the expert who provided the estimation of the value of the settlement claims to be paid under the Plan at the confirmation hearing on behalf of

"the Plan Proponents" (both Dow Corning and claimants), "did not incorporate an estimate of the cost of paying tissue expander claimants the payment prescribed for 'Breast Implant' claimants"; and that "the specific tissue expander claims at issue were not specifically raised at the confirmation hearing." (*Id.* Page ID #15733-34.) As the district court recognized, while Dr. Dunbar identified 1,041 potential tissue expander claims, he expressly excluded them from the breast implant claims he estimated, and instead "listed tissue expanders [in his analysis] under 'Other Products,'" which were entitled to none of the compensation reserved for breast implant claims. (*Id.*) As a result, "tissue expanders were not given any estimate." (*Id.* Page ID #15734.)

The district court dismissed all of this undisputed evidence as "not relevant." (RE #924, 10/08/13 Opinion, Page ID #15732.) Instead, the court adopted the "CAC's main argument" – *i.e.*, that in certain unspecified conversations documented nowhere in the record "Dow Corning Claimants were specifically told that the Plan's offers would be the same as those in the RSP," a settlement reached in a different proceeding before a different court (MDL-926 in the Northern District of Alabama) involving other implant manufacturers. (*Id.*) The district court cited no record evidence identifying any claimant who was ever "told" that the Plan's settlement offers would be the same as those in the RSP; nor did the court cite any record evidence from the RSP to support its interpretation of that

settlement plan. Rather, the only record citation the district court provided was to Section 4.03 of the Dow Corning Plan's SFA. That provision, as the district court acknowledged, merely referenced "the protocols and procedures developed in connection with the Revised Settlement Program" – not *substantive* rules regarding which products were eligible for compensation – and said nothing about the meaning of "breast implants" contained in the definition of "Breast Implant" in Section 1.17 of the Plan. (*Id.* Page ID #15736.)

The district court ignored its own prior finding that, under the RSP, Dow Corning's tissue expanders were *not* treated as "breast implants" – just the opposite: they were treated as *non*-breast implant products for purposes of the settlement's multiple manufacturer reduction. (RE #673, 6/10/09 Opinion, Page ID #8749 (emphasis added).) The district court provided no explanation for reversing its original finding, despite the fact that Dow Corning specifically raised the district court's prior finding in its briefing on remand. (RE #782, DCC's Mem. re Extrinsic Evidence of the Meaning of "Breast Implant" and "Tissue Expander," p. 10)

As a result of the district court's ruling, approximately fourteen years after the parties agreed upon, and the bankruptcy court confirmed, a Plan that expressly provided settlement compensation solely for claims based on "Breast Implants" and specific "Covered Other Products," Dow Corning is now informed that in

addition to the hundreds of millions of dollars being paid to compensate those claims, the Plan further mandates substantial additional expenditures for tissue expander claims. This is the case even though (1) it is undisputed, and the district court found, that "tissue expanders" and "breast implants" "mean different things"; (2) there is nothing in the extensive record of the bankruptcy proceedings suggesting that "breast implants" include tissue expanders, and in fact all the evidence demonstrates the contrary; (3) the district court found that tissue expander claims were not even estimated in the bankruptcy proceedings; (4) the only "evidence" the district court cited was the suggestion (supported by no record citation) that tissue expanders were treated as breast implants under a settlement agreement in the separate RSP proceeding, to which Dow Corning was not a party – a suggestion that is contrary to the district court's own express finding in a prior ruling, which recognized that Dow Corning tissue expanders were *not* treated as breast implants under the RSP; and (5) there is no reliable scientific evidence that Dow Corning's tissue expander products can even cause any disease, much less that any tissue expander claimant ever had a potentially valid claim.[12]

[12] Indeed, the subsequent scientific evidence shows that even Dow Corning's breast implant products do not cause disease, as reflected in a string of federal court decisions holding that contrary causation claims are scientifically unreliable and inadmissible under Rule 702 and *Daubert*. *See, e.g., Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1313, 1317 (11th Cir. 1999) (breast implant causation claims based on "unreliable foundation"); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881, 883-84 (10th Cir. 2005) (breast implant causation claims contrary to

SUMMARY OF ARGUMENT

The district court erred in holding that a tissue expander 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 defining which Dow Corning devices are settlement-eligible, much less state that claimants treated with Dow Corning tissue expanders – but who never received a 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 received Dow Corning breast implants, a term that has a well-established meaning that excludes "tissue expanders." The district court specifically found that tissue expanders and breast implants "mean different things," yet decided to ignore the "formidable dump" of record evidence documenting this ordinary and technical meaning.

"a significant body of epidemiology"); *Meister v. Med. Eng'g Corp.*, 267 F.3d 1123, 1127, 1129, 1132 (D.C. Cir. 2001) ("uniform body of evidence including epidemiological studies failing to establish a causal link between silicone breast implants and connective tissue disease"); *Pozefsky v. Baxter Healthcare Corp.*, 2001 WL 967608, at *6 (N.D.N.Y. Aug. 16, 2001) (excluding expert opinion contrary to "the overwhelming weight of scientific authority hold[ing] that there is no connection between silicone breast implants and defined or atypical connective tissue disease"); *Grant v. Bristol-Myers Squibb*, 97 F. Supp. 2d 986, 992 (D. Ariz. 2000) ("overwhelming evidence" showing breast implants do not cause disease).

