United States District Court,
D. Minnesota.

Synovis Life Technologies, Inc,
Plaintiff.
v.
W.L. GORE & ASSOCIATES, INC,
Defendant.

Civil No. 07-1396 (DWF/SRN)

Jan. 23, 2009.

James R. Mayer, Esq., Laura L. Myers, Esq., Lora Mitchell Friedemann, Esq., Darren B. Schwiebert, Esq., Fredrickson & Byron, PA, counsel for Plaintiff.

Aslan Baghdadi, Esq., and Lawrence J. Gotts, Esq., Paul, Hastings, Janofsky & Walker; and Calvin L. Litsey, Esq., Charles F. Knapp, Esq., and Kevin P. Wagner, Esq., Faegre & Benson LLP; and Jessica L. Copland, Esq., and John T. Gallager, Esq., Morgan & Finnegan, LLP, counsel for Defendant.

MEMORANDUM OPINION AND ORDER

DONOVAN W. FRANK**, District Court.**

INTRODUCTION

This matter is before the Court on the issue of patent claim construction pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996).

BACKGROUND

This litigation involves allegations by Plaintiff Synovis Life Technologies, Inc. ("Synovis") that Defendant W.L. Gore & Associates, Inc. ("W.L.Gore") infringed one or more of claims 37 through 48 of U.S. Patent No. 7,128,748 (the "'748 Patent"). The parties disagree as to the meaning of several terms in the '748 Patent.

I. Claim Construction Principles

Patent claim construction, *i.e.,* the interpretation of the patent claims that define the scope of the patent, is a matter of law for the court. Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed.Cir.1995), *aff'd,* 517 U.S. 370 (1999). Proper claim construction requires an examination of the intrinsic evidence of record, including the claims of the patent language, the specification, and the prosecution history. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). The starting point for claim construction is a review of the words of the claims themselves. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005) *(en banc)* (citation omitted), *cert. denied,* 126 S.Ct. 1332 (2006); *see also* Vitronics, 90 F.3d at 1582 ("First,

we look to the words of the claims themselves, both asserted and unasserted, to define the scope of the patented invention."). The words of a claim generally carry "the meaning that the term would have to a person of ordinary skill in the art at the time of the invention." Phillips, 415 F.3d at 1313. Claims must also be read in view of the specification. Id. at 1315. The specification is "the single best guide to the meaning of a disputed term." *Id*. The specification may prescribe a special definition given to a claim term, or a disavowal of claim scope by the inventor. *Id*. at 1316. In such cases, the inventor's intention that is expressed in the specification is dispositive. *Id*. The Court may not, however, import limitations from the specification into the claims. *Id*. at 1323. The Court should also consider the patent's prosecution history, which provides evidence of how the United States Patent and Trademark Office ("USPTO") and the inventor understood the patent. *Id*. at 1317. The Court may, in its discretion, consider extrinsic evidence, though it is less reliable than intrinsic evidence. *Id*. at 1317-18. FN1 In most situations, however, intrinsic evidence will resolve any ambiguity in a disputed term, and when it does so, it is improper to rely on extrinsic evidence. Vitronics, 90 F.3d at 1583. The court may use a dictionary or technical treatise to "assist in understanding the commonly understood meaning" of a term, so long as any meaning found in such sources does not contradict the definition that is found in the patent documents. *Id*. at 1322-23.

FN1. Gore seeks to rely on the deposition testimony of the co-inventors of the '748 Patent, Drs. Nicholas Oray and Daniel Mooradian. To the extent that such testimony has been offered to show the subjective intent of the inventors, it is not relevant to the issue of claim construction. Howmedica Osteonics Corp. v. Wright Med'l Tech., Inc., 540 F.3d 1337, 1347 (Fed.Cir.2008). To the extent that the testimony is relevant, the Court declines to consider it because the intrinsic evidence resolves any ambiguities in the disputed claim terms. *See* Vitronics, 90 F.3d at 1583.

II. The '748 Patent

The '748 Patent, entitled "Circular Stapler Buttress Combination," was issued on October 31, 2006. The Patent relates to circular surgical staplers and surgical stapling procedures that include the use of buttress material that is delivered to a tissue site to connect previously severed tissue portions. ('748 Patent at Abstract; c. 1, ll: 6-10.) More particularly, the '748 Patent relates to reinforcing staple line seams formed by circular staplers during surgery to join together two sections of hollow organs (*i.e* ., intestines) while keeping the interior passageway of the organ open.

The terms that are in presently in dispute appear in claims 37 and 38 of the ' 748 Patent: FN2

FN2. The Court reproduces claims 37 and 38 as representative examples.

