

United States District Court,
E.D. Texas, Lufkin Division.

TYCO HEALTHCARE GROUP LP,
Plaintiff.

v.

APPLIED MEDICAL RESOURCES CORP,
Defendant.

Civil Action No. 9:06-CV-151

Nov. 18, 2008.

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***MEMORANDUM OPINION AND ORDER CONSTRUING CLAIM TERMS OF UNITED STATES
PATENT NOS. 5,304,143, 5,685,854, 5,603,702, 5,895,377, AND 5,542,931.***

KEITH F. GIBLIN, United States Magistrate Judge.

In accordance with 28 U.S.C. s. 636(b)(1), Federal Rule of Civil Procedure 72, and the Local Rules for the United States District Court for the Eastern District of Texas, the District Court referred the above-captioned civil action to the undersigned United States Magistrate Judge for all pre-trial proceedings, including a determination of non-dispositive pretrial motions and proceedings and entry of findings of fact and recommended disposition on case-dispositive motions. FN1

FN1. At the time this court conducted the Markman hearing, this proceeding was assigned to the docket of United States District Judge Ron Clark who referred the matter to the undersigned for considering. On September 26, 2007, Judge Clark referred the case to this court for all further proceedings and entry of judgment in accordance with the parties' consent to proceed before a United States Magistrate Judge under 28 U.S.C. s. 636(c). *See Reference Order* [Clerk's doc. # 98].

Plaintiff Tyco Healthcare Group LP ("Tyco") alleges that Defendant Applied Medical Resources

Corporation ("Applied") infringes U.S. Patent Nos. 5,304,143 (the '143 patent), 5,685,854 (the '854 patent), 5,603,702 (the '702 patent), 5,895,377 (the '377 patent), and 5,542,931 (the '1 patent). The court conducted a *Markman* hearing to assist it in interpreting the meaning of the claim terms in dispute. Having carefully considered the patents, the prosecution history, the parties' briefs, and the arguments of counsel, the court now makes the following findings and construes the disputed claim terms. FN2

FN2. While this Order governs in the event of any conflict between the Order and the Court's preliminary analysis at the hearing, the record may clarify the bases for the conclusions set out herein. The transcript of the claim construction hearing will be cited as "Tr. p. ____, l. ____."

I. Claim Construction Standard of Review

Claim construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996) ("*Markman II*"). "The duty of the trial judge is to determine the meaning of the claims at issue, and to instruct the jury accordingly." *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed.Cir.1995) (citations omitted).

" [T]he claims of the patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed.Cir.2005) (*en banc*) (citation omitted). "Because the patentee is required to 'define precisely what his invention is,' it is 'unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.'" *Phillips*, 415 F.3d at 1312 (quoting *White v. Dunbar*, 119 U.S. 47, 52, 7 S.Ct. 72, 30 L.Ed. 303 (1886)).

The words of a claim are generally given their ordinary and customary meaning. *Phillips* 415 F.3d at 1312. The "ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." FN3 *Id.* at 1313. Analyzing "how a person of ordinary skill in the art understands a claim term" is the starting point of a proper claim construction. *Id.*

FN3. Based on the patents at issue, the technology involved, and the parties agreement, the court defines one of ordinary skill in the art to be "a person with a bachelor of science degree in mechanical engineering, biomechanical engineering or biomedical engineering and having 2-5 years experience in the design or development of devices in the pertinent art, or a person without a bachelor's degree in the above disciplines but having at least 5 years experience in the design or development of devices in the pertinent art."

A "person of ordinary skill in the art is deemed to read the claim term not only in context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313. Where a claim term has a particular meaning in the field of art, the court must examine those sources available to the public to show what a person skilled in the art would have understood disputed claim language to mean. *Id.* at 1414. Those sources "include 'words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.'" *Id.* (citation omitted).

"[T]he ordinary meaning of claim language as understood by a person of skill in the art may be readily

apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." Phillips, 415 F.3d at 1314. In these instances, a general purpose dictionary may be helpful. *Id.*

However, the *Phillips* Court emphasized the importance of the specification. "[T]he specification 'is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.'" Phillips, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996)). A court is authorized to review extrinsic evidence, such as dictionaries, inventor testimony, and learned treatises, but their use should be limited to edification purposes. Phillips, 415 F.3d at 1317, 1319.

The intrinsic evidence, that is, the patent specification, and, if in evidence, the prosecution history, may clarify whether the patentee clearly intended a meaning different from the ordinary meaning, or clearly disavowed the ordinary meaning in favor of some special meaning. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed.Cir.1995). Claim terms take on their ordinary and accustomed meanings unless the patentee demonstrated "clear intent" to deviate from the ordinary and accustomed meaning of a claim term by redefining the term in the patent specification. *Johnson Worldwide Assoc., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed.Cir.1999).

The "'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent." Phillips, 415 F.3d at 1321. However, the patentee may deviate from the plain and ordinary meaning by characterizing the invention in the prosecution history using words or expressions of manifest exclusion or restriction, representing a "clear disavowal" of claim scope. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed.Cir.2002). It is clear that if the patentee clearly intended to be its own lexicographer, the "inventor's lexicography governs." Phillips, 415 F.3d at 1316.

II. Construction of Means Plus Function Terms

Determining the claimed function and the corresponding structure of means-plus-function clauses are matters of claim construction. *WMS Gaming Inc., v. Int'l Game Tech.*, 184 F.3d 1339, 1347 (Fed.Cir.1999). Claim construction of a means-plus-function limitation involves two steps. *See Medical Instrumentation and Diagnostics v. Elekta*, 344 F.3d 1205, 1210 (Fed.Cir.2003). The court must first identify the particular claimed function, and then look to the specification and identify the corresponding structure for that function. *Id.* "Under this second step, 'structure disclosed in the specification is corresponding structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim.'" *Id.* (citations omitted). "While corresponding structure need not include all things necessary to enable the claimed invention to work, it must include all structure that actually performs the recited function." *Default Proof Credit Card System, Inc. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1298 (Fed.Cir.2005).

III. Claim Construction of '143 and '854 Patents

The '143 patent involves a valve assembly adapted for introduction of an elongated object into a patient's body. The invention discloses two valves. The first valve is formed of a resilient material and defines an aperture for reception of an object. The aperture is configured such that insertion of the instrument into the aperture will cause the resilient material of the valve body to engage the outer surface of the instrument in a substantially fluid tight manner. In general alignment with the first valve, a second valve is positioned adjacent and distal, defining an aperture, and it is formed of a flexible material at least in the region

defining the aperture. A pair of manually operable clamps are provided to selectively permit the aperture of the second valve to be opened or closed so as to permit entry of the object such that the object first passes through the first valve and the second valve prior to entry into the patient's body. The '854 patent is a continuation patent and shares the same specification.

