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KYPHON INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

(SAN FRANCISCO DIVISION)

MEDTRONIC, INC., MEDTRONIC VASCULAR, INC., MEDTRONIC USA, INC., MEDTRONIC VASCULAR GALWAY LTD., MEDTRONIC SOFAMOR DANEK, INC., and SDGI HOLDINGS, INC.,

Plaintiffs,

v.

KYPHON INC.,

Defendant.

Civil Action No. C06-02559 SI

KYPHON INC.'S AMENDED RESPONSIVE CLAIM CONSTRUCTION BRIEF

Date: April 25, 2007
Time: 3:30 p.m.
Judge: Hon. Susan Illston
Courtroom: 10

I. INTRODUCTION

Defendant Kyphon Inc. ("Kyphon") respectfully submits this brief in opposition to the claim constructions proposed by the Medtronic Plaintiffs and in support of Kyphon's proposed claim constructions.[1] After asserting the patents-in-suit against Kyphon's very different technology in apparent retaliation for Kyphon's 2005 Tennessee lawsuit against it, Medtronic now attempts to broaden the scope of its vascular catheter patents to cover Kyphon's pioneering products for treating spinal fractures. Medtronic's proposed claim constructions overlook key intrinsic evidence and attempt to rewrite history. The Court should reject them.

The patents-in-suit are three patents that Medtronic bought from C.R. Bard[2] concerning balloon dilatation catheters for performing angioplasty procedures and another balloon catheter patent from Micro Interventional Systems[3] that claims a spherical balloon of a specific diameter range to block blood flow through gentle and minimal contact with blood vessels. As Medtronic recognizes, balloon catheters were well-known in the art and in commercial use long before any of these patents was filed. To distinguish this crowded art, the patents-in-suit necessarily require specific structural features aimed to improve the performance of balloon catheters for angioplasty or other procedures performed inside the human vascular system. Medtronic's efforts to now erase these features in order to read the patents on an entirely different technology fail. The weakness of Medtronic's case on the merits perhaps explains its reliance on a misleading and ultimately irrelevant story about Kyphon's corporate history and the conception of its patented technology. The issue at hand is the scope of Medtronic's patents, not the tale Medtronic would tell a jury if its case somehow survived that long.

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[1] Medtronic's brief spans 39 pages in violation of the Local Rules, which require opening briefs to be 25 pages or less. Civ. L.R. 7-4(b). Medtronic has also cited at least ten exhibits in its brief (Exs. E-J, P, Q, T and U) not included in the Joint Claim Construction Statement filed January 26, 2007 (Doc. No. 122). Kyphon seeks appropriate relief for these violations.

[2] Medtronic acquired C.R. Bard ("Bard") in 1998. Bard designed balloon catheters to repair blockages in the blood vessels of the heart.

[3] Medtronic acquired Micro Interventional Systems ("MIS") in 1996. MIS developed catheters that can be threaded into blood vessels in the brain to treat blockages and vascular malformations.

II. BACKGROUND

A. The Patents-in-Suit

The parties dispute the meanings of a number of claim limitations, but at least one dispositive limitation exists in each asserted claim. The Saab '349 patent requires a "sleeve" that is "collapsible." The Barbere '191 and '856 patents require an attachment "between the proximal region of the catheter shaft and [the] distal connection" to serve a particular function. And the Preissman '173 patent requires a balloon of a "spherical shape." These are all improvements beneficial for catheters used in the body's vascular system and not improvements used by Kyphon's spinal products to which Kyphon "owes its existence." (Doc. 133 at 2.)

1. Patent No. 4,820,349 Issued to Saab

The Saab '349 patent is directed to an improved dilatation catheter that can be more easily navigated through blocked blood vessels through the use of both a collapsible sleeve and a collapsible balloon. (Ex. A.)[4] The application was filed in 1987, and the patent issued in 1989 after overcoming prior art without a collapsible sleeve.

The patent discloses a catheter with "a high degree of trackability over a guidewire through tortuous blood vessels" and a "low profile for the balloon as well as for the distal segment of the catheter." (*Id.* at Abstr., 2:15-29; *see also id.* at 1:40-60, 3:22-55.) The catheter has a collapsible sleeve in addition to a collapsible balloon to provide these advantages. Both the sleeve (24) and the balloon (28) have a thin wall that allows them to collapse and closely conform around the distal (far) shaft extension 16 (*i.e.*, the inner tube):

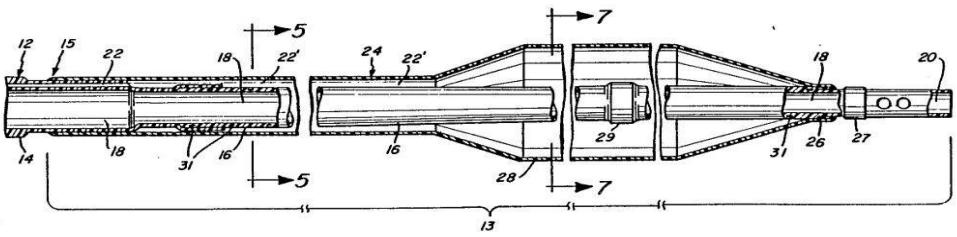


Fig. 2

(*Id.*; *see also id.* at 4:45-56, 5:7-16.) The patent specifies the actual thickness of the material forming the integral sleeve and balloon to ensure it is thin enough to collapse around the inner

[4] Exhibits referenced throughout this Brief are appended to the Declaration of Shelley K. Mack in Support of Kyphon Inc.'s Responsive Claim Construction Brief, filed herewith.

tube under negative pressure. (*Id.* at 5:65-6:2.)

Medtronic asserts independent claim 1, which requires "[a] dilatation catheter comprising" "a sleeve extending over the distal segment of the shaft" with "the proximal end of the sleeve being attached to the shaft" and "the distal end of the sleeve being attached to the distal end of the shaft." (*Id*. at 8:34-57.) Claim 1 also has several limitations directed to the sleeve:

> the sleeve having an integral enlarged diameter balloon portion, both the balloon and the sleeve being formed from a thin walled, flexible material and being inflatable and deflatable, both the sleeve and balloon being collapsible about the shaft in response to a negative pressure applied to the inflation lumen,
>
> whereby the diameter of the catheter in the region of the sleeve may be made to conform closely to the smaller reduced diameter of the distal segment of the shaft. (*Id*. at 8:47-57.)

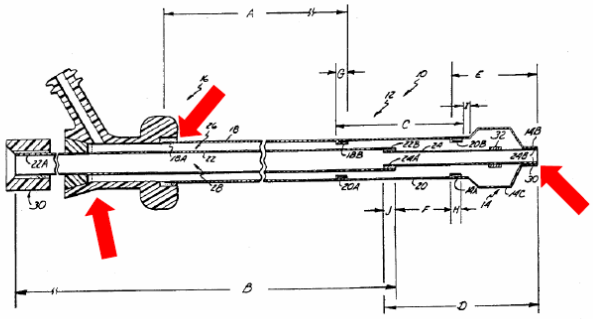
2. Patents Nos. 5,759,191 and 6,179,856 Issued to Barbere.