The district court erred for multiple reasons. *First*, New York law, which governs the interpretation of the Plan (*see* Argument Sec. I below), makes clear that the plain meaning of the terms is dispositive. *Cerand v. Burstein*, 72 A.D.3d 1262 (N.Y. App. Div. 3d Dep't 2010). Here, however, the district court refused to consider the undisputed extrinsic evidence demonstrating that the ordinary meaning of "breast implant" does not include tissue expanders on the ground that there was some undocumented "intent," discerned by the court from some unspecified place outside the evidentiary record, that is contrary to this plain meaning. In doing so, the court violated well-settled New York law.

Second, the district court's ruling ignores the extrinsic evidence showing that tissue expander claims were never treated as "breast implants" during the bankruptcy proceedings. The district court found that the tissue expander claims were expressly excluded from the estimation of tort claims – the debtor's overwhelmingly largest liability – during the confirmation proceedings. (RE #924, 10/08/13 Opinion, Page ID #15733-34.) Nonetheless, the district court simply ignored this evidence and pronounced that it was "not relevant." (*Id.* Page ID #15732.) In doing so, the court ignored the objective evidence regarding the meaning of Plan language that well-settled principles of interpretation and this Court's express instructions directed it to consider. *See In re Settlement Facility*, 628 F.3d at 772.

Finally, the district court erred as a matter of law by relying on unsupported assertions regarding a different case to which Dow Corning was not a party. Having found no evidence in the Dow Corning bankruptcy proceedings suggesting that anyone considered tissue expanders "breast implants" entitled to compensation, the district court looked instead to the supposed practice under the Revised Settlement Program in MDL-926. The district court maintained that the parties had agreed in the Dow Corning Settlement Facility Agreement that claims would be processed in the same manner as in the RSP. However, as the district court itself recognized, the only provision of the SFA cited by the court merely referenced the "procedures and protocol" used under the RSP – not substantive determinations regarding what claims would be paid. The district court's ruling is therefore premised on a misinterpretation of the Plan's plain language. Moreover, the district court cited nothing in its decision to support the assertion that tissue expanders were treated as "breast implants" in the RSP. Worse, the district court's ruling contradicted – with no explanation whatsoever – its previous finding that Dow Corning tissue expanders were *not* treated as "breast implants" for purposes of the RSP and that the practice under the RSP "len[t] credibility to *DCC's claim* that even under the RSP tissue expanders were *not* considered 'Breast Implants.'" (RE #673, 6/10/09 Opinion, Page ID #8749 (emphases added).) Such an

unexplained and unjustified about-face from its own prior finding constitutes clear error. *See U.S. v. City of Warren, Mich.*, 138 F.3d 1083, 1092-93 (6th Cir. 1998).

STANDARD OF REVIEW

In the prior appeal, this Court articulated an intermediate standard of review applying a heightened level of scrutiny of the district court's decision beyond the traditional abuse of discretion standard. *In re Settlement Facility*, 628 F.3d at 771-72. Under this standard, as under the abuse of discretion standard, the district court's legal rulings remain subject to *de novo* review. *Id.*; *In re Eagle-Picher Indus., Inc.*, 447 F.3d 461, 463-64 (6th Cir. 2006).[13]

However, given the nature of the district court's ruling here, it is not clear that it is entitled to any deference. The standard this Court articulated in the prior appeal was premised on the fact that "[t]he district court judge who entered the

[13] *See also, e.g., In re Shenango Group Inc.*, 501 F.3d 338, 346 (3d Cir. 2007) (review of plan interpretation 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); *Performance Unlimited, Inc. v. Questar Publishers, Inc.*, 52 F.3d 1373, 1378 (6th Cir. 1995) (in applying abuse of discretion standard "legal conclusions are given *de novo* review"); *Sault Ste. Marie Tribe of Chippewa Indians v. Granholm*, 475 F.3d 805, 816 (6th Cir 2007) ("The admissibility of extrinsic evidence is a question of law and is properly within our province to determine."). Even under an abuse of discretion standard, a court abuses its discretion where 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*, 52 F.3d at 1378.

orders at issue – Judge Denise Page Hood – has presided over this bankruptcy case continuously since 1995" and was "present on the bench for two [of the thirteen] days of the Plan's confirmation hearings." *In re Settlement Facility*, 628 F.3d at 772. On remand, however, the district court based its ruling not on the record of the proceedings over which it presided – which it dismissed as irrelevant – but rather on findings relating to an entirely different proceeding, the MDL-926 Revised Settlement Program before the U.S. District Court for the Northern District of Alabama. Moreover, the district court itself previously made findings directly contrary to its decision on remand, concluding that the proceedings under the RSP actually supported Dow Corning's position here. Thus, the district court's ruling should be accorded no deference. *See City of Warren*, 138 F.3d at 1092-93; *In re Weber*, 25 F.3d 413, 416 (7th Cir. 1994) (abuse of discretion inapplicable where court not interpreting its "own order").

