United States District Court,
N.D. California, San Jose Division.

BOSTON SCIENTIFIC CORP., et al,
Plaintiffs.
v.
MICRUS CORP,
Defendant.

No. C 04-04072 JW

March 21, 2008.

Background: Exclusive licensee of patents relating to methods and devices for treating vascular medical problems, 1999 WL 1549278, and exclusive distributor of products manufactured pursuant to those patents brought infringement action. Defendant asserted counterclaims that distributor infringed patents for anatomically shaped vasoocclusive device, 1997 WL 1520719, and patents for method and apparatus for occlusion and reinforcement of aneurysms, 1998 WL 1391567.

Holdings: Following motions granting in part and denying in part motions for summary judgment, 2008 WL 171049, in a related action, the District Court, James Ware, J., in construing claim terms, held that:
(1) "body cavity," as used in claim of patent for endovascular electrolytically detachable wire and tip for the formation of thrombus in arteries, veins, aneurysms, vascular malformations and arteriovenous fistulas, was not limited to a "body cavity" in a human being;
(2) phrase, "means for delivering the device to a desired portion of a vesicle," as used in claim of patent for an anatomically shaped vasoocclusive device and method of making same, met the criteria for having a limitation expressed in means-plus-function format; and
(3) phrase "strand of flexible material further comprises a first portion and a second portion," as used in claim of patent for an anatomically shaped vasoocclusive device and method of making same, meant a single strand of flexible material comprising two distinct parts.

Claims construed.

Court-Filed Expert Resumes

5,645,558, 5,766,219, 5,895,385, 6,010,498. Construed.

Allison H. Stiles, Michael G. Strapp, Amanda K. Kessel, Daniel M. Forman, J. Anthony Downs, Patrick Shaun Thompson, Paul F. Ware, Jr., Roland Schwillinski, Russell W. Binns, Goodwin Procter LLP, Boston, MA, Julie Lynn Fieber, Michael Francis Kelleher, Folger Levin & Kahn LLP, San Francisco, CA, for Plaintiff.

Rainer Schulz, pro se.

Eric P. Xanthopoulos, Rip J. Finst, Douglas E. Lumish, Matthew D. Powers, Weil Gotshal & Manges LLP, Redwood Shores, CA, for Defendant.

FIRST CLAIM CONSTRUCTION ORDER

JAMES WARE**, District Judge.**

I. INTRODUCTION

Boston Scientific Corp. and Target Therapeutics, Inc. FN1 ("Plaintiffs," or collectively, "Boston Scientific") bring this action against Micrus Corp. ("Defendant" or "Micrus") for alleged patent infringement of two patents relating to methods and devices for treating vascular medical problems. Plaintiffs allege that Defendant willfully infringed, and continues to infringe (1) U.S. Patent No. 5,895,385 (the "'385 Patent") entitled "Endovascular Electrolytically Detachable Wire and Tip for the Formation of Thrombus in Arteries, Veins, Aneurysms, Vascular Malformations and Arteriovenous Fistulas;" and (2) U.S. Patent No. 6,010,498 (the "'498 Patent") also entitled "Endovascular Electrolytically Detachable Wire and Tip for the Formation of Thrombus in Arteries, Veins, Aneurysms, Vascular Malformations and Arteriovenous Fistulas." FN2 (*See* Complaint for Patent Infringement, Docket Item No. 1.)

FN1. Target Therapeutics is a wholly-owned subsidiary of Boston Scientific. (Joint Case Management Statement, Docket Item No. 58.)

FN2. Target is the exclusive licensee of the '385 and '498 patents and Boston Scientific is the exclusive distributor of products manufactured pursuant to these patents.

Micrus has asserted counterclaims that Boston Scientific infringes U.S. Patent Nos. 5,645,558 (the "'558 Patent") and 5,766,219 (the "'219 Patent") each entitled "Anatomically Shaped Vasoocclusive Device and Method of Making Same;" and 6,168,615 (the "'615 Patent") entitled "Method and Apparatus for Occlusion and Reinforcement of Aneurysms." Micrus has also asserted counterclaims for, *inter alia,* antitrust violations, disparagement, and unfair business practices. (*See* Docket Item No. 23.)

On June 1, 2007, the Court conducted a hearing in accordance with Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), to construe language of the asserted claims over which there is a dispute. This First Claim Construction Order sets forth the Court's construction of the disputed terms with respect to Boston Scientific's '385 and '498 Patents, and Micrus' '578 and '219 Patents.

II. BACKGROUND

The parties' patents-in-suit generally relate to coil delivery systems which are medical devices used to insert embolization coils into a selected site within a blood vessel. They are commonly used in the treatment of brain aneurysms. A full summary of the patented invention may be found in the Court's October 7, 2003 Order Following Claim Construction in a related action entitled, *Boston Scientific Corp., et al. v. Cordis*

Corp., CV No. 02-1474-JW. (hereafter, " *Boston v. Cordis,* October 7, 2003 Order," Docket Item No. 177.) In fact, the Court has construed some of the submitted words and phrases for construction in this case in *Boston v. Cordis;* thus, when appropriate, the Court will make references to its previous Orders in *Boston v. Cordis*.