Like the Saab patent, the Barbere '191 and '856 patents (both part of the same patent family) are directed to improved angioplasty catheters. (Exs. B and C.) They disclose coaxial catheters with an additional attachment between the catheter's inner and outer tubes and near enough to the balloon to make the catheters stiffer and resist telescoping when pushed through arterial blockage. The applications were filed in 1993 and 1997, and the patents issued in 1998 and 2001 after an appeal to the Board of Patent Appeals. The patents share a common specification and claim nearly identical subject matter.[5]

Angioplasty catheters were well known in the art at the time of the invention and have an outer tube, a coaxial inner tube, and an inflatable balloon. (Ex. B at 1:20-44.) In catheters of this type, the inner and outer tubes were connected at their proximal (near) ends by a Y-fitting and at their distal (far) ends by a balloon (one end of the balloon being attached to the distal end of the outer tube and the other end of the balloon being attached to the distal end of the inner tube). The figure below (from a patent discussed during the prosecution of the '191 patent, but not deemed prior art) depicts such connections. The arrows show the connections of the inner and outer tubes at the Y-fitting (lower left) and via the balloon (lower right) as well as the connection between the

[5] Because the written descriptions of the Barbere patents are identical (*compare* Ex. B *with* Ex. C), only the '191 patent specification is cited herein.

outer tube and the Y-fitting (upper left):



(Ex. K, Fig. 3.)

Barbere sought to improve such existing angioplasty balloon dilatation catheters by reducing their tendency to "collapse or buckle axially" during a procedure when the distal end of a catheter is pushed through an arterial blockage. (Ex. B at 2:3-19; *see also id.* at 2:36-45, 2:64-3:7, 4:56-63.) To do so, Barbere added a third attachment between the outer and inner tubes, near the catheter's distal end. This additional attachment is a ring-like spacer (38) interposed between the inner and outer tubes (18 and 20) as shown below in Figure 2:

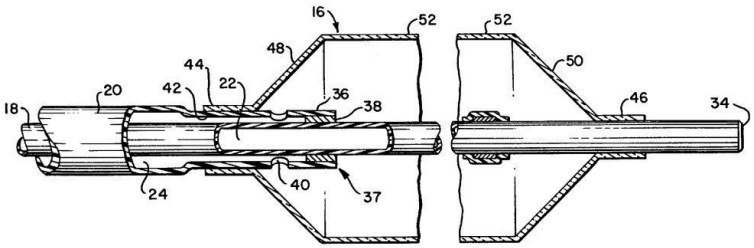


Fig. 2

(*Id*. at Fig. 2; *see also id*. at 4:9-18; Ex. F (5/22/95 Am.) at 3-4.)

Medtronic asserts independent claim 1 of the '191 patent and independent claim 9 of the '856 patent. Both recite a "two tube, two lumen" "balloon dilatation catheter,"[6] which includes an "inner tube defining a guidewire lumen." Both require "an elongate, flexible catheter shaft . . . formed from an inner tube . . . and a surrounding outer tube coaxial with the inner tube and defining an annular inflation lumen therebetween." Both claims also require a connection between the inner and outer tubes at a location between the shaft's "proximal region" and distal connection to perform a claimed function:

[6] The preamble of claim 9 of the '856 patent reads "dilation catheter," but the prosecution history reveals that the PTO mistakenly transcribed the word "dilatation" when printing the patent.

the outer tube being attached to the inner tube at a location between the proximal region of the catheter shaft and said distal connection to resist axial telescoping of the inner tube with respect to the outer tube when the catheter is advanced against a resistance at the distal region of the catheter. (Ex. B at 5:26-31.)[7]

3. Patent No. 5,759,173 Issued to Preissman *et al*.

The Preissman '173 patent is directed to a catheter that blocks blood flow while minimizing contact with the walls of the blood vessels of the brain. (Ex. D.) According to the patent, prior-art catheters had the tendency to kink, collapse, rupture, or otherwise fail when used in "regions of tortuosity" such as the brain vasculature. (*Id*. at 1:34-2:12.) Thus, to solve this problem, the patent discloses a catheter that includes a braided reinforcement layer over the inner tube that increases strength and reduces the risk of injury to blood vessels. (*Id*. at 2:50-66.)

The application was filed in 1996, and the patent issued in 1998 after the applicants filed new claims in response to a final rejection and distinguished prior art that had elongated rather than spherically shaped balloons. Medtronic asserts independent claim 1 and dependent claim 4 of the Preissman patent, both of which require catheters with balloons of a "spherical shape."

B. Kyphon's Products Accused of Infringement

Kyphon pioneered a procedure called Kyphoplasty for treating vertebral compression fractures. Typically, Kyphoplasty involves creating a pathway into a crushed or fractured vertebra, guiding a small orthopaedic balloon (called an inflatable bone tamp or "IBT") through the pathway, expanding the IBT to move the fractured bone back toward its pre-fractured state, deflating and removing the IBT, and filling the cavity with bone cement to stabilize the fracture. Medtronic accuses three of Kyphon's KyphX Xpander® IBTs and one of its KyphX® Express™ IBTs of infringing one or more of the asserted patents.[8] All three accused KyphX Xpander® IBTs are identical in structure and vary only in the uninflated length of the balloon at the device's

[7] Claim 9 of the '856 patent contains the same language, except the phrase "against a resistance at the distal end of the catheter" is replaced by "against a resistance encountered adjacent the distal end of the catheter." (Ex. C at 5:26-27.)

[8] Although claims should not be construed with reference to accused products in order to tailor a claim construction to cover or exclude those products, awareness of accused products can be useful to supply the parameters and scope of the claim construction analysis. *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co*., 442 F.3d 1322, 1330-31 (Fed. Cir. 2006); *see also Lava Trading, Inc. v. Sonic Trading Mgmt., LLC*, 445 F.3d 1348, 1350 (Fed. Cir. 2006) (explaining that, "[w]ithout the vital contextual knowledge of the accused products," a court "lacks a proper context for an accurate claim construction").

distal end. The accused KyphX® Express™ IBTs are smaller versions of the Xpander® IBTs designed to access the vertebra through a smaller aperture. They have the same structural configuration as the Xpander® IBTs and have two different lengths of balloons. Medtronic has accused only the 10 mm size of the Express™ IBT of infringement.

III. CLAIM CONSTRUCTION LAW

As Medtronic recognizes (Doc. 133 at 4-5), the Federal Circuit recently reaffirmed the basic principles of claim construction. *See generally, Phillips v. AWH Corp*., 415 F.3d 1303, 1317 (Fed. Cir. 2005) (*en banc*). Contrary to Medtronic's suggestion, however, the Federal Circuit embraced the importance of reading claim language in light of the written description: "[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.'" *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

The Federal Circuit explained that the words of a claim should be given their ordinary meaning to people of skill in the art at the time of the invention, but that the ordinary meaning cannot be understood in a vacuum:

> Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.

Id. at 1312-13. Thus, patent "claims 'must be read in view of the specification, of which they are a part.'" *Id.* at 1315 (quoting *Markman v. Westview Instruments, Inc*., 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996)).

The Federal Circuit also affirmed that, in addition to the specification, the file history should be considered. *Id.* at 1317. This is especially important because a patentee may limit the scope of his or her claims by expressly disclaiming or disavowing certain features during prosecution, even if the additional limitation on the claim's scope does not appear expressly in the claim language. *Id*. ("[T]he prosecution history can often inform the meaning of the claim language by demonstrating . . . whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.").