The disputed terms in the '143 patent are contained in Claims 1, 12, 13, 22, 26, and 30. The claims with the disputed terms in italics, are set forth below:

1. Valve assembly for sealed reception of an elongated object, which comprises:

(a) valve body defining a longitudinal axis and having at least one opening configured and dimensioned to permit entry of the elongated object;

(b) flexible resilient valve member defining an aperture positioned in general alignment with said at least one opening; and

(c) means associated with said flexible resilient valve member to facilitate expansion of said aperture to permit entry of the elongated object therethrough in sealed engagement therewith, said means to facilitate expansion of said aperture adapted for radial displacement relative to said longitudinal axis and positioned to expand said aperture upon contact with the elongated object as the elongated object is at least partially inserted into said at least one opening of said valve body.

12. Valve assembly for introduction of an elongated object into a patient's body, which comprises:

(a) valve body member defining a proximal inlet opening and a distal outlet opening;

(b) first valve member formed of a flexible elastomeric resilient material and defining an aperture for reception of the elongated object, said aperture being configured and dimensioned such that the insertion of the elongated object into said aperture causes said flexible resilient material defining said aperture to resiliently engage and conform to an outer surface portion of the elongated object in substantially fluid tight manner;

(c) second valve member positioned adjacent said first valve member and in general alignment therewith, said second valve member defining an aperture in general alignment with said aperture of said first valve member, and being formed of a flexible resilient material at least in the region adjacent to and defining said aperture; and

(d) means engageable with the elongated object upon insertion thereof into said proximal inlet opening of said valve body member, and adapted to be radially displaced relative to a central axis defined by said valve body member to facilitate expansion of said aperture of said first valve member to facilitate entry of the object therein.

13. The valve assembly according to claim 12 wherein said first and second valve members are *formed integral of a flexible elastomeric resilient material*, said first valve member connected to said second valve member at the proximal end thereof, said first valve member being positioned at least partially within said second valve member.

22. Valve assembly for sealed reception of an elongated object into a patient's body, which comprises:

(a) valve body defining a first inlet opening and a second outlet opening;

(b) flexible resilient valve member defining an aperture positioned in general alignment with at least said first inlet opening for reception of the elongated object, said aperture being configured and dimensioned such that the insertion of the elongated object into said aperture will cause the flexible resilient material defining said aperture to resiliently engage and conform to the outer surface of the elongated object in a substantially fluid tight manner; and

(c) means engageable with the elongated object upon insertion thereof into said first inlet opening and adapted to be displaced away from a central axis defined by said valve body to expand said aperture of said resilient valve member to facilitate entry of the elongated object therein.

26. Valve assembly for sealed reception of an elongated object, which comprises:

(a) valve body defining a generally longitudinal axis and having at least one opening configured and dimensioned to permit entry of the object;

(b) flexible resilient valve member positioned within said valve body and defining an aperture positioned in general alignment with said at least one opening of said valve body; and

(c) at least two projecting members associated with said flexible resilient valve member and extending in a generally distal direction, each said at least two projecting members having at least a portion thereof adapted to move generally radially to facilitate expansion of said aperture to permit entry of the elongated object therethrough in sealed engagement therewith.

30. Valve assembly according to claim 29 wherein said at least two projecting members contact at least a portion of said resilient valve member and are positioned for engagement with the elongated object upon insertion thereof into said at least one opening of said valve body, at least portions of said at least two projecting members *adapted for generally radial displacement relative to said longitudinal axis upon engagement by the elongated object to cause radial expansion of said aperture.*

The disputed terms in the '854 patent are contained in Claims 1, 6, and 10.

1. A trocar assembly having a channel defined along an elongated axis, the trocar assembly being adapted to receive an instrument having a particular cross-sectional dimension, said trocar assembly comprising:

an elastomeric septum disposed in said channel and including portions defining an orifice having in a relaxed state a first cross-sectional area and in an expanded state a second cross-sectional area; and

means responsive to the particular dimension of the instrument for expanding said orifice to the second cross-sectional area.

6. A seal assembly adapted to receive an elongated object and to form a seal around the object, the assembly comprising:

a housing defining a channel configured to receive the object moving generally axially through the channel;

a septum extending across the channel of the housing and forming an outer seal with the housing;

portions of the septum defining a hole in communication with the channel on both sides of the septum, the hole having a size sufficient to receive the object with the hole portions forming an inner seal with the object;

the septum being formed of an elastomeric material having properties for producing a friction force which resists movement of the object through the septum; and

means responsive to insertion of the object into the channel for reducing the friction force on the object.

10. A trocar assembly adapted to receive an instrument having a particular cross-sectional dimension, said trocar assembly comprising:

a housing;

an elastomeric member disposed within said housing and defining an orifice having in a relaxed state a first cross-sectional area and in an expanded state a second cross-sectional area; and

means responsive to the particular dimension of the instrument for expanding said orifice to the second cross-sectional area.

1. "To facilitate expansion." Used Claims 1 and 12 of the '143 patent.

Tyco proposes "to make expanding the aperture easier." Applied suggests "to assist in the expansion." Both parties agree that the court should look to the ordinary use of the term "facilitate." Applied objects to Tyco's definition on the basis that it encompasses even the most indirect and passive role in the attainment of the desired expansion. Tyco maintains that its definition is correct because it covers instances where the fingers make it easier to expand the aperture of the valve (1) by assisting in spreading the aperture, and (2) by distributing the force applied to the inner surface of the valve more evenly.

Reference to common dictionaries does not resolve the issue because the term "facilitate" is defined as both "to assist" and "to make easier." *See, e.g., OXFORD ENGLISH DICTIONARY ONLINE available at <http://dictionary.oed.com>.* The court, therefore, is guided by the specification, which states:

The fingers provide an interface between the first valve means and objects inserted therein and *assist* in spreading the opening of the first valve means for entry of the instrument. *Further*, the fingers distribute the force over the inner surface of the first valve means. '143 patent, col 4, ll. 18-22 (emphasis added).

Fingers 78 are positioned within diaphragm inner wall 30a and are sufficiently flexible to conform to the shape of the inner wall while providing some degree of stability to the inner wall. Fingers 78 also *assist* in spreading inner wall 30a to expand aperture 34 when an instrument is inserted by distributing the spreading force more evenly. In addition to facilitating expansion of the aperture 34 to conform to instrument 76, fingers 78 minimize the risk of damage to elastomeric inner wall 30a '143 patent, col. 6, ll. 42-51(emphasis added).

Therefore, it appears that the patentee repeatedly used the term "assist" to describe how the fingers facilitate expansion. This term is consistent with the ordinary meaning of "facilitate". Based on the specification, the claim language, and ordinary use of the term, the court concludes that the term **"to facilitate expansion"** means "to assist expansion."

2. Adapted Clauses

There are five "adapted" clauses. Tyco devotes less than two pages of its brief to these terms. Applied only addresses these terms in a single foot note. Tyco proposes the same construction for these five terms: "Part of each finger may be moved in a direction away from the axis of the valve body to make expanding the aperture easier upon contact with an instrument." Applied suggests a slightly different construction for each term. The dispute centers on the term "displacement." Tyco objects to Applied's definition of "able to be moved away" or "able to move away" as being imprecise because it suggests detachment or separation of the fingers. For ease of reference, and because each term is slightly different, the court will proceed term by term.