III. STANDARDS AND PROCEDURES FOR CLAIM CONSTRUCTION

A. *General Principles of Claim Construction*

Claim construction is a matter of law, to be decided exclusively by the Court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 387, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). When the meaning of a term used in a claim is in dispute, the Court invites the parties to submit their respective proposed definitions and a brief, outlining the basis for their proposals. In addition, the Court conducts a hearing to allow oral argument of the respective proposed definitions. After the hearing, the Court takes the matter under submission, and issues an Order construing the meaning of the term. The Court's construction becomes the legally operative meaning of the term that governs further proceedings in the case. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). The Court recognizes that claim construction is a fluid process, wherein the Court may consider a number of extrinsic sources of evidence so long as they do not contradict the intrinsic evidence. However, the Court acknowledges that greater weight should always be given to the intrinsic evidence. Phillips v. AWH Corp., 415 F.3d 1303, 1324 (Fed.Cir.2005).

B. *Construction from the View Point of an Ordinarily Skilled Artisan*

A patent's claims define the scope of the patent: the invention that the patentee may exclude others from practicing. Id. at 1312. The Court generally gives the patent's claims their ordinary and customary meaning. In construing the ordinary and customary meaning of a patent claim, the Court does so from the viewpoint of a person of ordinary skill in the art at the time of the invention, which is considered to be the effective filing date of the patent application. Thus, the Court seeks to construe the patent claim in accordance with what a person of ordinary skill in the art would have understood the claim to have meant at the time the patent application was filed. This inquiry forms an objective baseline from which the Court begins its claim construction. Id.

The Court proceeds from that baseline under the premise that a person of ordinary skill in the art would interpret claim language not only in the context of the particular claim in which the language appears, but also in the context of the entire patent specification, of which it is a part. Id. at 1313. Additionally, the Court considers that a person of ordinary skill in the art would consult the rest of the intrinsic record, including any surrounding claims, the drawings, and the prosecution history-if it is in evidence. Id.; Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324 (Fed.Cir.2002). In reading the intrinsic evidence, a person of ordinary skill in the art would give consideration to whether the disputed term is a term commonly used in lay language, a technical term, or a term defined by the patentee.

C. *Commonly Used Terms*

In some cases, disputed claim language involves a commonly understood term that is readily apparent to the Court. In such a case, the Court considers that a person of ordinary skill in the art would give to it its widely accepted meaning, unless a specialized definition is stated in the patent specification or was stated by the patentee during prosecution of the patent. In articulating the widely accepted meaning of such a term, the Court may consult a general purpose dictionary. Phillips, 415 F.3d at 1314.

D. ***Technical Terms***

If a disputed term is a technical term in the field of the invention, the Court considers that one of skill in the art would give the term its ordinary and customary meaning in that technical field, unless a specialized definition is stated in the specification or during prosecution of the patent. In arriving at this definition, the Court may consult a technical art-specific dictionary or invite the parties to present testimony from experts in the field on the ordinary and customary definition of the technical term at the time of the invention. Id.

E. ***Defined Terms***

The Court acknowledges that a patentee is free to act as his or her own lexicographer. Acting as such, the patentee may use a term differently than a person of ordinary skill in the art would understand it, without the benefit of the patentee's definition. Vitronics Corp., 90 F.3d at 1582. Thus, the Court examines the claims and the intrinsic evidence to determine if the patentee used a term with a specialized meaning.

The Court regards a specialized definition of a term stated in the specification as highly persuasive of the meaning of the term as it is used in a claim. Phillips, 415 F.3d at 1316-17. However, the definition must be stated in a clear words, which make it apparent to the Court that the term has been defined. *See* id.; Vitronics Corp., 90 F.3d at 1582. If the definition is not clearly stated or cannot be reasonably inferred, the Court may decline to construe the term pending further proceedings. Statements made by the patentee in the prosecution of the patent application as to the scope of the invention may be considered when deciding the meaning of the claims. Microsoft Corp. v. Multi-Tech Systems, Inc., 357 F.3d 1340, 1349 (2004). Accordingly, the Court may also examine the prosecution history of the patent when considering whether to construe the claim term as having a specialized definition.

[1] [2] In construing claims, it is for the Court to determine the terms that require construction and those that do not. *See* U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed.Cir.1997). Moreover, the Court is not required to adopt a construction of a term, even if the parties have stipulated to it. Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc., 429 F.3d 1364, 1376 (Fed.Cir.2005). Instead, the Court may arrive at its own constructions of claim terms, which may differ from the constructions proposed by the parties.

