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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 SUR-REPLY CLAIM CONSTRUCTION BRIEF

Date: April 25, 2007
Time: 9:00 a.m.
Judge: Hon. Susan Illston
Courtroom: 10

I. Introduction

Medtronic's proposed claim constructions are aimed to read the key inventive feature out of each patent-in-suit.

The Saab patent discloses a catheter with a collapsible sleeve in addition to a collapsible balloon. It requires both a "sleeve" and a "balloon," "both the sleeve and balloon being collapsible about the shaft." Kyphon's products do not have a sleeve, much less an expandable and collapsible sleeve. Instead, they only have a balloon. Thus Medtronic must insist that the required "sleeve" and "balloon" are not just "integral," which Kyphon has never disputed, but that they really are the same thing, so that any catheter with a balloon would satisfy the "sleeve" limitation.

The Barbere patents disclose a new attachment of a catheter's inner and outer tubes on the catheter shaft, in addition to the existing attachments of the tubes at each catheter's end. They require an attachment "between the proximal region of the catheter shaft and [the] distal connection to resist axial telescoping." Kyphon's products do not have an attachment between the proximal and distal ends of the catheter shaft. Thus Medtronic has to argue that the required attachment between the inner and outer tubes of the catheter shaft can be at the Y-fitting, which is another structure entirely, so that any catheter with a Y-fitting—and there are hundreds if not thousands of those in the prior art—would thereby meet the attachment limitation.

The Preissman patent discloses a catheter with a spherically shaped balloon to minimize the balloon's contact with the inside wall of a blood vessel. Kyphon's products do not have a spherically shaped balloon. Instead, they have elongated balloons to maximize their ability to compact bone. Thus Medtronic is forced to argue, contrary to its position on the same issue in a prior case, that "spherical" does not really mean spherical, so that any catheter with an oval or elliptical balloon would satisfy the "spherical shape" limitation.

In addition to being reflected in the plain language of the asserted claims, these key features are the very things that purportedly distinguished these inventions from the prior art. During prosecution, Medtronic's predecessors told the Patent Office what their claimed inventions

were about, and what they were not about, in clear and unambiguous terms.[1] These statements show that the Saab patent does not encompass catheters with sleeves too thick to "collapse in the manner of [the] invention." These statements also confirm that the Barbere patents do not encompass catheters where the claimed connection between inner and outer tubes is "at" the Y-fitting (i.e., where the connection is the Y-fitting itself) and that the Preissman patent really does require balloons of a "spherical" rather than an oval, elliptical, or elongated shape.

Medtronic complains again and again that Kyphon reads limitations into the claims from the written description, preferred embodiments, and prosecution history, but just the opposite is true—Medtronic plainly reads limitations out of the claims. Saab's "collapsible" "sleeve," Barbere's "coaxial" shaft, and Preissman's "spherical" balloon are all explicit claim limitations. Construing claims so transparently to cover accused products, and so contrary to the import of the intrinsic evidence, is inappropriate and should be rejected.

II. Argument

A. Medtronic Reads the Collapsible Sleeve Out of the Saab Patent.

1. "Sleeve" and "Balloon" Do Not Mean the Same Thing.

Medtronic construes "sleeve" and "balloon" so as to permit "balloon" to be coextensive with "sleeve," and thus reads the sleeve limitation out of the claim.[2] But the sleeve and the balloon are two different, though related, things.

First, "sleeve" should be construed as "a tubular piece fitting over a rod or the like." Kyphon explained that this construction adopts the ordinary meaning of sleeve and is taken right from a dictionary. (Doc. No. 149 at 10 n.11.) Medtronic's proposed construction ("a structure that fits over another") ignores the plain meaning of "sleeve" and would broaden the term to anything that fits over another—not just a sleeve, but a hat as well. In the context of the Saab patent, which involves a *tubular* catheter, Medtronic's broad reading makes no sense and would provide the jury

[1] Indeed, as Kyphon pointed out in the briefs filed in connection with its Rule 11 motion, the inventors reiterated the same thing in their depositions in this case. Only Medtronic's lawyers construe these patents differently.

