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

MEDTRONIC VASCULAR INC., et al,
Plaintiffs.
v.
BOSTON SCIENTIFIC CORP., et al,
Defendants.

Civil Action No. 2:06-CV-78

Dec. 13, 2007.

Background: Parties sought construction of claim terms in suit alleging infringement of patents describing a new design for a balloon dilation catheter commonly used in angioplasty procedures.

Holdings: The District Court, T. John Ward, J., held that:
(1) term "guide wire tube" meant a tube for passage of a guide wire;
(2) term "balloon" did not provide sufficient textual reference to include sterilization process; and
(3) elastic stress response was limited to the conditions under which the measurement was made.

Claims construed.

6,190,358, 6,210,364, 6,283,939, 6,605,057. Construed.

Samuel Franklin Baxter, McKool Smith, Marshall, TX, Bradley Wayne Caldwell, Jason Dodd Cassady, Mark L. Mathie, Theodore Stevenson, III, Thomas Guy Fasone, III, McKool Smith, Dallas, TX, Joshua Wright Budwin, McKool Smith, Austin, TX, for Plaintiffs.

Edward Han, John E. Nilsson, Mark Douglas Wegener, Matthew M. Wolf, Howrey, LLP, Washington, DC, Elizabeth L. Derieux, Sidney Calvin Capshaw, III, Brown McCarroll, Longview, TX, Georgianna L. Witt, Howrey, LLP, Houston, TX, Robert E. McAlhany, Jr., Howrey, LLP, East Palo Alto, CA, Wallace Wu, Howrey, LLP, Los Angeles, CA, for Defendants.

MEMORANDUM OPINION AND ORDER

T. JOHN WARD**, District Judge.**

After considering the submissions and the arguments of counsel, the Court issues the following order concerning the claim construction issues:

I. Introduction

Plaintiffs Medtronic Vascular, Inc., Medtronic USA, Inc., Medronic Inc., and Medtronic Vascular Galway (collectively, "plaintiffs") accuse Defendants Boston Scientific Corp., Scimed Life Systems, Inc. and Boston Scientific Scimed, Inc. (collectively, "defendants") of infringing claims of United States Patent Nos. 6,190,358 ("the '358 patent"), 6,605,057 ("the '057 patent"), 6,210364 ("the '364 patent"), and 6,283,939 ("the "9 patent"). The ' 057 patent is a continuation of the '358 patent and are collectively referred to as "the Fitzmaurice patents." The "9 patent is a continuation of the '364 patent and are collectively referred to as "the Anderson patents."

II. Background of the Technology

A. The Fitzmaurice Patents (the '358 patent and '057 patent)

The Fitzmaurice patents describe a new design for a balloon dilation catheter. A balloon dilation catheter is commonly used in angioplasty procedures which are performed to treat coronary artery disease. Angioplasty involves the insertion of a balloon dilation catheter into a patient. A guide wire, a flexible and thin wire, is first used to locate the obstructed artery. The balloon catheter with a guide wire lumen, a lengthwise passageway, is pushed over the guide wire and positioned in the appropriate location. The balloon at the end of the catheter is then inflated which pushes the plaque against the artery wall. This opens the blockage and increases the blood flow through the artery.

In general, the new design described in the patents involves two inventive aspects-1) reducing the amount of blood that enters the guide wire lumen, and 2) improving the way a stiffening wire is attached to the inside of the catheter. FN1

FN1. The claims involving specific methods for attaching a stiffening wire to a catheter are not being asserted in this case.

B. The Anderson Patents (the '364 patent and "9 patent)

The Anderson patents relate to the materials and properties of the balloons used as a component of balloon dilation catheters. Dilation catheter balloons traditionally fall into two groups: compliant (possessing a high distensibility, i.e. can expand well beyond their nominal diameter when inflated) and noncomplaint (possessing a high "elastic stress response," i.e. they can be repeatedly expanded without substantially increasing their nominal diameter). The Anderson patents are directed to balloons that exhibit the advantage of a high elastic stress response (as found in noncompliant balloons) combined with the advantage of high distensibility (as found in compliant balloons).