(1) "Adapted for radial displacement relative to said longitudinal axis and positioned to expand said aperture upon contact with the elongated object (as the elongated object is at least partially inserted into said at least one opening of said valve body)." Used in Claim 1.

Tyco suggests "part of each finger may be moved in a direction away from the axis of the valve body to make expanding the aperture easier upon contact with an instrument."

Applied suggests "able to be moved away from the longitudinal axis so as to cause the aperture to expand upon contact with the elongated object." Neither party seeks to construe the phrase "as the elongated object is at least partially inserted into said at least one opening of said valve body," and accordingly the court will not construe this portion of the phrase.

The dispute is over the construction of "displacement." Tyco suggests "moved in a direction away from" and Applied proposes "able to be moved away from." As a practical matter, there is very little, if any, distinction between these proposals. The specification states "manipulation of the instrument in any direction will not affect the seal, since the elastomeric material defining the opening 34 will conform to the movements of the instrument and assume an elliptical or other shape necessary to maintain contact." '143 patent, col. 8, ll. 8-13. Common dictionaries refer to "displacement" as "shifting" or "moving." *See, e.g., THE MERRIAM-WEBSTER THIRD NEW INTERNATIONAL DICTIONARY, UNABRIDGED (2002).* Based on the specification and ordinary usage, the court will construe this term as "able to be moved in a direction away from."

Tyco argues that "part of each finger" should be added to the construction because a jury may feel that the entire finger(s) would completely detach from the structure instead of being connected at the proximal end as the patent teaches. Applied responded that Tyco's argument required the court to add language which was not in the claim and, in no uncertain terms, assured the court that they would not argue to this court or to a jury that the fingers detach. Tr., p. 40. This court initially found Tyco's argument persuasive. However, a close inspection of patent at issue reveals that the patentee, for whatever reason, chose to insert the similar language in claims 26 and 30 which reflect that a "portion" or "portions" of the projecting members are adapted to move in a direction away from the longitudinal axis. The patentee did not include this language

in Claims 1, 12, and 22. Therefore, the court declines to include this language in the construction of Claims 1, 12, and 22. Further, it would be redundant to add the language to Claims 26 and 30.

Tyco argues that the court should substitute the term "instrument" for "elongated object" which somewhat narrows the claims. Tyco did not argue that the phrase "elongated object" should necessarily be construed; Tyco contended in so many words that the patentee acted as his own lexicographer. Tyco argued that it would be helpful for the jury to know that the objects which are inserted are actually medical instruments. Therefore, Tyco argues that the term "elongated object" should be construed as "instrument" in light of the specification. Applied responded that the '143, '702, and '377 broadly claimed "elongated objects" and the patentee in the '143 did not act as his own lexicographer and specifically define "elongated object" to mean "instrument". Tr., p. 42.

When a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must clearly express that intent in the written description. *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1370 (Fed.Cir.2005). However, the Federal Circuit has held that a claim term may be clearly redefined without an explicit statement of redefinition and may define claim terms "by implication". *Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1268 (Fed.Cir.2001).

In the Summary of the Invention, the patentee stated that his invention was a valve assembly adapted for introduction of an *elongated object* into a patient's body. '143 patent, col. 2, ll. 59-60 (emphasis added). Later in the specification, the patentee noted that "[t]he objects *contemplated* are surgical instruments such as clip applicators, dissectors, graspers, laser and electrocautery devices, drainage or fluid introduction tubes, or the like." '143 patent, col. 3, ll. 35-38 (emphasis added).

However, when discussing a preferred embodiment, the patentee stated that [t]hereafter, the trocar is removed and elongated objects, such as surgical instruments *or the like* may be introduced into a patient's body through the valve assembly and cannula as described hereinabove." '143 patent, col. 4, ll. 43-46 (emphasis added). This certainly leaves open the possibility that, in a preferred embodiment, other elongated objects similar to surgical instruments may be inserted into the body cavity. In the Detailed Description of the Preferred Embodiments, the patentee stated the "[t]he present invention contemplates introduction into a patient's body of all types of surgical instruments including clip applicators, lasers, photographic devices, tubes, etc. All such objects are referred to herein as 'instruments'." '143 patent, col. 5, ll. 18-22.

Again, the claim language, however, expressly does not use the word "instruments." The patent does not specifically define "elongated objects" as "instruments." Moreover, the "or the like" language in column 4 indicated that the patentee intended the scope of the term "elongated objects" to possibly extend beyond surgical instruments. The patentee did not define this term by implication. The court finds no reason to substitute "instrument" for "elongated object" in the claims at issue.

Based upon the specification and the claim language, the court concludes that "**adapted for radial displacement relative to said longitudinal axis and positioned to expand said aperture upon contact with the elongated object**" means "able to be moved in a direction away from the longitudinal axis and positioned to expand the aperture upon contact with the elongated object."

(2) "Adapted to be radially displaced relative to a central axis defined by said valve body member to facilitate expansion of said aperture of said first valve member to facilitate entry of the object"

therein." Used in Claim 12.

Applied suggests "able to be moved away from the longitudinal axis so as to assist in the expansion of the aperture, thereby easing the passage of the elongated object through the aperture." This phrase is very similar to (1) above. The main difference is that in this phrase, based on the claim language, the term "aperture" specifically refers to an opening of the first valve member.

Based on the discussion above, the court construes this term as follows: "**adapted to be radially displaced relative to a central axis defined by said valve body member to facilitate expansion of said aperture of said first valve member to facilitate entry of the object therein**" means "able to be moved in a direction away from the central axis of the valve housing so as to assist in the expansion of the aperture of the first valve member, thereby assisting the entry of the elongated object therein."

(3) "Adapted to be displaced away from a central axis defined by said valve body to expand said aperture of said resilient valve member to facilitate entry of the elongated object therein." Used in Claim 22

Applied suggests "able to be moved away from the longitudinal axis so as to expand the aperture, thereby easing the passage of the elongated object through the aperture." The "aperture" in this claim is described as being "configured and dimensioned such that insertion of the elongated object into said aperture will cause the flexible resilient material defining said aperture to resiliently engage and conform to the outer surface of the elongated objection in a substantially fluid tight manner." '143 patent, col. 11, ll.43-48. This is consistent with the description of the "aperture" as being an opening in the inner wall. *See* '143 patent, col. 7, ll. 67- col. 8, l. 4.

For the reasons stated above, the court construes this term to mean "able to be moved in a direction away from the central axis of the valve body so as to expand the aperture of the resilient valve member, thereby assisting the entry of the elongated object therein."

(4) "Adapted to move generally radially to facilitate expansion of said aperture to permit entry of the elongated object therethrough in sealed engagement therewith." Used in Claim 26.

Applied suggests "able to be move away from the longitudinal axis so as to assist in the expansion of the aperture, thereby permitting the elongated object to enter while maintaining its seal with the valve." The words in this term are discussed fully above. The court construes this term to mean "able to be moved in a direction away from the longitudinal axis to assist expansion of the aperture, thereby permitting entry of the elongated object while maintaining its sealed contact with the valve."

(5) Adapted for generally radial displacement relative to said longitudinal axis upon engagement by the elongated object to cause radial expansion of said aperture." Used in Claim 30.