ARGUMENT

I. The District Court Erred As A Matter Of Law By Refusing To Consider Extrinsic Evidence That This Court Directed It To Consider And That Demonstrated, As The District Court Itself Found, That The Plain Meaning Of The Term "Breast Implant" Does Not Include Tissue Expanders.

In interpreting a confirmed plan, courts apply contract principles since the plan is effectively a contract between the debtor and all its creditors. *In re Dow Corning Corp.*, 456 F.3d 668, 676 (6th Cir. 2006). State law governs those

interpretations, and a Plan must be enforced as written. *Id.* The Plan here states that interpretation of the Plan "shall be governed by and construed in accordance with the laws of the State of New York and applicable federal law." (RE #700 Ex. B, Plan, Page ID #10127, § 6.13; *see also* RE #924, 10/08/13 Opinion, Page ID #15730.)

Under established principles of contract interpretation, the terms of a confirmed plan must be construed according to their "plain, ordinary meaning," *Constr. Interior Sys., Inc. v. Marriott Family Rests., 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"). Moreover, "[i]f trade practice, custom or usage has infused special meaning into the[] words, which both parties bargained with reference to, then it should be proved affirmatively, and findings should be made with regard to it." *Sault Ste. Marie Tribe of Chippewa Indians v. Granholm*, 475 F.3d 805, 815 (6th Cir. 2007), quoting *Booth v. N. Am. Aluminum Corp.*, 423 F.2d 545, 547 (6th Cir. 1970).

These well-established principles are followed under New York law, where the plain meaning of contract terms likewise governs. *Cerand*, 72 A.D.3d at 1265. Where, however, terms have acquired meaning as a term of art, "the technical meaning is preferred over the common or ordinary meaning." *See Madison Ave.*

Leasehold, LLC v. Madison Bentley Assocs. LLC, 30 A.D.3d 1, 8 (N.Y. App. Div. 1st Dep't 2006).

The district court's ruling here violates these settled principles of construction. The Dow Corning Plan limits settlement compensation to claimants who received "Breast Implants." (RE #700 Ex. B, Plan, Page ID #10073, § 1.17.) It does not authorize any settlement option for claimants who were implanted with "tissue expander" products. As the unrebutted evidence discussed above and the district court's own findings demonstrate, there is no dispute that the medical community and the FDA understand that tissue expanders and breast implants are completely separate and distinct products, that tissue expanders and breast implants are treated differently for regulatory purposes, or that product literature for Dow Corning tissue expanders does not describe them as "breast implants." (*See, e.g.*, RE #51, Jakubczak Aff., Page ID #180-81, ¶¶ 11-13 *quoting* FDA Breast Implant Consumer Handbook 10 (2004).)[14] Moreover, as this Court previously recognized,

[14] The fact that the Plan defined the term "Breast Implant" using the term "breast implant" – which at first blush seems merely circular – instead reflects that the ordinary meaning understood by the medical community, the FDA and the general public is so common and well-accepted that further definition is not necessary. *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"); *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

the purpose of tissue expander products is completely different from breast implants: "Their purpose is to expand the patient's skin around the device; and upon accomplishing that purpose, they are typically (if not always) removed." *In re Settlement Facility*, 628 F.3d at 771. Indeed, no "reasonable lay person" would think that a "tissue expander" was a "breast implant": "[I]f one hundred average Americans were approached on the street and asked to define a breast implant, none would describe a tissue expander. If a tissue expander were then described to them, and they were asked if a tissue expander was a breast implant, the vast majority would say no." *Id.* at 777 (Batchelder, J., concurring in part and dissenting in part). Accordingly, under the plain and ordinary meaning of these terms, tissue expander claimants are not entitled to compensation under the Plan's settlement options for Breast Implant claims.

The district court agreed, specifically finding that "'Breast Implant' and 'Tissue Expander' mean different things." (RE #924, 10/08/13 Opinion, Page ID #15732.) Nonetheless, the court proceeded to ignore this evidence of the term's ordinary and technical meaning and, indeed, almost all of what this Court previously described as "a formidable dump" of extrinsic evidence containing

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part circular, itself depending on the meaning of the word 'bank,' Congress evidently relied on common understanding to fill the gap"); *FTC v. Verity Int'l, Ltd.*, 443 F.3d 48, 57-58 (2d Cir. 2006) (undefined statutory term given its ordinary meaning).

"great detail." *See In re Settlement Facility*, 628 F.3d at 772. Instead, the district court suggested that there was some idiosyncratic, never-documented "inten[t]" that was at odds with this plain meaning, and that it could therefore entirely *ignore* the ordinary meaning of the language as well as the substantial extrinsic evidence Dow Corning submitted regarding accepted trade, custom and usage. (RE #924, 10/08/13 Opinion, Page ID #15732.) In doing so, the district court disregarded this Court's express instructions and committed a fundamental error of law. *See, e.g., Bridgeport Music*, 410 F.3d at 798; *Granholm*, 475 F.3d at 814 ("This industry specific definition creates a latent ambiguity that may only be resolved with the aid of extrinsic evidence. Thus, the district court erred in refusing to consider such evidence."); *Constr. Interior Sys.*, 984 F.2d at 756.[15]

The law is clear that a court cannot disregard as "irrelevant" the plain and ordinary meaning given to terms used in a plan of reorganization. To the contrary, this Court "interpret[s] the Plan's provisions according to their *plain meaning*, in an ordinary and popular sense." *Perez v. Aetna Life Ins. Co.*, 150 F.3d 550, 556 (6th Cir. 1998) (emphasis added).