[2] Notably, Medtronic recognizes that a collapsible sleeve "is the key to the claim 1 invention." (Doc. No. 151 at 20.)

no guidance.

Second, Kyphon does not dispute that the "balloon" and "balloon portion" should be construed the same way, or that the sleeve is *integral* with the balloon.[3] (Doc. No. 151 at 17-19.) Kyphon proposes that both terms be construed as "formed *integrally* with, but . . . distinct from," each other. That two things are integral, however, does not mean they cannot also be *distinct*. Medtronic's contention that "nothing in the claim language precludes the 'sleeve' and the 'balloon/balloon portion' from being *unitary* and coextensive" (Doc. No. 151 at 18) ignores the claim language, which requires "*both*" a balloon "and" a sleeve, and reads the "sleeve" requirement right out of the claim. (*See* Doc. No. 149 at 8-10.)

2. During Prosecution, Saab Clearly and Unambiguously Disclaimed Sleeves Too Thick to Collapse as Required by the Invention.

None of Medtronic's many proffered arguments overcomes what Saab told the Patent Office in clear and unambiguous terms to disclaim sleeves having wall thicknesses greater than 0.0045 inches. Thus, as Kyphon's proposed construction makes clear, a "sleeve having a wall thickness of 0.0045 inches or more is not collapsible in the manner of the invention."

Medtronic's first argument—that there was no disclaimer because Saab distinguished Pope on other grounds (Doc. No. 151 at 20)—is contrary to law. *See, e.g.*, *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1374 (Fed. Cir. 2007) ("An applicant's invocation of multiple grounds for distinguishing a prior art reference does not immunize each of them from being used to construe the claim language. Rather, as we have made clear, an applicant's argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well."); *see also Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1477 n.* (Fed. Cir. 1998) (holding that when an applicant distinguishes a reference on multiple grounds, "any of those grounds may indicate the

[3] The authority on which Medtronic relies regarding the meaning of "integral" only confirms Kyphon's construction. (*See* Doc. No. 151 at 19 (citing *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1371 (Fed. Cir. 2006), as upholding a construction of "integral" as "formed as a unit").) *Vanguard* did not construe "integral" as "one single structure" as Medtronic contends. (Doc. No. 151 at 19.) That the sleeve and balloon are "integral," or formed as a unit, means they must be identifiably distinct parts of something rather than the very same thing.

proper construction of particular claim terms"). Likewise, Medtronic's argument that there was no disclaimer because Saab did not amend the claims in view of Pope (Doc. No. 151 at 20) is also contrary to law. The law does not require amendment of claims for prosecution history disclaimer to limit their scope. *See, e.g.*, *Seachange Int'l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1372- 73 (Fed. Cir. 2005) (stating only that a clear and unmistakable disavowal of scope during prosecution is required for prosecution disclaimer to limit the meaning of a claim term).

Medtronic's next argument—that "although the thickness of the Pope sleeve was mentioned [during prosecution], ... [t]here was no broad statement regarding the thickness of another sleeve" (Doc. No. 151 at 20)—fails on the facts. Saab broadly stated that "*such a* catheter" (not just "*the* Pope catheter") with thick walls would not collapse as required by his invention:

> [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*. . . . (Doc. No. 148, Ex. E at 7.)

Thus, according to Saab, *any* thick-walled catheter sleeve will not collapse in the manner of the invention, for there is no other reasonable way to interpret what was said.