Applied suggests "able to be moved away from the longitudinal axis so as to cause the aperture to expand upon contact with the elongated object." The words in this term are discussed fully above. The court construes this term to mean: "able to be moved in a direction away from the longitudinal axis to cause expansion of the aperture upon contact with the elongated object."

3. (1) "Means associated with said flexible resilient valve member to facilitate expansion of said

aperture to permit entry of the elongated object therethrough in sealed engagement therewith, said means to facilitate expansion of said aperture adapted for radial displacement relative to said longitudinal axis and positioned to expand said aperture upon contact with the elongated object as the elongated object is at least partially inserted into said at least one opening of said valve body." Used in Claim 1 of the '143 patent.

(2) "Means engageable with the elongated object upon insertion thereof into said proximal inlet opening of said valve body member, and adapted to be radially displaced relative to a central axis defined by said valve body member to facilitate expansion of said aperture of said first valve member to facilitate entry of the object therein." Used in Claim 12 of the '143 patent.

(3) "Means engageable with the elongated object upon insertion thereof into said first inlet opening and adapted to be displaced away from central axis defined by said valve body to expand said aperture of said resilient valve member to facilitate entry of the elongated object therein." Used in Claim 22 of the '143 patent.

Where a claim includes the word "means," a presumption is invoked that 35 U.S.C. s. 112 para. 6 applies. *See Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241,1248 (Fed.Cir.2005). The parties agree that these phrases are means-plus-function terms. Again, at the hearing, the parties informed the court that they agree that the corresponding structure: "Fingers 78."

With regard to the function, while the parties indicate that they agree on the function, they do not specifically state what the function is for these clauses, and the phrases are actually made of a number of disputed and agreed terms.

(1) This first phrase is actually two separate means clauses: (a) "Means associated with said flexible resilient valve member to facilitate expansion of said aperture to permit entry of the elongated object therethrough in sealed engagement therewith," and (b) "Means to facilitate expansion of said aperture adapted for radial displacement relative to said longitudinal axis and positioned to expand said aperture upon contact with the elongated object as the elongated object is at least partially inserted into said at least one opening of said valve body."

(a) This portion of the phrase involves the disputed term "to facilitate expansion." For the reasons discussed above, this term will be construed to mean "to assist expansion." Moreover, the parties agreed that "valve member" means "a structure that can be used to control the passage of liquid or gas." The parties also agreed that "engagement" means "contact(s)." The term "aperture" is discussed at length above.

Based on the claim language, the function is "to assist expansion of the opening in the inner wall so as to permit entry of the elongated object through the opening while maintaining its sealed contact with the valve member."

(b) The second means clause involves the disputed terms: "to facilitate expansion," and "adapted for radial displacement relative to said longitudinal axis and positioned to expand said aperture upon contact with the elongated object as the elongated object is at least partially inserted into said at least one opening of said valve body." Both of these phrases are discussed above.

Based on the prior interpretation of these terms, the court concludes that the function is: "to assist expansion

of the opening and to be able to be moved in a direction away from the longitudinal axis and positioned to expand the opening in the inner wall upon contact with the elongated object."

(2) The second phrase involves a previously discussed term, "adapted to be radially displaced relative to a central axis defined by said valve body member to facilitate expansion of said aperture of said first valve member to facilitate entry of the object therein," and "means engageable with the elongated object upon insertion thereof into said proximal inlet opening of said valve body member." For the reasons discussed above, the "adapted" clause means "able to be moved in a direction away from the central axis of the valve housing so as to assist expansion of the opening of the first valve, thereby assisting the entry of the elongated object."

The parties agreed that "valve member body" means "housing for a valve." The parties also agreed that "engagement" and "engage" mean "contact(s)." While the parties do not discuss the terms "proximal" and "inlet," these terms may also be confusing to the jury.

The specification states: "The valve housing 15 includes neck 18 at the distal end having an aperture 20 dimensioned for reception of an appropriate sheath tube such as a cannula 22 to form the cannula assembly 10. The proximal end of the valve housing 15 includes inlet opening 24 which includes annular partition 26 for supporting a dual diaphragm." '143 patent, col. 5, ll. 39-44. In Figure 1, the proximal end is depicted as being on the same side as the elongated objects are inserted, and opposite the side with the cannula. '143 patent, Fig. 1. The patent also discloses that "[t]he first valve means is formed of an elastomeric resilient material and extends across the proximal inlet opening of the valve body, and defines an aperture configured and dimensioned for reception of the object" '143 patent, col. 3, ll. 11-13.

The claim itself describes a "proximal inlet opening and a distal outlet opening." '143 patent, col. 9, ll. 36-37. The court concludes that "proximal inlet" should be defined as "the entrance opposite the sheath tube." This is consistent with common dictionary definitions. *See* THE MERRIAM-WEBSTER THIRD NEW INTERNATIONAL DICTIONARY, UNABRIDGED (2002) ("proximal" means "next to or nearest the point of attachment or origin") ("inlet" means "a place of entrance").

Based on the specification and the claim language, the function is: "To be in contact with the elongated object upon the object's insertion into the entrance opposite the sheath tube and able to be moved in a direction away from the central axis of the valve housing so as to assist expansion of the opening of the first valve, thereby assisting the entry of the elongated object."

(3) The third phrase involves two clauses: "Means engageable with the elongated object upon insertion thereof into said first inlet opening" and "adapted to be displaced away from central axis defined by said valve body to expand said aperture of said resilient valve member to facilitate entry of the elongated object therein." The only difference in the first clause from the discussion above is the substitution of the word "first" for "proximal."

The court concludes that the function is: "To be in contact with the elongated object upon the objects insertion into the first entrance and able to be moved in a direction away from the central axis of the valve housing so as to expand the opening of the resilient valve member, thereby assisting the entry of the elongated object."

4. "Means responsive to the particular dimension of the instrument for expanding said orifice to the

second cross-sectional area." Used in Claim 1 and 10 in the '854 patent.

"Means responsive to insertion of the object into the channel for reducing the friction force on the object." Used in Claim 6 in the '854 patent.

The parties agree, and the court finds, that these are means-plus-function terms. The parties discuss these terms in conjunction with the three terms above and advance the same arguments. As noted, the parties agreed that the structure is: "Fingers 78."

While the parties indicate that the function is agreed upon for these terms, the parties do not articulate what the function is. Based on the claim language, the parties' agreements, and the specification, the function for "means responsive to the particular dimension of the instrument for expanding said orifice to the second cross-sectional area" is: "To expand the opening to the second cross-sectional area in response to the particular size of the instrument."

The function for "means responsive to insertion of the object into the channel for reducing the friction force on the object" is: "To reduce the friction force on an object being inserted into the channel."

5. "Formed integral of a flexible elastomeric resilient material." Used in the '143 patent, Claim 13.

Claim 13, with the disputed terms in italics, states:

The valve assembly according to claim 12 wherein said first and second valve members are *formed integral of a flexible elastomeric resilient material*, said first valve member connected to said second valve member at the proximal end thereof, said first valve member being positioned at least partially within said second valve member.