IV. DISCUSSION

A. ***Boston Scientific's '385 Patent***

1. Claim 7 of the '385 Patent

Claim 7 provides:

An apparatus for use in occluding a **body cavity** comprising: FN3

FN3. Unless otherwise indicated, all bold typeface is added by the Court for emphasis.

a **wire;** and

a detachable elongate distal tip coupled to said wire, said elongate distal tip being**a relaxed coil** capable of being multiply folded upon itself.

a. "body cavity"

[3] The parties dispute the construction of the phrase, "body cavity," which is used in the Preamble to Claim 7. In particular, the parties dispute whether the phrase should be limited to a "body cavity" in a human being or whether the phrase includes animals.

In *Boston v. Cordis,* Plaintiff accused a different defendant of infringing Claim 7 of the '385 Patent. In that case, the parties stipulated to construe the phrase "body cavity" as limited to human beings.FN4 The Court is not bound to that stipulation in this case.FN5

FN4. The parties stipulated to a definition of the phrase "body cavity" to be "any opening or passageway in the human body, such as arteries, veins, aneurysm, vascular malformations, arteriovenous fistulas and the like." *See Boston v. Cordis,* CV No. 02-1474.

FN5. To avoid an inconsistent construction, the Court is disposed to reject the proffered stipulation and construe the phrase consistently in the other case when the matter returns to the Court's attention.

The phrase "body cavity" is used in the Preamble to Claim 7 but is not used elsewhere in the specification.FN6 However, in the background section of the specification, the inventors discuss published articles in which skilled artisans test medical devices for occluding aneurysms in research animals. Thus, a skilled artisan would understand that the inventors use the phrase "body cavity" broadly to mean an opening or passageway in the body of an animal. *See also,* STEDMAN'S MEDICAL DICTIONARY, 329 (28th ed.2006).

FN6. The phrase "vascular cavity" is frequently discussed in the specification. For example, the section of the specification entitled "Brief Summary of the Inventions" states: "The invention is a method for forming an occlusion within a **vascular cavity** having blood disposed therein comprising the steps of endovascularly disposing a wire and/or tip near an endovascular opening into the vascular cavity." A skilled artisan would understand "vascular cavity" to be a species of the genus "body cavity."

Accordingly, the Court construes the phrase **"body cavity,"** as it is used in Claim 7 of the '385 Patent to mean: **an opening or passageway in a body.**

b. "wire"

In *Boston v. Cordis,* the Court construed "wire" as used in the subject claim to mean a: "thin, flexible, continuous length of metal, usually of circular cross section." (*Boston v. Cordis,* October 7, 2003 Order at 9.) There are two issues with respect to the construction of the word "wire." The first issue is whether, as used in Claim 7, "wire" includes the "tip" structure. The second issue is a request that the Court reconsider its definition of "wire" as a "flexible, metal" object.

i. Whether "wire" as used in Claim 7 includes a tip structure

[4] In the "Summary of the Invention" section of the specification, the inventors define "wire" as a word with a "collective" meaning:

The term "wire" should be understood to collectively include both guidewires and tips and simply wires without distinct tip structures. However, the tip may also simply be the extension of the wire itself without substantial distinction in its nature.

('385 Patent, Col. 4:9-11.) The inventors' "collective" definition equates "wire" with "guidewires." It also groups a "wire" with a tip structure and a "wire" without a distinct tip structure. One of skill in the art reading the specification would understand that in their definition, the inventors are discussing alternative embodiments of "wire." Since a "wire" with a tip structure recites a different and arguably an inconsistent limitation than a "wire" without a tip structure, each claim must be examined to determine the appropriate definition.

The Court finds that as used in Claim 7, "wire" means a wire without a tip structure, because the second element of Claim 7 is "a detachable elongate distal tip coupled to said wire." If the word "wire" is defined as including a tip structure the second element would be redundant or would render Claim 7 arguably invalid for indefiniteness.FN7 Thus, the applicable definition of the word "wire" as used in Claim 7 excludes a tip structure.

FN7. An ambiguity would exist because the claim would disclose a "distal tip coupled to" a wire which already included a distal tip structure.

ii. Whether "wire" means a metal structure

[5] "Wire" is a word with a commonly understood meaning. As set out above, when inventors use commonly understood words, the Court considers that a person of ordinary skill in the art would give the word its commonly understood meaning, unless a specialized definition is stated in the patent specification or was stated by the patentee during prosecution of the patent. In articulating a widely accepted meaning of a word, the Court may consult dictionaries. Phillips, 415 F.3d at 1314.

Numerous dictionaries define "wire" as metal that has been drawn into a very long, thin thread or rod, usually circular in cross-section. *See, e.g.,* WEBSTER'S NEW TWENTIETH CENTURY DICTIONARY, 2098 (2d ed.1983). In the STEDMAN'S MEDICAL DICTIONARY, "wire" is defined as a pliable metal object: "A slender, pliable rod or thread of metal, used in surgery and dentistry." 2152 (28th ed.2006).