Medtronic next argues that if comments during prosecution are ambiguous, no waiver occurs, and then declares that Saab's statements "are subject to different interpretations." (Doc. No. 151 at 21.) Yet Medtronic never says what these different reasonable interpretations could be, and, as Kyphon demonstrated, Medtronic's earlier arguments about the *size* of the catheter do not appear anywhere in the prosecution history and do not make sense. (*See* Doc. No. 149 at 11-12.) Simply put, Saab's statement that a catheter with a 0.0045 inches thick wall "would not collapse in the manner of applicant's invention" is a clear and unmistakable disclaimer.[4]

[4] Contrary to Medtronic's assertion, *3M Innovative Properties Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1373 (Fed. Cir. 2003), has nothing to do with this case. (*See* Doc No. 151 at 20-21.) Medtronic does not explain why Saab's disclaimer was purportedly "broader than necessary to distinguish the prior art," but nonetheless inexplicably declares "that is precisely the case here." (Doc. No. 151 at 20.) Saab stated explicitly that sleeves greater than 0.0045 inches are not collapsible in the manner of his invention. This statement is specific, not broad.

Medtronic also argues that, even in the face of the prosecution history, the scope of the Saab patent could not have been limited because the term "collapsible about the shaft" has been "clearly defined in the specification," and "defines a diameter that is effectively the same as that of the distal shaft extension." (Doc. No. 151 at 20.) Medtronic cites no case law to support the proposition that disclaimers during prosecution can be negated by a "definition" in the specification. To the contrary, statements made during prosecution may limit or negate broader disclosures in the specification. See, e.g., Fantasy Sports Props., Inc. v. Sportsline.com, Inc., 287 F.3d 1108, 1115-16 (Fed. Cir. 2002) (holding that although dependent claims attempt to further define a term, that definition is overcome by Fantasy's disclaimer of subject matter in the prosecution history).

Finally, Medtronic's claim differentiation argument based on dependent claim 19 is a non-starter. Claim 19 requires a wall thickness "no greater than about 0.0005 [inches]," not "no greater than 0.0045 inches." Thus, the claims have different scope under Kyphon's constructions.

3. Medtronic Also Reads Other Features Out of the Saab Patent.

Medtronic incorrectly contends that Kyphon did not propose an "alternative plain and ordinary meaning" for the term "dilatation catheter" and that Kyphon does not dispute Medtronic's construction. (Doc. No. 151 at 9, 12.) Kyphon opposes Medtronic's construction because it reads "dilatation" entirely out of the claim. Medtronic continues to argue that the term is not a limitation because it appears in the preamble (*see* Doc. No. 151 at 9-15),[5] but "*a* dilatation catheter" provides antecedent basis for "*the* catheter" that appears in the body of the claim. *See NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1306 (Fed. Cir. 2005) ("When 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." (internal quotation omitted)); *Electro Sci. Indus. v. Dynamic Details, Inc.*, 307 F.3d 1343, 1348 (Fed. Cir. 2002) ("References throughout the rest of the claim to 'circuit boards' rely upon and derive antecedent basis from this preamble language. Therefore, this preamble definition limits the term 'circuit boards' throughout

[5] Medtronic contends that Kyphon failed to address the cases cited by Medtronic (Doc. No. 151 at 10), but Kyphon did so on page 7 of its brief (Doc. No. 149 at 7).

the claim."); *Rapoport v. Dement*, 254 F.3d 1053, 1059 (Fed. Cir. 2001) ("[W]ithout treating the phrase 'treatment of sleep apneas' as a claim limitation, the phrase 'to a patient in need of such treatment' would not have a proper antecedent basis.").[6] The prosecution history also supports Kyphon's proposed construction of "dilatation catheter" because Saab *confirmed* the plain meaning of the term by distinguishing his invention from the prior art based on field of use.

B. Medtronic Reads the Critical Attachment Out of the Barbere Patents.

1. The Patents Require an Attachment Between the Proximal Region and the Distal Connection of the Catheter Shaft.

Medtronic's constructions of the attachment-related terms throw out the key to Barbere's invention—an additional attachment between the two existing and obvious connections at both ends of the catheter. Kyphon, however, does not construe any disputed claim language as an "additional" or "extra" attachment, as Medtronic wrongly suggests (Doc. No. 151 at 21), but instead construes the terms "catheter shaft" and "proximal region" language in accord with their plain meaning and other intrinsic evidence.

