

United States District Court,
N.D. Illinois, Eastern Division.

LEDERGERBER MEDICAL INNOVATIONS, LLC, and Dr. Walter Ledergerber,
Plaintiffs/Counterclaim Defendants.

v.

W.L. GORE & ASSOCIATES, INC,
Defendant/Counterclaim Plaintiff.

Feb. 17, 2009.

Raymond P. Niro, Christopher J. Lee, Dean D. Niro, Dina Marie Hayes, Kara Leta Szpondowski, Richard Burns Megley, Jr., Robert A. Conley, Niro, Scavone, Haller & Niro, Ltd., Chicago, IL, for
Plaintiffs/Counterclaim Defendants.

John N. Scholnick, Fiona A. Burke, Patricia Brown Holmes, Stacie Rachel Hartman, Schiff Hardin LLP, Chicago, IL, Carol Ann Lewis, Newark, DE, Danielle V. Tully, David H. Pfeffer, Hiroyuki Yasuda, Jordan Grant Garner, Matthew K. Blackburn, Richard Straussman, Morgan & Finnegan LLP, James W. Gould, Locke Lord Bissell & Liddell, LLP, New York, NY, Scott Hawranek, W.L. Gore & Associates, Inc., Flagstaff, AZ, for Defendant/Counterclaim Plaintiff.

MEMORANDUM OPINION AND ORDER

VIRGINIA M. KENDALL, District Judge.

Plaintiffs Ledergerber Medical Innovations, LLC and Dr. Walter Ledergerber (collectively, "Plaintiffs") have sued Defendant W.L. Gore & Associates, Inc. ("Gore") for infringement of United States Patent No. 6,921,418 ("the '418 patent"), entitled "Dual-Sided, Texturized Biocompatible Structure." The Court held a claims construction hearing, at which time it heard evidence and argument regarding the construction of various claims in the '418 patent. The Court's construction of these terms is set forth below.

BACKGROUND

In the mid-1980's, when surgeons insert implants into the human body, scar tissue would form over and around the surface of the implant. The scar tissue would cause hardened tissue masses in the area surrounding the implant. In addition to being unsightly, the scar tissue posed health risks to the patients who received the implants. Beginning in 1987, Dr. Ledergerber patented a series of inventions that manage scar tissue in the area surrounding an implant by providing an implant with a textured surface. To accomplish this, the implants utilize polytetrafluoroethylene in an expanded form ("ePTFE"). One side of the implant sheet has an untextured surface, while the other side has a textured surface that includes a series of channels. The structure of the implant forces the scar tissue to grow into the channels. Because scar tissue will not grow on the untextured surface, the implants direct the scar tissue away from the surface of the implant. The patent at issue, United States Patent No. 6,921,418 ("the '418 patent"), includes implants used

for treating hernias and brain trauma. Plaintiffs contend that several of Gore's products infringe on the '418 patent.

STANDARD OF REVIEW

Claim construction resolves disputed meanings in a patent to clarify and explain what the claims cover. *See Terlep v. Brinkmann Corp.*, 418 F.3d 1379, 1382 (Fed.Cir.2005). The construction of the claims at issue is a legal determination to be made by the court. *See id.* (*citing* *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed.Cir.1995)). Generally, the terms of a claim are given the ordinary and customary meaning that the terms would have to a person of ordinary skill in the art at the time of the filing date of the patent application. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed.Cir.2005). When interpreting an asserted claim, the court looks first to intrinsic evidence: the words of the claims, the patent specification, and the prosecution history. *See Vitronics Corp. v. Conceptiontronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996).

The claim language is the starting point for claim construction analysis because it frames and ultimately resolves all issues of claim interpretation. *See Robotic Vision Sys., Inc. v. View Eng'g Inc.*, 189 F.3d 1370, 1375 (Fed.Cir.1997). In some cases, the "ordinary and customary" meaning of the claim language may be readily apparent, even to lay judges, and the court applies the widely accepted meaning of the commonly understood words. *See Phillips*, 415 F.3d at 1314. In such cases, a general purpose dictionary may be helpful. *See id.* In many cases, however, the court must proceed beyond the bare language of the claims and examine the patent specification. *See id.* at 1314-15. "The person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. The specification is usually dispositive; "it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (*quoting* *Vitronics Corp. v. Conceptiontronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996)). In the specification, the patentee provides a written description of the invention that allows a person of ordinary skill in the art to make and use the invention. *See id.* at 1323. At times, the patentee uses the specification to "set forth an explicit definition for a claim term that could differ in scope from that which would be afforded by its ordinary meaning." *Rexnord Corp. v. Laitram Corp.* , 274 F.3d 1336, 1342 (Fed.Cir.2001).