Tyco proposes "the first and second valve members are attached or connected together and made from a flexible elastomeric resilient material." Applied suggests "made from a single piece of flexible elastomeric resilient material, rather than from separate pieces that were joined together."

The parties focus on the term "integral." The parties refer to this term in two different manners. Tyco refers to component parts which are connected to make a whole, while Applied refers to a single piece. Both positions are consistent with common usage of the word. *See* OXFORD ENGLISH DICTIONARY ONLINE *available at* <http://dictionary.oed.com> (integral means "whole, entire, complete" and it also means "of or pertaining to a whole.").

The specification states:

[T]he first and second valve means are preferably formed integrally of a flexible elastomeric resilient material, with the first valve means connected to the second valve means at the proximal ends thereof, the first valve means being positioned at least partially within the second valve means. The first and second valve means are joined at their proximal ends and are attached to the valve body across the proximal opening.

'143 patent, col. 3, ll. 41-49. The specification also states that the "first and second valves are molded integrally of synthetic or natural rubber and are connected at a common proximal end which defines the

proximal opening. The first valve means has a generally conical shape and is positioned within the second valve means in a generally concentric fashion." '143 patent, col. 4, ll. 47-53. The claim language also states that the first valve member is connected to the second valve member and is "positioned at least partially within said second valve member." '143 patent, col. 9, ll. 65-67.

The term "integral" modifies "formed" and, based on the specification, is directed toward what the valves are made up of when they are formed. The specification teaches that the valve must be made wholly or entirely of the elastomeric material. There is nothing, however, which indicates that the valves must be made only from a single piece of the material, as suggested by Applied. Moreover, using Tyco's definition would simply repeat the second half of the claim.

Finally, the parties agree that "elastomeric" means "a material that can stretch and tends to return to its normal shape."

"Formed integral of a flexible elastomeric resilient material" means "formed entirely, but not necessarily from a single piece, of a material that can stretch and tends to return to its normal shape."

IV. Claim Construction of '702 and '377 Patents

The '702 patent involves a valve assembly for sealed reception of an elongated object. The assembly includes a valve body having at least one opening configured to permit entry of an elongated object and an elongated seal member formed of a resilient material and defining an aperture in general alignment with the opening of the valve body. The aperture is configured such that insertion of the instrument into the aperture will cause the resilient material of the valve body to engage the outer surface of the instrument in a substantially fluid tight manner. There is also at least one elongated guard member disposed within the seal member in supporting contact with the inner surface.

The guard member is positioned to engage the elongated object upon at least partial insertion of the elongated object into the valve body. The guard member includes at least a first substantially rigid portion adapted to be displaced relative to the longitudinal axis to facilitate expansion of said aperture of the seal member upon entry of the object therein and a second portion having less rigidity than the first portion for the guard member to enhance passage of the elongated object through the valve body. The '854 patent is a continuation patent and shares the same specification.

All of the disputed terms in the '702 patent are contained in Claims 1, 3, 6, and 11. The claims with the disputed terms in italics are:

1. Valve assembly for sealed reception of an elongated object, which comprises:

(a) valve body having at least one opening configured and dimensioned to permit entry of an elongated object and defining a central longitudinal axis;

(b) an elongated seal member formed of a resilient material and defining an aperture in general alignment with the opening of the valve body, the aperture being configured and dimensioned such that the insertion of the object into the aperture causes the resilient material defining the aperture to resiliently engage the outer surface of the object in a substantially fluid tight manner; and

(c) a plurality of elongated guard members disposed within the seal member in contact with the inner surface thereof, the guard members positioned to engage the elongated object upon at least partial insertion of the elongated object into the valve body, each of the guard members including at least a first substantially rigid portion and a second portion having less rigidity than the first portion, each guard member *adapted to be displaced relative to the longitudinal axis to facilitate expansion of the aperture of the seal member upon entry of the object therein.*

3. The valve assembly according to claim 1 wherein *each guard member is a monolithically formed integrated unit.*

6. A valve assembly for sealed reception of an elongated object, which comprises:

(a) a valve housing having a longitudinal opening configured and dimensioned to permit entry of an elongated object;

(b) an elongated resilient seal member at least partially positionable within the valve housing and defining an aperture to permit entry of the elongated object therein in a substantially fluid tight manner; and

(c) a plurality of guard members disposed within the seal member and concentrically arraigned about a central longitudinal axis defined by the valve housing and positioned to engage the elongated object upon insertion of the elongated object within the valve housing, each guard member *adapted to be radially displaced during introduction of the elongated object within the valve assembly to engage portions of the valve member adjacent, but proximal to, the aperture to expand the aperture, each guard member having an end portion of less rigidity than the remaining portions of the guard member, the end portion dimensioned to reduce the force required to advance the elongated object through the valve housing.*

11. The valve assembly according to claim 6 wherein the elongated seal member includes a central *frustoconical* portion defining the aperture and a *circumferential portion*, the circumferential portion including a bellows structure, the bellows structure engageable with the valve housing and dimensioned to maintain a substantially fluid tight seal with the valve housing notwithstanding manipulation of the elongated object within the aperture.

All of the disputed terms in the '377 patent appear in Claims 6 and 8. Claims

6. A valve assembly for sealed reception of an elongated object, which comprises:

(a) a valve housing having a longitudinal opening configured and dimensioned to permit entry of an elongate object;

(b) an elongated resilient seal member at least partially positionable within the valve housing and defining an aperture to permit entry of the elongated object therein in a substantially fluid tight manner; and

(c) a plurality of guard members disposed within the seal member and concentrically arraigned about a central longitudinal axis defined by the valve housing and positioned to engage the elongated object upon insertion of the elongated object within the valve housing, the guard members arranged such that at least end portions of adjacent guard members are in overlapping relation, each guard member *adapted to be radially displaced during introduction of the elongated object within the valve assembly to contact portions of the*

valve member adjacent, but proximal to, the aperture to facilitate passage of an elongated object therethrough, the end portions of the guard members being substantially flexible relative to the remaining portions of the guard members to effectively minimize force required to advance the elongated object through the guard members.

8. A valve assembly for sealed reception of an elongated object, which comprises:

(a) a valve housing having a longitudinal opening configured and dimensioned to permit entry of an elongated object; and

(b) an elongated resilient seal member at least partially positionable within the valve housing, the seal member including an inner portion and a peripheral portion, and defining a central longitudinal axis, the inner portion *defining a frusto conical configuration* and having an aperture in general alignment with the central longitudinal axis to permit entry of the elongated object therein in a substantially fluid tight manner, the peripheral portion including a bellows structure characterized by extending in a longitudinal direction, the bellows structure *in coaxial arrangement about at least a portion of the inner portion* and being dimensioned to maintain a substantially fluid tight seal with the valve housing notwithstanding manipulation of the elongated object within the aperture in either a longitudinal or radial direction.

1. "Adapted" Clauses

There are three "adapted" clauses in these patents. Tyco proposes the same construction for these three terms: "Part of each member may be moved in a direction away from the axis of the valve body to make expanding the aperture easier upon contact with an instrument." Applied suggests a slightly different construction for each term.