Nothing in the specification indicates explicitly or implicitly, that the inventors intended to import a novel or specialized meaning to "wire." Indeed, the specification indicates that the inventors used "wire" with its commonly understood definition. Although the specification does not contain an express description of all wires as composed of metal, it expressly specifies metal in some embodiments. For example, in one embodiment, the inventors discuss an embodiment, which includes a "wire" composed of stainless steel:

FIG. 1 is an enlarged side view of a first embodiment of the distal end of the wire and tip shown in partial cross-sectional view. A conventional Teflon laminated or similarly insulated **stainless steel wire 10** is disposed within a protective microcatheter (not shown). Stainless steel wire 10 is approximately 0.010-0.020 inch (0.254-0.508 mm) in diameter.

In another embodiment, the specification discloses use of a "wire" is a process involving electrolytic separation-also a process involving metal:

When the tip is separated from the wire by electrolytic separation of the tip from the wire, a portion of the wire connected between the tip and the body of the wire is comprised of stainless steel and exposed to the bloodstream so that upon continued application of a positive current to the exposed portion, the exposed portion is corroded away at least at one location and the tip is separated from the body of the wire.

Therefore, the Court declines to exclude "flexible" or "metal" from its construction.

Accordingly, the Court construes the word **"wire,"** as it is used in Claim 7 of the '385 Patent to mean: **A component of the invention which is a thin, flexible, continuous length of metal, usually of circular cross-section, not including a tip structure.**

c. "detachable elongate distal tip coupled to said wire"

The parties dispute the construction of the phrase, "detachable elongate distal tip coupled to said wire."

The Court had previously construed the word "detachable" to mean: "attached but capable of being detached or disconnected without any axial force and without significant radial force." (*Boston v. Cordis,* October 7, 2003 Order at 15.) The construction was subsequently modified to mean: "attached but capable of being detached or disconnected without any axial force and without significant radial force." (*Boston v. Cordis,* Docket No. 592 at 12, hereafter, " *Boston v. Cordis,* July 26, 2004 Order.")

The Court previously construed the phrase "elongate distal tip" to mean: "a tip or piece that is attached to the wire but can be detached from the wire." (*Boston v. Cordis,* October 7, 2003 Order at 16.)

Finally, the Court previously construed the word "coupled" to mean: "connected or attached." (*Id.* at 17.)

The Court finds no basis for changing its construction. Accordingly, the Court construes **"detachable elongate distal tip coupled to said wire,"** as it is used in Claim 7 of the '385 Patent to mean: **a tip that is connected or attached to the wire and that is capable of being detached or disconnected from the wire.**

d. "relaxed coil"

[6] Claim 7 includes as a limitation an elongate distal tip "being a relaxed coil." The parties dispute the construction of the phrase, "being a relaxed coil." FN8

FN8. In *Boston v. Cordis,* the Court construed the phrase "relaxed coil" as it is used in Claim 7 of the '385 Patent to mean: "a coil that is less rigid; a loose coil that has an overall shape that is easily deformed." (*Boston v. Cordis,* October 7, 2003 Order at 18.)

In claim construction, the Court presumes that the inventors use the same words and phrases with the same meaning, unless the inventors demonstrate a clear intent to give them different meanings in different contexts. Southwall Techs. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed.Cir.1995). Although the phrase

"relaxed coil" does not appear in the written description of the '385 Patent, the inventors use the phrase in other claims of the '385 Patent. For example, Claim 14 claims:

a **relaxed coil** having no substantial memory of its predisposed shape other than at most a relaxed simple helical shape

Similar language is used with a related term, namely, "relaxed wire," which appears in Claim 24:

A method for forming an occlusion within a body cavity having fluid disposed therein comprising the steps of: disposing **a relaxed wire** into said body cavity, said relaxed wire having no substantial memory of its predisposed shape other than at most a relaxed, simple helical shape

Claims 7, 14 and 24 use the same modifier, "relaxed." However, Claim 7 does not contain the limitation that the coil have no "substantial memory" of a "predisposed shape other than at most a relaxed simple helical shape." Before drawing significance from this difference, the Court considers other intrinsic evidence for the meaning of "relaxed coil."

[7] In the absence of any discussion of claim language in the written description, the Court may derive a definition from how the phrase is used during the prosecution of the patent or during the prosecution of a related patent. Microsoft Corp., 357 F.3d at 1349.

The application which was issued as the '385 Patent is a continuation of U.S. Patent No. 5,354,295.FN9 The prosecution historyof the earlier filed ' 295 Patent is significant because in it, the inventors discuss the "relaxed coil" limitation as it is used in the ' 295 Patent. Initially, Claim 1 of the original '295 application did not contain the phrase "relaxed coil." Instead, Claim 1 provided:

FN9. The file history on the face of the '385 Patent does not show that it is a continuation of the '295 Patent. However, in Reissue proceedings the file history of the application later issued as the '385 Patent was modified to state it was a continuation of the '295 Patent. (*See* UCR 13779-81.)