III. General Principles Governing Claim Construction

"A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using or selling the protected invention." Burke, Inc. v. Bruno Indep. Living Aids, Inc., 183 F.3d 1334, 1340 (Fed.Cir.1999). Claim construction is an issue of law for the court to decide. Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

To ascertain the meaning of claims, the court looks to three primary sources: the claims, the specification, and the prosecution history. Markman, 52 F.3d at 979. Under the patent law, the specification must contain a written description of the invention that enables one of ordinary skill in the art to make and use the invention. A patent's claims must be read in view of the specification, of which they are a part. Id. For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. Id. "One purpose for examining the specification is to determine if the patentee has limited the scope of the claims." Watts v. XL Sys., Inc., 232 F.3d 877, 882 (Fed.Cir.2000).

Nonetheless, it is the function of the claims, not the specification, to set forth the limits of the patentee's claims. Otherwise, there would be no need for claims. SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 (Fed.Cir.1985) (en banc). The patentee is free to be his own lexicographer, but any special definition given to a word must be clearly set forth in the specification. Intellicall, Inc. v. Phonometrics, 952 F.2d 1384, 1388 (Fed.Cir.1992). And, although the specification may indicate that certain embodiments are preferred, particular embodiments appearing in the specification will not be read into the claims when the claim language is broader than the embodiments. Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (Fed.Cir.1994).

This court's claim construction decision must be informed by the Federal Circuit's decision in Phillips v. AWH Corporation, 415 F.3d 1303 (Fed.Cir.2005) (en banc). In Phillips, the court set forth several guideposts that courts should follow when construing claims. In particular, the court reiterated that "the *claims* of a patent define the invention to which the patentee is entitled the right to exclude." 415 F.3d at 1312 (emphasis added) (*quoting* Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed.Cir.2004)). To that end, the words used in a claim are generally given their ordinary and customary meaning. Id. The ordinary and customary meaning of a claim term "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. at 1313. This principle of patent law flows naturally from the recognition that inventors are usually persons who are skilled in the field of the invention. The patent is addressed to and intended to be read by others skilled in the particular art. Id.

The primacy of claim terms notwithstanding, Phillips made clear that "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. Although the claims themselves may provide guidance as to the meaning of particular terms, those terms are part of "a fully integrated written instrument." Id. at 1315 (*quoting* Markman, 52 F.3d at 978). Thus, the Phillips court emphasized the specification as being the primary basis for construing the claims. Id. at 1314-17. As the Supreme Court stated long ago, "in case of doubt or ambiguity it is proper in all cases to refer back to the descriptive portions of the specification to aid in solving the doubt or in ascertaining the true intent and meaning of the language employed in the claims." Bates v. Coe, 98 U.S. 31, 38, 8 Otto 31, 25 L.Ed. 68 (1878). In addressing the role of the specification, the Phillips court quoted with approval its earlier observations from Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998):

Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

Consequently, Phillips emphasized the important role the specification plays in the claim construction process.

The prosecution history also continues to play an important role in claim interpretation. The prosecution history helps to demonstrate how the inventor and the PTO understood the patent. Phillips, 415 F.3d at 1317. Because the file history, however, "represents an ongoing negotiation between the PTO and the applicant," it may lack the clarity of the specification and thus be less useful in claim construction proceedings. Id. Nevertheless, the prosecution history is intrinsic evidence. That evidence is relevant to the determination of how the inventor understood the invention and whether the inventor limited the invention during prosecution by narrowing the scope of the claims.

Phillips rejected any claim construction approach that sacrificed the intrinsic record in favor of extrinsic evidence, such as dictionary definitions or expert testimony. The *en banc* court condemned the suggestion made by Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed.Cir.2002), that a court should discern the ordinary meaning of the claim terms (through dictionaries or otherwise) before resorting to the specification for certain limited purposes. Id. at 1319-24. The approach suggested by Texas Digital-the assignment of a limited role to the specification-was rejected as inconsistent with decisions holding the specification to be the best guide to the meaning of a disputed term. Id. at 1320-21. According to Phillips, reliance on dictionary definitions at the expense of the specification had the effect of "focus[ing] the inquiry on the abstract meaning of words rather than on the meaning of the claim terms within the context of the patent." Id. at 1321. Phillips emphasized that the patent system is based on the proposition that the claims cover only the invented subject matter. Id. What is described in the claims flows from the statutory requirement imposed on the patentee to describe and particularly claim what he or she has invented. Id. The definitions found in dictionaries, however, often flow from the editors' objective of assembling all of the possible definitions for a word. Id. at 1321-22.