IV. ARGUMENT

A. Claim Construction of the Saab '349 Patent

1. "Dilatation Catheter" Should Not Be Expanded to Encompass Any Catheter that Can Be Inserted into Any Body Cavity

Kyphon's accused products are used in the spine rather than the vascular system. Thus, Medtronic must interpret "dilatation catheter" to reach any catheter that can be inserted into any body cavity. The Court should instead construe the term "dilatation catheter" as "a catheter for dilating a constricted blood vessel with an inflatable balloon."

As an initial matter, the term "dilatation catheter" (which appears in the preamble) should be construed. Because other claim terms (such as "*the* catheter") derive antecedent basis from the preamble, it is a limitation here.[9] *See, e.g.*, *Bicon, Inc. v. Straumann Co*., 441 F.3d 945, 952 (Fed. Cir. 2006) (quoting *Eaton Corp. v. Rockwell Int'l Corp*., 323 F.3d 1332, 1339 (Fed. Cir. 2003)) ("[W]hen the limitations in the body of the claim 'rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention.'") The authority Medtronic cites in support of essentially ignoring the preamble is inapposite. (Doc. No. 133 at 5-6.) For example, *LG Elecs., Inc. v. Bizcom Elecs*., *Inc.*, 453 F.3d 1364, 1372 (Fed. Cir. 2006), relied on the use of an indefinite article. And *C.R. Bard, Inv. v. M3 Systems, Inc*., 157 F.3d 1340, 1350 (Fed. Cir. 1998), recognized that a preamble stating the intended use or purpose of an invention actually limits claim scope when it "provides antecedents for ensuing claim terms," which is the case here.

Claim 1 requires a "dilatation catheter," which means a catheter used for dilatation. The specification is singular in its focus that "dilatation catheters" are catheters for use in the vascular system. It states, for example, "[t]he invention relates to improvements in balloon dilatation catheters such as those used in angioplasty procedures and, particularly percutaneous transluminal coronary angioplasty." (Ex. A at 1:6-9; *see also id.* at 1:11-2:22, 2:54-67, 3:24-33, 3:49-55, 5:26-54; 7:28-47, 8:4-16.)

Moreover, Saab specifically distinguished prior art on this basis during prosecution:

[9] The same principle holds true for both Barbere patents-in-suit as well.

> *The Hattler catheter is not a dilatation catheter intended for use in dilatation of arteries or angioplasty procedures. Rather, it is directed to an infusion catheter* in which the lumens are open at the distal end of the catheter to permit infusion of liquids or the like into veins. (Ex. E (8/10/88 Am.) at 10.) [10]

Thus, Saab differentiated prior art catheters used for infusion rather than dilatation and stated that his invention is for dilatation of blood vessels—*i.e.*, "dilatation of arteries or angioplasty procedures." Accordingly, the patent is limited to catheters for use in the vascular system and Medtronic's attempt to read out the "dilatation" limitation is improper. *See, e.g.*, *Texas Instr., Inc. v. ITC*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (rejecting a patentee's claim construction because it would "read an express limitation out of the claims"). The fact that the patent has apparatus claims does not alter this conclusion. Indeed, the *Catalina* case on which Medtronic relies (Doc. No. 133 at 7) recognized that statements of use in the preamble limit apparatus claims when an applicant relies on those uses to distinguish prior art during prosecution. *Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc*., 289 F.3d 801, 809 (Fed. Cir. 2002). That is the case here.

2. Because the Saab Patent Requires Both a Collapsible Sleeve and a Collapsible Balloon, Medtronic's Efforts to Make Balloon" and Sleeve" Mean the Same Thing Should Be Rejected

Because Kyphon's accused products have only a balloon without a distinct non-balloon sleeve portion, Medtronic's proposed constructions of "sleeve," "balloon"/ "balloon portion," and "both the sleeve and the balloon being collapsible about the shaft" are all intended to escape the requirement that there be both a collapsible sleeve and a collapsible balloon. But the plain language of the claim, the written description, the figures, and the prosecution history all show that "sleeve" and "balloon" are not interchangeable terms: one refers to the non-balloon portion of the sleeve (simply, the "sleeve") and one refers to the "balloon portion" of the sleeve. Thus, the Court should reject Medtronic's constructions reading "sleeve" out of the claim and instead construe these terms as follows:

[10] Unless otherwise noted, all emphasis throughout this Brief has been added.

"sleeve" – "A tubular piece fitting over a rod or the like."[11]

"balloon"/ "balloon portion" – "A portion of the sleeve having an enlarged diameter relative to the rest of the sleeve. The balloon is formed integrally with, but is distinct from, the rest of the sleeve."

"both the sleeve and balloon being collapsible about the shaft" – "Both the sleeve and the balloon collapse about the shaft when deflated. A sleeve having a wall thickness of 0.0045 inches or more is not collapsible in the manner of the invention."

a. The "Sleeve" and "Balloon" Limitations Are Distinct Requirements

The plain language of claim 1 demonstrates that the "sleeve" and the "balloon" are two distinct things. The claim requires that "the sleeve hav[e] an integral enlarged diameter balloon portion," that "*both* the balloon *and* sleeve" be formed from a particular type of material, and that "*both* the sleeve *and* balloon" be collapsible about the shaft in response to negative pressure. (Ex. A at 8:47-53.) Use of the words "both" and "and" in claim 1 means that the sleeve and balloon are different claim elements. Kyphon does not, as Medtronic suggests, dispute that the balloon is a portion of the sleeve.[12] (Doc. No. 133 at 16-17.) The actual claim language, however, precludes an inflatable/deflatable balloon alone, in the absence of a distinct non-balloon sleeve portion, from satisfying both the sleeve and balloon limitations.

The plain language of claim 1 also requires that both the balloon and the sleeve collapse about and "conform closely" to the shaft when deflated: "the sleeve having an integral enlarged diameter balloon portion, both the balloon and the sleeve being formed from a thin walled, flexible material and being inflatable and deflatable, *both the sleeve and balloon being collapsible*

[11] Kyphon's proposed construction of "sleeve" simply adopts the term's ordinary meaning as used in the specification (Ex. A at 3:43-48) and as shown by the dictionaries on which Kyphon relies (Doc. No. 122 at 6). The Federal Circuit endorses such extrinsic support for the ordinary meaning of common words. *Phillips*, 415 F.3d at 1314 ("In some cases, the 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. . . . In such circumstances, general purpose dictionaries may be helpful.") In an attempt to avoid the plain meaning, Medtronic cites a dictionary definition of sleeve (Doc. No. 133 at 15, Ex. P) that it did not include as extrinsic evidence in the Joint Claim Construction Statement (Doc. No. 122 at 6-7).

[12] To support its construction of these terms, Medtronic again cites extrinsic evidence (Doc. No. 133 at 16-17, Ex. Q) not included in the Joint Claim Construction Statement (Doc. No. 122).

about the shaft in response to a negative pressure applied to the inflation lumen." (Ex. A at 8:47-57.) Thus, the sleeve and the balloon cannot be one and the same.