A method for forming an occlusion within a vascular cavity having blood disposed therein comprising the steps of:
endovascularly disposing **a wire** near an endovascular opening into said cavity;

disposing a distal tip of said wire into said vascular cavity to pack said cavity to mechanically form said occlusion within said vascular cavity about said distal tip; and

detaching said distal tip from said wire to leave said distal tip within said vascular cavity,

whereby said vascular cavity is occluded by said distal tip; and any thrombus formed by use of said tip.

(UCR 132.)
On February 8, 1993, the inventors requested, among other things, permission to amend Claim 1 from "a wire" to "a relaxed coil wire:"

(once amended) A method for forming an occlusion within a vascular cavity having blood disposed therein

comprising the steps of:

endovascularly disposing a ***relaxed coil*** wire near an endovascular opening into said cavity, *said relaxed coil wire having no substantial memory of its predisposed shape other than at most a relaxed, simple helical shape;*

disposing a distal tip of said wire into said vascular cavity to [pack] *substantially space fill* said cavity to mechanically form said occlusion within said vascular cavity about said distal tip; and

detaching said distal tip from said wire to leave said distal tip within said vascular cavity *without substantially increasing the temperature of said distal tip and wire,*

whereby said vascular cavity is occluded by said distal tip; and any thrombus formed by use of said tip.

(UCR 168.)

In remarks submitted with the February 8 amendment, the inventors distinguished their "relaxed coil" from a coil disclosed by Ritchart in U.S. Patent 4,994,069:

The catheter delivers the stretched wire to a vascular cavity and is disposed from the catheter. The stretched wire then reassumes its prior convoluted condition to form an irregular helical mass. It is intended to form a randomly coiled substantially space-filling mass lodged within the vascular cavity. The convoluted mass provides a substantially spaced-filling body around which a thrombus or occlusion can be formed through natural body processes.

Essential to the operation of Ritchart is that the wire have a memory which returns it from its stretched to its relaxed condition as the wire is released from the catheter into the vascular cavity. See column 2, line 56-60. In Ritchart, the relaxed conformation of the wires is produced by helical windings in the wire which has a winding diameter substantially equal to that of the vascular cavity to be occluded. The irregularities in the helical winding cause the wire to adopt a substantially random folded pattern when released from the catheter into the cavity. See column 2, lines 61-67. In another embodiment, a spiral shape is contemplated for the relaxed confirmation. Column 3, lines 10-13.

An occlusion coil with this feature is more difficult to fabricate than a coil which is disposed within the catheter in a relaxed configuration and when disposed out of the catheter does not undergo any process wherein it conforms to some earlier shape or configuration. In additions, a wire having a preferred or memorized shape inherently requires that it have some type of springiness in order to conform to its predisposition configuration. This inherent springiness makes the coil less pliable. It is in fact this springiness that causes it through irregularities in the bends in the helix to form the random mass discussed by Ritchart. However, the coil will form a shape completely independently of the shape of the vascular cavity and will be modified only to the extent that a balance of force is obtained between the random mass, which the coil attempts to form, and the constraining force of the wall of the vascular cavity.

(UCR 174-176.) The way the inventors differentiate the "relaxed coil" of their invention from the coil claimed by Ritchart in the prosecution of the ' 295 Patent shows that they had a specialized meaning for the phrase. In the '295 Patent's prosecution, the inventors state that unlike the Ritchart coil, which is in a "relaxed condition" when it is unconstrained and assumes a predisposed shape, their "relaxed coil" has no

predisposed shape. Thus, by "relaxed coil" the inventors meant a coil which did not have a predisposed shape.

In addition, the inventors described the Ritchart coil as capable of being in a "relaxed condition" when it was released from the catheter into a vascular cavity; once deployed into the cavity, the stress imposed upon the coil would be released. The coil would "relax" in the sense that it would spring back to a predisposed, unstressed, relaxed shape. On the other hand, the inventors stated that "relaxed coil" of their invention did not refer to the presence or absence of stress upon the coil under particular circumstances as it might be used. The inventors state that the coil of the invention is "relaxed" in the sense that it is inherently flexible and pliable. In other words, the inventors distinguish their pliable and hence "relaxed coil," from the Ritchart coil which had a memory of shape to which it conformed under a relaxed condition when no stress was being placed upon it.FN10

FN10. A coiled bed spring in a mattress when no one is sleeping in the bed is an example of a "relaxed coil," meaning a coil free of stress. A coiled telephone handset wire is an example of a "relaxed coil," meaning a coil which is flexible and pliable.