Phillips does not preclude all uses of dictionaries in claim construction proceedings. Instead, the court assigned dictionaries a role subordinate to the intrinsic record. In doing so, the court emphasized that claim construction issues are not resolved by any magic formula. The court did not impose any particular sequence of steps for a court to follow when it considers disputed claim language. Id. at 1323-25. Rather, Phillips held that a court must attach the appropriate weight to the intrinsic sources offered in support of a proposed claim construction, bearing in mind the general rule that the claims measure the scope of the patent grant. The court now turns to a discussion of the disputed claim terms.

IV. Terms in Dispute-Fitzmaurice Patents

A. Agreed Constructions

The parties have stipulated to the construction of the following terms in the claims:

"Distal" means "farther from the catheter operator."

"Proximal" means "closer to the catheter operator."

B. Disputed Constructions

1. "a distal portion of a first length"

The plaintiffs propose "the distal extremity of the guide wire tube in which the inner diameter is decreased in size for a short distance." The defendants propose that this term carry its plain meaning.

The plaintiffs propose the same construction as they advanced in *Medtronic AVE Inv., et al. v. Cordis Corp.*, 2:03-cv-212, ("the *Cordis* case"), and reassert that their proposed construction of this term is proper in light of SciMed Life Sys., Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337 (Fed.Cir.2001). The defendants do not present any arguments on this term in their briefing.

The court previously addressed this term in its Claim Construction Order issued on April 23, 2007 (Dkt # 229 in the *Cordis* case) ("the Cordis Order"). After carefully considering the arguments raised by the parties in this case, the court is not persuaded to alter its construction from the *Cordis* case. *See* Cordis Order at 8-10. Accordingly, the Court concludes that this term does not requires construction.

2. "a proximal portion of a second length longer than the first length"

The plaintiffs propose "a proximal section of the guide wire tube that is longer and has a larger inner diameter than the distal portion." The defendants propose that this term carry its plain meaning.

As with the term "a distal portion of a first length," the plaintiffs rest on their arguments made in the *Cordis* case (which include a similar SciMed argument), and present no new arguments. The defendants do not present any arguments on this term in their briefing.

The court declined to construe this term in the *Cordis* case. *See* Cordis Order at 10-11. After carefully considering the arguments raised by the parties in this case, the court is not persuaded to alter its decision from the *Cordis* case. Accordingly, the Court concludes that this term does not requires construction.

3. "guide wire tube" or "guide wire tube" FN2

FN2. The claims in the '358 patent uses the term "guide wire", while the claims in the '057 patent uses the term "guidewire." The parties agree that "guide wire" and "guidewire" are identical. For claim construction purposes, "guide wire" refers to both terms.

[1] The plaintiffs propose "a tube with an inner diameter that tapers between a proximal and distal portion." The defendants propose "a tube for passage of a guide wire with an inner and outer diameter that tapers between a proximal and a distal portion."

The plaintiffs raise two arguments in support of their construction: (1) under SciMed, the sole embodiment is the crux of the invention and the claims should be construed accordingly, and (2) claim 2 of the '358 patent adds the limitation that the outer diameter reduces or tapers, and therefore the doctrine of claim differentiation creates a presumption that this limitation is not in claim 1.

The court is not persuaded by the plaintiffs' argument that the claims should be construed according to the sole disclosed embodiment. *See* Cordis Order at 8-10. The plaintiffs' claim differentiation argument, however, has more merit. Claim 2, which depends from claim 1, adds the sole limitation that "the outer diameter of the distal portion of the guide wire tube is smaller than the outer diameter of the proximal portion of the guide wire tube." '358 Patent at 38-41. A construction of the term "guide wire tube" that requires the outer diameter to taper would render claim 2 meaningless.