Neither party advances any arguments different from those discussed in the '143 and '854 patents. This invention and the invention disclosed in the '143 patent share many similarities.

(1) "adapted to be displaced relative to the longitudinal axis to facilitate expansion of the aperture of the seal member upon entry of the object therein" Used in the '702 patent, Claim 1.

Tyco proposes "part of each guard member may be moved in a direction away from the axis of the valve body to make expanding the aperture easier." Applied suggests "able to be moved away from the longitudinal axis so as to assist in the expansion of the aperture upon insertion of the object." The parties have agreed that these terms should be construed in the same way as the term appears in the '143 patent.

Again, Tyco argues that Applied's construction creates the impression that the whole guard member has to be detached and moved. Applied assured the court that it would not argue that point to the jury. However, in this patent, it does not appear that the patentee inserted in other claims that "portions" or "a portion" of the guard members are adapted to be displaced as was done in the '143 patent. The crux of the invention is that a seal must be maintained. As previously stated, claims are construed in light of the specification of which they are a part.

Based on the specification and the claim language, the court concludes this phrase means "a portion of each guard member may be moved in a direction away from the longitudinal axis of the valve body to assist expansion of the aperture upon insertion of the object."

(2) "adapted to be radially displaced during introduction of the elongated object within the valve assembly to engage portions of the valve member adjacent, but proximal to, the aperture to expand the aperture" Used in '702 patent, Claim 6.

Tyco proposes "part of each guard member may be moved in a direction away from the axis of the valve housing to make expanding the aperture easier upon contact with the instrument."

Applied proposes "able to be moved away from the longitudinal axis during introduction of the elongated object to contact the valve adjacent but proximal to the opening so as to expand the aperture."

For the reasons discussed above, the court construes this term to mean: "a portion of each guard member may be moved in a direction away from the longitudinal axis during introduction of the elongated object to contact the valve member adjacent, but proximal to, the aperture so as to expand the aperture."

(3) "adapted to be radially displaced during introduction of the elongated object within the valve assembly to contact portions of the valve member adjacent, but proximal to, the aperture to facilitate passage of an elongated object therethrough" Used in the '377 patent, Claim 6.

Tyco proposes "part of each guard member may be moved in a direction away from the axis of the valve housing to make expanding the aperture easier upon contact with the instrument."

Applied proposes "able to be moved away from the longitudinal axis during introduction of the elongated object to contact the valve adjacent but proximal to the aperture so as to ease the passage of the elongated object."

For the reasons discussed above, the court construes this term to mean: "a portion of each guard member may be moved in a direction away from the longitudinal axis during introduction of the elongated object to contact the valve adjacent, but proximal to the aperture, to assist passage of the elongated object therethrough."

2. "each guard member is a monolithically formed integral unit" Used in '702 patent, Claim 3.

Tyco proposes "at least two portions of each guard member are attached or connected together." Applied suggests "each guard member is formed as a single piece."

The specification states that the "[t]he preferred guard member is a monolithically formed single piece unit wherein the first portion of the guard member defines a cross-sectional dimension which is greater than the cross-sectional dimension of the second portion, thus providing the more rigid characteristic to the first portion." '702 patent, col. 3, ll. 34-40. The specification also discloses:

Guard elements are fabricated from a suitable material such as high density polyethylene and, as noted above, are preferably monolithically formed by injection molding techniques to define a single element. *It is also possible for the finger portion 148 and flap portion 150 of guard element 140 to be individually formed and subsequently connected by adhesives or the like.*

'702 patent, col. 7, ll. 55-59 (emphasis added). Importantly, this contrasts "monolithically formed" with the

being "individually formed and subsequently connected."

Tyco's proposal relates to this alternative embodiment where the members are made separately and are later attached or connected together. While Tyco is correct that a preferred embodiment cannot be imported from the specification to the claim, the specification is the best guide in determining the meaning of the claim. Phillips, 415 F.3d at 1315.

Here, the specification provides clear guidance on this term-"monolithically" refers to forming a single element as opposed to two or more elements being individually formed and connected together. This is consistent with common dictionary definitions. *See* OXFORD ENGLISH DICTIONARY ONLINE available at <http://dictionary.oed.com> (defining the term "monolithically" as "forming a solid unbroken mass"). The court notes that this term is different from "formed integral" in the '143 patent, as that claim did not include the term "monolithically."

Based on the specification, and the claim language, the court concludes that this term means "formed as a single piece or unit."

3. "each guard member having an end portion of less rigidity than the remaining portions of the guard member" Used in '702 patent, Claim 6.

Tyco proposes "each guard member has an end portion that is less thick than the remaining portions of the same guard member." Applied argues that no construction is necessary.

The only phrase Tyco seeks to construe is "rigidity," and Tyco simply inserts the word "thick." Tyco argues that the specifications only describe varying the thickness of the portions of the guard members as a way of varying rigidity. Tyco contends that their construction reflects the only method of varying rigidity that is set forth in the specifications and that any other method is neither disclosed nor enabled. Applied responds that Tyco is simply importing a preferred embodiment from the specification into the broader claim.

The Federal Circuit has noted that "the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms. For instance, although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." Phillips, 415 F.3d at 1323. The Federal Circuit has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment. *Id.* To avoid importing limitations from the specifications into the claims, the court should determine whether the patentee is setting out specific examples of the invention to teach one of ordinary skill in the art to make and use the invention, or whether the patentee intends for the claims and the embodiments in the specification to be strictly coextensive. *Id.* Although claims need not be limited to the preferred embodiment when the invention is more broadly described, neither do the claims enlarge what is patented beyond what the inventor described as his invention.

In the Summary, the patentee described his invention as a valve assembly with a guard member that includes "at least a first substantially rigid portion to be displaced relative to the longitudinal axis to facilitate expansion of the aperture of the seal member and a second portion having less rigidity than the first portion of the guard member to enhance passage of the elongated object through the valve body." '377 patent, col. 3, ll. 25-31. However, in the next paragraph, he described the "preferred guard member" as

having a first portion which "defines a cross-sectional dimension which is greater than the cross sectional dimension of the second portion, thus providing the more rigid characteristic to the first portion." '377 patent, col. 3, ll. 38-43. Therefore, it is apparent that the patentee did not describe nor limit his invention in the manner that Tyco claims.

In the Detailed Description of the Preferred Embodiments, the specification teaches that "the outer flap 150 of each guard element 140 defines first and second portions 154, 156 of varying thickness. The first or proximal portion 154 has a cross-sectional dimension or thickness which is greater than the thickness of the second or distal portion 156 of the outer flap 150." '702 patent, col. 7, ll. 14-19. The specification also discloses that "[p]referably, the first portion 154 is from about two to three times thicker in cross-sectional dimension than second portion 156." '702 patent, col. 7, ll. 19-21. The patent goes on to state that "[S]uch dimensioning of outer flap 150 ensures that guard elements 140 are sufficiently rigid to cause stretching of the seal surface portions 110 defining seal aperture 130 to thereby increase the dimension of the aperture 130 and facilitate insertion of the instrument therethrough....." '702 patent, col. 7, ll. 24-33(emphasis added). These are all descriptions of a preferred embodiment in which the patent connects the thickness of the guard elements with the rigidity of the guard elements.