37. A combination medical device comprising:
a) a circular stapler instrument, comprising a staple cartridge component and corresponding anvil component, and

b) one or more portions of buttress material adapted to be a) stably positioned upon the staple cartridge and/or anvil components of the stapler instrument prior to, or at the time of, use, b) while in position upon the stapler instrument component(s), to then be delivered to a tissue site in combination with the stapler instrument components, c) upon delivery of the components and positioned material portion(s) to the tissue site, to provide a first region of buttress material as a staple line buttress seal between joined tissue sections

upon activation of the stapler instrument, and optionally, d) to permit the removal of one or more portions of a second region of the buttress material upon activation of a stapler instrument knife provided by the stapler instrument,

wherein at least one of the buttress material portions comprises two or more regions, including a first region adapted to serve as the staple line buttress itself, together with a second region adapted to assist in positioning and/or retaining the buttress material upon a stapler component, and wherein one or more portions of the second region are adapted to be removed from the tissue site upon formation of the staple seam and activation of a stapler knife, the second region being generally concentric to the first region, the first and second regions cooperating to provide a desired three dimensional and/or topographic structure adapted to position and/or retain the materials in place upon the respective stapler component.

38. A combination according to claim **37** wherein the first and second regions are adapted to be separated upon activation of a stapler knife, in a manner sufficient to permit the separated first region to provide a buttressed surgical seam between abutting tissue portions and to permit the separated second region to be removed from the tissue site.

('748 Patent c. 15, ll: 37-67; c. 16, ll: 1-8.)

A. "buttress material"

The parties dispute the meaning of the term "buttress material" as it appears in claims 37, 41, and 45 of the '748 Patent. Synovis contends that the jury can easily grasp the meaning of the term and therefore no construction is necessary. Alternatively, if the Court decides to construe the term, Synovis asserts that that the term "buttress material" should be construed as "material useful for reinforcing a seam." (Joint Proposed Claim Construction Statement ("Joint Statement") at 4.) Gore, on the other hand, asserts that the Court should construe "buttress material" as "biomaterial formed from animal tissue designed to be used in a surgical procedure to reinforce a staple line." (Id.) The parties' dispute therefore centers on whether the term "buttress material" is limited to "biomaterial formed from animal tissue."

In support of its construction, Synovis points to the specification of the '748 Patent, beginning with the description of the Technical Field, which states:

In one aspect, the invention relates to surgical staplers, including circular staplers. In another aspect, the invention relates to surgical stapling procedures that include the use of buttress and reinforcing materials formed of stabilized tissues and polymeric [FN3] materials. In yet another aspect, the invention relates to the preparation and use of preformed heterologous tissues for implantation within the body.

FN3. Polymeric refers to plastic materials.

('748 Patent c. 1, ll: 5-12.) In addition, Synovis points to portions of the specification that explain, for example, that "a variety of references teach the preparation of 'buttress,' or 'pledget' or 'reinforcing' materials for use in combination with conventional surgical staplers." (Id., c. 2, ll: 7-10.) Synovis asserts that the specification shows that "buttress" and "reinforce" have similar meanings. Synovis further maintains that the '748 Patent uses "buttress material" to mean "material useful for reinforcing a seam." (*See* '748 Patent c. 6, ll: 11-14 ("FIG. **4** shows a cross-section view of the overall process of creating a reinforced stapled connection for tubular tissue ..."). Finally, Synovis argues that Gore's proposed construction departs from

the language of the claim and would improperly limit the claims to a single disclosed embodiment.

Gore asserts that the term "buttress material" is explicitly defined in the specification as being composed of "biomaterial formed from animal tissue." Gore contends that this definition is mandated by the description of the invention which Gore contends describes only the use of biomaterial. In addition, Gore asserts that the inventors consistently describe the use of animal tissue in buttress material throughout the patent, and particularly that the written description focuses exclusively on the use of animal tissue.

The term "buttress material" appears in the claim language of claims 37, 41, and 45 simply as "buttress material" and is not expressly limited to "biomaterial formed from animal tissue." Gore does not dispute that the claim language lacks an express limitation to "biomaterial formed from animal tissue," but instead asserts that the specification provides an explicit definition of "buttress material." In support, Gore points to a portion of the Detailed Description of the specification, which reads: "Circular stapler buttress material is composed of biomaterial which is typically bovine pericardium sheet fixed onto a preformed shape using a tanning solution." ('748 Patent c. 7, ll: 5-6.) The patent specification "may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess." Phillips, 415 F.3d at 1316. Here, however, when viewing the patent in its entirety, the Court finds that the specification does not transform the plain meaning of "buttress material" to be limited to "biomaterial formed from animal tissue." First, the language cited by Gore reveals that "bovine pericardium" is only an example of a buttress material and that the patentee contemplated the use of additional materials. The use of the word "typically" immediately preceding "bovine pericardium" underscores the notion that "bovine pericardium" was not meant to be the exclusive material for "buttress material." In addition, the Background of the Invention portion of the specification references three patents that disclose non-woven polyethylene as a buttress material. (*See* '748 Patent c. 2, ll: 10-12; Mayer Decl. para. 2, Ex. B at c. 2, ll: 41; para. 3, Ex. C at c. 2, ll: 42-43; para. 4, Ex. D at c. 3, ll: 29-30.) FN4

FN4. Gore argues that these patents were not incorporated by reference, are not part of the patent's written description, and thus do not aid in claim interpretation. The Court disagrees. Even if the patents were not incorporated by reference, they are listed on the first page of the patent under "References Cited." The Court concludes that these patents can shed light on claim interpretation. *See, e.g.,* Arthur A. Collins, Inc. v. N. Telecom Ltd., 216 F.3d 1042, 1045 (Fed.Cir.2000) ("When prior art that sheds light on the meaning of a term is cited by the patentee, it can have particular value as a guide to the proper construction of the term, because it may indicate not only the meaning of the term to persons skilled in the art, but also that the patentee intended to adopt that meaning.").