The language in claim 2 that is directed to the outer surface of the guide wire tube is very similar to the language in claim 1 that refers to the guide wire lumen (which is created by the inner surface of the guide wire tube). Claim 1 states that "the lumen having a first diameter for the distal portion of the guide wire tube and a second diameter larger than the first diameter for the proximal portion of the guide wire tube." '358 Patent at 7:16-21. Both the plaintiffs' and defendants' proposed constructions, which require the inner diameter to taper, would render this express language of claim 1 superfluous. The patentee expressed the concept of "reduced or tapered" guide wire tube walls, both inner and outer, by using the language directed to the diameters of the distal and proximal portions. *See* '358 Patent at 2:60-61. Accordingly, "guide wire tube" means "a tube for passage of a guide wire."

4. "the lumen having a first diameter for the distal portion of the guide wire tube and a second diameter larger than the first diameter for the proximal portion of the guide wire tube"

[2] The plaintiffs propose that this term carry its plain meaning. The defendants propose "the lumen having a first diameter for the distal portion of the guide wire tube and a second diameter for the proximal portion of the guide wire tube that is greater than the first diameter such that a reservoir is created in the guide wire lumen."

The plaintiffs argue that this term is similar to the "proximal portion of a second length longer than the first length" term that the court declined to construe in the *Cordis* case. *See* Cordis Order at 10-11.

The defendants argue that according to Phillips and SciMed "the claims cannot be read so broadly as to cover balloon catheters without such a 'reservoir.' " Defendants' Response Brief at 4. The defendants provide three arguments in support of this construction. First, the lone embodiment of the patent, as shown in Fig. 7, includes a reservoir. The brief description of the drawings states that the Fig. 7 shows "the reservoir formed inside the guide wire lumen." '358 Patent at 3:21-22. The defendants cite to the plaintiffs' brief in the *Cordis* case, as well as the plaintiffs' expert's declaration in the *Cordis* case, to show that the plaintiffs agree that there is only one disclosed embodiment. Defendants' Response Brief at 4-5 (citing Plaintiffs' Opening Brief in the *Cordis* case at 7).

Second, the defendants argue that the prosecution history makes it "clear that the large diameter portion of the claimed guide wire lumen must form a 'reservoir.' " Defendants' Response Brief at 5. The statements that the defendants point to in the prosecution history are contained in excerpts from the inventor's notebook. As an example, the inventor's notebook contains a statement that "[t]he larger diameter lumen acts as a reservoir supplying heparin lubricant to the tip of the catheter." *Id*. at 5-6 (citing Wu Decl. Ex. 9 at MEDBSC00002727).

Finally, the defendants argue that the plaintiffs' statements to this court in the *Cordis* case result in the plaintiffs being judicially estopped from arguing that "the guide wire lumen need not possess a reservoir." *Id*. at 7. The statements relied on by the defendants come from the plaintiffs' briefing in the *Cordis* case. *Id*. at 6.

It is noteworthy that the definition proposed by the defendants is nearly identical to the claim language with the addition of the limitation "that a reservoir is created in the guide wire lumen." Notwithstanding the plaintiffs' statements made in the *Cordis* case, the defendants' proposed construction results in improperly importing limitations from the specification. In essence, the defendants' argument boils down to asking this

court to limit the claims of the patent to the sole disclosed embodiment.

The court also notes that the language of claim 3 counsels against the defendants' proposed construction. Claim 3, which depends from claim 1, adds the limitation that "the guide wire lumen is adapted to receive an anticoagulant solution." '358 Patent at 7:43-45. Including the limitation of a reservoir in claim 1 as urged by the defendants would render claim 3 redundant.

With respect to the defendants' prosecution history argument, there is no evidence that the inventor made a clear and unmistakable disavowal of the claim scope. The inventor's notebook that contains the statements relied on by the defendants was provided by the prosecuting attorney to support an invention date that swore behind the reference relied on by the examiner.