Like the language of claim 1, the written description consistently uses words such as "both," "each of" and "and," showing that the sleeve and balloon are distinct and that both must collapse. For example, "*[t]he thin flexible wall of each of the sleeve and balloon enable* ***them*** *to collapse* closely against the smaller diameter of the distal segment of the shaft . . . ." (*Id*. at 2:49-54; *see also id*. at Abstr., 5:12-16, 2:46-49, 7:11-20.) The patent also includes figures that separately illustrate the sleeve and the balloon in collapsed states, confirming that they are distinct elements. (*Id*. at 4:7-8 ("FIG. 6 is an illustration *of the sleeve* similar to FIG. 5 *with the sleeve collapsed* about the catheter shaft."); *id*. at 4:12-13 ("FIG. 8 is an illustration similar to FIG. 7 but *with the balloon in a collapsed configuration*.").) Indeed, the patent explains that the expanded and collapsed diameters of the sleeve are considerably smaller (and different) than the expanded and collapsed diameters of the balloon. (*Id*. at 7:28-31; *see also id*. at 7: 31-47.)

b. The Prosecution History of the Saab Patent Confirms that Collapsibility Depends on Thickness

The collapsible sleeve that enables the catheter's outer diameter to "conform closely" to the shaft's diameter was the key feature setting Saab's invention apart from prior art balloon catheters during prosecution. To explain what "collapsible" meant, Saab turned to the wall thickness. Saab told the PTO that a "thin wall" was necessary for his invention:

> [*T*]*here is no disclosure in Hattler that such a balloon and sleeve as claimed by applicant could be formed from a* ***thin wall*** *flexible material inflatable and deflatable to collapse the sleeve and balloon* in response to negative pressure applied to the inflation lumen. (Ex. E (8/15/88 Am.) at 10.)

And Saab *specifically* explained and distinguished prior art catheters with sleeves too thick to collapse as required by his application:

> [I]t is apparent from the Pope '378 patent that the thickness of the tube 12 is very substantial. Note in col. 2, line 66 to col. 3, line 2, a statement of the inner and outer diameters of the tubular catheter 12 from which it may be determined that *the wall thickness of the tube 12 is 0.0045." Such a catheter* ***would not collapse*** *in the manner of applicant's invention. Note, by comparison, that the wall thickness of the sleeve in applicant's invention is of the order of 0.0005."* Applicant's sleeve is of the order of one-tenth the thickness of that described in

> Pope. The Pope device cannot provide the advantages of applicant's invention and clearly does not disclose or suggest applicant's claimed structure. (*Id*. at 7.)

Although all balloons obviously collapse in some manner when they deflate, and thus always occupy a "reduced profile" when deflated as compared to when inflated, Saab nevertheless explained that particularly thick sleeves/balloons cannot collapse "in the manner of [his] invention." Far from "peripheral," as Medtronic claims (Doc. No. 133 at 18), this disclaimer unequivocally defined the upper bound of what renders something "collapsible" within the scope of the claimed invention so that the catheter's outer diameter can "conform closely" to the shaft. Accordingly, for a device to satisfy the collapsible sleeve/balloon limitation, the sleeve's wall cannot be thicker than 0.0045 inches. A patentee may not state that the claims of a patent do not cover a particular device during prosecution and then change that position during litigation. *See Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003).

Medtronic complains that Kyphon asserts that the thickness must be less than 0.0045 inches "based solely" on this part of the prosecution history (Doc. No. 133 at 18), but that is all the law requires. *See, e.g., Southwall Techs., Inc. v. Cardinal IG Co*., 54 F.3d 1570, 1576 (Fed. Cir. 1995). ("The prosecution history limits the interpretation of claim terms so as to exclude *any interpretation that was disclaimed during prosecution*.") The *Cordis* case that Medtronic cites is inapposite. (Doc. No. 133 at 19 (citing *Cordis Corp. v. Medtronic AVE, Inc*., 339 F.3d 1352, 1360-61 (Fed. Cir. 2003)).) In *Cordis*, the applicant commented that the wall thickness of a prior art reference varied by 0.001 inch, but did not rely on that variance as the basis for distinguishing its invention. 339 F.3d at 1360-61. Here, however, Saab clearly stated that the thickness of the Pope tube was the very basis for differentiation because Pope's thick catheter "would not collapse in the manner" of Saab's invention and that the sleeve in Saab's claimed devices "is of the order of one-tenth the thickness of that described in Pope." (Ex. E (8/15/88 Am.) at 7.)

Medtronic also makes an argument based on overall sleeve *size* to justify ignoring its thickness argument during prosecution, but its latest argument does not appear anywhere in the intrinsic record or make logical sense. (Doc. No. 133 at 18-19.) Finally, Medtronic's argument that the thickness limitation does not explicitly appear in the claim language (Doc. No. 133 at 19)

is beside the point. *See Springs Window*, 323 F.3d at 995-96 (rejecting the patentee's argument in litigation that arguments made during prosecution could be disregarded "because the distinguishing features 'were not and are not reflected in the claims'"). In sum, Kyphon's constructions properly interpret the claim scope in light of the intrinsic record that Barbere created, which Medtronic cannot change.

B. Claim Construction of the Barbere '191 and '856 Patents

1. "Balloon Dilatation Catheter" Should Not Be Expanded to Encompass Any Catheter that Can Be Inserted into Any Body Cavity

Like the Saab patent, the Barbere patents are limited to "a catheter for dilating a constricted blood vessel with an inflatable balloon." Medtronic's effort to expand the patents to cover any catheter that can be inserted into any body cavity fails for two reasons. First, Barbere consistently represented his invention as limited to use in the vascular system during prosecution. (*See, e.g.*, Ex. F (5/14/90 Am.) at 2 ("[T]elescoping presents difficulties particularly when the catheter is used in tortuous irregularly shaped arteries . . . ."); *id*. (5/17/95 Am.) at 2 ("Applicant's invention concerns improvements in a coaxial, two lumen balloon dilatation catheter intended to be advanced to and then pushed into a vascular obstruction to enable the balloon to dilate the obstruction.").) Indeed, the Board of Patent Appeals noted this clear limitation in scope: "Applicant's invention pertains to a two tube, two lumen coaxial *balloon dilatation catheter for use in percutaneous transluminal coronary angioplasty*" (*Id*. (10/23/97 BPAI Ruling) at 2.)

Second, Barbere distinguished prior art catheters used in blood vessels for purposes other than dilatation to unblock a stenosis:

> Although the Corday catheter has a balloon, *it is for a completely different purpose*, namely, for retroperfusion in which the balloon is adapted to seal off a segment of a blood vessel temporarily while blood is perfused into the vessel. *The catheter in Corday is not intended to be advanced into or through a stenosis and is not intended to serve a dilating function, to enlarge the flow lumen through a stenosis*. In short, *the Corday catheter is never subjected to the kind of use to which dilatation catheters are put* and does not meet with the same problems. (*Id*. (5/14/90 Am.) at 3-4.)

This disclaimer means the Barbere patents are limited to catheters for dilatation of blood vessels.

