

United States District Court,  
D. Massachusetts.

**ARROW INTERNATIONAL, INC., and Arrow International Investment Corp,**  
Plaintiffs.

v.

**SPIRE BIOMEDICAL, INC,**  
Defendant.

Civil Action No. 06-11564-DPW

**Oct. 31, 2006.**

Brian E. Whiteley, Carolyn A. Marcotte, Scibelli, Whiteley and Stanganelli, LLP, Boston, MA, for  
Plaintiffs.

Daniel J. Gleason, Thomas J. Engellenner, Nutter, McClennen & Fish, LLP, Boston, MA, for Defendant.

### ***MEMORANDUM AND ORDER***

**DOUGLAS P. WOODLOCK, District Judge.**

Arrow International Investment Corp. is the owner of United States Patent No. 6,872,198 ('198), entitled "Double-Y-Shaped Multi-Lumen Catheter with Selectively Attachable Hubs." Arrow International, Inc. is the parent corporation of Arrow International Investment and the exclusive licensee of this patent. Plaintiffs (collectively "Arrow") have refiled this action FN1 alleging that Defendant Spire Biomedical, Inc.'s ("Spire") manufacture and sale of the Pourchez RetrO high flow kink resistant catheter infringes the ' 198 patent. Spire has counterclaimed for a declaratory judgment of noninfringement, invalidity, and unenforceability.

FN1. I dismissed a previous case between the parties, *Arrow International and Arrow International Investment Corp. v. Spire Biomedical, Inc.*, Civil Action No. 05-10671-DPW, raising essentially the same contentions as those presented here because I found that the plaintiff was required to exhaust administrative remedies in the Patent and Trademark Office before pursuing the litigation in federal court. *Arrow Int'l v. Spire Biomedical, Inc.*, 443 F.Supp.2d 182 (D.Mass.2006). As anticipated, *id.* at 186, the Plaintiffs have refiled after exhausting their remedies at the administrative level. The parties have agreed for case management purposes that the briefing and argument of the *Markman* issues conducted in No. 05-10671 are sufficient and may be used for purposes of claim construction in this refiled case.

### **I. BACKGROUND**

Hemodialysis is a process by which blood is extracted from a patient and purified outside the body. It has

been the principal treatment for kidney failure and other renal diseases for over fifty years.FN2

FN2. The first successful hemodialysis machine was invented by Willem Kolff, of the Netherlands, in 1945. *See generally*, Paul Heiney, *The Nuts and Bolts of Life: Willem Kolff and the Invention of the Kidney Machine* (2003).

Depending on a patient's condition, there are different ways to access the patient's blood stream for hemodialysis. For patients with relatively strong blood flow, blood can be accessed from an arm, through either the patient's own blood vessels or a surgically implanted graft. Two venipunctures are made at the access site, one allowing blood to flow out of the patient, and the other carrying blood back into the patient.

For patients with insufficient blood flow, a catheter is inserted directly into the heart. A catheter is a hollow, flexible tube for insertion into a body cavity, duct, or vessel to allow the passage of fluids or to distend a passageway. '198 patent, col. 1, ll. 21-23. Catheters used for hemodialysis consist of two or more separate lumens, or tubes. The "arterial" lumens carry away blood to be cleaned, and the "veinal" lumens return blood once it has been filtered. One end of the catheter, the "proximal" end, is placed inside the heart. The "distal" end remains outside the body and is attached to the hemodialysis machine.

The proximal end of the catheter is inserted through an incision either in the abdomen or the neck, and tunneled through the body until it reaches its proper position in the heart. Inserting the catheter into the abdomen and tunneling up towards the neck is called antegrade tunneling. Starting at the neck and moving down into the heart is called retrograde tunneling.

The '198 patent teaches a retrograde tunneling technique for implanting a multi-lumen hemodialysis catheter. The catheter consists of an elongated, central, multi-lumen tube portion with extension tubes protruding at both ends. '198 patent at col. 2, ll. 62-64, 66-67; col. 3, ll. 1-4, 6-8. The central portion has a cylindrical outer shape and is segmented internally into separate lumens. *Id.* at col. 2, ll. 65-66. Arterial and veinal extension tubes on both the proximal and distal ends separate from the central tube, forming Y-shaped branches. *Id.* at col. 7, ll. 14-20; col. 8, 44-50.