The defendants' "judicial estoppel" argument is likewise unpersuasive. As this term was not in dispute in the *Cordis* case and the court did not address the issue of a reservoir, judicial estoppel simply does not apply here. New Hampshire v. Maine, 532 U.S. 742, 750-51, 121 S.Ct. 1808, 149 L.Ed.2d 968 (2001) (discussing the general considerations in applying judicial estoppel, which include: (1) a party taking a position "clearly inconsistent" with its earlier position; (2) the party's success in persuading a court to accept that earlier position, and (3) whether the party would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped).

This term is straightforward as written and will be easily understood. Therefore, no construction is needed.

5. "blood is substantially prevented from entering the proximal portion of the guide wire lumen"

The plaintiffs propose "blood from outside the catheter is substantially prevented from traveling through the distal portion of the guide wire tube into the proximal portion of the guide wire tube." The defendants do not offer any construction with respect to this term.

The plaintiffs request that the court revisit its decision in the *Cordis* case not to construe this term. No new arguments are presented in support. Rather, the plaintiffs reiterate that the "claims, specification, and logic do not suggest any correlation between the reduced diameter tip and any flow of blood into the catheter through the side or exit port." Plaintiffs' Opening Brief at 12. The defendants' response is silent.

After carefully considering the arguments raised, the court is not persuaded to alter its construction from the *Cordis* case. Accordingly, the Court concludes that this term does not requires construction.

6. "a less viscous anticoagulant is allowed to coat the surface of the guide wire within the distal portion of the guide wire lumen"

The plaintiffs propose "an anticoagulant composition, having less resistance to flow than blood, in the proximal portion of the guide wire tube is allowed to coat the surface of the guide wire in the distal portion of the guide wire tube." The defendants propose "a less viscous anticoagulant is allowed to fill and remain in the reservoir during the procedure so as to coat the surface of the guide wire within the distal portion of the guide wire lumen."

As with the "the lumen having a first diameter ..." term discussed above (disputed term # 4), the defendants argue that the court should read in a reservoir limitation. *See* Defendants' Response Brief at 7-11. In support of its construction, the defendants argue that statements in the patent and the prosecution history show that

the function of the wherein clause is to create a reservoir. The defendants also asserts that judicial estoppel applies.

For the same reasons discussed with respect to disputed term # 4 above, the defendants' arguments are unpersuasive. After carefully considering the arguments raised by the parties in this case, the court will not alter its construction from the *Cordis* case. *See* Cordis Order at 8-10. Accordingly, this term means "an anticoagulant composition, having less resistance to flow than blood, in the proximal portion of the guide wire tube is allowed to coat the surface of the guide wire in the distal portion of the guide wire tube."

7. "stiffening wire"

The plaintiffs propose "a thin and elongated metal structure that imparts stiffness to the catheter." The defendants propose "a thin and elongated solid metal structure that imparts stiffness to the catheter."

After carefully considering the arguments raised by the parties in this case, the court is not persuaded to alter its construction from the *Cordis* case. *See* Cordis Order at 8-10. Accordingly, "stiffening wire" means "a thin and elongated solid metal structure that imparts stiffness to the catheter."

8. "positioned within the catheter shaft"

The plaintiffs propose that this term carry its plain meaning. The defendants propose "connected at spaced locations to the inner wall of the catheter shaft."

The defendants argue that the patent never suggests or teaches that the stiffening wire would not be attached at all. In support, the defendants cite a few passages from the specification, including a statement in the Summary of Invention section: "[t]he stiffening wire is attached to the inner wall of the catheter shaft at a plurality of points along its length...." '358 Patent at 2:37-41.

The defendants' argument is not persuasive. Claim 6, which depends from claim 5, recites only one additional limitation: "the stiffening wire is attached to the inner wall of the catheter shaft at least two spaced locations." '358 Patent at 7:49-51. In light of claim 6, the meaning of "positioned within the catheter shaft" can be informed by the presumption of claim differentiation. Nothing in the intrinsic record rebuts this presumption.

This phrase is easily understood as written and no construction is needed.

V. Terms in Dispute-Anderson Patents

A. Agreed Constructions

The parties do not agree on any terms.