First, "catheter shaft" should be construed as "the portion of the catheter distal to the Y-fitting (or equivalent thereof) formed from the inner tube and the coaxial outer tube." This is the plain meaning of the term. It is straightforward that the "catheter shaft" does not include the catheter's Y-fitting as Medtronic contends because the catheter's Y-fitting is a *branched connector*, not a *single shaft* formed of *coaxial tubes*. Since the claim itself defines the shaft as "formed from" coaxial tubes, and since the "Y" part of the Y-fitting is formed from branched arms, *not* coaxial tubes, plain logic and fundamental claim interpretation principles demand that the Y-fitting cannot be part of the catheter shaft as that "shaft" is *claimed*.

The drawings and specification compel this construction. Figure 1 shows a catheter which "includes a shaft, indicated generally at 10. The catheter has a proximal end 12 . . . ." (Doc. No.

[6] The authorities Medtronic cites are inapposite. (Doc. No. 151 at 9-10.) In *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801 (Fed. Cir. 2002), the phrase at issue appeared only in the preamble and not in the body of claim 1 of the patent-in-suit, and the district court had construed the phrase without discussing whether it was actually a limitation of that claim. *Id.* at 807-08. Likewise, in *IMS Tech., Inc. v. Hass Automation, Inc.*, 206 F.3d 1422, 1434 (Fed. Cir. 2000), the term at issue was not found in the body of the claim—instead, it only appeared in the preamble. *IMS*, 206 F.3d at 1427-28.

148, Ex. C at 3:29-30.) As the figure plainly shows, the shaft 10 consists of the coaxial tubes; it does not include the Y-fitting 26. Conversely, no portion of the catheter "upstream" or to the left of the Y-fitting in Figure1 is ever described as the catheter "shaft"; instead, the inputs to the Y-fitting are always called "proximal tubes," and they connect (via the Y-fitting) to the coaxial tubes which make up the catheter shaft. (*Id*. at 3:54-63.) The intrinsic evidence thus squares perfectly with common sense and Kyphon's construction, but not Medtronic's construction.

Second, and for the same reasons, "proximal region" of the catheter shaft should be construed as "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." This is the plain meaning of the "proximal region" of the catheter shaft—the region that is more proximal than the distal region. There is also no dispute that the "proximal region" refers to the proximal region of the shaft itself, but, as shown, Medtronic wrongly contends that the shaft includes the Y-fitting. Here again the specification is consistent only with Kyphon's construction—the Y-fitting is described as being at the proximal end of the *catheter*, but never as being part of the catheter *shaft's* proximate end. (*Id*. at 3:31 ("[T]he catheter has a proximal end 12."); *id*. at 3:54-57 ("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.").)

Medtronic argues that "catheter shaft" and "proximal region" must mean something other than their plain meanings because the examiner "gave public notice that the 'catheter shaft' . . . include[s] the Y-fitting" (Doc. No. 151 at 22) but this argument fails for several reasons. First, no amount of prosecution history can justify ignoring an express limitation in a claim and thus *broaden* the claim beyond what it says it encompasses. Were that the law, claim language could often be rendered meaningless by comments during prosecution that sought to broaden the invention's scope. Second, Medtronic actually misrepresents the examiner's statements. (Doc. No. 151 at 22-23, 25; Doc. 133 at 26 (contending that the examiner "*expressly defined* the 'proximal region' as 'at the extreme proximal end,' 'a miniscule sliver,' and 'adjacent the proximal end.'").) For example, the examiner did not "expressly define" "proximal region" as a "miniscule sliver," as

Medtronic contends. Instead, in an amendment, Barbere said, in the context of the Patent Office's claim interpretation standard (which is much broader than the standard this Court is now to apply), "[t]he Examiner explained during the interview that despite the explicit language *in the Yock patent* . . . a minuscule sliver of the attachment *could be considered* 'a proximal region' and the remaining attachment could be considered distal of this proximal region." (Ex. L ['856 history, 6/26/00 Amend.] at 7 (emphasis added)). Medtronic does not address the different claim construction standards used during prosecution versus during litigation, which more than explain the approach the Patent Office took.