The insertion technique involves making an incision in the skin of the patient in the upper chest or neck area and inserting the proximal veinal and arterial extension tubes inside the patient. *Id.* at col. 5, ll. 33-36. A physician then creates a subcutaneous tunnel with the entrance near the insertion incision and the exit at a location on the body away from the neck region. *Id.* at col. 5, ll. 36-39. The distal end of the catheter is guided through the tunnel until the ends of the extension tubes are exposed. *Id.* at col. 5, ll. 39-44. The exposed tubes are secured to the patient with sutures or other means, and connected to a fluid exchange machine. *Id.* at col. 5, ll. 44-46, 55-58.

The '198 patent issued on March 25, 2005. The named inventors worked for Diatek, a company focused on developing catheters for use with the retrograde insertion technique. Arrow purchased the assets of Diatek in 2003. Neither Arrow nor Diatek has developed or sold any products within the scope of the '198 patent.

## II. INFRINGEMENT: THE CLAIM CONSTRUCTION STEP

Arrow alleges that Spire is infringing claims 1-3 of the '198 patent. These claims disclose a particular method of inserting a catheter having a particular construction.

Claim 1 provides:

A method for surgically implanting a double-Y-shaped multi-lumen catheter tube into a patient, the multi-lumen catheter including an elongated, central, multi-lumen tube portion, a proximal and portion including a single-lumen proximal veinal extension tube and a single-lumen proximal arterial extension tube each having a proximal tip, and a distal end portion including a single-lumen distal veinal extension tube each having a distal end, the method comprising:

- (a) making an incision in the skin of the patient;
- (b) inserting the proximal tips of the proximal veinal and arterial extension tubes through the incision and placing the proximal tips in the patient;
- (c) forming a subcutaneous tunnel having a first end proximate to the incision and a second end remote from the first end of the tunnel;
- (d) guiding the distal veinal and arterial extension tubes and at least a portion through the subcutaneous tunnel such that at least the distal ends of the distal veinal and arterial extension tubes extend outwardly from the tunnel through the second end of the tunnel; and
- (e) securing at least a portion of the distal end portion of the catheter to the patient.

'198 patent, col. 11, ll. 9-33.

Claims 2 and 3 are dependent claims. Claim 2 provides:

A method according to claim 1, the method further comprising respectively connecting the distal arterial and veinal extension tubes to arterial and veinal legs of a fluid exchange device.

Id. at col. 11, ll. 34-37. Claim 3 provides:

A method according to claim 2, wherein connecting the distal arterial and veinal extension tubes to arterial and veinal legs of a fluid exchange device comprises connecting the distal arterial extension tube to the arterial leg with a first connector hub, and connecting the proximal veinal extension tubes to the veinal leg with a second connector hub.

Id. at col. 11, ll. 38-43.

Determination of patent infringement requires a two-step analysis: first, the claims must be construed, and second, the accused device must be compared to the construed claims. *Mars, Inc. v. H.J. Heinz Co., L.P.*, 377 F.3d 1369, 1373 (Fed.Cir.2004) (citation omitted). "The first step is a question of law; the second step is a question of fact." *Freedman Seating Co. v. American Seating Co.*, 420 F.3d 1350, 1357 (Fed.Cir.2005). This memorandum focuses on claim construction following a *Markman* hearing. Whether the accused device and method read on the '198 patent will be addressed at the conclusion of discovery.

## **A. Legal Principles of Claim Construction**

It is a "bedrock principle" of patent law that "the claims 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) (quoting *Innova/Pure Water, Inc., v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1115 (Fed.Cir.2004)). The claims are "of primary importance, in the effort to ascertain precisely what it is that is patented." *Id.* (quoting *Merrill v. Yeomans*, 94 U.S. 568, 570, 24 L.Ed. 235 (1876)).

Thus, the starting point for claim construction is the claim term itself. In general, claim terms are given the "ordinary and customary meaning" that they would have to a person of ordinary skill in the art in question at the time of the invention. *Id.* at 1313. In cases in which a word is used in an ordinary or lay manner, claim construction involves little more than adopting the "widely accepted meaning of commonly understood words." *Id.* at 1314.

When the meaning of the claim term is not ordinary but technical, the Federal Circuit has identified a hierarchy of sources to aid in claim construction. The intrinsic record, including the claim terms, the remainder of the specification, and the prosecution history, provide the best guidance as to the meaning of the claims. *Id.* at 1313-14. The context in which a term is used in the asserted claim and the use of the term in other claims can be "highly instructive." *Id.* at 1314. The claims, however, "do not stand alone;" they "must be read in view of the specification, of which they are a part." *Id.* at 1315. The specification is "always highly relevant to the claim construction analysis." *Id.* Indeed, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1317.