However, this is only a preferred embodiment and does not equate "rigid" with "thick" in instances in which the outer flap is constructed of two regions of different materials. This is a possibility that seems to be left open by the specification and the claim language. *See* '702 patent, col. 7, ll. 53-59. It is apparent that the patentee is setting out specific examples of the invention to teach one of ordinary skill in the art to make and use the invention. It is not clear that he intended for the claims and the embodiments in the specification to be strictly coextensive. The court cannot import a specific preferred embodiment into the claim. Rigidity, a term which is scientific in nature and which could be confusing to the jury, has to do with an object's resistance to a change in form. *See* MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS (2003) (defining "rigidity" as "the quality or state of resisting change in form."). The claim language and the specification support this definition. Therefore, the court defines the term "**each guard member having an end portion of less rigidity than the remaining portions of the guard member**" to mean "each guard member has an end portion that is less resistant to a change in shape than the remaining portions of the same guard member."

4. "The end portions of the guard members being substantially flexible relative to the remaining portions of the guard members to effectively minimize force required to advance the elongated object through the guard members." Used in the '377 patent, Claim 6.

Tyco proposes: "the end portions of the guard members being substantially more flexible than the remaining portions of the guard members to sufficiently reduce the force under the circumstances required to insert the elongated object." Applied suggests: "the end portions of the guard members being substantially more flexible than the remaining portions of the guard members so as to reduce the force required to insert the elongated object to the minimum level possible under the circumstances."

Tyco's objection to Applied's proposal is based upon the inclusion of "to the minimum level possible." Tyco argues that Applied's proposed language is not in the claims or in the specifications. Tyco contends that Applied's construction would make the invention itself basically useless because, theoretically, if there was no resistance at all as the instrument went through the seal a surgeon could not control the instrument. Tyco also contends that one skilled in the art would not understand the claim to require the force to be reduced to the minimum level possible.

The specification states:

Such dimensioning of outer flap 150 ensures that guard elements 140 are sufficiently rigid to cause stretching surface of the seal surface portions 110 defining seal aperture 130 and facilitate insertion of the instrument therethrough and, in addition, provide sufficient flexibility to minimize the force required to advance the instrument through the guard element and seal arrangement.

'377 patent, col. 7, ll. 25-33.

The specification also states "the relatively thin and less rigid second portion 156 of outer flap 150 reduces the force required to pass the instrument through the guard mount and seal arrangement" '377 patent, col. 7, ll. 43-45.

Applied's suggestion implies that force cannot be reduced further. Based on the claim language and the specification, all that is claimed is that the force is reduced by including flexibility at the end portions of the guard members. The court declines to adopt Applied's addition of "at the minimum level possible."

"The end portions of the guard members being substantially flexible relative to the remaining portions of the guard members to effectively minimize force required to advance the elongated object through the guard members" means "the end portions of the guard members being substantially more flexible than the remaining portions of the guard members so as to effectively reduce the force required to insert the elongated object."

5. "Frustoconical" Used in the '702 patent, Claim 11.

"Defining a frusto conical configuration." Used in '377 patent, Claim 8.

Tyco proposes "shape resembling a cone with the narrow end cut off." Applied proposes "[a portion] having the shape of a cone with its tip removed." At first blush, there is very little distinction between the parties' proposals. The dispute is over Tyco's use of the word "resembling." Tyco argued that "resembling" should be included because the construction should not be limited to a mathematically perfect cone. At the hearing, Applied admitted it did not believe that the claim language required a mathematically perfect cone and that it would they could not and would not argue to the jury that a mathematically perfect cone was required. Tr. pp. 135-136. Applied argues that the patentee could have included "resembling" in the claim language but did not and it is not clear how far one can get away from a generally conical shape and still be "resembling a frustocone".

The patent describes that the "sealing element 110 includes a generally frustoconical interior portion 128 defining aperture 130" '702 patent, col. 6, ll. 25-27; '377 patent, col. 6, ll. 27-29. The specification also states that "the guard elements 140 in their fully assembled position may be oriented define a generally frusto-conical configuration so as to be positioned within the frustoconical portion 128 of seal 110." '702 patent, col. 8, ll. 40-43; '377 patent, col. 8, ll. 41-44.

In general, a "frustum" is simply the portion of a regular solid left after cutting off the upper part by a plane parallel to the base. *See* OXFORD ENGLISH DICTIONARY ONLINE *available at* <http://dictionary.oed.com>. As disclosed in the specification, a "conical" frustum is a shape which is formed

by cutting off the top of the cone by a plane parallel to the base. This is consistent with ordinary usage of the term. See THE MERRIAM-WEBSTER THIRD NEW INTERNATIONAL DICTIONARY, UNABRIDGED (2002).

This court agrees with Applied and feels that other shapes could certainly "resemble" a cone but not be cone-shaped. However, of course, a mathematically perfect cone is not required. "**Frustoconical**" means "having the shape of a cone with the narrow end, or tip, removed." "**Defining a frusto conical configuration**" means "a configuration in the shape of a cone with the narrow end, or tip, removed."

6. "Circumferential portion" Used in the '702 patent, Claim 11.

Tyco proposes "the circular portion of the seal that includes the bellows structure." Applied suggests "a portion located around, rather than axially displaced from, the frustoconical portion." Applied argues that the ordinary and customary meaning of "circumferential" should not apply because Tyco narrowed the definition of this claim during the prosecution of the patent.

"The doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed.Cir.2003). "[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." *Id.* at 1324. "We have, however, declined to apply the doctrine of prosecution disclaimer where the alleged disavowal of claim scope is ambiguous." *Id.* at 1324.

During the prosecution history, the patentee proposed a new claim 21, which stated in part "... the bellows structure dimensioned to maintain a substantially fluid tight seal with the valve housing notwithstanding manipulation of the elongated object within the aperture." Def's, Ex. 7, p. 4. The PTO rejected this claim in a summary fashion stating that:

Claims 16 and 19-21 are rejected ... as being anticipated by Smith et al. Smith et al disclose conical members (474) (col. 10 lines 14-26), a bellows (12), a duckbill sealing member (244) with hinged dilators (228a and 228b) to assist in opening the duckbill (244) valve assembly (col. 9, lines 46-62). See Def's Ex. 8, p. 2.

In response, the patentee amended claim 21 to state "... the bellows structure circumferentially disposed about at least a portion of the inner portion and being dimensioned ..". Def's Ex. 10, p. 2. The patentee goes on to state that in Smith "the bellows 12 is not circumferentially disposed about gasket 18, but is in distal relation to the gasket. Thus, the gasket 18 is not supported within the bellows 12 ... In addition, the relative longitudinal placement of the bellows structure undesirably increases the overall size of the Smith '304 device." Def.'s Ex. 10, p. 3. Applied argues that the patentee disclaimed valves having bellows that are axially displaced from the aperture-defining inner portion of the valve. Claim 21 was subsequently withdrawn by the patentee without further review from the PTO.