Moreover, the law (including cases on which Medtronic relies)[7] shows that it is the *applicant's* statements during prosecution that are controlling, not the examiner's. (*See* Doc. No. 149 at 18-19 (discussing *Springs Window Fashions LP v. Novo Industries, L.P.*, 323 F.3d 989, 993-95 (Fed. Cir. 2003);[8] *Laitram Corp. v. Morehouse Indus., Inc.*, 143 F.3d 1456, 1462 (Fed. Cir. 1998)); *see also* Doc. No. 149 at 19 (discussing *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1327-30 (Fed. Cir. 2001).) Here, Barbere's explicit statements show conclusively that the attachment required by the patents is not "at" the Y-fitting, but instead is "between" the Y-fitting and the distal end of the catheter shaft. Barbere's detailed, consistent, and repeated statements during prosecution all confirm Kyphon's constructions and contradict Medtronic's. (*See* Doc. No. 149 at 16-18.)

In addition to the statements Barbere made during the prosecution of the '191 patent, Barbere made it plain during the prosecution of the '856 patent that (1) he meant a "coaxial" shaft

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[7] Kyphon apologizes for mistakenly addressing a case not cited by Medtronic in its responsive brief (Doc. No. 151 at 25), but the *Inverness* case on which Medtronic relies does not help its cause. *See Inverness Medical Switzerland GmbH v. Princeton Biomeditech Corp.*, 309 F.3d 1365, 1372-73 (Fed. Cir. 2002). Although the Federal Circuit held that the applicant's statements were not sufficiently clear and unambiguous to deviate from the ordinary meaning of the claim term in that case, *id*. at 1372, here, the ordinary meaning of the disputed claim terms *and* Barbere's statements distancing the invention from connections "at" the Y-fitting *both* support Kyphon's constructions of "catheter shaft" and "proximal region."

[8] Medtronic wrongly suggests that *Springs Window Fashions* is no longer good law because *Pall Corp. v. PTI Techs. Inc.*, 259 F.3d 1383, 1392 (Fed. Cir. 2001), was vacated by the Supreme Court. (*See* Doc. No. 151 at 24.) The Supreme Court did so in light of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), *see PTI Techs., Inc. v. Pall Corp. Techs., Inc.*, 535 U.S. 1109 (2002), but this does not impact the authority of *Springs Window Fashions*.

when he claimed it and (2) the claims do not cover an attachment at the proximal end of that coaxial shaft, by the way in which he described the prior art and then differentiated his invention from their structure. (*See, e.g.,* Ex. L at 9 MEDC000548] ("The insert (16) of the [prior art] Burns patent is located *at the proximal end* **of the coaxial arrangement**, not distally of the proximal end." (italics in original, bolding added)); *id.* at 10 [MEDC000549] ("As discussed with the reference to the [prior art] Burns patent, the attachment between the outer and inner tubes in the [prior art] Yock [reference] occurs *at the proximal end* **of the coaxial arrangement**." (italics in original, bolding added)). In sum, once it is recognized that the Y-fitting cannot be part of the "coaxial" shaft, the remaining claim construction issues become straightforward.

2. Medtronic Also Reads Other Features Out of the Barbere Patents.

a. "Balloon Dilatation Catheter"

As with the Saab patent, Medtronic's construction of "balloon dilatation catheter" incorrectly reads the "dilatation" requirement out of the claim, even though the term constitutes a limitation. Moreover, as with the Saab patent, the prosecution history lends additional support to Kyphon's proposed construction. Barbere distinguished Corday on an even narrower basis than vascular versus non-vascular field of use. Specifically, Barbere distinguished Corday because it disclosed a *retroperfusion* catheter for *sealing* blood vessels rather than a *dilatation* catheter for *dilating* blood vessels to unblock a stenosis. (Doc. No. 149 at 13.) Medtronic attempts to avoid this statement by focusing on other bases for distinction (i.e., that Corday does not disclose a coaxial catheter), but again, it is what Barbere said that matters. And Medtronic cites no authority for its dubious argument that statements made in response to a rejection pursuant to 35 U.S.C. § 103 rather than 35 U.S.C. § 102 are entitled to less weight. (*See* Doc. No. 151 at 14-15.)

b. "Guidewire Lumen"

The Court should reject Medtronic's attempt to read the "guidewire" limitation out of the asserted claims. "Guidewire lumen" is not defined in the claim itself as Medtronic contends[9] (Doc. No. 151 at 26), and it is incorrect to construe "guidewire lumen" simply as "lumen."