The specification supports this conclusion by confirming the singular focus of the '191

and '856 patents: catheters used in the vascular system that do not buckle or collapse when meeting resistance. (Ex. B at 1:23-33, 1:62-2:2, 2:14-18; *see also, id*. at 1:17-19, 1:46-61, 2:36-45, 2:56-3:11.) Thus, while the patents may not be limited to coronary artery catheters, they *are* limited to catheters for dilating constricted vessels.[13]

2. The Barbere Patents Require an Attachment Distal to the Y-Fitting, and the Terms "Catheter Shaft" and "Proximal Region" Must Be Construed Accordingly

Kyphon's accused products do not have an extra attachment between the inner and outer tubes anywhere along their length. Instead, the tubes are attached only at the Y-fitting and via the balloon. Not surprisingly, then, Medtronic's proposed constructions of "catheter shaft" and "proximal region" allow the requisite extra attachment to be at the Y-fitting. But an attachment at the Y-fitting was in the prior art, would not prevent axial telescoping, and is not "between" the structures specified in the claims — and Barbere told the PTO exactly that. Therefore, the Court should reject Medtronic's constructions and construe the relevant terms as follows:

> "catheter shaft" – "The portion of the catheter distal to the Y-fitting (or equivalent thereof) formed from the inner tube and the coaxial outer tube."
>
> "proximal region" – "The region of the catheter shaft distal to the Y-fitting (or equivalent thereof) and extending from the proximal end of the catheter shaft to the distal region of the catheter shaft."

a. Medtronic's Construction of "Catheter Shaft" Conflicts with the Plain Language of the Claims

Medtronic's construction of "catheter shaft" impermissibly broadens the meaning of the term to the "body of the catheter including the Y-fitting."[14] Indeed, to prove infringement, Medtronic *must* include the Y-fitting within its definition of "shaft" because of the absence of any other interconnection between the coaxial tubes in the accused Kyphon products. But Medtronic is wrong in contending that "[i]f the Y-fitting meets the claimed criteria for the 'catheter shaft' —

[13] Kyphon's construction does not read in the limitation of "during angioplasty procedure" as Medtronic contends. (Doc. 133 at 7.) Nor do any of Kyphon's constructions of the requisite catheters in all of the asserted patents require use in angioplasty; therefore Medtronic's claim differentiation argument is inapposite. (*Id*. at 8.)

[14] Medtronic's construction of "proximal region" as a "*very small area* adjacent the proximal end" is also contrary to the plain meaning of "region." Moreover, the dictionary definitions of "proximal" and "distal" on which Medtronic relies (Doc. No. 133 at 24, Exs. T, U) were not provided in the Joint Claim Construction Statement (Doc. No. 122 at 17).

which it does — then there is no basis to exclude it from the interpretation of 'catheter shaft.'" [15] (Doc. No. 133 at 23.) In fact, the Y-fitting does not meet the "claimed criteria for the 'catheter shaft.'"

More specifically, the "catheter shaft" is defined in Claim 1 as "formed from an inner tube . . . and a surrounding outer tube coaxial with the inner tube and defining an annular inflation lumen therebetween." Based on this language, Medtronic argues that, "in catheters where inner and outer tubes are present in a Y-fitting, the catheter shaft necessarily must include the Y-fitting." (*Id*. at 21.) But the catheter shaft is formed from two coaxial tubes and the Y-fitting is a fitting (*i.e.,* a connector), not a tube. Moreover, the claim is written to require that the catheter shaft is "*formed from*" coaxial inner and outer tubes, not that the catheter shaft "includes" coaxial inner and outer tubes and thus can include additional parts. Obviously, the two branches of a Y-fitting are not coaxial.[16] Thus, because the Y-fitting is not *formed from* coaxial inner and outer tubes, as required by the plain claim language, the Y-fitting is not part of the "catheter shaft," as the shaft is defined within the claim.

In addition, since the shaft is "formed" only of the coaxial inner and outer tubes, the claims specify that "shaft" is "elongate [and] *flexible*." The Y-fitting, however, is not flexible — it is a rigid piece designed to maintain the "Y" separation of two non-coaxial passages proximal of the coaxial shaft itself. Therefore, the "shaft" does not include the Y-fitting. Claim constructions that conflict directly with claim language must be rejected, as Medtronic recognizes. (Doc. No. 133 at 25 (citing *RF Delaware, Inc. v. Pacific Keystone Technologies, Inc*., 326 F.3d 1255, 1263-64 (Fed. Cir. 2003).)

[15] Medtronic's description of the Y-fitting disclosed in the Barbere patents is misleading. Medtronic includes Figure 1 of the '191 patent, but has omitted reference numbers for the following elements: catheter shaft (10), inner tube (18) and outer tube (20) (shown in Figure 2), which are all distal to the Y-fitting, and the flexible proximal tubes (28) and (30), which are both proximal to the Y-fitting. (Doc. No. 133 at 21.) Medtronic then claims that, "according to Figure 1, the inner and outer tubes extend *through* the Y-fitting." (*Id*. at 21-22.) The *proximal* tubes (28) and (30) in Figure 1, however, are not the same as the *inner* and *outer* tubes (18) and (20) in Figure 2.

[16] Moreover, in the accused Kyphon products, the outer tube terminates at the distal end of the Y-fitting and does not extend through the Y-fitting.

b. The Prosecution History Bars Medtronic's Constructions of "Catheter Shaft" and "Proximal Region"

Contrary to Medtronic's argument, the prosecution history makes plain that the extra attachment between the coaxial tubes required by the Barbere patents cannot be located at the Y-fitting. (Doc. No. 133 at 21-23, 26-29.) An attachment at the Y-fitting was known in the prior art. Indeed, the purported advantage of the Barbere patents was the additional attachment between the coaxial tubes near the balloon, and Barbere said so explicitly and consistently during prosecution. Medtronic's entire analysis of the prosecution history ignores what Barbere said his invention actually was.

Barbere added the term "proximal region" during prosecution to overcome prior art with attachments at the Y-fitting. (That is why the term appears in the claims but not in the written description.) The examiner rejected Barbere's claims in view of the Simpson patent, a prior art catheter with tubes attached at the proximal end by a Y-fitting and at the distal end by a balloon. (Ex. F (5/10/94 Office Action) at 2-3; Ex. I (Simpson patent) at 4:61-5:14, Figs. 3, 4.) The examiner stated that "[t]his attachment inherently resists axial telescoping of the inner tube with respect to the outer tube, especially at the proximal portions of the tubes." (Ex. F (5/10/94 Office Action) at 2.)

In response, to distinguish the Simpson patent, Barbere amended the claims to add the key limitation "between the proximal region of the catheter shaft and said distal connection." (*Id.* (11/19/94 Am.) at 2, 10-11.) Barbere emphasized that the invention was not about a connection between inner and outer tubes ***at*** the Y-fitting, but instead was about an inner tube-outer tube connection ***distal of*** the Y-fitting, ***between*** the Y-fitting and the distal end of the catheter shaft:

> The claims as amended also define patentably over Simpson. . . . The claims have been amended further to define that the outer tube is attached to the inner tube at a location ***between*** the proximal region of the catheter shaft and the distal connection. That ***necessarily*** distinguishes over Simpson where the connection referred to by the Examiner (via side arm 76 [of Y-fitting 66]) is ***at the proximal region*** of the catheter. (*Id.* at 10-12.)

Thus, Barbere stated, deliberately and unequivocally, that his invention did not encompass balloon catheters with inner and outer tubes connected only at the Y-fitting and their distal ends.