B. Disputed Constructions

1. a balloon

[3] This term appears in the '364 patent, but not in the "9 patent. The plaintiffs propose that this term carry its plain meaning. The defendants propose "a balloon sterilized by the sterilization process disclosed at

10:66-11:9 of the '364 patent, which consists of (1) a preconditioning step at a temperature about 35 to about 45 (deg.)C and a relative humidity of about 55% for about 15 hours, (2) then an ethylene oxide treatment step at a temperature of about 35 to about 45 (deg.)C and a relative humidity of about 55% with ethylene oxide for about 6 hours, and (3) then an aeration step at a temperature of about 35 to about 45 (deg.)C for about 22 hours in order to permit the ethylene oxide to dissipate."

The plaintiffs argue that the defendants seek to improperly import two limitations into the claim: (1) that the balloon must be sterilized, and (2) that the sterilization must occur by the sterilization method described in the specification.

According to the defendants, the proper claim construction for "balloon" (as well as "sterilized balloon" in the "9 patent, discussed infra) should include the sterilization process described in the specification ("the Anderson Process"). Defendant's Response Brief at 15-21. Numerous citations in the specification support the defendants' position that the "Anderson Process is critical." Id. at 15 (citing the '364 patent at 11:14-17 (the Anderson Process is "an important factor in determining the final physical characteristics of the balloons and balloon catheters of this invention"); 10:51-54 ("[i]n order to preserve a balloon's distensibility, elastic stress response, [and] wall tensile strength ..., the balloon formed must [ ] be subject to" the sterilization process disclosed); and 11:17-22 (the sterilization disclosed is "necessary to ensure a clinically useful and sale [sic] finished balloon and balloon catheter with an overall advantageous combination of physical properties ...")).

The defendants also point to statements made during the prosecution of the ' 939 patent that further express the importance of the sterilization process. For example, in remarks made to distinguish prior art the applicants stated that the balloons in the prior art "are not prepared by substantially the same process disclosed in Applicants' specification, namely the sterilization steps of the present invention, which give rise to the novel and unobvious properties of the claimed invention...." Wu Decl. Ex. 11 ["9 file history] at MEDBSC00004242-43.

The defendants further support their construction by pointing to a recently decided Federal Circuit case, Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361 (Fed.Cir.2007) (reading a process limitation into a claim for a product formed by the process). In Andersen, the court noted that the "specification [ ] indicates that the claimed physical properties of the composite structural members are attributable to the process that is used to make them." Id. at 1372. Since the '364 specification describes the use of the sterilization process as a requirement rather than a preference, the defendants argue that the term "balloon" should be limited to the process that created its properties. Id. at 1372-73.

The defendant further argues that the prosecution history is analogous to that in the Andersen case. As in this case, the applicant of the patent at issue in Andersen "clearly disclaimed structural members made through a direct extrusion process." Id. at 1373-74. Here, the applicants clearly distinguished their inventionfrom those balloons that underwent traditional sterilization.

At oral argument the plaintiffs argued that the term "balloon" alone is insufficient to provide a textual reference in the claim to associate the sterilization process. *See* MBO Laboratories, Inc. v. Becton, Dickinson & Co., 474 F.3d 1323, 1330-31 (Fed.Cir.2007). The MBO Labs court stated that "[n]one of the disputed terms ... can be reasonably be construed to impose the simultaneously-safety requirement." Id. at 1330. The court, however, recognized that the "patentee [in MBO Labs] has clearly indicated via the specification and the prosecution history that the invention provides, as an essential feature, immediate

needle safety upon removal from the patient." Id.

The court agrees that the term "balloon" does not provide sufficient textual reference to include the sterilization process. Accordingly, the term "balloon" does not need to be construed.

2. a sterilized balloon

This term appears in the "9 patent, but not in the '364 patent. The plaintiffs propose that this term carry its plain meaning. The defendants propose the same construction they advance for the term "balloon," above. The parties present nearly identical arguments for this limitation as they did for the term "balloon."