Claim differentiation further suggests that the patentee did not intend to limit "buttress material" in claims 37, 41, and 45 to "biomaterial formed from animal tissue." "Differences among claims can also be a useful guide in understanding the meaning of particular claim terms." Phillips, 415 F.3d at 1314. Here, claim 1 of the '748 Patent contains the term "buttress material" as it is appears in independent claims 37, 41, and 45. ('748 Patent c. 12, ll: 27.) Claim 2, which is dependent on claim 1, reads in part: "A combination according to claim **1** wherein the buttress material comprises preformed animal tissue." (Id., c. 12, ll: 49-50.) Thus, it is presumed that the patentee did not intend for the "buttress material" in independent claim 1 to be limited to animal tissue.FN5 *See, e.g.,* Phillips, 415 F.3d at 1315 (noting that "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim"). In addition, because claims 37, 41, and 45 also lack the "preformed animal tissue" limitation, it is presumed that the patentee did not intend for those claims to be so limited.

FN5. Gore also asserts that the patent differentiates between "buttress" and other "reinforcing" materials, and that "reinforcing" materials could encompass polymeric materials, but the "buttress material" does not. The Court disagrees. A reading of the patent, which references patents that disclose how to use polymeric materials, demonstrates that the terms "buttress" and "reinforcing" materials are the same.

Based on the intrinsic evidence of the '748 Patent, the Court concludes that the term "buttress material" is properly construed as a "material useful for reinforcing a seam."

B. "Region" Limitations

1. "first region of buttress material"

The parties dispute the meaning of the term "first region of buttress material" as it appears in claims 37 and 45 of the '748 Patent. Synovis contends that no construction is necessary, but alternatively that if the Court decides to construe the term, it should be construed as "a region of buttress material." (Joint Statement at 15.) Gore, on the other hand, asserts that the Court should construe "first region" as "portion of buttress material adapted to remain in position within the body." (Id.)

Synovis maintains that the use of the "first region" and "second region" is patent-law convention used to distinguish between repeated instances of an element or a limitation. Synovis asserts that the use of either no construction or its alternative construction would convey the meaning of the terms without adding meaning that is not part of the claim language, creating redundancies, or complicating the language of the claim. Synovis also asserts that Gore is attempting to impose an improper limitation into the claim language. Gore asserts that Synovis' proposed construction impermissibly deletes the word "first" from the term "first region" and would render the claim unintelligible. In addition, Gore contends that the term "region" is generic and must be understood in terms of the written description.

The use of "first" and "second" regions can be a way to distinguish between repeated instances of an element or limitation. *See* 3M Innovative Properties Co. v. Avery Dennison Corp., 350 F .3d 1365, 1371 (Fed.Cir.2003). Here, the use of "first" is used to identify a part of the buttress material ("first region of buttress material"). Limitations to this region appear elsewhere in the claim language. Importing those limitations into the term "first region" would be redundant and unnecessary. The Court concludes that the term "first region" has a meaning that is readily understandable and construction is not necessary.

2. "second region of buttress material"

The parties also dispute the meaning of the term "second region of buttress material" as it appears in claims 37 and 45 of the '748 Patent. Synovis contends that no construction is necessary, but alternatively that if the Court decides to construe the term, it should be construed as "a region of buttress material." (Joint Statement at 16.) Gore, on the other hand, asserts that the Court should construe "second region" as "region of buttress material which forms an integral raised center portion." (Id.; Tr. at 151.)

Synovis makes many of the same arguments that it made in support of its construction of "first region," namely that the use of the "first region" and "second region" is common patent-law convention and that Gore's construction would add meaning that is not part of the claim language, therefore creating redundancies and complicating the language of the claim.

In addition to the arguments made with respect to the construction of "first region," Gore asserts that its construction is compelled in light of the specification, Synovis' admissions,FN6 and the prosecution history. Gore asserts that the specification describes the "second region of buttress material" as being "generally concentric to, and integral with, the first region, providing a desired three dimensional and/or topographic structure adapted to position and/or retain the materials in place upon the respective stapler component." ('748 Patent c. 3, ll: 48-56.) Gore also asserts that Synovis agreed that the claims are limited to structures in which the second region alone provides the three-dimensional structure and that Synovis cannot now assert that the first region is part of that structure. Gore further asserts that the claims must be limited so as to require the second region of buttress material to have an integral raised center portion to ensure the claims are supported by the written description and enabled.

FN6. Gore cites to Synovis' responses to Request for Admissions wherein Synovis admitted that the second region is within and circumscribed by the interior boundary of the first region. (Gore Ex. 12 at Nos. 11 & 13.)