Indeed, Barbere left no doubt that an attachment at the Y-fitting is not "between the proximal region of the catheter shaft and . . . distal connection" by explaining that connections at the proximal end of the shaft actually cause rather than prevent axial telescoping. Immediately after pointing out that the Simpson patent's Y-fitting was "at" the proximal region and thus could not provide the claimed connection, Barbere further explained:

> [T]he examiner's conclusion that attaching the inner and outer tubes at their proximal ends ". . . inherently resists axial telescoping of the inner tube with respect to the outer tube . . ." is incorrect. *To the contrary, in the prior art devices that exhibit the axial buckling problem with which applicant's invention is concerned, the connection of the inner and outer coaxial tubes at their proximal ends, but not in a more distal location, is part of the cause of the problem*. Where the outer and inner tubes are connected only at their proximal ends, when the distal end of the catheter (including the balloon and/or distal portion of the inner tube) is unable to advance, continued pushing on the outer tube is transmitted through that proximal connection to the inner tube. That, in turn is what causes the inner tube to buckle. (*Id*. at 11.)

Barbere then reiterated that his invention aimed to reduce telescoping at the *distal end* of the catheter when advanced through a blockage:

> The examiner should note that the problem with which the invention is concerned is not axial telescoping at the proximal ends of the tubes, but rather, the effect of the *telescoping at the distal end* which enables the balloon to become bunched up, thereby increasing the resistance to further advancement of the catheter. The invention avoids that problem. (*Id*.)

Ultimately, Barbere again explained that the inventive attachment is located near the balloon at the catheter's distal end to the Board of Patent Appeals:

> The present invention first recognizes and then solves the problem of buckling of the inner tube 18 and subsequent telescoping of the outer tube 20 by providing a secure anchor joint at 37 between the inner tube 18 and the outer tube 20 *near one end of the balloon*. (*Id*. (7/24/96 Appeal Br.) at 6.)

In allowing the claims, the Board clearly stated its understanding of the location of the additional attachment: "[Barbere] endeavors to overcome this alleged deficiency in the prior art by anchoring the distal end of the outer tube to the inner tube *at a location within the balloon* to prevent telescoping of the outer tube over the inner tube at the location of the balloon." (*Id.* (BPAI Ruling) at 2.) Medtronic ignores these critical parts of the prosecution history and the

appeal that establish that a connection at the Y-fitting was not Barbere's invention. (Doc. No. 133 at 27.)

Because Barbere repeatedly argued during prosecution that the required attachment could not be at the Y-fitting, Medtronic's constructions encompassing the Y-fitting must be rejected. "It is well established that 'the prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.'" *Springs Window*, 323 F.3d at 994 (quoting *Pall Corp. v. PTI Techs. Inc.*, 259 F.3d 1383, 1392 (Fed. Cir. 2001)).

Medtronic attempts to avoid the effect of Barbere's clear disclaimer by arguing that the Examiner rejected Barbere's arguments during prosecution. (Doc. No. 133 at 22-23, 26-29.) This is of no moment. In *Springs Window*, the patentee argued there was no disclaimer because the examiner disagreed with its statements during prosecution. *Id.* at 994. Contrary to Medtronic's contention that "in *Springs Windows* [sic], the examiner, in allowing the claims, relied on and adopted the applicant's position" (Doc. No. 133 at 29), the court emphasized that the examiner's reasons for allowance were unknown: "[t]he notice of allowance offers no explanation of the examiner's reasoning," 323 F.3d at 995. And the Federal Circuit held that this does not matter: "[i]n any event, the examiner's remarks do not negate the effect of applicant's disclaimer." *Id.* at 993-95 (explaining that, regardless of what the examiner said, the patentee is "held to ***what he declares*** during the prosecution of his patent"); *see also, Laitram Corp. v. Morehouse Indus., Inc.*, 143 F.3d 1456, 1462 (Fed. Cir. 1998) ("Regardless of the examiner's motives, arguments made during prosecution shed light on what the applicant meant by its various terms. The fact that an examiner placed no reliance on an applicant's statement distinguishing prior art does not mean that the statement is inconsequential for claim construction.") (internal citation omitted); *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 175 Fed. Appx. 350, 356 (Fed. Cir. 2006) (unpublished) ("It is irrelevant what the Examiner thought [the patentee] was disclaiming. It was [the patentee's] own statements that created the disclaimer."). Thus, an examiner need not acquiesce to an applicant's arguments for disclaimer to occur.

Inverness does not hold otherwise. (Doc. No. 133 at 29 (citing *Inverness Medical Switzerland GmbH v. Warner Lambert Co.*, 309 F.3d 1373 (Fed. Cir. 2002).) Instead, *Inverness*

held that the prosecution history of the patent-in-suit did not preclude a broad meaning because the court was "not convinced that the prosecution history demonstrates that the patentee clearly was using the disputed language in a limited sense that would foreclose the broader" meaning and because "[i]t is inappropriate to limit a broad definition of a claim term based on prosecution history that is itself ambiguous." 309 F.3d at 1379-82. Thus, the finding of no disclaimer did not turn on whether the examiner rejected the applicant's statements. Indeed, all of the authority cited by Medtronic considers the remarks of the applicant — not the examiner — in analyzing prosecution disclaimer. *See DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1327-30 (Fed. Cir. 2001) (analyzing *the applicant's* remarks about the prior art during prosecution and concluding that the prosecution history clearly reflects *the applicant's* disclaimer); *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999) ("Nowhere in the passages cited to us does *the applicant* squarely describe the nature of the connection . . . in the pending claims.") Thus, just as with the Saab patent addressed above, Barbere's remarks during prosecution limit the scope of the claimed inventions.

3. The Barbere Patents Require an Opening in the Catheter Shaft for Passage of the Guidewire Over Which the Catheter Is Advanced

a. "Guidewire Lumen"

The Court should construe the "guidewire lumen" required by the asserted claims of the Barbere patents to mean "an opening through the catheter shaft for passage of the guidewire over which the catheter is advanced."[17] The Court should reject Medtronic's invitation to read the "guidewire" limitation entirely out of the claims in an impermissible attempt to broaden their scope and read "guidewire lumen" simply as "lumen."[18] *See, e.g.*, *Texas Instr.*, 988 F.2d at 1171.

The common specification shows that the "guidewire lumen" accepts a guidewire — that is why it is called a "guidewire lumen." The written description explains (and the parties agree) that the guidewire lumen is located in the catheter shaft. (Ex. B at 2:21-27.) It also explains that the inner tube defines a lumen adapted to receive a guidewire:

[17] Kyphon does not contend that a guidewire itself has to be provided with the catheter for the claim to be infringed, as Medtronic suggests. (Doc. No. 133 at 29.)

[18] Despite the claim language and the fact that all vascular catheters must track over a guidewire to pass through the body's tortuous pathways, Medtronic nevertheless must try to read "guidewire" out of the claim because none of Kyphon's catheters use a guidewire, meaning of course that none has a "guidewire lumen."

> *The inner tube* 18 *defines an inner lumen* 22 *adapted to receive a guidewire*, indicated generally in FIG. 1 at 15 with the proximal and distal ends of the guidewire 15 protruding from the proximal and distal ends of the catheter. (*Id*. at 3:46-50.)
>
> The guidewire lumen 22 extends from the proximal end of the catheter fully to the distal tip of the catheter and terminates in an outlet opening 34. Thus, *the guidewire* 15, which is longer than the catheter *may be passed through the guidewire lumen* 22 and may exit from the outlet tip 34, with the proximal end of the guidewire 15 protruding proximally from the proximal tube 28. (*Id*. at 3:64-4:3.)

The written description further explains that the catheter is advanced through the vascular system over the guidewire passed through this lumen:

> From the foregoing, it will be appreciated that after the guidewire has been desirably placed in the patient's coronary anatomy, *the physician will then advance the catheter over and axially along the guidewire*. (*Id*. at 4:48-51.)