[9] The claim language that Medtronic quotes means only that the claim requires a "guidewire lumen"—it does not define the term.

Medtronic states that Kyphon's construction of "guidewire lumen" as "adapted to receive a guidewire does not mean that the device must have a guidewire." (Doc. No. 151 at 26.) Kyphon agrees, and said so explicitly in its responsive brief. (Doc. No. 149 at 18 n.17 ("Kyphon does not contend that a guidewire itself has to be provided with the catheter . . . .").)

c. "Means for Accessing"

Medtronic fails to rebut the presumption that these phrases are means-plus-function elements. As such, they require structure in addition to the lumens (and the openings at their ends) that are already claimed. Medtronic agrees with Kyphon that the function is accessing the inflation lumen (in both patents) and also the guidewire lumen (in the '856 patent), but contends that the phrases do not need to be construed pursuant to 35 U.S.C. § 112, ¶ 6 because the claims disclose sufficient structure for performing the "accessing" function. (*See* Doc. No. 151 at 30.) The claims do not disclose *any* structure for performing this function, however, let alone *sufficient* structure.[10] As Kyphon explained, "'[o]penings' alone" are not sufficient structure disclosed in the claim so as to not construe these phrases in accordance with 35 U.S.C. § 112, ¶ 6.[11] (Doc. No. 149 at 20.) *See Personalized Media Commc'ns, LLC v. ITC*, 161 F.3d 696, 703 (Fed. Cir. 1998) (explaining that, in deciding whether the presumption has been rebutted, "the focus remains on whether the claim as properly construed recites sufficiently definite structure to avoid the ambit of § 112 ¶ 6"). Moreover, sufficient structure must be disclosed with the claim element itself rather than elsewhere in the claim to remove a "means" element from the reach of 35 U.S.C. § 112, ¶ 6.

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[10] The *ASM* case does not support Medtronic. (*See* Doc. No. 151 at 31 (faulting Kyphon for not discussing *ASM America, Inc. v. Genus, Inc*., 260 F. Supp. 2d 827, 863 (N.D. Cal. 2002).) In *ASM*, the defendant argued that sufficient structure was not disclosed in the specification, and that, for this reason, the claim was invalid as indefinite. *See id*. at 861. Here, sufficient structure is set forth in the patent. Further, in *ASM* the claim had been amended to add sufficient structure such that it was no longer subject to 35 U.S.C. § 112, ¶ 6—i.e., the claim included additional words describing the structure that performed the claimed function. *ASM America*, 260 F. Supp. 2d at 862. Thus, the court held that "[t]he claim, as issued, now contains specific limitations describing the structure of the gas flow means." *Id*. The case certainly did not hold that, in general, "an aperture provides sufficient structure to remove a term from the means-plus-function analysis" as Medtronic contends. (*See* Doc. 151 at 31.)

[11] Further, Medtronic's argument based on other claims of the '856 patent—"the fact that the 'means' for accessing at issue is addressed in claims 6 and 7 as an opening"—is nonsensical. (*See* Doc. No. 151 at 31.) Claims 6 and 7 do not define the "means" set forth in the asserted claims.

See, e.g., *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531 (Fed. Cir. 1996) ("To invoke this statute, the alleged means-plus-function claim *element* must not recite a definite structure which performs the described function."). Medtronic can point to no claim language in the "means for accessing" element that would constitute the requisite structure.