Although prosecution history and extrinsic evidence are appropriate tools for claim construction, they should be used cautiously. Prosecution history may be valuable in that it demonstrates how the inventor understood the invention, but it represents an ongoing negotiation between the PTO and the applicant and "often lacks the clarity of the specification." *Id.* Technical dictionaries and expert testimony may help a judge better understand the underlying technology, but they are unreliable sources. Dictionaries are neither part of the patent nor created at the same time; expert testimony is generated for litigation and may contain bias that is absent in the intrinsic record. *Id.*

In conducting claim construction, courts should also be aware of the "danger of reading limitations from the specification into the claim." *Id.* at 1323. The distinction between proper claim construction and improper limitation turns on "whether a person of skill in the art would understand the embodiments to define the outer limits of the claim term or merely to be exemplary in nature." *Id.*

In sum, the touchstone of claim construction is the meaning of claim language as understood by a person of skill in the art. In the case of lay usage, determining this meaning may require only the consultation of a general purpose dictionary. If the claim term is technical, a court should rely most heavily on the claims and the specification, followed by the prosecution history, and finally, extrinsic evidence.

## **B. Construction of Disputed Claim Terms**

With these principles in mind, I turn to consideration of the disputed claim terms. The three terms at issue here are related to claim 1. First, the parties debate the extent of the preamble and its limiting effect. Second, if the preamble is limiting, the parties disagree on the meaning of the term "Y-shaped." Finally, the parties contest the meaning of "securing" as used in claim 1(e).

## 1. Preamble

Claim 1 includes the following introductory phrase:

A method for surgically implanting a double-Y-shaped multi-lumen catheter tube into a patient, the multi-lumen catheter including an elongated, central, multi-lumen tube portion, a proximal end portion including a single-lumen proximal veinal extension tube and a single-lumen proximal arterial extension tube each having a proximal tip, and a distal end portion including a single-lumen distal veinal extension tube each having a distal end, the method comprising:

'198 patent at col. 11, ll. 9-17.

The parties dispute which portion of this language constitutes the preamble and whether that portion limits claim 1. Spire argues that the preamble includes all of the language preceding the transition phrase "the method comprising," and contends that this language operates as a limitation on the claim. Arrow concedes that the structural description of the catheter is part of the body of the claim and is limiting, but it insists that the first sixteen words, up to the word "including," are merely introductory and consequently, not limiting.

A patent claim typically consists of three parts: the preamble, the transition, and the body. Donald S. Chisum, *Chisum on Patents* s. 8.06[1][b] (2005); Bristol-Myers Squibb Co. v. Immunex Corp., 86 F.Supp.2d 447, 450 (D.N.J.2000). The preamble is an introductory phrase that summarizes "the invention, its relation to the prior art, or its intended use or properties." Chisum at s. 8.06[1][b][i]. It is composed of the language preceding the transition phrase. *See* Bicon, Inc. v. The Straumann Co., 441 F.3d 945, 949 (Fed.Cir.2006) (defining the preamble as "everything in the claim preceding the word 'comprising.' "). Thus, in this case, the preamble is the 66 words preceding the transition phrase "comprising."

The more important question for construing claim 1, however, is not where the preamble begins and ends, but whether it is limiting. A preamble "limits the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed.Cir.2002) (quoting *Pitney Bows, Inc. v. Hewlett Packard Co.*, 182 F.3d 1298, 1305 (Fed.Cir.1999)). Conversely, a preamble is not regarded as limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use of the invention." *Id.* (quoting *Rowe v. Dror*, 112 F.3d 473, 478 (Fed.Cir.1977)). The Federal Circuit has repeatedly stated that there is no 'litmus test' for determining whether preamble language is limiting. *Id.* To the contrary, whether to treat a preamble as limiting "is determined on the facts of each case in light of the claim as a whole and the invention described in the patent." *Bicon*, 441 F.3d at 952 (quotation omitted).

Here, the preamble does more than merely identify the invention's purpose and intended field of use; it describes in detail the structure of the specific catheter to which the claimed method relates. The body of the claim includes references to "proximal tips," "proximal veinal and arterial extension tubes," "distal veinal and arterial extension tubes," "distal ends" and "central tube portion," none of which have meaning without the description of the catheter in the preamble. '198 patent, col. 11, ll. 19-21, 26-29, 32. Clearly, the claim, standing alone, does not set forth the complete invention.