The court may also look to the patent's prosecution history. *See Phillips*, 415 F.3d at 1317. While the prosecution history often lacks the clarity of and is less useful than the specification, it may inform the court of the meaning of a claim term by illustrating how the inventor understood the invention as well as how the inventor may have limited the scope of the invention. *See id.* The prosecution history is generally relevant if a particular interpretation of the claim was considered and specifically disclaimed during the prosecution of the patent. *See Schumer v. Lab. Comp. Sys.*, 308 F.3d 1304, 1313 (Fed.Cir.2002).

Finally, a court may also consult "extrinsic evidence," such as dictionaries, treatises, and expert testimony, to "shed useful light on the relevant art." *Phillips*, 415 F.3d at 1317-18. Generally, extrinsic evidence is "less reliable" than intrinsic evidence and is "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. With respect to the use of dictionaries, technical or general, a court may consult such evidence "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." *Id.* at 1322-23.

DISCUSSION

I. Agreed-Upon Terms

The parties agree upon the constructions of several terms found in the '418 patent. The Court adopts the agreed-upon constructions, as set forth in the Parties' Final Joint Claim Construction Chart. At the claim construction hearing, the parties indicated that they also agree upon the construction of the terms "ePTFE" and "laminated structure." The Court also adopts the constructions agreed upon at the hearing.

II. Disputed Terms

The parties dispute the meaning of the following twelve terms and phrases used in the '418 patent: (1) "sheet"; (2) "non-textured"; (3) "textured"; (4) "continuous"; (5) "channels"; (6) "formed by cutting"; (7) "troughs"; (8) "wells"; (9) "the plane of the ridge regions"; (10) "the plane of the trough regions"; (11) "stimulate high tissue ingrowth"; and (12) "arranged to disorganize scar tissue." The former eight terms initially appear in claim 1 of the '418 patent. The ninth and tenth terms initially appear in claim 7 of the '418 patent. The eleventh and twelfth terms initially appear in claims 8 and 9 of the '418 patent, respectively.

A. "Sheet"

Claim 1 of the '418 patent describes "an implantable sheet for implantation in a body" Plaintiffs propose that "sheet" means "a relatively thin structure, such as a layer or covering." Gore contends that the term refers to "a piece of material having a length, width and thickness."

Plaintiffs rely upon the dictionary definition of "sheet." *See* Pl. Claim Constr. Mem., Ex. H, *Random House Dictionary of the English Language Second Edition*, at 1762 (1987). While a court may rely on a dictionary to construe ordinary and customary claim terms, it may only do so when it considers the definition in the context of intrinsic evidence and only then to the extent that the "definition does not contradict any definition found in or ascertained by a reading of the patent documents." Phillips, 415 F.3d at 1318-19, 1322-23. Gore claims that Plaintiffs' proposed construction is contrary to the preferred embodiments of the expander identified within the '418 patent's Abstract, Summary of the Invention and Detailed Description. However, Gore fails to specify how the phrase "a relatively thin structure, such as a layer or covering" necessarily precludes expandable structures. Considering the proposed definitions in the context of the intrinsic evidence presented, the Court concludes that Plaintiffs' proposed construction comports with the specification and language of the claim. In contrast, Gore's proposed construction of "sheet" is overbroad and would include nearly every conceivable tangible object, regardless of the object's thickness. Accordingly, the Court determines that the term "sheet" means "a relatively thin structure, such as a layer or covering."

B. "Non-textured"

Claim 1 of the '418 patent describes a sheet with two surfaces, "the first surface being non-textured, and the second surface being textured" Plaintiffs contend that "non-textured" means "smooth," while Gore contends that "non-textured" means "completely lacking macroscopic surface characteristics."