It is clear from the specification that the corresponding structure for performing the claimed function is a Y-fitting and a pair of flexible proximal tubes.[12] (*See* Doc. No. 148, Ex. B at 3:54-63.) Medtronic contends that the corresponding structure is "the openings at the proximal end of the Y-fitting, not the Y-fitting itself." (Doc. 151 at 31.) But openings at the end of the Y-fitting cannot exist without the Y-fitting. Medtronic also contends that the examiner "defined the 'proximal end of the catheter' as the proximal end of the Y-fitting" (Doc. No. 151 at 31 (citing Doc. No. 133 at 36-38)), but the examiner was referring to the Simpson patent, not Barbere's invention. Moreover, the fact that Simpson did not have proximal tubes has nothing to do with whether proximal tubes are part of the corresponding structure disclosed in *Barbere's* specification, which they are.

d. "Means for Communicating" and the "Aperture" Means

The Court should reject Medtronic's constructions of these limitations, which attempt to read them out of the asserted claims. Because the Barbere patents require an attachment between the inner and outer tubes in between the proximal and distal connections, the patents also require a way for the inner and outer lumens to communicate.[13] And this way is clearly spelled out in the patents. Claim 1 of the '191 patent requires a "means for communicating the annular inflation lumen with the interior of the balloon to facilitate inflation and deflation of the balloon . . ." This is a means-plus-function element, and corresponding structure is set forth clearly in the

[12] Kyphon's construction is not wrong because it does not refer to structural equivalents, as Medtronic contends. (*See* Doc. No. 151 at 31-32.) Kyphon agrees that the means-plus-function limitations encompass structures equivalent to those disclosed, but what is equivalent to the structures disclosed is a *question of fact*, i.e., an issue of infringement rather than claim construction. *See, e.g.*, *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1430 (Fed. Cir. 2000).

[13] Kyphon does not suggest that claim 1 requires an attachment that must "plug" the inflation lumen, and therefore does not read in an additional limitation, as Medtronic suggests. (*See* Doc. No. 151 at 28.)

specification. Claim 9 of the '856 patent also requires a "means for communicating the annular inflation lumen with an interior of the balloon," but, unlike claim 1 of the '191 patent, sets forth corresponding structure within the claim itself: "at least one aperture associated with the outer tube to facilitate inflation and deflation of the balloon."

First, the "means for communicating" element in the '191 patent must be construed pursuant to 35 U.S.C. § 112, ¶ 6 for the same reasons set forth above. The structure of "an opening associated with the outer tube within the balloon" that Medtronic proposes is nowhere to be found in claim 1, and the corresponding structure is set forth in the specification: "a pair of circumferentially spaced apertures are formed in the wall of the outer tube within the balloon." (Doc. No. 148, Ex. B at 4:18-23; *see also* Fig. 2 (40).) Medtronic even admits that this is the associated structure.[14] (*See* Doc. No. 151 at 28 (citing the '191 patent at 4:18-23).) Because claim 1 already requires "an annular inflation lumen" between the coaxial inner and outer tubes and because what Medtronic calls "an opening" is merely the end of the lumen, the end of the lumen cannot also be the required "means for communicating the annular inflation lumen with the interior of the balloon." Barbere claimed *both* an "annular inflation lumen" and a "means for communicating" this lumen. Claim differentiation (between claims 1 and 3) again has no role here because of the differences in scope even when claim 1 is interpreted under 35 U.S.C. § 112, ¶ 6.

Second, the "aperture" limitation in the '856 patent should be construed as "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." Here, both parties agree that structure is disclosed in the claim language, but again, Medtronic attempts to read this limitation out of the claim by construing it as part of what is already claimed—the end of the interior passage of the outer tube. Medtronic also attempts to justify its construction of this term by its construction of the related

[14] Medtronic attempts to escape this fact by suggesting that "[o]nly the corresponding structure necessary to perform the function is the corresponding structure," in reliance on *Omega Engineering, Inc, v. Raytek Corp*., 334 F.3d 1314, 1321 (Fed. Cir. 2003). (Doc. No. 151 at 29.) *Omega* simply explained that only clearly associated structure (rather than unnecessary and unassociated structure) in the specification is corresponding. There is no dispute that the structure to which Kyphon points is clearly associated.

means-plus-function element in the '191 patent,[15] but as shown, both of Medtronic's constructions read a requirement out of the claims.