Applied argues that even though Claim 21 was withdrawn, because Claim 11 uses the term "circumferentially," any disclaimer as to Claim 21 should apply to Claim 11. Applied does not cite, and the court did not find, a case which supports this argument. Claim 21 was withdrawn and the two claims are not worded the same. It is unclear, therefore, why a disclaimer impacting cancelled Claim 21 would affect

Claim 11, a claim not rejected by the PTO.

Moreover, even assuming that the alleged disavowal would apply to Claim 11, there has been no unmistakably clear statement by the patentee to disclaim any subject matter. *See Omega Eng'g, Inc.*, 334 F.3d at 1324. The patentee discusses how his invention is an improvement over Smith, but does not clearly make the affirmative statement that Applied seeks to impute. Based on the record before the court, the court cannot find a prosecution disclaimer which applies to Claim 11.

"Circumferential portion" describes a portion in the direction of the circumferential axis. *See, e.g.*, '702 patent, col. 6, ll. 25-31. With regard to Tyco's proposal of "includes the bellows structure," there is no reason to incorporate this phrase as it is already in the claim. Tyco agreed to this at the hearing.

The court concludes that "circumferential portion" means "the portion located at a position on a circle or circular arc around, but at a distance from, the longitudinal axis."

7. "In coaxial arrangement about at least a portion of the inner portion." Used in the '377 patent, Claim 8.

Tyco proposes "the portion of the seal member having the bellows structure and the inner portion of the seal member have common axes." Applied suggests "a portion located around, rather than axially displaced from, the frustoconical portion." Applied argues that the alleged disclaimer made during the prosecution of the '702 patent applies to this claim as well.

Applied's argument is fairly inventive. Applied argues that in prosecuting the '377 patent, which is a continuation of the '702 patent, the patentee added Claim 20 which was identical to the cancelled Claim 21 of the '702 patent discussed above. Def's Ex. 12, p. 2. Claim 20 was subsequently rejected by the PTO over Vandebroek. The PTO stated "Vandebroek discloses the elongated resilient seal member 30 in figure 19. The seal has an inner portion with an opening 34 to allow a device to pass therethrough and a peripheral portion including a bellows structure at 250." Def.'s Ex. 13, p. 4.

In response to this rejection, the patentee amended Claim 20 to specify that the bellows extend in the longitudinal direction. The applicant also replaced the phrase "circumferentially disposed" with "in coaxial arrangement," but made *no* comment on this change. Def's Ex. 14, p. 4-8. This claim was allowed and issued as Claim 8.

Applied argues that while there was no clear disavowal during the prosecution of the '377 patent (as no statement was made), the PTO only allowed this claim to issue because it was relying on the applicant's prior disclaimer in the prosecution of the '702 patent of valves having bellows that are axially displaced from the aperture-defining inner portion.

Assuming for the moment that there was a disclaimer during the prosecution of the '702 patent, it does not follow that the disclaimer would apply to Claim 8 of the '377 patent. Applied cites a recent case in support of its position. In that case, the Federal Circuit stated that district court did not err in holding that "the examiner's action in allowing the continuation claims without further prosecution was based on the prosecution argument in the parent." *See Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313, 1317 (Fed.Cir.2007). Here, however, the continuation claims did undergo further prosecution, and in fact the examiner initially rejected Claim 20. The patentee made no clear statement of disavowal in amending this

claim and the PTO allowed the claim. Under these circumstances, it is not clear if any initial disavowal would even apply to this claim.

Moreover, as noted above, the evidence does not show that the patentee actually made a disclaimer during the prosecution of the '702 patent. The court, therefore, finds no reason to limit the scope of this claim based on the prosecution history.

There is nothing in the specification or the claim language which suggests that the ordinary and plain meaning of this term should not be applied. In ordinary usage, "coaxial" means "having a common axis." See OXFORD ENGLISH DICTIONARY ONLINE *available at* <http://dictionary.oed.com>; THE MERRIAM-WEBSTER THIRD NEW INTERNATIONAL DICTIONARY, UNABRIDGED (2002).

"In coaxial arrangement about at least a portion of the inner portion" means "arranged having a common axis at least about a portion of the inner portion of the seal."

V. Claim Construction of "1 Patent

The "1 patent relates to a valve assembly adapted for introduction of surgical instruments into a patient's body which includes a valve body formed of a flexibly resilient material that defines an aperture for reception of an instrument. The aperture is configured and dimensioned such that insertion of the instrument into the aperture will cause the resilient material of the valve body to engage the outer surface of the instrument in a substantially gas tight manner. The valve assembly also includes a biasing member for closing the valve body to form a gas tight seal prior to inserting the instrument therethrough.

The disputed terms are located in Claims 1 and 3. These claims, with the disputed terms in italics, state:

1. In a cannula subassembly which includes a cannula housing, a cannula mounted to said cannula housing, and a valve body mounted within said cannula housing, said valve body defining an opening for receipt of a surgical instrument, the improvement comprising:

a plurality of projecting members *monolithically formed on and projecting from said valve body* surrounding said opening.

3. A cannula subassembly according to claim 1, wherein said projecting members are *integrally molded as part of said valve body*.

"Monolithically formed on and projecting from said valve body." Used in Claim 1.

"Integrally molded as part of said valve body." Used in Claim 3.

For "monolithically formed," Tyco proposes "joined together and extending from the valve body." Applied suggests "formed as one piece with, and projecting from, the valve."

For "integrally molded," Tyco proposes "molded together with the valve body." Applied suggests "created as part of the valve body using a single mold cavity."

The specification states that "the proximal end portion 16 further includes a plurality of splines 32 attached

to an inner wall 34 and preferably integrally molded as part of the inner wall 34. Alternatively, splines 32 may be insert molded and may include rigid members below the surface of the inner wall 34, e.g. metallic strips or the like." The specification also discloses that "the nubs are fabricated of the same elastic material as the valve assembly 10a and molded integrally with the valve body." "1 patent, col. 5, ll. 37-39; *see also* "1 patent, Fig. 10.

With regard to "monolithically," the specification states: "A properly placed ridge or set of ridges 126 or 127 monolithically formed on the inner wall 34 substantially fills the gap 128 as shown in Fig. 18." "1 patent, col. 6, ll. 36-39; *see also* Fig. 18.

Claim 1 states "a plurality of projecting members monolithically formed on and projecting from...." Claim 3, which is dependent on Claim 1, states "wherein said projecting members [from Claim 1] are integrally molded as part of said valve body." The difference between Claims 1 and 3 is in how the projecting members on the valve body are formed. Based on the claim language and specification, monolithically formed suggests the members could be molded, but they do not have to be—they could also be machined or otherwise formed from the material making up the valve body. Claim 3 specifically requires the projecting members to be formed by a molding process and the use of "integrally" means that this process must occur at the same time as the molding of the valve body and from the same material. This is consistent with the doctrine of claim differentiation as well.

"Monolithically formed on and projecting from said valve body" means "formed from the material making up the valve body and projecting from the valve body." **"Integrally molded as part of said valve body"** means "molded at the same time, and from the same material, as the valve body."

It is so ordered.

E.D.Tex.,2008.

Tyco Healthcare Group LP v. Applied Medical Resources Corp.

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