Further support for the inventors' meaning of "relaxed coil" is provided by a later response by the inventors to an office action in the prosecution of the '295 Patent. On May 20, 1993, the Examiner sent an office action, rejecting Claim 1 on the ground that the "relaxed coil" phraseology in the claim was not supported in the specification. (*See* UCR 188-190.) On August 24, 1993, the inventors responded to the rejection of the phrase "relaxed coil." FN11 In doing so, the inventors explainedwhat they meant by the phrase and why the Examiner should find that there was support in the specification for using the phrase in Claim 1: FN12

FN11. The August 24, 1993, response was part of a request to amend the Claims. The amendment did not affect the "relaxed coil" phrase, which had been introduced in the February 8, 1993 amendment. For reference, the request asked that Claim 1 be amended to read:
(twice amended) A method for forming an occlusion within a vascular cavity having blood disposed therein comprising the steps of:

endovascularly disposing a relaxed coil wire near an endovascular opening into said vascular cavity, said relaxed coil wire having so substantial memory of its predisposed shape other than at most a relaxed, simple helical shape;
disposing a distal tip of said wire into said vascular cavity to substantially space fill said cavity to mechanically form said occlusion within said vascular cavity about said distal tip; and
nonthermally detaching said distal tip from said wire to leave said distal tip within said vascular cavity, *wherein nonthermal detachment is defined as a detachment* without substantially increasing the temperature of said distal tip and wire,
whereby said vascular cavity is occluded by said distal tip, and any thrombus formed by use of said tip. (UCR 193.)
FN12. The italic is from the original. The bold-face text is added by the Court for emphasis.

Claims 1, 3, 5-8, 10, 12-16 and 18-22 are pending in the application and have each been rejected under 35

U.S.C. 112, first paragraph, as failing to be supported by the specification. In particular, the Examiner takes the position that the limitations added by the amendment filed February 8, 1993 lacks support in the disclosure as filed. The Examiner has characterized these limitations as relating to the detachment of a relaxed coil without substantially increasing the temperature of the distal tip and wire wherein the coil has no substantial memory of the shape and is generally shapeless.
The applicant respectfully disagrees. The applicant describes in the Detailed Description of the Preferred Embodiments the insertion of a platinum tip into a vascular cavity *so that the cavity is packed with the tip* to obstruct the blood flow or access of blood in the cavity, page 14, lines 4-6. **The tip is described as being elongate and flexible so that when it packs in the cavity, *it is folded upon itself a multiple number of times,* page 14, lines 6-8.**

The applicant continues by stating that although the microcoil is prebiased to form a cylindrical or conical envelope, secondary coil 28 is *extremely soft and its overall shape is easily deformed,* page 16, lines 9-10. Once disposed out of the tip of the microcatheter, secondary **coil forms the shape shown in Figure 1 and *is loosely deformed* to the interior shape of the** aneurysm**,** page 15, lines 12-14.

In alternative embodiment, the importance and premium paid for flexibility of the microcoil is emphasized when it is stated that *a degree* of ***flexibility*** *of the wire is sacrificed by the inclusion even of thread-like tip 18, so that the embodiment of Figure 2 provides a more flexible tip,* page 17, lines 19-20.

In describing the embodiment of Figure 3, the applicant states at page 18, lines 17-19, that *platinum coil 56 is not prebiased, nor does it contain any internal reinforcement, but is a free and open coil* similar in that respect to the stainless steel coil 36 of the embodiment of Figure 2. However, platinum coil 56 is particularly distinguished by its length of approximately *1 to 50 centimeters and by its flexibility*. The *platinum or platinum alloy used is particularly* ***pliable*** *and the diameter of the wire used to form platinum coil 56 is approximately 0.001-0.005 inch in diameter,* page 18, lines 17-23.

Still further in regard to mechanically filling or occluding the aneurysm, the applicant states at page 20, beginning at line 15, that the disclosure must be read to expressly include formation of the occlusion within the aneurysm by a mechanical mechanisms without the resort to application of electrical current. A mechanical mechanism is disposed in the vascular cavity to impede, slow or otherwise initiate clotting of the blood or formation of the occlusion. Mechanical thrombus is particularly illustrated in connection with the catheter of Figure 6. At page 21, line 11, *a statement is made that coil 102* ***has sufficient length and flexibility that it can be inserted or coiled loosely in a vascular cavity.*** In this embodiment, the hairs 104 provide a means for substantially filling the cavity even though the multiple folding of the microcoil itself may not be able to do so. The point is emphasized that *full packing through a* ***loose coiling*** is expressly taught and supported in the specification.

References in the amended claims of the applicant to a relaxed coil which substantially space fills the cavity into which it is inserted is reasonably supported by the specification. The more functional phrase "to substantially space fill" has been substituted for the initial wording of "pack." The applicant respectfully submits that the two terms are substantially interchangeable and contemplate the same concept.

A relaxed coil which is flexible and which can be multiply folded in order to pack or substantially space fill a cavity necessarily can be described as relaxed or having no memory of a predisposed shape. Such a coil can be called not only flexible, but shapeless in that there is no preferred shape, but it assumes the shape into which it is folded within the vascular cavity.

(UCR 194-196.) These passages from the prosecution history of the '295 Patent confirm that by tip "being a relaxed coil," the inventors meant a tip made of a coil which is flexible, pliable, and has no predisposed shape.
The Court notes that interlineations were made on the face of the originally filed written description supporting the '295 Patent application. The interlineations added the words "relaxed," "undefined or shapeless" to the description FN13 of the coil. These changes are undated but must have been allowed because they are included in the written description of the issued ' 295 Patent.FN14 The amended language does not appear in the written description for the '385 Patent. However, this omission is not regarded as significant to claim construction.