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[15] *See also, e.g., Schreiber v. Philips Display Components Co.*, 580 F.3d 355, 368 (6th Cir. 2009) ("The district court erred in concluding that the relevant provisions of the CBA are unambiguous and failing to consider the SPDs and extrinsic evidence."); *In re Exide Techs.*, 544 F.3d 196, 210-12 (3d Cir. 2008) (court "erred in concluding that the provision was unambiguous and failing to allow extrinsic evidence to be introduced").

Purported idiosyncratic meanings that a party attempts to ascribe to such language, years after the fact, are legally irrelevant. "'A signatory to a contract is bound by its ordinary meaning even if he gave it an idiosyncratic one.'" *Brown-Graves Co. v. Cent. States, S.E. & S.W. Areas Pension Fund*, 206 F.3d 680, 684 (6th Cir. 2000). "[T]he meaning of a word depends on what it denotes to members of the appropriate linguistic community, not on idiosyncratic usages that people may be able to devise." *Blue Cross Blue Shield of Mass., Inc. v. BCS Ins. Co.*, 671 F.3d 635, 638 (7th Cir. 2011). Accordingly, "[w]hen interpreting the meaning of a contract, it is the objective intent of the parties that controls…. The secret or subjective intent of the parties is irrelevant." *Klos v. Polskie Linie Lotnicze*, 133 F.3d 164, 168 (2d Cir. 1997). *See also Ortony v. Northwestern Univ.*, 736 F.3d 1102, 1104 (7th Cir. 2013) ("the construction of a contract is an objective exercise; private beliefs and meanings do not matter"); *Vision Info. Servs., LLC v. Comm'r of Internal Revenue*, 419 F.3d 554, 558-59 (6th Cir. 2005) ("It is clear, therefore, that it is not the real intent but the intent expressed or apparent in the writing which is sought; it is the objective, not the subjective, intent that controls," citing 11 WILLISTON ON CONTRACTS § 31:4 (4th ed. 1999)); *Bach v. Friden Calculating Mach. Co.*, 155 F.2d 361, 365 (6th Cir. 1946) ("As was said by Professor Corbin in, 'Cardozo on the Law of Contracts,' 52 Harvard Law Review 446, 'The meaning that will determine legal effect is that which is arrived at by objective

standards; one is bound, not by what he subjectively intends, but by what he leads others reasonably to think that he intends.' This line of authorities has been consistently followed in this court."); *Hotchkiss v. National City Bank of N.Y.*, 200 F. 287, 293 (S.D.N.Y. 1911), ("A contract has, strictly speaking, nothing to do with the personal, or individual, intent of the parties.") (Hand, J.); 11 WILLISTON ON CONTRACTS § 32:2 (4th ed. 2013); *Sally v. Sally*, 225 A.D.2d 816, 818-19 (N.Y. App. Div. 3d Dep't 1996) (evidence of parties' uncommunicated subjective understanding of ambiguous language in contract is irrelevant); *Padovano v. Vivian*, 217 A.D.2d 868, 869 (N.Y. App. Div. 3d Dep't 1995) (even if phrase "good working order" were ambiguous, "[e]xtrinsic evidence of [the parties'] uncommunicated subjective intent [would be] irrelevant"); *Cutter v. Peterson*, 203 A.D.2d 812, 814 (N.Y. App. Div. 3d Dep't 1994) ("It is not what a party subjectively thought was meant or intended by the offer or acceptance made, but 'what a reasonable person in the position of the parties would have thought [was] meant,'" *quoting* 2 WILLISTON ON CONTRACTS § 6:57 (4th ed. 2013)).

The CAC presented no objective evidence that they or anyone else understood that tissue expander claimants would receive compensation out of the finite, fixed fund from which all personal injury creditors must draw. To the contrary, the district court's findings confirm that the only conclusion an objective observer could have reached was that tissue expander claimants would *not* receive

compensation under any settlement option in the Plan. As the district court found, "'Breast Implant' and 'Tissue Expander' mean different things." (RE #924, 10/08/13 Opinion, Page ID #15732.) The district court's decision to disregard the ordinary meaning of the Plan language and the undisputed history of the bankruptcy proceedings and instead accept the CAC's undocumented assertion about the supposed idiosyncratic "intent" of certain persons who are not even identified in the evidentiary record – contrary to the well-documented intent of Dow Corning and the Tort Claimants' Committee, and the dozens of creditor classes and interests who voted to approve the Plan as written – is inconsistent with settled law and this Court's express instructions. *See In re Settlement Facility*, 628 F.3d at 772-73.

II. The District Court Erred By Holding That Tissue Expander Claims Could Recover Under the Plan Even Though It Found That The Confirmation Hearing Evidence Demonstrated That Tissue Expanders Were Not Considered Breast Implants.