Arrow does not dispute that the structural definition of the catheter is limiting. Rather, it argues that the initial portion of the preamble that describes the catheter as a "double-Yshaped" is not part of the structural

definition and, therefore, is not limiting.FN3 In effect, Arrow argues that the term "Y-shaped" is not necessary to give meaning to the claim.

FN3. Arrow argues that the entire phrase, "A method for surgically implanting a double-Y-shaped multi-lumen catheter tube into a patient, the multi-lumen catheter including ...," is not limiting, but the dispute centers on the term "double-Y-shaped."

The term "double-Y shaped," however, is necessary to give meaning to the claim. First and foremost, "double-Y-shaped" defines the particular catheter that is the object of the method described in the claim body. Although the phrase "double-Yshaped" does not appear in the claim body, the specification underscores its importance as a structural feature. *See Catalina Marketing*, 289 F.3d at 808 ("[W]hen reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation."). The specification discusses in detail the catheter described in the preamble, and repeatedly refers to it as "Y-shaped." FN4 It describes a preferred embodiment in which the extension tubes are joined to the central tube by a "Y-shaped" junction. ' 198 patent at col. 3, ll. 64-65; col. 4, ll. 8, 11, 27, 30, 57. It specifies the degrees of the angles that form the "Y" shape. *Id.* at col. 7, ll. 14-20; col. 8., ll. 44-50. It explains how a connector and a sheath can be used to hold the distal extension tubes (the forks of the "Y") together so that the catheter can be threaded through the subcutaneous tunnel. *Id.* at col. 9, l. 44-col. 10, l. 17; Figs. 8A. B. Each of the eight figures depict a Y-shaped catheter, and the patent title describes it as such.FN5 Thus, the term "double-y-shaped" provides structurally significant information necessary to understand the claims.

FN4. The specification describes the catheter as "Y-shaped" fifteen times in the Summary of the Invention and the Detailed Description.

FN5. The patent title is of little significance in claim construction. *Pitney Bowes, Inc., v. Hewlett-Packard Co.*, 182 F.3d 1298, 1312 (Fed.Cir.1999) ("The purpose of the patent title is "not to demarcate the precise boundaries of the claimed invention but rather to provide a useful reference tool for future classification purposes."). Nevertheless, the use of a term in the patent title when it is also used throughout the specification may serve as evidence that a preamble is limiting. *See Poly-America, L.P. v. GSE Lining Technology, Inc.*, 383 F.3d 1303, 1310 (Fed.Cir.2004) ("The specification is replete with references to the invention as a "blown-film" liner, including the title of the patent itself and the 'Summary of the Invention.'").

Arrow analogizes this case to *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363 (Fed.Cir.2003). The patent-in-suit in *Altiris* claimed a method for intercepting and controlling the boot process of a digital computer and a digital computer system programmed to perform that method. *Id.* at 1366. The preamble of the claim at issue read:

A method for gaining control of a computer prior to the normal boot sequence operating on a digital computer system, said digital computer system including:

means for storing data;

means for processing data;

means for connecting said digital computer system to an external source of commands;

means for displaying data; and means for inputting data;

the method comprising:

*Id.* at 1367. The question presented was whether the preamble dictated the sequence in which the testing and booting steps of the claimed method were to be performed. *Id.* at 1371. The court held that it did not, and therefore, was not limiting. *Id.* at 1372. The body of the claim, not the preamble, indicated the sequence of the steps. *Id.* The preamble merely recited the purpose of the invention. *Id.*

Arrow correctly observes that the preamble in *Altiris* is similar to that of claim 1 of the '198 patent in that it introduces a claimed method and a related device using the format "A method for ... including ... the method comprising." However, the similarities end there. The dispute in *Altiris* was whether the preamble limited the claimed process, not the structure of the apparatus used in the practice of the process. In that case, the claimed method, including the sequence of steps, was fully described in the body of the claim. The preamble, while it contained structural information, added nothing with respect to the method beyond a brief statement of purpose. In contrast, the issue here is whether a term in the preamble describing a structural aspect of the claimed device limits the device. There is no dispute that the preamble in this case gives "life, meaning, and vitality" to the claim body with respect to the structure of the catheter to be tunneled.FN6

FN6. Arrow contends that the Federal Circuit in *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363 (Fed.Cir.2003), held that the preamble consisted of the introductory phrase up to the word, "including." There is no basis for this assertion. To be sure, the issue in *Altiris* involved language in the preamble that preceded the word "including," but the extent of the preamble cannot be inferred from this alone. The Federal Circuit made no distinction between the part of the preamble preceding "including" and that between "including" and "comprising." Moreover, in *Altiris*, the word "including" is followed by a colon and a list of the structural components of the device. Claim 1 of the '198 patent has only a comma after "including," which presents a weaker case for truncating the preamble.