Thus, "*guidewire* lumen" is not simply any inside lumen of any inner tube as Medtronic contends. (Doc. No. 133 at 29-30.) It is instead the inside lumen that accepts a guidewire; common sense establishes that a lumen that does not accept a guidewire is not a "guidewire lumen."

b. Means-Plus-Function Limitations Related to "Guidewire Lumen"

The following phrases in the '191 and '856 patents should be construed consistently with "guidewire lumen" as means-plus-function elements pursuant to 35 U.S.C. § 112, ¶ 6:

> "means at the proximal end of the catheter for accessing each of the guidewire and inflation lumens" (Ex. B at 6:1 (claim 1 of the '191 patent).)
>
> The function performed is accessing each of the guidewire and inflation lumens. The corresponding structure is a Y-fitting and a pair of flexible proximal tubes, one of the proximal tubes being in communication with the guidewire lumen and the other proximal tube being in communication with the annular inflation lumen, and fittings at the proximal ends of the proximal tubes by which appropriate fluid devices such as syringes, inflation devices or the like may be connected.
>
> "means at the proximal end of the catheter for accessing the inflation lumen" (Ex. C at 8:35-36 (claim 9 of the '856 patent).)
>
> The function performed is accessing the inflation lumen.[19]

[19] Kyphon's proposed construction in the parties' January 26, 2007 Joint Claim Construction Statement mistakenly included the same proposed function as that for the similar element in the '191 patent. (Doc. No. 122 at 31.)

> The corresponding structure is a Y-fitting and a pair of flexible proximal tubes, a flexible proximal tube in communication with the annular inflation lumen, and a fitting at the proximal end of the proximal tube by which appropriate fluid devices such as syringes, inflation devices or the like may be connected.

Use of the word "means" in a claim creates a presumption that the element should be construed pursuant to 35 U.S.C. § 112, ¶ 6. *See, Personalized Media Comms., LLC v. ITC*, 161 F.3d 696, 703-04 (Fed. Cir. 1998). Construction of a means-plus-function element requires two steps: determining the claimed function and then identifying the corresponding structure in the specification that performs that function. *See, JVW Enters. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1330 (Fed. Cir. 2005). Medtronic argues that these disputed phrases are not means-plus-function elements because the "means" are simply the openings. (Doc. No. 133 at 35-38.) But its argument fails because the claims specify corresponding functions and do not go "on to elaborate sufficient structure, material, or acts within the claim itself to perform entirely the recited function." *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1427-1428 (Fed. Cir. 1997).

First, the claims clearly specify corresponding functions. The claimed function in "means at the proximal end of the catheter for accessing each of the guidewire and inflation lumens" in the '191 patent (Ex. B at 6:1-2) is accessing both of the guidewire and inflation lumens. Likewise, the claimed function in "means at the proximal end of the catheter for accessing the inflation lumen" in the '856 patent (Ex. C at 8:35-36) is accessing the inflation lumen.

Second, as in *Sage Products*, "[n]either claim explicitly recites the structure, material or acts needed to perform functions." 126 F.3d at 1427-28. "Openings" alone are not sufficient to access the lumens. Instead, the written description straightforwardly sets forth the corresponding structure:

> The proximal end of the catheter is provided with *a Y-fitting* 26 which may be molded from an appropriate plastic and *to which is connected a pair of flexible proximal tubes* 28, 30. The Y-fitting 26 is formed so that *the proximal tube 28 is in communication with the guidewire lumen 22* in the inner tube 18 and *the proximal tube 30 is in communication with the annular inflation lumen 24. Each of the proximal tubes 28, 30 is provided with a fitting 32 at its proximal end by which appropriate fluid devices such as syringes, inflation devices or the like may be connected*. (Ex. B at 3:54-63.)

4. The Barbere Patents Require an Opening in the Wall of the Outer Tube or a Structure Associated with the Outer Tube; the "Means for Communicating the Annular Inflation Lumen with the Interior of the Balloon . . ." and "At Least One Aperture Associated with the Outer Tube to Facilitate Inflation and Deflation of the Balloon" Must Be Construed Accordingly

The Barbere patents require an opening in the wall of the outer tube or structure associated with the outer tube. The Court should construe the following phrase (which appears in claim 1 of the '191 patent but not in the '856 patent) as a means-plus-function element as follows:

> "means for communicating the annular inflation lumen with the interior of the balloon to facilitate inflation and deflation of the balloon, the inflation lumen comprising the sole lumen in communication with the interior of the balloon"
>
> The function performed is communicating the annular inflation lumen with the interior of the balloon.
>
> The corresponding structure is a pair of circumferentially spaced apertures formed in the wall of the outer tube within the balloon.

Again Medtronic disputes that this is a means-plus-function element. Medtronic's construction is basically that the "means for communicating the annular inflation lumen with the interior of the balloon" is the opening at the end of the annular inflation lumen. (Doc. 133 at 30-34.) This is illogical—there is no support for Medtronic's position that the "means for communicating" a first thing with a second thing can be the first thing. Medtronic's construction is also physically impossible. Apertures in the tube walls are integral to the invention because of the extra attachment near the balloon. This attachment plugs the annular passage of the lumen, so one or more apertures are needed in the side wall to allow the inflation medium to flow into the balloon. Medtronic's construction reads this limitation out of the claims and should be rejected.

The written description clearly identifies as the corresponding structure a pair of circumferentially spaced apertures formed in the wall of the outer tube that extend into the balloon, which thereby communicate the annular inflation lumen with the interior of the balloon:

> A pair of circumferentially spaced (e.g., 180°) apertures 40 are formed in the outer tube within the balloon to communicate the inflation lumen 24 with the interior of the balloon so as to permit inflation and deflation of the balloon with an appropriate liquid as will be familiar to those skilled in the art. (Ex. B at 4:18-23; *see also,* Fig. 2 (40).)

Both the claim and written description are explicit that such communication allows for inflation and

deflation of the balloon. Given this structure, Medtronic is incorrect that the structure is "simply an opening," which is not definite structure in the claim language to perform this function as Medtronic contends. (Doc. No. 133 at 32.)

The Court should consistently construe the following phrase (which appears in claim 9 of the'856 patent but not in the '191 patent):

> "at least one aperture associated with the outer tube to facilitate inflation and deflation of the balloon" – "at least one opening in either the wall of the outer tube or a structure associated with the outer tube to allow for inflation and deflation of the balloon." (Ex. C at 8:30-32.)

As shown above, at least one aperture is associated with the outer tube to permit inflation and deflation of the balloon. (*Id*. at 4:17-22, Fig. 2.) Given the geometry and arrangement of the catheter, an aperture also must be on the side wall of the outer tube (or a structure associated with the outer tube) within the balloon itself to facilitate inflation and deflation. (*See, e.g*., Ex. F (5/17/95 Am.) at 3 ("One or more ports communicate the annular inflation lumen with the interior of the balloon to facilitate inflation and deflation of the balloon."); *id*. (7/22/96 Ap. Br.) at 6 ("Since the inflation lumen 24 now no longer extends into the balloon interior, one or more ports 40 are provided in the outer tube 20 to allow inflation fluid to be introduced and withdrawn from the balloon 16.").) Medtronic's construction ignores how the specification discloses this geometry of the claimed catheter and thus should be rejected.