Even if the district court could ignore this plain meaning, however, its decision would still constitute reversible error under the circumstances here. The record of the bankruptcy proceedings demonstrates that the meaning of the term "breast implant" in the Plan is the same as the meaning of that term in its ordinary sense.

As the district court specifically found, there is *nothing* in the record of the Dow Corning bankruptcy proceedings suggesting that the parties understood the

term "breast implant" in any way other than its ordinary meaning, which excludes tissue expander products. As the district court recognized, when addressing the claims that would be entitled to compensation under the Plan, "the specific tissue expander claims at issue were not specifically raised at the confirmation hearing." (RE #924, 10/18/13 Opinion, Page ID #15734.) In particular, the estimation of the tort claims that would receive compensation under the Plan that Dr. Dunbar presented on behalf of both the claimants and Dow Corning "did not specifically estimate the cost of paying tissue expander implant claims." (*Id.* Page ID #15733.) Indeed, Dr. Dunbar's analysis expressly excluded tissue expanders, "list[ing] tissue expanders in his analysis under 'Other Products,'" that would *not* be eligible for the Settlement Option. (*Id.*) In contrast, Dr. Dunbar presented detailed estimates of the numbers and total cost of "Breast Implant" claims as well as claims based on other Dow Corning medical products compensated under the Plan (so-called "Other Covered Products" which exclude, *inter alia*, tissue expanders). In fact, this record is undisputed; in their submission below, the CAC conceded that "Dr. Dunbar did not specifically estimate the cost of paying tissue expander implant claims" and that "[t]he confirmation hearing did not separately focus on tissue expander implants." (RE #783, 4/11/11 CAC Br. at 8.)[16]

[16] In its brief filed in the prior appeal, the CAC made a similar acknowledgment: "Mr. Dunbar list[ed] 'tissue expanders' as among products that were not 'covered' by the 'Other Products' Settlement Option" and "Mr. Dunbar was not required to

The entire purpose of the bankruptcy filing was to resolve claims involving Dow Corning breast implant products – not tissue expanders. *See* 456 F.3d at 671; 86 F.3d at 485. As temporary skin-growth enhancers, tissue expanders simply were not alleged to cause the same risk of immunological effects leading to disease that was hypothesized with breast implants; nor were tissue expanders subject to the FDA moratorium that spawned the breast implant litigation. Accordingly, 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." *In re Dow Corning Corp.*, 244 B.R. at 658. "All are unsecured, unliquidated and disputed tort claims arising out of the Debtor's sale and manufacture of silicone-gel breast implants." *Id.* In addition, "[a]ll of the [breast implant] claimants used the Debtor's products in the same manner." *Id.* at

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estimate the separate value of such claims." (11/13/09 CAC App. Br. at 37-38.) Skirting the absence of any evidence from the Dow Corning case supporting their position, the CAC has from time to time attempted to suggest that the records from other bankruptcy proceedings support their position. However, the CAC has submitted no evidence to support their assertions regarding these proceedings, Judge Hood did not rely on them in her decision, and as Judge Batchelder observed, on their face the CAC's arguments demonstrate that where tissue expanders were intended to be covered, bankruptcy plans have done so expressly, in contrast to Dow Corning's Plan: "All of these examples … are strong evidence that tissue expanders were *not* intended to be included in the [Dow Corning] Plan definition; the fact that other manufacturers' tissue expanders were repeatedly and expressly listed indicates that all relevant parties understood that the two products were different, and knew how to write an inclusive definition." *In re Settlement Facility*, 628 F.3d at 778 (concurring in part and dissenting in part) (emphasis in original).

656. These findings could not have been made if tissue expanders were included within the "breast implant" claims, given that – as this Court previously recognized – such products have a fundamentally different purpose, use, and structure. *See In re Settlement Facility*, 628 F.3d at 771.

The district court's ruling is at odds not only with this undisputed record, but with well-settled bankruptcy law. Where – as here – there is a mass of contingent tort claims that cannot be liquidated without unduly delaying the bankruptcy proceedings, estimation is required. Pursuant to Section 502(c) of the Bankruptcy Code, "[t]here *shall be* estimated for purposes of allowance under this section" "*any* contingent or unliquidated claim, the fixing or liquidation of which, as the case may be, would unduly delay the administration of the case." 11 U.S.C. § 502(c) (emphasis added). Accordingly, where actual liquidation would unduly delay administration of the bankruptcy estate, estimation is mandatory. *See, e.g.*, *A.H. Robins Co. v. Piccinin*, 788 F.2d 994, 1011-12 (4th Cir. 1986) ("That duty of estimation in a proper case under section 502(c) is not a permissive one; it is a mandatory obligation of the bankruptcy court."); *In re Corey*, 892 F.2d 829, 834 (9th Cir. 1989) ("[A] court shall estimate any contingent or unliquidated claim[] against the estate that 'would unduly delay the administration of the case'"); *In re G-I Holdings, Inc.*, 323 B.R. 583, 598-99 (Bankr. D.N.J. 2005) ("Section 502(c) of the Bankruptcy Code is drafted in mandatory terms. That is, any contingent or

unliquidated claim 'shall' be estimated so long as the 'liquidation' of the particular claim would 'unduly delay the administration of the case.'"); *see also* COLLIER ON BANKRUPTCY § 502.04 (16th ed. 2013).