First, the Court concludes that Gore's acquiescence argument, which is based primarily on the '748 Patent's prosecution history, is unavailing. Gore asserts that the applicants agreed to incorporate the language of "Paragraph 18" FN7 of the published application into newly submitted claims during the patent's prosecution. Gore asserts that in doing so, Synovis implicitly agreed that the new claims (including claims asserted in this action) would be limited to structures in which the second region alone provides the three-dimensional structure. The Court disagrees.

FN7. Paragraph 18 of the published application corresponds to the following language of the '748 Patent:

The buttress material portions preferably provide two or more regions, including a first region adapted to remain in position within the body in order to serve as the staple line buttress itself, together with one or more portions of a second region adapted to assist in positioning and/or retaining the buttress material upon a stapler component. Preferably, the one or more portions of the second region are adapted to be removed from the tissue site upon activation of the stapler knife. The second region is generally concentric to, and integral with, the first region, providing a desired three dimensional and/or topographic structure adapted to position and/or retain the materials in place upon the respective stapler component. Generally, the second region is internal to the circular seam formed, and can be removed together with the severed ends of the joined tissue portions in order to provide an unobstructed lumen for the joined tissue portions.

('748 Patent c. 3, ll: 39-56.)
In a summary of a March 20, 2006 interview between the examiner and the applicant, the examiner noted that "[c]laims will be amended to incorporate the allowable subject matter of claim 10 [FN8] into claim 1, and in another independent claim, subject matter from paragraph 0018 of the specification will be combined with the language of claim 1." (Gore Ex. 8.) In the Remarks section in the applicants' April 3, 2006 Amendment to the patent application, the applicants stated with respect to the same interview:

FN8. Claim 10 recited a "raised center portion."

In the course of the [March 20] interview it was agreed that claims 1 and 11 would be allowable if amended to incorporate the limitations of claims 10 and 20, respectively, and without the need to include original intervening claims. It was also agreed that new claims would be allowable if added to incorporate discussion found in paragraph [0018] of the application as published, which claims are now provided as new claims 41-42, 45-46, 49-50, and 53-56 [FN9] ....
FN9. The new claims encompassed the claims being asserted in this action.

(Gore Ex. 9.)

Thereafter, the applicant added the "raised center portion" language to claim 1. The applicant also incorporated language that is supported by Paragraph 18 into new claims, including the claims asserted here. Gore argues that Paragraph 18 described the three-dimensional structure as in the second region and therefore that claims 37 and 45 must be construed to contain that limitation. The applicants also, however, added new language to issued claims 37 and 45; namely, "the first and second regions cooperating to provide a desired three dimensional and/or topographic structure." The addition of the "cooperating to provide" language, which was allowed by the examiner, demonstrates that the applicants did *not* agree that all of the patent claims would be limited to structures in which the second region alone provides the three-dimensional structure via a "raised center portion." FN10

FN10. The Court notes that Paragraph 18 does not contain the "raised center portion" language. Therefore, that the applicants acknowledged that the issued claim 37 "incorporated discussion" from Paragraph 18 does not limit claim 37 to a "raised center portion."

Gore's proposed construction seeks to add a limitation by construing "second region" in claims 37 and 45 as "region of buttress material which forms an integral raised center portion." There are claims in the '748 Patent that contain that limitation; in particular, claim 1 expressly contains the "raised center portion" element. The asserted claims, however, do not.FN11 The Court declines to import that limitation into the asserted claims. Moreover, the Court concludes that the term "second region of buttress material has a meaning that is readily understandable and no construction is necessary.

FN11. Gore also cites to the examiner's Reasons for Allowance, which read in part: "None of the prior art of record ... discloses a kit with a buttress material portion for each of the cartridge and anvil components of a stapler and a combination medical device comprising a circular stapler instrument and one or more buttress materials, where each of the buttress portions or materials comprises, inter alia, a circumferential disc with an integral raised center portion." (Gore Ex. 10.) This statement, which is part of the patent's prosecution history, is not enough to warrant a departure from the plain language of the asserted claims. First, the examiner did not indicate that the "integral raised center portion" was to become an element in all of the asserted claims. Moreover, in the applicants' Amendment, the "raised center portion" language was expressly added to other claims (*i.e.*, claim 1), but *not* to the language of claims 37 and 45. Thus, the Court presumes that claims 37 and 45 do not contain that limitation.

C. The "staple line/seal/seam" limitations

The parties dispute the meaning of the following terms as they appear in claims 37, 39, 41, 43, 45, and 47 of

the '748 Patent. All of the terms are related to the seal or seam formed when the stapler is fired.

1. "staple seam"

Synovis contends that no construction is necessary, but if the Court decides to construe "staple seam," it should be construed as "a seam between two joined sections of tissue." (Joint Statement at 9.) FN12 Gore, on the other hand, asserts that the Court should construe this term as "seam formed when tissue sections are joined with staples." (Id.) The Court concludes that the term "staple seam" is properly construed as a "seam formed when tissue sections are joined with staples."