C. Claim Construction of the Preissman '173 Patent[20]

1. "Spherical Shape" Means the Balloon Must Be Recognizably SphericalRather than Oval or Elliptical

Because Kyphon's products use balloons that are elongated rather than spherical, Medtronic seeks to broaden the meaning of "spherical shape." The Court should construe "spherical shape" as "a shape that is spherical like a globe or a basketball" and reject Medtronic's attempt to broaden this limitation to encompass any "sphere-like shape" -- clearly intended to

[20] Kyphon initially proposed that the Court construe the term "balloon catheter" as "a catheter having an inflatable balloon for use in a blood vessel," because of the Preissman patent's singular focus on the fragile blood vessels of the body and the brain in particular. Nevertheless, unlike for the Saab and Barbere patents, the applicant did not specifically focus on the use of the invention during prosecution as a manner of distinguishing relevant prior art. Nor does the term (which appears in the preamble) provide antecedent basis as it does in those patents. Accordingly, Kyphon focuses instead on the more salient limitations of the '173 patent's claims.

include shapes that no one in the real world would define as "sphere," such as something that is oval or elliptical like a football or a blimp. (Doc. No. 133 at 12-13 (contending that the requisite shape of the balloon is more like an oval or ellipse than a globe or a basketball).)

The plain meaning of "spherical" is spherical — not oval or elliptical. Kyphon does not contend that "spherical" requires a mathematically perfect sphere, and Kyphon does not read in limitations as Medtronic suggests. (Doc. No. 133 at 11-12.) Instead, Kyphon's construction includes "like a globe or a basketball" to show that being spherical in the real world is good enough to maintain the essence of the "spherical" limitation. This part of Kyphon's construction is borrowed directly from the construction of the term "spherically-shaped" in another recent Medtronic lawsuit — a construction with which Medtronic agreed when trying to help that Court understand what the term's ordinary meaning encompasses. (Ex. J at 5 ("[C]onsistent with the agreement of counsel, the Court construes "spherically-shaped" to mean "approximately spherical, such as a globe or basketball.").)[21] Medtronic simply has no support from case law, dictionaries, or anywhere else for its contrary contention in this case that the ordinary meaning of spherical can include oval or elliptical, like a football or blimp.

Medtronic's attempt to escape the "spherical" limitation rests on Figure 1 of the Preissman patent (Doc. No. 133 at 12), but such reliance is contrary to law. Patent drawings are not precise enough to support Medtronic's conclusion. *See, Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956 (Fed. Cir. 2000) ("[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue."). Indeed, the specification is essentially silent on the "spherical shape" limitation because this limitation was only claimed after prosecution on what *was* disclosed in the specification (the reinforced-wall catheter invention) failed, and new claim sets had to be filed. In short, Figure 1 cannot help Medtronic escape the plain words of the claim.

If the term "spherical" were interpreted to encompass shapes that are not spherical, such

[21] Medtronic did not challenge that construction on appeal. *See Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006). Although the Court is not bound by precedent to utilize the definition proposed, it seems as useful here as it was in the prior case.

as oval or elliptical, it would be entirely unclear how oval or how elliptical an accused product would need to be to be considered "spherical." And Kyphon can find no dictionary that defines oval or elliptical as "approximately spherical" in any sense. It is as if Medtronic would prefer to read "spherical shape" as "non-cylindrical" and encompass all shapes beyond what was in the prior art. But that, as shown next, is precluded by the prosecution history.

2. The Applicants Disclaimed Any Broader Meaning of Spherical

In addition to the plain meaning of the claim language, an examination of the file history demonstrates that the applicants disclaimed any broader meaning of "spherical shape" during prosecution and really meant to claim "spherical," not some other, much broader term. The "spherical shape" limitation was added in an amendment filed after multiple rejections of other subject matter by the Patent Office, and neither the disclosure nor the claims originally submitted referenced this limitation. The new claims required a catheter with an inner and outer tube (the "outer sheath" and "inner tubular member") and a balloon with a "spherical shape" within a diameter range of from 4 mm to 14 mm:

> an elastomeric balloon attached to the distal ends of the inner tubular member and the outer sheath to receive inflation medium from the inflation lumen, wherein the balloon is inflatable to a spherical shape having a diameter from 4 mm to 14 mm.

(Ex. G (7/9/97 Am.) at 2; *see also,* Ex. D at 10:29-33.)

The Applicants relied on the spherical shape and inflation diameter limitations to distinguish prior art. The prosecution history thus shows that the "spherical shape" limitation was critical. Specifically, the examiner rejected the amended claims in view of a catheter having an "expansible member" with a portion "at least partially made to a substantially cylindrical shape" as disclosed in the Nobuyoshi prior art patent. (Ex. G (4/9/97 Office Action) at 2; Ex. I at 7:60-61.) In response, applicants distinguished Nobuyoshi by arguing that its expansible member was not spherical as required by the pending claims:

> Although the Nobuyoshi patent discloses a medical catheter having an expansible member, *at no point does the patent show or suggest a spherical balloon mounted on such a catheter*. The Nobuyoshi catheter instead discloses an expansible member having at least "a portion of substantially cylindrical shape for easily dilatating [sic] the stricture portion of the blood vessel …" (Col. 14, lines 20-24).

> *No text or figure is directed towards a spherical member. This distinction alone should be sufficient to traverse the current rejections*. (Ex. G (7/14/97 Am.) at 3.)

The applicants also argued that spherical and non-spherical balloons are not equivalent because only a spherical balloon allows "minimal mechanical disruption of the vascular wall:"

> To conclude equivalence would be to oversimplify the analysis of the expansible members on the Nobuyoshi catheter and the present invention. The geometry of a spherical expansible member offers specific performance advantages that are not found in cylindrical members. *A spherical balloon, when fully inflated to the diameter of a blood vessel, will contract the vessel wall only at the sphere's greatest circumference while a cylindrical balloon will contact the vessel wall over the cylinder's entire length*. . . . In particular operations of the present catheter, such as aneurysm repair, we wish to slow or stop fluid flow with minimal mechanical disruption to the wall of the vasculature. The spherical shaped balloon can occlude the vessel with *only tangential contact* of the balloon with the vessel wall. A cylindrical balloon risks excessive disturbance of the vessel wall, which is particularly undesirable …. (*Id.* at 3-4 (emphasis in original).)

Only a spherical shape like a globe or ball will contact the vessel wall at its "greatest circumference" and is capable of "only tangential contact." Such is not possible with a blimp-shaped or elongated balloon.

Thus, even if "spherical" could have had a broader meaning, the applicants disclaimed any such meanings during prosecution. *See Pall Corp*., 259 F.3d at 1392; *Ekchian v. Home Depot, Inc*., 104 F.3d 1299, 1304 (Fed. Cir. 1997). The prosecution history simply leaves no doubt that the claims of the Preissman patent require a balloon that is spherical in shape, not simply oval or elliptical.[22]

V. CONCLUSION

Kyphon respectfully requests that the Court reject Medtronic's proposed constructions and construe the claims of the patents-in-suit as set forth above.

Dated: March 27, 2007 FISH & RICHARDSON P.C.

By: /s/ John M. Farrell
John M. Farrell
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[22] Kyphon actually has no issue with the suggested term "sphere-like," as long as "sphere-like is interpreted to mean "like a globe or basketball" rather than oval or elliptical.

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