Here, Dow Corning faced tens of thousands of unliquidated tort claims that threatened to overwhelm the company. These claims would have taken years, if not decades, to litigate, which would have interminably delayed confirmation of a plan of reorganization and thwarted the overarching purpose of Dow Corning's bankruptcy filing.

To demonstrate that the Plan was feasible and the funds set aside for the Settlement Facility would be adequate, Dr. Dunbar provided – on behalf of both Dow Corning and the Tort Claimants' Committee – an estimation of the projected numbers and cost of all Breast Implant claims and Covered Other Products claims during the confirmation hearings. (RE #924, 10/08/13 Opinion, Page ID #15733-34.) As the district court found, tissue expander claims were expressly excluded from that estimation. (*See id.*; RE #51 Ex. A, F. Dunbar, Analysis of Other Product Claims (June 23, 1999), Page ID #176.) Authorizing payment of such claims that the district court found were never estimated therefore would be at odds with the Plan, the confirmation hearing record, and well-settled bankruptcy law.

III. The District Court Erred By Basing Its Decision On The Alleged Practice Under A Settlement Agreement In Another Proceeding Before A Different Court Involving Different Parties, Which The District Court Itself Had Previously Found Actually Supports Dow Corning's Interpretation Of The Plan.

Having ignored the mass of undisputed extrinsic evidence documenting the Plan's ordinary and technical meaning as well as the undisputed history of the bankruptcy proceedings, the district court then proceeded to rely on settlement terms adopted by certain other manufacturers in proceedings before another court to which Dow Corning was not a party: the MDL proceedings leading to the Revised Settlement Program. The district court's reliance on the RSP as "evidence" of the parties' purported "intent" constitutes further error for several reasons.

First, the district court's ruling is premised on a fundamental legal error – a misinterpretation of the Plan documents. The district court itself recognized that the Settlement Facility Agreement provision upon which it relied states only that the claims administrator should look to the "protocols and procedures" under the RSP – not the *substantive* determinations under the RSP regarding which claims would be paid and at what amounts. (RE #924, 10/08/13 Opinion, Page ID #15736.) Specifically, Section 4.03 of the SFA provides that "the Claims Office shall operate using the claims-processing *procedures* and quality control *process* applied by the Initial MDL Claims Administrator" and that "[i]t is expressly

intended that the Settling Breast Implant Claims shall be *processed* in substantially the same manner in which claims filed with the MDL 926 Claims Office under the Revised Settlement Program [are] *processed* except to the extent criteria or *processing* guidelines are modified by this Settlement Facility Agreement or the Claims Resolution Procedures…." (RE #700, Ex. C, SFA, Page ID #10185, § 4.03 (emphasis added).) As Judge Batchelder noted in her concurrence and dissent, "[t]he language makes clear … that the guarantee is a procedural guarantee, not a substantive one; even if the previous review of claims allowed compensation for claims based on the use of tissue expanders (and the evidence supporting this claim is sketchy, at best), there was no substantive guarantee going forward, only a guarantee that the procedures would not change." *In re Settlement Facility*, 628 F.3d at 778 (Batchelder, J., concurring in part and dissenting in part). Accordingly, the district court's ruling is premised upon a fundamental misinterpretation of the Plan's plain language. If the district court's interpretation of Section 4.03 provision were correct, it would rewrite the Dow Corning Plan in ways the parties never contemplated.

Moreover, the claimants' proposed interpretation makes no sense. Dow Corning was not a party to the RSP. Accordingly, the products at issue, compensation amounts and negotiated terms under which RSP claims would be paid were completely different from the Dow Corning Plan: the proceedings

involved different products, made by different manufacturers, subject to different compensation rules and different settlement dynamics and negotiations unique to the RSP settlement. Those manufacturers determined which of their products would be subject to settlement in arms-length negotiation of the terms of the RSP. Those determinations, by strangers to Dow Corning, have no bearing on settlement eligibility in the Dow Corning Plan.

Not surprisingly, the terms of the heavily negotiated Dow Corning Plan diverge from the RSP. One example is the inclusion of a stand-alone rupture benefit in Dow Corning's Plan and the absence of such a benefit in the RSP. Under the RSP, claimants who had ruptured breast implants but no disease received no recovery just for rupture; in contrast, under the Dow Corning Plan, such claimants receive a $20,000 stand-alone rupture payment. (RE #700, Ex. D, SFA Annex A, Page ID #10234, § 6.02(a)(iii).) No one would argue that Dow Corning claimants should be denied this rupture benefit simply because the RSP did not provide one.

Second, even if the RSP had any relevance to substantive determinations regarding whether tissue expander claims would be paid under the Dow Corning Plan, as the district court previously found in its June 10, 2009 Order, under the RSP Dow Corning tissue expanders were *not* treated as "breast implants": "[T]issue expanders made by Dow Corning did not trigger the 50% reduction in

benefits that the breast implants did[,] lending credibility to DCC's claim that even *under the RSP tissue expanders were not considered 'Breast Implants.'*" (RE #673, 6/10/09 Opinion, Page ID #8748-49 (emphasis added).)