FN13. The Court presumes that the word "relaxed" was not part of the original written description because if it were, the May 20, 1993, rejection by the Examiner, which is discussed later in the Order, on the ground that there was no support for "relaxed coil" would not make sense.

FN14. There is evidence that the interlineations were made after August 24, 1993, because "Remarks" made by the inventors on that date contain quotations from the written description and the quotations do not include the language as amended by the interlineations.

Accordingly, the Court construes the phrase **"elongate tip being a relaxed coil,"** as it is used in Claim 7 of the '385 Patent to mean: **an elongate tip composed of a coil that is flexible, pliable, and that has no preferred shape.**

2. Claim 10 of the '385 Patent

Claim 10 provides:

The improvement of claim 7 further comprising a **catheter** having a pair of radiopaque markers disposed thereon and having a distal end, said wire having a radiopaque marker disposed thereon, said marker on said wire being positioned in the proximity of one of said pair of markers on said catheter when said wire is fully deployed in said body cavity, said other marker of said pair of markers on said catheter indicating said distal end of said catheter.

[8] The Preamble of Claim 10 recites: "The improvement of claim 7 further comprising ..." The use of the phrase "the improvement" in a patent claim is commonly used in the Preamble of a "Jepson" claim. This format for stating a patent claim stems from *Ex Parte Jepson,* in which a patent was granted for adding an improvement to a well-known device. 243 O.G. 525 (1917). In approving this form of claim, the Commissioner stated:

The whole apparatus upon which the applicant's invention is engrafted is not a part of his invention, and yet it must be considered and is as essential as the pedestal of a statue is essential.

Id. at 257. Traditionally, in a Jepson claim, the Preamble recites prior art which forms no part of the inventor's patentable contribution, and the preamble ends with the phrase, "the improvement comprising." The patented subject matter is the material in the body of the claim which follows the word "comprising."

See California Car Wash Systems, Inc. v. Danco, Inc., 348 F.Supp. 958, 960 (D.Colo.1972).

[9] [10] In this case, the Preamble to Claim 10 recites that it depends from Claim 7. Thus, Claim 10's Preamble "The improvement of claim 7" suggests Claim 7 is a Jepson-type claim, i.e., it claims an improvement. However, Claim 7 is not a Jepson-type claim because it does not claim an "improvement" on the prior art; a dependent claim in Jepson format that depends from an independent claim which is not in *Jepson* format creates an ambiguity, which makes the dependent claim arguably indefinite. When, despite an ambiguity, the "meaning of the claim is discernible," the court should proceed to construe the claim in accordance with that meaning. *See* Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed.Cir.2001).

Even if the Court regards Claim 10 as a regular claim, it is still arguably indefinite because the Preamble refers back to a missing antecedent. The Preamble of Claim 10 refers back to "The improvement of claim 7." Claim 7 does not recite an "improvement." Therefore, Claim 10 is ambiguous as to what is meant by "The improvement of claim 7." FN15

FN15. The Court notes that Claims 8 and 9 of the '385 Patent are also introduced by the phrase "The improvement of claim 7," and therefore, they also lack an antecedent claim.

However, Claim 7 does disclose an "apparatus." The Court could assume that when the inventors stated in Claim 10, "The improvement of claim 7," the inventors meant, "the apparatus of claim 7." This assumption may not be reasonable in light of other claims of the '385 Patent. For example, in Claim 13, which is disclosed as a dependent claim from Claim 7, the Preamble states "The apparatus of claim 7." Thus, the inventors demonstrate an appreciation for the difference between claiming "an apparatus" in a prior claim and disclosing further limitation on "the apparatus" in a dependent claim. There are other claims which differentiate between an express disclosure of "an apparatus" and an "improvement" in independent claims, followed by further limitations on "the apparatus" FN16 or "the improvement" FN17 in dependent claims. Therefore, a construction of "improvement" based on an assumption that the inventors meant "the apparatus" arguably might be judicial rewritingof the Claim, a practice against which the Federal Circuit has admonished. *See* Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed.Cir.1999) (citing Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 799 & n. 6 (Fed.Cir.1990)).

FN16. Independent Claim 1 discloses "an apparatus." Dependent Claims 2-5, claim further limitations on "The apparatus of claim 1."

FN17. The Preamble to independent Claim 15, discloses "an improvement comprising" the limitations disclosed in the body of the claim. Dependent Claim 16, clearly refer back to "the improvement of claim 15." Dependent Claims 17-23, clearly refer back to dependent or independent claims which expressly disclose an "improvement."