The '418 patent's specifications describe numerous individual villi and great irregularity of the surface of the material. *See* U.S. Patent No. 6,921,418 at 3:32-35. Such a description is consistent with the plain and ordinary use and understanding of the term "textured" because it considers the tactile characteristics of the surface. *See* Pl. Claim Constr. Mem., Ex. H, *Random House Dictionary of the English Language Second Edition*, at 1964 (defining "textured" as "the visual and *especially* tactile quality of a surface") (emphasis added). The phrase "great irregularity of the surface of the material" essentially states that one surface is not

smooth, without regard to the visibility of the irregularity. Under Gore's proposed definition, a material would only be textured when it has visible characteristics on the surface. Therefore, Gore's definition would ignore the important tactile element included within the plain and ordinary understanding of the term "textured."

To support its position, Gore relies on the prosecution history of the '418 patent and the rejection of a dependent claim for a sheet that included holes. The Patent Office rejected claims covering a channeled sheet and holes for failure to comply with the written description requirement in 35 U.S.C. s. 112. *See* Joint App., Ex. B at FH343. The Court recognizes it must interpret patents with reference to cancelled or rejected claims so that the claim construction process does not change the scope of a patent to cover claims previously eliminated from the patent. *See Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 21, 220-21 (1940); *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1338 (Fed.Cir.2006). However, the rejection of the design that included holes in the sheet did not alter or inform the meaning of the term "non-textured" in Claim 1. The rejection for failing to comply with the writing requirement does not mandate that the term "non-textured" can only describe the visible characteristics of the sheet without reference to the sheet's tactile qualities. Therefore, the Court finds that the term "non-textured" means "smooth."

C. "Textured"

The parties agree that "textured" is the opposite of "non-textured." Accordingly, based on the Court's determination that "non-textured" means "smooth," "textured" means "not smooth."

D. "Continuous"

Claim 1 of the '418 patent describes "a plurality of continuous, parallel channels extending into the thickness dimension of the sheet, the channels being formed by cutting the second surface of the sheet" Plaintiffs claim that "continuous" means "uninterrupted," while Gore contends that "continuous" means "endless."

In the context of the '418's specifications, based on the concentric series of parallel channels that appears in the '418 patent's specifications, the term "endless" accurately describes each channel because within each channel, there is no beginning or ending point. Additionally, "endless" is consistent with a plain and ordinary understanding of the word "continuous." *See* Pl. Claim Constr. Mem., Ex. H, *Random House Dictionary of the English Language Second Edition*, at 440 (defining "continuous" as "uninterrupted in time; without cessation"). Although "uninterrupted" is also an accepted meaning of "continuous," the term "uninterrupted" implies a temporal component. *See id.* With respect to descriptions of spacial dimensions, such as the descriptions of the parallel channels on a sheet, the term "endless" is more appropriate than the temporal term "uninterrupted." Accordingly, the Court determines that "continuous" means "endless."

E. "Channels"

Claim 1 of the '418 patent describes "a plurality of continuous, parallel channels extending into the thickness dimension of the sheet, the channels being formed by cutting the second surface of the sheet" Plaintiffs contend that "channels" mean "grooves or furrows," while Gore claims that "channels" refers to "partial thickness openings."

Based upon the specifications of the '418 patent, a series of cuts or channels results in the individual villi and surface irregularity on the material. In a corresponding illustration, it is clear that the cuts or channels

create grooves on the material's surface. *See* U.S. Patent No. 6,921,418, at Fig. 12. The illustration contained within the specifications of the '418 patent shows that the inventor meant to give the term "channels" its commonly understood meaning: "grooves or furrows." Because nothing in the specifications indicates that the inventor intended to give the term "channels" a meaning other than its commonly understood meaning, the Court determines that "channels" means "grooves or furrows."

F. "Formed by Cutting"

Claim 1 of the '418 patent describes "a plurality of continuous, parallel channels extending into the thickness dimension of the sheet, the channels being formed by cutting the second surface of the sheet" Plaintiffs claim that "formed by cutting" means "formed by the act of a person or thing that cuts," while Gore claims that "formed by cutting" means "created using a blade or through die cutting."