Under the RSP, as under the Dow Corning Plan, a "multiple manufacturer" discount was applied where a claimant received more than one "breast implant" or set of "breast implants" from different manufacturers – *i.e.*, where more than one manufacturer's product was implanted – in order to avoid a situation where a claimant received what would amount to a double recovery by virtue of the fact that she received implants from more than one manufacturer. Thus, if a claimant received a breast implant from a manufacturer that was not a party to the RSP settlement (such as Dow Corning), the claim would be reduced by 50% because the claimant would still presumably have a claim against the non-settling manufacturer (in order to avoid a potential windfall). (*See* RE #40 Ex. 3, 1/25/02 SF-DCT email.)

Unlike Dow Corning breast implants, however, there was *no* multiple manufacturer reduction under the RSP for Dow Corning tissue expanders. If a claimant had a Dow Corning tissue expander and some other manufacturer's breast implant, the MDL claims office would pay 100% of the claim because Dow Corning tissue expanders *were not considered to be breast implants*. (RE # 40 Ex. 3, 1/25/02 SF-DCT email.) This was not only the district court's finding, but

in fact it is *undisputed*. In its prior brief before this Court, while it maintained that other manufacturers' tissue expanders were treated as breast implants under the RSP, the CAC agreed that Dow Corning tissue expanders were not treated as "breast implants" merely noting that "[t]he record does not reflect *why* they [the parties to the RSP] chose to treat Dow Corning's tissue expanders differently." (11/13/09 CAC App. Br., Page ID #37, at 32 n.8 (emphasis added).)

Third, whatever "meeting of the minds" may have occurred among the parties to the RSP, the parties in the Dow Corning bankruptcy consistently treated tissue expanders – including tissue expanders manufactured by the parties to the RSP – as distinct products that are *not* "breast implants." For example, claimants have consistently maintained that tissue expanders are *not* breast implants for purposes of the Dow Corning Plan's multiple manufacturer reduction. The Plan's multiple manufacturer reduction provides that Breast Implant 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 silicone gel breast implant manufactured by or attributed to Bristol, Baxter or 3M." (RE #700 Ex. D, SFA Annex A, Page ID #10238-39, § 6.02(d)(v), at A-12 to A-13.) The CAC has consistently maintained that tissue expanders are *not* "breast implants" for purposes of this multiple manufacturer reduction and, accordingly, that Plan settlement payments to Breast Implant claimants should not be reduced

by 50% where they have been implanted with another manufacturer's tissue expander product. This means that, if the district court's interpretation of the Plan were to stand and tissue expanders were deemed "breast implants," the recoveries received by many actual breast implant claimants would be reduced by half.[17]

The CAC's allegation that tissue expanders are "breast implants" for purposes of one section of the Plan – yet not for purposes of the Plan's section regarding multiple manufacturer reduction – is flatly inconsistent with this course of performance and 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. 1st Dep't 2003) (holding that a "phrase should presumptively be given the same meaning" in different portions of a contract); *Finest Invs. v. Sec. Trust Co. of Rochester*, 96 A.D.2d 227, 230 (N.Y. App. Div. 4th Dep't 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]dentical words and phrases within the same statute should normally be given the same meaning.").

Fourth, the nonsensical nature of the position the CAC takes here is underscored by the fact that it would lead to inequitable windfall recoveries when

[17] Indeed, Dow Corning would be entitled to a refund of overpayments from potentially thousands of claimants who received other manufacturers' tissue expanders before receiving a Dow Corning breast implant.

applying the RSP's multiple manufacturer reduction. Under the CAC's position, an individual with a Dow Corning tissue expander and some other manufacturer's breast implant could recover twice with no multiple manufacturer reduction – 100% from the RSP (with no reduction because Dow Corning tissue expanders were not considered breast implants under the RSP) and an additional 50% from the Dow Corning Settlement Facility. In contrast, a claimant with the exact same medical conditions who was implanted with a Dow Corning breast implant and another manufacturer's breast implant would only take the reduced 50% recovery from each settlement facility. In other words, the claimant with short-term exposure to a Dow Corning tissue expander would receive *more* in total from both programs than the claimant who had two different breast implants and, what's more, would be eligible for *more than 100%* recovery. Such windfall recoveries and inequitable results are both illogical and inconsistent with the intent and terms of both the RSP and the Plan.

Fifth, there is no rational basis to provide a disease settlement option to individuals with tissue expanders, much less one that would afford compensation identical to that received by Class 5, 6.1 and 6.2 claimants who received breast implants. Under the Plan, the compensation for Breast Implant recipients ranges from $10,000 to $300,000 based largely on type and severity of disease or symptoms claimed. (*See* RE #700 Ex. D, SFA Annex A, Page ID #10239-40, at

A-13 to A-14.) These are significant settlement values. It would not make sense to provide such monetary awards for a product that is nothing more than a temporary surgical prep device, and that was not associated with any plausible disease allegations.