FN12. Synovis originally proposed using the word "joint" instead of "seam," but abandoned that proposal during the *Markman* hearing. (Tr. at 64.)

2. "staple line buttress seal between joined tissue sections"

Synovis contends that no construction is necessary, but if the Court decides to construe the term, the term should be construed as "a reinforced seal between two joined sections of tissue, having both tissue and buttress material." (Joint Statement at 6.) Gore, on the other hand, asserts that the Court should construe this term as "seal formed by buttress material positioned between abutting terminal sections of the first and second tissue portions." *(Id.)*

Synovis asserts that its proposed construction captures the notion of reinforcement inherent in the term "staple line buttress" and reflects the concept of a buttress seal, which Synovis maintains is necessarily composed of both buttress and tissue. Gore argues that its proposed construction is based upon the plain language of the term, making clear that the seal specifically includes buttress material that is positioned between abutting sections of tissue.

Both parties' constructions provide for a seal between two sections of tissue. The parties' dispute centers on where the buttress material and tissue are located after the seal is formed. Synovis asserts that the tissue ends up between the two sections of the buttress material. (Tr. at 66.) Gore maintains that the asserted claims require the buttress material to be between the abutting terminal portions of the first and second tissue portions.

Gore contends that the specification demonstrates that the buttress material ends up between portions of tissue. For example, Gore relies on a portion of the Detailed Description, which explains that in an embodiment, the staple cartridge buttress has "a circumferential flat disc-like portion **(26)** adapted to be positioned upon the open face **(34)** of the staple cartridge component **(12),** and to ultimately be positioned between the abutted tissue sections (and adjacent to the anvil buttress disc-like portion **(32))** in order to serve as a staple line buttress." ('784 Patent c. 4, ll: 54-65.) The specification further explains that "[t]he buttress materials comprise a generally planar circumferential exterior region ... to be positioned between the abutting sections of tissue in order to form a seal therebetween." *(Id.,* c. 5, ll: 37-41). In addition, Gore points to the portions of the specification describing the staple cartridge component "being adapted to retain and position a terminal section of the first tissue portion," *(id.,* c. 5, ll: 7-8), and the stapler anvil component as "adapted to retain and position a terminal section of the second tissue portion." *(Id.,* c. 5, ll: 17-20.) Gore maintains that the specification describes the terminal sections of the tissue portions as being positioned directly on the cartridge and anvil and, further, that the buttress material is positioned between the abutting sections of tissue.

Synovis contends that Gore's construction would improperly exclude all embodiments in the '748 Patent and render the claims inoperable. Synovis asserts that the buttress material in the '748 Patent is always depicted as abutting the stapler and anvil components. ('748 Patent FIGS. 1-3.) In addition, Synovis asserts that the tissue is always shown over the buttress material. (Id., FIGS.4a-d.) Synovis further asserts that the buttress seal is between the sections of tissue to be joined (for example two sections of intestine), and not between abutting terminal ends of that tissue.

Synovis asserts that the portions of the Detail Description (primarily Column 4 of the '748 Patent) cited by Gore in support of the notion that the buttress material is in between the tissue refer only to FIG. 2 of the '748 Patent and that FIG. 2 represents an embodiment of the buttress material before the tissue in involved. (Tr. at 67.) Synovis asserts that Column 4 of the ' 748 Patent therefore describes the orientation of the components prior to the tissue becoming involved. Synovis argues that the portion of the specification that refers to the overall process of creating a seal, including the process when the tissue is involved, demonstrates that the terminal ends of the tissue portions become sandwiched between the buttress material. For example, Synovis points to the language of Column 6 of the '748 Patent, which refers to Figures 4a-4d. Figures 4a-4d illustrate the process for creating a seam. (Id., c. 6, ll: 11-14 ("FIG. 4 shows a cross-section view of the overall process of creating a reinforced stapled connection for tubular tissue in four steps, from top to bottom, using a preferred embodiment of this invention.).) Figures 4a-4c all show that the buttress material lies on the open face of both the stapler and the anvil components and that the tissue being sealed ends up in between portions of buttress material.FN13

FN13. Gore asserts that the Court should not rely on Figure 4 because 4d is incorrect. Gore asserts that Figure 4d must be inaccurate because it depicts buttress material being removed that is not near the joined tissue sections. The portion of buttress material being removed, however, is specifically labeled "severed material." ('748 Patent c. 6, ll: 44.) That there is not a label for the remaining buttress material does not mean that there is none or that the "severed material" is meant to encompass all of the buttress material.

The language of the claim term "staple line buttress seal between joined tissue sections," provides that the seal is between joined tissue sections. This is consistent with the specification, which explains that buttress material along with joined tissue sections make up the seal. For example, the Abstract of the '748 Patent explains that "[t]he buttress material is retained and provides an improved seal between the joined tissue sections." The Summary of the Invention reads in part: "to provide a first region of buttress material as a staple line buttress seal retained between joined tissue sections." ('784 Patent c. 2, ll: 48-51.) According to the claim language and the specification, it is the seal that remains between the joined tissue sections (*i.e.,* two sections of intestine).