The prosecution history also supports the conclusion that the descriptive phrase "double-y-shaped" is limiting. The prosecution history describes the invention twice as a "double-yshaped multi-lumen catheter." Notice of Allowability at AI 804506,804509 (Def. Response Ex. B). The examiner also states that the patent was allowed because "the art of record does not teach or render obvious a method for surgically implanting a double-y-shaped multi-lumen catheter tube having the guiding step as claimed." *Id.* at AI 804509.

It is true that in this case, the prosecution history alone cannot support a determination that the preamble is limiting. Only "[c]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation." *Catalina Marketing*, 289 F.3d at 808. Such "clear reliance" is not present here; there is no evidence that the patentees specifically relied upon the term "double-y-shaped" to distinguish their patent over the prior art. Notice of Allowability at AI 804506,804509 (Def. Response Ex. B). Nevertheless, the examiner's use of the term "double-y shaped" to describe the claimed invention supports the conclusion that the double-y shape is a significant structural feature.

Where the "claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed.Cir.1995). The claims, the specification, and the prosecution history indicate that the protected invention here consists of a method of inserting a "double-Y-shaped multi-lumen catheter." Thus, the entire preamble limits the method described in Claim 1.

## 2. "Y-shaped"

Spire contends that the term "Y-shaped" should be construed as describing something "shaped like the letter Y." Spire argues that, as a result, the definition requires that the top two branches of the letter "Y" form some perceptible angle less than 180 degrees. Arrow proposes a definition that does not restrict the angle, but merely denotes the splitting of the lumens from the central portion of the multi-lumen catheter to create separate extension tubes at either end. Arrow's definition would include, say, an apparatus with junctions shaped like the letter "T" or like an arrow (<-).

"Y-shaped" is a simple, non-technical term whose ordinary meaning is self-explanatory: having the shape of the letter "Y". Thus, I construe the term "Y-shaped" in the patent strictly to denote this shape. The angle between the two forks or branches of the letter "Y" distinguishes it from the letter "T" (exactly 180 degrees), a single, vertical line (zero degrees), and an arrow shape (greater than 180 degrees). In order to take the shape of the letter "Y", the inside angle between the branches of a "Y-shaped" apparatus must be less than 180 degrees.FN7

FN7. Admittedly, the branches of the letter Y necessarily form *two* angles between them, summing 360 degrees. The angle referred to here is the angle between the branches that is not bisected by the trunk of the letter (designated as (alpha) and (theta) in Figures 2 and 5, respectively). I refer to this angle as the "inside" angle, even though the description is somewhat tautological.

It follows, also, that the minimum angle between the branches of the "Y" must be greater than zero. I recognize, in the context of this case, that a "Y" shape may be created by splitting separate extension tubes at either end from the central tube. The extension tubes may be located directly beside each other so that the angle between them is so imperceptible as to approach zero degrees, but the separation of the two tubes from the central tube nevertheless creates a "Y-shape" in the sense that a divergence-some separation greater than 0 degrees-is present where the tubes intersect. Thus, for something to be in the shape of the letter Y, there must be two branches intersecting at a single trunk separated by an inside angle that measures between 0 and 180 degrees.

The specification supports this definition. In a preferred embodiment, the proximal extension tubes are joined to the central portion by a Y-shaped junction, or "trunk." *Id.* at col. 8, ll. 22-25, 34-38. There is an angle of separation of approximately 5 degrees between the arterial and veinal tubes. *Id.* at col. 8, ll. 44-48. The extension tubes at the distal end are arranged similarly, with the angle of separation ranging between 10 and 30 degrees. *Id.* at col. 7, ll. 14-19. These angles fall well below the 180 degree limit and form recognizable, albeit in the case of the proximal ends, barely discernible, "Y" shapes. *See* Figures 2, 5.