As an initial matter, the distinction between the groupings in the *Andersen* case does not apply to the distinction between "balloon" and "sterilized balloon." In Andersen, two groups of claims were at issue. The first group, or Group I, claimed "an intermediate composite capable of being extruded into structural members." Andersen, 474 F.3d at 1371. The second group, or Group II, claimed "the extruded structural members themselves." Id. The Federal Circuit held that the district court had properly limited the term "composite composition" in Group I to be in the form of either pellets or linear extrudate. The district court reasoned that because the Group II claims are directed to finished products they should not be limited to the characteristics of an intermediate material. The Federal Circuit, however, found that the district court erred by not also construing the term "composite structural member" in Group II to include "an intermediate step of pelletization or linear extrusion" given the intrinsic evidence. Id. at 1375. In this case, both the "balloon" claims and "sterilized balloon" claims are directed to finished products.

Rather, the issue before this court is whether there is sufficient "textual reference in the actual language of the claim with which to associate a proffered claim construction." Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed.Cir.1999). Unlike the term "balloon," the term "sterilized balloon" provides a clear association with the sterilization process described in the specification. With the addition of the term "sterilized," the claim explicitly recites a term in need of definition. *See* MBO Labs., 474 F.3d at 1330-31 (citations omitted). The specification unequivocally teaches the necessity of the Anderson Process of sterilization. *See, e.g.,* '364 patent at 11:17-22 (the sterilization disclosed is "necessary to ensure a clinically useful and sale[sic] finished balloon and balloon catheter with an overall advantageous combination of physical properties ...").

For these reasons, the court adopts the defendants' construction for "sterilized balloon." FN3

FN3. The court draws this distinction between the terms "balloon" and "sterilized balloon" after careful study of, and reliance on, both MBO Laboratories, Inc. v. Becton, Dickinson & Co., 474 F.3d 1323 (Fed.Cir.2007) and Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361 (Fed.Cir.2007). The Federal Circuit issued these opinions within two days of each other, and the panels included a common judge.

3. wherein the ratio of said hard segments to said soft segments is such as to provide

[4] The plaintiffs propose that this term carry its plain meaning. The defendants propose "wherein the ratio of said hard segments to said soft segments is substantially lower than 50% such as to provide."

The defendants admit that the specification does not disclose any specific values for the ratio between hard and soft segments in this block copolymer. Defendants' Response Brief at 23. To support its inclusion of the

"substantially lower than 50%" limitation, the defendants rely on statements made during prosecution to distinguish the present invention from U.S. Patent No. 4,950,239 ("the Gahara patent"). Id. at 23-26. Specifically, the applicant stated that the ratio was "considerably different" and "substantially lower than" that in the Gahara patent. Wu Decl. Ex. 16 at MEDBSC00003949. The "50%" comes from a passage in the Gahara patent's specification. Wu Decl. Ex. 17 at BSCMDT0112650 [Gahara Patent at 3:54-62] ("[t]he proportion of 'soft' segments derived from the component (b) in the polyurethane is advantageously in the range of about 2 to 50 percent preferably in the range of about 2 to 25 percent ...").

The plaintiffs argue that the applicants' statements distinguished the Gahara patent on the basis that it was directed to a noncompliant balloon. Plaintiffs' Reply Brief at 12. In addition, the plaintiffs argue that "the applicants' statements in the prosecution history relied on by [the defendants] are subject to multiple reasonable interpretations and thus no prosecution history estoppel should attach." Id. at 13.

The alleged disclaimer in the prosecution history, however, is too vague to support a limitation of "substantially lower than 50%." *See* Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323-25 (Fed.Cir.2003) ("where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender"). The prosecution statements do not attempt to quantify, but rather state that the applicant's invention differed from the prior art.

At oral argument, the defendants argued that under Phillips the court should look to the discussion in the prosecution history to inform the meaning of the claim term. Nothing in the patent, or the prosecution history, quantifies this ratio. The court declines defendants' invitation to import this numeric limitation from the specification of a prior art patent. Accordingly, the term does not need to be construed.

4. elastic stress response

[5] The plaintiffs propose "a measure of the elasticity of a balloon calculated using the equation [shown in the '364 patent at 5:8]." The defendants propose "a value calculated according to the definition provided at 4:66-5:13 of the '364 patent."