Finally, the CAC's position would mean that individuals who had short-term exposure to Dow Corning's tissue expander products would receive settlement values that are much larger than claimants having *long-term* exposure to implants categorized as "Covered Other Products": *e.g.*, hip or knee joint, chin, nose, wrist, fingers, and tempromandibular joint ("TMJ") implants, which – unlike tissue expanders – are specifically eligible for settlement compensation under the Plan and in many cases were the subject of significant pre-chapter 11 litigation. (RE #700 Ex. D, SFA Annex A, Page ID #10246-47, 10289-305, § 6.03(a) & Schedule I, Part II; *see also In re TMJ Implants Prods. Liab. Litig.*, 844 F. Supp. 1553 (J.P.M.L. 1994).) Again, this is a plainly nonsensical result.

* * *

In sum, as the district court found in its ruling before remand, the practice under the RSP actually supports Dow Corning's position. (RE #673, 6/10/09 Opinion, Page ID #8749.) This prior finding was not only correct, but it also makes clear that the district court's contrary ruling after remand was clearly

erroneous. The district court's unexplained change in position on remand alone warrants reversal of its decision.

In *U.S. v. City of Warren, Michigan*, for example, this Court reversed a district court order similarly premised upon factual findings that were at odds with the district court's prior order. 138 F.3d at 1092-93. *City of Warren* involved allegations of discriminatory recruitment practices by a local municipality. While the district court rejected claims that the city's recruitment practices for municipal workers (other than police and firemen) were discriminatory, the district court had previously found that "recruiting practices for police and firefighter positions had a disparate impact on black potential employees" and that "the city's recruiting methods were substantially the same for all municipal job opportunities, police, fire and others." *Id.* Accordingly, this Court reversed the trial court's ruling, holding that its "limitation of its finding that Warren's recruitment methods violated Title VII only as to police and firefighter recruitment" was "inconsistent with its own findings of fact" and thus "clearly erroneous." *Id.*, citing 18B WRIGHT, MILLER & COOPER, FEDERAL PRACTICE AND PROCEDURE: JURISDICTION § 4478 (2d ed. 1981); *cf. Molecular Tech. Corp. v. Valentine*, 925 F.2d 910, 915 (6th Cir. 1991).

Here, no such logical reconstruction of the district court's orders is even necessary to uncover the inconsistency in the district court's factfinding: the

district court originally, and expressly, found that the RSP record supported Dow Corning, but then premised its post-remand decision declaring tissue expander claimants eligible for Breast Implant settlement options solely on the proposition that it did not. As in *City of Warren*, the district court's latter finding is therefore clearly erroneous.

CONCLUSION

For the foregoing reasons, Dow Corning respectfully requests that the Court reverse the district court's order, hold that tissue expanders are not "Breast Implants" under the Dow Corning Plan, and enter judgment in favor of Dow Corning.

January 9, 2014

Respectfully submitted,

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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 12,901 words.

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CERTIFICATE OF SERVICE

I certify that on January 9, 2014, 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.

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DESIGNATION OF RELEVANT DOCUMENTS

00-00005 District Court

Record Entry	Filing Date	Description of Filing	Page ID
40	07/19/2004	Motion Of Claimants' Advisory Committee To Interpret The Amended Joint Plan Section 1.17 Regarding The Definition Of "Breast Implant"	1 - 15 of 15
40 (Ex. 1)	07/19/2004	Exhibit 1 to Dkt. 40: Dow Corning Wright Silastic Tissue Expander H.P. Pamphlet (00/00/0000)	7 of 15
40 (Ex. 3)	07/19/2004	Exhibit 3 to Dkt. 40: E-mail From V. Willard at SF-DCT to D. Greenspan and D. Pendleton re Tissue Expanders (01/25/2002)	9 of 15
51	07/19/2004	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	166 - 174
51 (Ex. A)	07/19/2004	Exhibit A to Dkt. 51: Dunbar Exhibit "Reported Proofs Of Claim For Covered Other Products (Includes EI Overlap)" (06/23/1999)	175 - 176

Record Entry	Filing Date	Description of Filing	Page ID
51 (Ex. B)	07/19/2004	Exhibit B to Dkt. 51: Affidavit Of Eugene Jakubczak In Support Of 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 (07/16/2004)	177 - 183
673	06/10/2009	Memorandum Opinion and Order Regarding Tissue Expander Issue by Judge Hood	8740 - 8751
700 (Ex. B)	10/13/2009	Exhibit B to Dkt. 700: Amended Joint Plan Of Reorganization dated February 4, 1999 (as updated June 1, 2004)	10059 - 10170
700 (Ex. C)	10/13/2009	Exhibit C to Dkt. 700: Settlement Facility And Fund Distribution Agreement Between Dow Corning Corporation and The Claimants' Advisory Committee (06/01/2004)	10171 - 10216
700 (Ex. D)	10/13/2009	Exhibit D to Dkt. 700: Dow Corning Settlement Program And Claims Resolution Procedures - Annex A To Settlement Facility And Fund Distribution Agreement (06/01/2004)	10217 - 10334
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783	04/11/2011	Memorandum Of Claimants' Advisory Committee Regarding Extrinsic Evidence Of The Parties' Intended Meaning Of "Breast Implant"	1 - 12 of 12
924	10/08/2013	Memorandum Opinion And Order Regarding Breast Tissue Expander Issue On Remand	15729 - 15738
927	10/22/2013	Dow Corning's Notice Of Appeal To The Sixth Circuit	15742 - 15754