Figures 7 and 8 illustrate the situation in which something closer to but still greater than zero degrees separates the extension tubes. These figures depict the extension tubes held closely together by a connector



or a sheath so that the catheter can pass through the subcutaneous tunnel. Figures 8A and B make clear that although the extension tubes (marked by numbers 18 and 20) are side by side and aligned with the central tube (number 10), the three parts retain their "Y" shape.

Although not illustrated in the diagrams, this near "zero degree" arrangement may also arise when no trunk piece is used to connect the extension tubes to the central tube. The specification describes an embodiment in which the trunks, labeled 30 and 32 in Figures 2 and 5, respectively, are eliminated. '198 patent at col. 7, 27-36; col. 8, ll. 57-67. The extension tubes are then connected directly to the central tube portion. This would result in the central tube essentially being split in two at each end. The angle between the tubes would be as close to zero as is imaginable but the splitting imports divergence and this arrangement would consequently be covered by the claims.

I recognize the specification states that the tubes may be arranged at "any desired angle." '198 patent at col. 7, ll. 19-20; col. 8, ll. 49-50. Arrow seizes upon this language to argue that "Y-shaped" should be construed with no limitation on the angle between the tubes. I disagree. In the context of the entire specification, which repeatedly describes the apparatus joints as "Y-shaped," the phrase "any desired angle" must be construed to refer only to the possible angles of a Y-shaped junction.

In sum, drawing from both parties' proposed definitions, the term "Y-shaped" denotes the shape of the letter "Y," meaning the shape formed by two branches which intersect at a single trunk to form an inside angle that measures between 0 and 180 degrees.

### 3. "*securing*"

The parties agree that the claim language covers various means of "securing" and that the object to be secured is "at least a portion of the distal end portion of the catheter." FN8 '198 patent, col. 11, ll. 32-33. They also agree that "securing" should be given its ordinary meaning. Spire proposes that "securing" be construed as "fastening the distal end portion to the patient." Arrow opposes the use of the word "fastening," but offers no alternative definition.

FN8. There appears to have been an initial misunderstanding as to whether the means for securing and the object to be secured were in dispute. The parties have clarified that neither is contested. *See* Pl. Reply Brief at 6, n. 2; Def. Brief at 11.

I agree that "securing" should be construed as it is commonly understood, which in this context, is to "hold fast," "to make fast," or "tie down." *See* Webster's Third New International Dictionary (1986). To hold or make "fast" and "tie down" suggests that the objects are fixed firmly in place. Consequently, I find that "securing" means "firmly fixing the distal end portion to the patient."

Spire proposes the term "fastening," a close, but not perfect synonym of "securing." Although "fastening" accurately captures this concept of fixing one object firmly to another, it can also imply that the two objects are attached to each other. "Securing" does not carry this same connotation. *Cf.* *Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1374 (Fed.Cir.2004) ("[T]he district court's adoption of ... a synonym of the claim term, disregards entirely the distinction between the two terms set forth in the usage note. Had the inventor meant [the synonym], he could have used that word. However, we must consider the word that the inventor actually chose and use the definitions of that term that are consistent with the written description.").

The specification devotes only two sentences to describing how the distal end is to be "secured," but it is clear from this brief explanation that "firmly fixing" is more accurate than "fastening." The first sentence states that the distal end is "secured by sutures or any other suitable means." '198 Patent at col. 5, ll.44-46. The second indicates that the tubes can be "secured" by placing a stabilizing cuff in a dilated portion of the subcutaneous tunnel. Id. at col. 5, ll. 52-54. Sutures firmly fix the tubes in place by holding them tightly to the patient's skin. This appears also to fit the definition of "fasten." But the same cannot necessarily be said of the stabilizer cuff, which is held in place, not by any attachment mechanism, but by pressure from the walls of the subcutaneous tunnel. This is "securing" as "firmly fixing" but it does not import the concept of "fastening." At the risk of tautology, I will provide a construction of "securing" as "firmly fixing" that I believe comprehends both circumstances.

**III. CONCLUSION**

For the reasons above, I hereby construe the disputed claims as set forth in the appendix which follows.

**APPENDIX**

| Claim term | Construction                                                                                                                                                              |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Preamble   | Limiting                                                                                                                                                                  |
| Y-shaped   | in the shape of the letter Y, meaning the shape formed when two branches intersect at a single trunk to form an inside angle of greater than 0 and less than 180 degrees. |
| Securing   | firmly fixing                                                                                                                                                             |

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