The Court next looks to the specification. It is evident that the language in Column 6 of the '748 Patent and the illustrations of Figure 4 are most relevant to the construction of this term. As detailed above, this section of the specification demonstrates an embodiment where the buttress material lies on the open face of both the stapler and the anvil and that the tissue being sealed ends up between portions of buttress material. Gore's proposed construction-"seal formed by buttress material positioned between abutting terminal sections of the first and second tissue portions"-is at odds with this embodiment. Gore's proposed construction would require not only that portions of buttress material lie on the open face of the stapler and anvil components, but also that the portions of buttress material touch each other when the seal is formed. If this configuration were required by the claim language, there would be no way for the tissue to be involved

with the seal. Therefore, the Court declines to adopt Gore's proposed construction. Instead, the Court construes the term as "a reinforced seal between two sections of tissue."

3. "buttressed surgical seam between abutting tissue portions"

Synovis contends that the term should be construed as "a reinforced seam between two joined sections of tissue, having both tissue and buttress material." (Joint Statement at 11.) Gore, on the other hand, asserts that the Court should construe "seam formed by buttress material positioned between abutting terminal sections of the first and second tissue portions." (Id.) For the reasons discussed with respect to the construction of "staple line buttress seal between joined tissue sections" above, the Court construes this term as "a reinforced seam between abutting tissue portions."

4. "staple line buttress itself"

Synovis contends that no construction is necessary, but if the Court decides to construe "staple line buttress itself," the term should be construed as "portion of a first region of buttress material that is within the reinforced seal, and is the only material that remains in the body." (Joint Statement at 8; Tr. at 64.) Gore, on the other hand, asserts that the Court should construe this term as "the portion of the buttress material that is stapled between abutting terminal sections of tissue and remains in position within the body and forms the staple line buttress seal." (Id.)

Synovis contends that its construction accurately captures the meaning of the term while keeping the term in context of the claims, which refer to a region "adapted to serve as the staple line buttress itself." Synovis asserts that Gore's proposed construction adds unnecessary language and unsupported limitations. In particular, Synovis asserts that Gore's construction would require that the entirety of the first region stay in the body and that the buttress material be positioned between abutting terminal sections of tissue.

Gore asserts that staple line buttress is the portion of the buttress material that is stapled between abutting terminal sections of tissue and remains within the body to form the staple line buttress seal. In support, Gore cites to the specification. (*See* '748 Patent c. 3, ll: 40-42 ("including a first region adapted to remain in position within the body in order to serve as the staple line buttress itself"); c. 4, ll: 53-58 ("a circumferential flat, disc-like portion adapted ... to ultimately be positioned between the abutted tissue sections ... to serve as a staple line buttress"); c. 5, ll: 37-41 ("The buttress materials comprise a generally planar circumferential exterior region ... to be positioned between the abutting sections of tissue in order for form a seal therebetween.").) Gore asserts that Synovis' proposed construction is incorrect by stating that only a "portion" of the first region remains in the body and that the specification indicates that portions other than the first region may remain in the body.

For the reasons discussed above with respect to the "staple line buttress seal between joined tissue sections" term, the Court does not construe the term "staple line buttress itself" to require that the portion of buttress material be "stapled between abutting terminal sections of tissue." Consistent with the ordinary meaning of the claim terms and the specification, the Court construes the term as "portion of the buttress material that is within the reinforced seal."

D. "stably positioned upon the staple cartridge and/or anvil components of the stapler instrument," "adapted to assist in positioning and/or retaining the buttress material," and "adapted to position and/or retain the materials in place"

The Court discusses the above terms together because the parties' proposed constructions are essentially the same for each term and the construction of the first term will apply to the construction of the second and third. Claim 37 and 45 of the '748 Patent refer to "buttress material adapted to be [ ] stably positioned upon the staple cartridge and/or anvil components of the stapler instrument." FN14 Synovis contends that no construction is necessary, but if the Court decides to construe the term, it should construe it as "located so as to avoid becoming dislodged, during the course of its normal use, from the staple cartridge and/or anvil components." (Joint Statement at 13.) Gore, on the other hand, asserts that the Court should construe the phrase as "positioned in a secure fashion upon the staple cartridge and/or anvil components of the stapler by virtue of its physical structure without the need for adhesives or ties." (Id.)

FN14. Claims 37, 41, and 45 refer to a region of buttress material that is "adapted to assist in positioning and/or retaining the buttress material." Claims 37, 41, 44, 45, and 48 all reference a structure "adapted to position and/or retain the materials in place ."

Synovis claims that its proposed construction is consistent with the language of the claim terms and with the intrinsic evidence. Specifically, Synovis asserts that the claim terms all discuss positioning and retaining the buttress material on the stapler components. Synovis points to language in the Summary of the Invention that explains that the buttress material is designed so as "to avoid being dislodged or delaminated from its position in the course of positioning." ('748 Patent c. 2, ll: 62-63.) Synovis asserts that Gore's inclusion of the requirement that the positioning occur "by virtue of its physical structure without the need of adhesives or ties" is unjustified. Synovis asserts that the specification repeatedly refers to adhesives, ties, and gels as optional features for further enhancing the positioning of the buttress material.