C. Medtronic Reads the Spherically Shaped Balloon Out of the Preissman Patent.

Medtronic attempts to broaden "spherical" to mean "oval or elliptical," but the term "spherical shape" should be construed as "a shape that is spherical like a globe or a basketball," based on its plain meaning as well as the prosecution history. This construction does not require a "perfect three-dimensional sphere" as Medtronic claims. (Doc. No. 151 at 15.) Instead, Kyphon simply attempts to define this claimed shape in a real-world manner by equating it to readily identifiable examples of spherically shaped objects. In addition, Kyphon's construction is appropriately based on the prior Medtronic case concerning the very same ordinary term "spherical," when Medtronic agreed with the very same real-world examples of spherical shapes. (*See* Doc. No. 149 at 23, Ex. J.)

Kyphon does not mischaracterize Medtronic's proposed constructions. In its opening brief, Medtronic explicitly equated "an oval or elliptical shape" with Medtronic's proposed construction of a "'sphere-like' shape." (Doc. No. 133 at 13; *see also id.* at 12 (referring to Figure 1 as "more of an oval or ellipsis").) Medtronic may not have used the words "football" or "blimp" (which Kyphon used to simply contrast "globe or basketball"), but Medtronic does not say that its construction excludes such shapes. Indeed, Medtronic goes so far as to say that its construction only excludes "cylindrical" shapes. Medtronic does not say that its construction excludes "oval or elliptical" shapes. (*See* Doc. No. 151 at 16.) Medtronic's proposed construction includes these shapes, and, for this reason, is improper.

Moreover, Figure 1 neither supports Medtronic's construction nor detracts from Kyphon's construction. First, Medtronic cannot properly rely on Figure 1 as a matter of law because of the lack of precision associated with patent drawings. (*See* Doc. No. 149 at 23.) Second, even if Kyphon's construction did have the effect of reading out the preferred embodiment, which

[15] Kyphon was far from silent on the issue of these related phrases in the two Barbere patents as Medtronic contends. (*See* Doc. No. 151 at 33.) Instead, Kyphon discussed the elements together and proposed that they be construed consistently. (*See* Doc. No. 23 at 21-22.)

Kyphon does not concede, this would not mean that Kyphon's construction is incorrect. The Federal Circuit has held that when there is a clear disclaimer during the prosecution history, it is appropriate to read out preferred embodiments. *See N. Am. Container, Inc. v. Plastipak Packaging, Inc*., 415 F.3d 1335, 1345 (Fed. Cir. 2005); *Rheox, Inc. v. Entact, Inc*., 276 F.3d 1319, 1320-27 (Fed. Cir. 2002); *Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc.*, 214 F.3d 1302, 1308 (Fed. Cir. 2000). Here, the applicants disclaimed any broader meaning of "spherical shape" during prosecution through the very real emphasis they placed on the properties of a sphere and how these properties would provide advantages that other shapes would not. The prosecution history does not demonstrate that the applicants simply argued that any non-cylindrical shape would provide the advantages of the invention. Instead, the applicants were very clear that it was the spherical shape in particular that provided all of the advantages.

The applicants for the Preissman patent added the "spherical shape" limitation as a last-ditch effort to obtain a patent during a continuation application after a final rejection. The terms "globe" and "basketball" do not appear in the written description as Medtronic emphasizes (Doc. No. 151 at 16), but neither does the term "spherical shape." As Kyphon has demonstrated, the examiner allowed the claims because no prior art of record disclosed a balloon with a "spherical shape." Thus, the meaning of "spherical" is not as broad as Medtronic contends.

III. Conclusion

For the reasons set forth above and its responsive brief, Kyphon respectfully requests that the Court construe the disputed claim terms as Kyphon proposes.

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