The parties agree that the terms "formed" and "created" are synonymous. The specifications of the '418 patent contemplate using a specific material that is "easily cut by a knife or by using die cutting technique." U.S. Patent No. 6,921,418, at 8:44-45. Plaintiffs contend that the phrase "formed by the act of a person or thing that cuts" is consistent with the ordinary meaning of "cutting" based upon the dictionary definition of the term. Although courts attempt to construct patent terms according to ordinary and customary definitions, when patent specifications expressly limit the meaning of general terms, the limitations contained within the patent control. *See Wang Labs., Inc. v. Am. Online, Inc.*, 197 F.3d 1377, 1381-84 (Fed.Cir.1999). Here, the patent expressly described "cutting" by use of a knife or a die cutter. Although there are other ways to cut material, such as through the use of lasers, the patent only disclosed cutting by a knife or a die cutter. Plaintiffs contend that the limitation on the term "cutting" exists only to differentiate cutting from tube extrusion. Nonetheless, in differentiating cutting from tube extrusion, the inventor specifically limited the term "cutting" to the use of a knife or die cutter. Because the patent specifically identifies two ways to cut the channels in the sheet, the intrinsic evidence shows that the term "cutting" as used in the '418 patent does not carry its ordinary meaning. Therefore, the Court determines that the term "formed by cutting" means "created using a blade or through die cutting."

G. "Troughs"

Claim 1 of the '418 patent describes the textured side of the material as having "a plurality of ridges disposed between the channels, forming troughs" Plaintiffs contend that "troughs" are "sheet structures, each formed by two successive ridges and an interposed channel" or, alternatively, "the surface structures formed by two successive ridges and an interposed channel ." Gore claims that the term "troughs" refers to "cuts made along an axis other than that of the channels."

The illustrations of the '418 patent show depressed surface areas formed by the surrounding channels and ridges present after cutting the surface material. *See* U.S. Patent No. 6,921,418, at Fig. 12. That illustration is consistent with the plain and ordinary meaning of the term "trough." Additionally, that construction is consistent with the surrounding language in claim 1. The patent's description of Fig. 12 is also consistent with Plaintiffs' construction of "troughs" because it uses the terms "trough" and "cuts" interchangeably. *See id.* at 3:32-37 ("Additional patterns of cuts or troughs may be made along any other axis as indicated"). Claim 1 contemplates cuts that create ridges that come together to form a series troughs. Therefore, the Court adopts the construction that "troughs" are "sheet structures, each formed by two successive ridges and an interposed channel."

H. "Wells"

Claim 1 of the '418 patent further describes the textured surface as "comprising a pattern of ridges and troughs, the pattern including a plurality of parallel wells." Plaintiffs claim that "wells" are "the lowest regions of the channels," while Gore contends that the term "wells" is fatally indefinite because it is not amenable to description.

The language of the patent describes the wells as a part of the ridges and channels formed by cutting the surface material. Based on the diagrams included with the patent, the ridges come together at an angle to create channels that have low points. *See id.* Fig. 12. The plain and ordinary meaning of "well" includes "something resembling a well in being ... deep" *See* Pl. Claim Constr. Mem., Ex. H, *Webster's Ninth New Collegiate Dictionary* (1987), at 1338. Therefore, in the context of the ridges and channels described in claim 1 of the '418 patent, the deepest part of the channels would be the well. The term "wells" is amenable to construction and the Court determines that "wells" are "the lowest regions of the channels."

I. "The Plane of the Ridge Regions"

Claim 7 of the '418 patent describes "[t]he sheet of claim 1 wherein the plane of the ridge regions is substantially parallel to the plane of the trough regions." Plaintiffs contend that "the plane of the ridge regions" means "the plane defined by the areas of the ridges." Gore claims that "the plane of the ridge regions" is fatally indefinite because it is not amenable to description.

In constructing claim 11 of the '418 patent, the parties have agreed that "planar" means "flat." The parties have also agreed that "ridges" are "raised narrow regions." Based upon their agreed usage of those terms, the "plane of the ridge region" is the flat area defined by the ridges. Therefore, the term "the plane of the ridge regions" is amenable to construction. Accordingly, the Court determines that "the plane of the ridge regions" means "the plane defined by the areas of the ridges."

J. "The Plane of the Trough Regions"

As previously stated, claim 7 of the '418 patent describes "[t]he sheet of claim 1 wherein the plane of the ridge regions is substantially parallel to the plane of the trough regions." Plaintiffs claim that "the plane of the trough regions" means "the plane defined by the areas of the troughs," while Gore claims that "the plane of the trough regions" is fatally indefinite because it is not amenable to description.