Gore asserts that Synovis' proposed substitution of the word "located" for "positioned" would not be helpful to the jury and that the concept of "normal use" is not supported by the claims and would add ambiguity. In addition, Gore asserts that Synovis' construction does not capture a critical aspect of the invention-that the stable positioning of the buttress materials is attributed to its physical structure. Gore also cites to portions of the specification that it argues describe the invention in a way that requires that the buttress material be capable of being stably positioned by virtue of its physical structure.

It is apparent that the parties' dispute centers on the inclusion of the language "by virtue of its physical structure without the need for adhesives or ties." With the exception of this language, there is no significant difference between the parties' proposed constructions. The Court concludes that the intrinsic evidence does not support the additional language proposed by Gore. First, the Summary of the Invention reads in part:

The preformed tissue portions permit the placement and retention of the portions upon respective stapler components, preferably without the need for adhesives, ties, and the like. The preformed tissue portions can be treated (e.g., chemically treated) and/or manipulated (e.g., sewn) to retain suitable three dimensional structure and topographic features (e.g., raised/indented portions, ridges) that permit them to be positioned in a secure fashion upon a respective stapler component, e.g., by press or friction fit onto the corresponding grooves, apertures, ridges and edges of the stapler device component.

('748 Patent c. 3, ll: 25-35.). The phrase "preferably without the need for adhesives, ties, and the like" suggests that the specification describes a desirable, but not mandatory, embodiment of the patent. *See* Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1357 (Fed.Cir.2003). The Summary of the Invention also reads: "By virtue of its physical structure, optionally aided with ancillary materials described herein, the

material retains sufficient properties, including shear resistance, to avoid being dislodged or delaminated from its position in the court of positioning." ('748 Patent c. 2, ll: 59-64.) In addition, there are several references in the patent specification to the potential use of adhesives. ('748 Patent c. 3, ll: 16-20 ("Also optionally, positioning of the material upon a respective component can be accomplished or facilitated by the use of ancillary materials, such as gels or ties."); id., c. 10, ll: 33-40 (example 1); id., c. 11, ll: 58-64 (example 2).)

The Court concludes that the specification does not support the addition of the language "without the need for adhesives or ties" to the otherwise clear and understandable claim language. In addition, the Court determines that the structure of the buttress material to be "stably positioned" is described in the claim language and declines to construe the claim term so as to add the language "by virtue of its physical structure." Instead, the Court determines that the meaning of the "stably positioned" terms are readily understandable and no construction is necessary.

E. "being generally concentric to"

The parties dispute the meaning of the term "being generally concentric to" as it appears in claims 37, 41, and 45 of the '748 Patent. Synovis contends that no construction is necessary, but if the Court decides to construe the term, it should be construed as "generally sharing a common axis or center." (Joint Statement at 19.) Gore, on the other hand, asserts that the Court should construe "being generally concentric to" as "having a common center (as circles one within another)." (Id.) The Court concludes that the term "being generally concentric to" is properly construed as a "having a common center (as circles one within another)."

F. "cooperating to provide a desired three dimensional and/or topographic structure"

The parties dispute the meaning of the term "cooperating to provide a desired three dimensional and/or topographic structure" as it appears in claims 37, 41, and 45 of the '748 Patent.FN15 Synovis contends that no construction is necessary, but if the Court decides to construe the term, that it should be construed as "cooperating to provide a structure that is not flat." (Joint Statement at 10.) Gore, on the other hand, asserts that the Court should construe this term as "forming an integral raised center portion." (Id.)

FN15. These claims refer to "the first and second regions [of buttress material] cooperating to provide a desired three dimensional and/or topographic structure." ('748 Patent c. 15, ll: 65-67.)

Synovis asserts that a jury is capable of understanding the term without further construction. Alternatively, Synovis asserts that its proposed construction is consistent with the claims and intrinsic evidence, including the file history, and that the term "not flat" encompasses the concepts of "three dimensional" and "topographic." Synovis relies on the specification, which Synovis asserts provides examples of buttress material with a structure that is three dimensional and/or topographic. Synovis further argues that the three-dimensional structure of the claimed buttress material contrasts with the prior art reference U.S. Patent No. 6,656,193, which Synovis asserts disclosed two flat circular buttress material embodiments. Synovis asserts that the examiner allowed independent claims 37 and 45 because they explicitly included limitations on the buttress material structure, specifically that the buttress material must include at least two portions that cooperate to provide a desired three-dimensional and/or topographic structure. Synovis claims that Gore's proposed construction seeks to introduce a limitation that does not exist in the claims, lacks support in the intrinsic evidence, and is an attempt to improperly limit the scope of the claim to a single preferred

embodiment.