Both parties agree that the correct equation for the "elastic stress response" is:

***625**

$$\left[\frac{\text{Balloon diameter at 5 bars after inflation to 10bars}}{\text{Balloon diameter at initial 5 bar inflation}} - 1\right] \times 100$$

The disagreement between the parties is whether the claim should be limited to the conditions under which this measurement is made. The plaintiffs' proposal is that the term means the above equation without any qualification. The defendants argue that the following language from the specification should be used to define this term: "Elastic stress response is determined by inflating a balloon to 5 bars at about 37 (deg.)C

and measuring the balloon's diameter. The balloon is then inflated to a pressure of 10 bars in about 20 seconds and held for an additional 20 seconds at 37 (deg.)C. The balloon's diameter is then measured. The internal pressure of the balloon is then decreased to 5 bars and the 'new' 5 bar diameter of the balloons is determined." '364 Patent at 4:66-5:5.

The plaintiffs contend that the passage cited by the defendants is just an embodiment and it would be improper to read in these limitation since the defendants do "not even attempt to apply the SciMed test." Plaintiffs' Reply Brief at 14. The defendants argue that a construction consisting of only the equation would be a partial and incomplete construction.

The court agrees that "[a] reasonable reading of the entire paragraph starting at col. 4, line 66 of the '364 patent ... that the measurement conditions ... are part of the definition." Defendants' Response Brief at 28. The phrase "for this invention" precedes the formula; however, the formula's parameters are explicitly defined prior to this phrase. Reading the paragraph as a whole, the patentee has chosen to define a measurement in specific terms with specific test conditions. In other words, the patentee is his own lexicographer for the term "elastic stress response."

Accordingly, the term "elastic stress response" means "a value calculated using the equation [shown in the '364 patent at 5:8] determined by inflating a balloon to about 5 bars at or about normal human body temperature and measuring the balloon's diameter. The balloon is then inflated to a pressure of about 10 bars in about 20 seconds and held for about an additional 20 seconds at or about normal human body temperature. The balloon's diameter is then measured. The internal pressure of the balloon is then decreased to about 5 bars and the 'new' 5 bar diameter of the balloons is determined."

5. wall tensile strength

[6] The plaintiffs propose "the tensile strength of a balloon's wall calculated using the equation [shown in the '364 patent at 3:55]." The defendants propose "a value calculated according to the definition provided at 3:52-56 of the '364 patent ... the burst pressure is determined at 37 degrees C."

Both parties agree that the correct equation for the "wall tensile strength" is:

$$\left[\frac{(\text{burst pressure (psi)}) \times (\text{nominal balloon diameter})}{2 \times (\text{wall thickness})}\right]$$

As with "elastic stress response," the parties disagree on whether the temperature at which the burst pressure is determined is limiting. This is a case where the patentees acted as their own lexicographers. '364 patent 3 :47-61. Accordingly, the term "wall tensile strength" means "a value calculated according to the equation [shown in the '364 patent at 3:55] where the burst pressure is determined at or about normal human body temperature."

6. distensibility

The plaintiffs propose "the percent radial expansion of a balloon calculated using the equation [shown in the '364 patent at 4:15]." The defendants propose "a value calculated according to the definition provided at 4:12-18 of the '364 patent ... all measurements take place at about 37 degrees C."

Both parties agree that the correct equation for the "wall tensile strength" is:

$$\left[\frac{\text{Diameter of balloon at 10 bars}}{\text{Nominal balloon diameter}} - 1\right] \times 100\%$$

The arguments for this term are identical to the "wall tensile strength." Accordingly, the term "distensibility" means "a value calculated according to the equation [shown in the '364 patent at 4:15] where measurements are taken at or about normal human body temperature."

VI. Conclusion

The Court adopts the constructions set forth in this opinion for the disputed terms of the '358, '057, '364, and "9 patents. The parties are ordered that they may not refer, directly or indirectly, to each other's claim construction positions in the presence of the jury. Likewise, the parties are ordered to refrain from mentioning any portion of this opinion, other than the actual definitions adopted by the Court, in the presence of the jury. Any reference to claim construction proceedings is limited to informing the jury of the definitions adopted by the Court.

E.D.Tex.,2007.
Medtronic Vascular Inc. v. Boston Scientific Corp.