As described above in Part I, the parties have agreed that "planar" means "flat." In construing claim 1, the Court has determined that "troughs" are "surface structures formed by two successive ridges and an interposed channel." *See supra*, Part G. Therefore, the "plane of the trough regions" is the flat area defined by the troughs. That construction is consistent with the prosecution history of the '418 patent, as the inventor originally described the "surface of the valley regions" located within the channels. Joint App., Ex. B, at FH 203. By replacing the term "surface" with the term "plane," the inventor described the flat area corresponding with the wells of the troughs. Because the only plane that runs parallel to the plane of the ridge regions corresponds with the plane of the wells located within the troughs, the term "plane of the trough regions" must refer to the plane created by the wells within the troughs. Therefore, the term "the plane of the ridge regions" is amenable to construction. Accordingly, the Court determines that "the plane of the trough regions" means "the plane defined by the areas of the troughs."

K. "Stimulate High Tissue Ingrowth"

Claim 8 of the '418 patent describes "[t]he sheet of claim 1 wherein the second surface is arranged to stimulate high tissue ingrowth." Plaintiffs contend that "stimulate high tissue ingrowth" means to "encourage an increased rate or level of tissue growing inward or into the second surface." Gore contends that "stimulate high tissue ingrowth" is fatally indefinite because it is not amenable to construction.

The specifications of the '418 patent detail that the ridges, channels and troughs exist on the textured surface of the implant in order to encourage the growth of scar tissue into the implant. *See* U.S. Patent No. 6,921,418, at 6:53-64, 8:53-64. The patent's specifications also disclose that the implant device should be made from materials that have a high degree of ultramicroporosity because such materials promote high levels of tissue growth into the implant. *See id.* at 8:21-23, 28-30. Therefore, the Court finds that "stimulate high tissue ingrowth" means to "encourage an increased rate or level of tissue growing inward or into the second surface."

Gore argues that the term "high tissue ingrowth" is fatally indefinite because no objective measure exists to provide notice whether the rate of tissue ingrowth is high or low. A claim is indefinite only when a person of ordinary skill in the art could not determine the scope of the claim. *See* Halliburton Energy Svcs., Inc., v. M-I LLC, 514 F.3d 1244, 1249 (Fed.Cir.2008). To show indefiniteness, an alleged infringer must show by clear and convincing evidence that a skilled person in the field could not determine the scope of the claim based upon background knowledge, the claim language, the specifications and the prosecution history. *See* Exxon Research Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed.Cir.2001). Gore has not introduced any evidence regarding whether a person of ordinary skill in the field could determine the boundaries of claim 8; rather, Gore's argument for indefiniteness relies upon speculation. Therefore, Gore has not shown by clear and convincing evidence that claim 8 is indefinite because it does not define when the rate of tissue ingrowth is high or low.

L. "Arranged to Disorganize Scar Tissue"

Claim 9 of the '418 patent describes "[t]he sheet of claim 1 wherein the second surface is arranged to disorganize scar tissue." Plaintiffs contend that "arranged to disorganize scar tissue" means "arranged to disrupt the natural formation of scar tissue." Defendants claim that "arranged to disorganize scar tissue" means "a silicone elastomer configured into concentric nested close geometric shapes that force scar tissue into concentric nested rings ."

The specifications of the '418 patent disclose that the implant exists to weaken the growth of scar tissue surrounding the implant by forcing the tissue to grow into the textured surface of the implant. *See* U.S. Patent No. 6,921,418, at 4:63-64. The textured molded covering of the implant may be made of "silicone elastomer or other suitable materials which serve to limit the force or scar contracture around the implant by disorganizing the scar tissue itself" *Id.* at 8:48-52; *see also id.* at 8:21-25. Because the express specifications of the '418 patent provide that silicone elastomer is not the only suitable material, it would be inappropriate for the Court to adopt Gore's proposed construction that the phrase "arranged to disorganize scar tissue" only includes silicone elastomer. Additionally, the '418 patent specifications do not limit the design to concentric nested rings. *See id.* at 8:65-9:4. Moreover, adopting Gore's proposed construction would have the effect of excluding the embodiment displayed in Figure 12 from claim 9 because Figure 12 utilizes channels rather than concentric rings. *See id.* at Fig. 12. Therefore, the Court determines that "arranged to disorganize scar tissue" means "arranged to disrupt the natural formation of scar tissue."

CONCLUSION AND ORDER

For the reasons stated, the Court construes the disputed terms as set forth above.

So ordered.

N.D.Ill.,2009.

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