Gore contends that Synovis' proposed construction is too general and that the patent provides no support for a reinforcement wherein the three-dimensional structure is not in the central, raised region. Instead, Gore asserts that its proposed construction, "forming an integral raised center portion," is supported by Figure 3 of the patent, which Gore asserts shows the second region as having an integral raised center portion that is three-dimensional on its own. Gore asserts that this second region does not need to "cooperate" with the first region to provide a three-dimensional structure. Gore further asserts that written description and the prosecution history of the '748 Patent support its proposed construction. In particular, Gore asserts that in a January 3, 2006 Office Action, the USPTO expressly allowed the claims because the examiner concluded that "[n]one of the prior art of record ... discloses a kit with a buttress material portion ..., where each of the portions comprise, inter alia, a circumferential disc with an integral raised center portion." (Gore Ex. 7 para. 9.) Gore further asserts that Synovis acquiesced to the inclusion of the subject matter of Paragraph 18 of the published application into all of the asserted claims. Gore maintains that Paragraph 18 makes clear that the second region provides the three-dimensional structure.

The Court first looks to the claim language, which expressly provides for "the first and second regions cooperating to provide a desired three dimensional and/or topographic structure." This language, on its face, contradicts Gore's proposed construction, which does not require the second region to cooperate with the first region to provide an integral raised center portion that is three-dimensional. Further, the specification provides examples of buttress material with three dimensional structure. The Summary of the Invention provides that buttress material portions can "retain three dimensional structure and topographic features (e.g., raised/indented portions, ridges) that permit them to be positioned in a secure fashion upon a restrictive stapler component, e.g., by press fit or friction fit onto the corresponding grooves, apertures, ridges and edges of the stapler device component." *(See* ' 748 Patent c. 3, ll: 29-35.) The specification also contains an example of a buttress material structure with a three-dimensional structure. Figures 2 and 3 both show a buttress material with a circumferential disc and an integral raised center portion. With respect to Figure 2, the specification calls the "interior circumferential regions" of the buttress material "nonplanar." ('748 Patent c. 5, ll: 46-47.) The specification also indicates that buttress structure is defined by the shapes they are adapted to fit onto. The Detailed Description explains: "The actual buttress portions used are defined by the shapes they are adapted to be positioned upon, which for a circular stapler are typically the staple cartridge and the anvil components." ('748 Patent c. 7, ll: 7-10.)

In addition, differences in the language of other claims suggest that claims 37, 41, and 45 are not limited to "forming an integral raised center portion." As explained above, claim 1 of the '748 Patent recites "a circumferential disc having an integral raised center portion," while claim 37 does not. Instead, claim 37 requires the first and second regions to cooperate to provide a three-dimensional or topographic structure.

Gore relies primarily on the prosecution history to limit the claim term. Gore's arguments are similar to those made with respect to the construction of the "second region of buttress material." The Court similarly rejects those arguments here. In addition, the Court concludes that Gore's proposed construction ("forming an integral raised center portion") is not supported by the intrinsic evidence. The Court further concludes that the term has a meaning that is readily understandable and no construction is necessary.

G. "upon activation"

The parties dispute the meaning of the term "upon activation" as it appears in claims 37, 38, 39, 41, 42, 43,

45, 46, and 47 of the '748 Patent. Synovis contends that no construction is necessary, but if the Court decides to construe the term, it should be construed as "immediately following or very soon after activation." (Joint Statement at 22.) Gore, on the other hand, asserts that the Court should construe "upon activation" as "as a result of activation." (Id.) The difference between the parties' proposed construction centers on the requirement in Gore's proposed construction of a causal relationship between the activation of the stapler and the severance of the second region.

Synovis asserts that its construction captures the commonly understood meaning of the work "upon," which connotes a temporal relationship between events. In support of its proposed construction, Gore cites to portions of the specification, which, it argues, supports a causal relationship. These include the following: "The former region is severed and discarded upon activation of the stapler to form an anastomoses." (Abstract.) "[T]o permit the removal of one or more portions of a second region of the buttress material upon activation of a stapler knife provided by the stapler." ('748 Patent c. 2, ll: 52-55); "Preferably, the one or more portions of the second region are adapted to be removed from the tissue site upon activation of the stapler knife." ('748 Patent c. 3, ll: 44-47); "Simultaneously, or thereafter, the distal end of an annular scalpel **(40)** is extended through the sandwiched tissue and buttress material, until it bottoms out in a recessed annular ring within the anvil, thereby severing an inner ring of the sandwiched tissue/buttress material." ('748 Patent, c. 6, ll: 38-41.) Gore maintains that the specification makes clear that the second region is severed from the first region *as a result of* the activation of the stapler.

The Court concludes that the term "upon activation" does not require a causal relationship between two events. For example, claim 37 provides in part: "wherein one or more portions of the second region [of buttress material] are adapted to be removed from the tissue site upon formation of the staple seam and activation of a stapler knife." Nothing in the claim language or specification suggests that the use of the term "upon activation" requires the activation of the stapler knife to cause the removal of the second region of buttress material. Therefore, the Court believes that the use of Gore's proposed construction would only add confusion to an otherwise understandable term. Thus, the Court declines to construe the term.

Therefore, **IT IS HEREBY ORDERED** that:

1. The claims at issue are construed as set forth in this Order.

D.Minn.,2009.
Synovis Life Technologies, Inc. v. W.L. Gore & Associates, Inc.