[11] Finally, an apparatus claim should recite a cooperative relationship among the structures disclosed in the claim. *See* In re Collier, 55 C.C.P.A. 1280, 397 F.2d 1003 (C.C.P.A.1968). A claim which does not recite a relationship between the structures may be incomplete. Id. at 1005; MPEP s. 2172.01. Claim 10 lacks a recitation of a cooperative relationship between the structures disclosed in independent Claim 7 and

the "catheter," the new structure disclosed in Claim 10. Unlike Claims 3 FN18 and 14,FN19 which disclose that the wire is "within" the catheter, Claim 10 does not disclose any relationship between the structures.

FN18. Claim 3 provides: The apparatus of claim 1 further comprising **a catheter** and where said wire and distal tip section are longitudinally **displaced within said catheter,** said catheter having a radiopaque proximal marker, said wire and distal tip section having collectively a single radiopaque marker, said displacement of said wire and distal tip section moving said single radiopaque marker to the proximity of said proximal marker on said catheter when said distal tip section is fully deployed in said cavity.

FN19. Claim 14 provides: An apparatus for forming an occlusion within a body cavity having fluid disposed therein comprising:
a catheter having a distal end for disposition in proximity to said cavity and having an electrode disposed thereon;

a conductive wire disposed in said catheter and longitudinally displaceable therein, said wire comprising:

a core wire having a distal portion; and

an elongate tip portion extending from said core wire for a predetermined lineal extent and adapted to being packed into said cavity and coupled to said distal portion of said core wire, said occlusion being formed by means of application of a current between said elongate tip portion and said electrode on said catheter when said elongate tip portion is disposed in said cavity, said elongate tip portion being a relaxed coil having no substantial memory of its predisposed shape other than at most a relaxed simple helical shape, whereby occlusion of said cavity is performed.

Accordingly, the Court invites the parties to address these issues and defers construction of Claim 10 pending further proceedings.

3. Claim 15 of the '385 Patent

Claim 15 provides:

In an apparatus having a wire for forming an occlusion in a body cavity having a fluid flowing therein, the improvement comprising:

a **deformable object temporally coupled** to said wire for disposition into said cavity having no preferred geometric form when disposed into said cavity, said deformable object capable of being multiply folded upon itself, said deformable object **substantially impeding movement of said fluid in said cavity to**

thereby form said occlusion, whereby said cavity is occluded by said object.

[12] Claim 15 is written in a "Jepson" format. As stated above, a Jepson format is one in which the Preamble describes prior art and then claims an "improvement" over the prior art. Dow Chemical Co. v. Sumitomo Chemical Co., 257 F.3d 1364, 1368 (Fed.Cir.2001). When a Jepson format is used, the Preamble is a limitation because it defines, in part, structural limitations of the claimed invention. *See* Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1029 (Fed.Cir.2002).

The Preamble to Claim 15 recites a "wire" as a structural limitation and recites a functional limitation of the "wire," i.e., "for forming an occlusion." Thus, the construction of the word "wire" as used in Claim 15 must include a capability of the "wire" itself to "form" an occlusion. The Court's construction of the word "wire" would include a "wire" capable of performing this function if the Court applies the construction of "wire" which includes the tip structure. However, the body of Claim 15 introduces an ambiguity. The body of Claim 15 recites "a deformable object temporally coupled to said wire for disposition into said cavity." The structure that meets this limitation is the distal tip. Thus, Claim 15 is arguably ambiguous in that it discloses coupling a tip structure (deformable object) to a "wire ... for forming an occlusion" which arguably means it already has a tip.

Accordingly, the Court defers consideration of Claim 15 pending any further proceedings that the parties may wish to initiate with respect to the arguable ambiguity.

4. Claim 16 of the '385 Patent

Claim 16 provides:

The improvement of claim 15 where said deformable object is **adapted to being packed into said body cavity to substantially obstruct said cavity.**

The parties dispute the phrase, "adapted to being packed into said body cavity to substantially obstruct said cavity."

[13] Claim 16 depends from Claim 15. The Court has declined to construe Claim 15 because the "wire" limitation of the Preamble conflicts with the "deformable object coupled to said wire." However, a dependent claim is presumed valid even though dependent upon an invalid independent claim. Shelcore, Inc. v. Durham Indus., Inc., 745 F.2d 621, 624 (Fed.Cir.1984). This is so because although a dependent claim includes all of the limitations of the independent claim from which it depends, the dependent claim adds limitations and might not be subject to the same asserted ground of invalidity. *See* 35 U.S.C. s. 282. However, Claim 16 suffers from the same arguable ambiguity because it adds a further limitation to the "deformable object" without adding any limitation which cures the arguable invalidity created by the "wire" limitation.

Accordingly, the Court defers consideration of Claim 16 pending further proceedings which address the arguable ambiguity of Claim 15.

5. Claim 19 of the '385 Patent

Claim 19 provides:

The improvement of claim 15 wherein said deformable object comprises **a means for slowing fluid movement in said cavity to initiate formation of said occlusion in said cavity.**

For the reasons recited with respect to Claim 16, the Court defers consideration of Claim 19 pending further proceeding with respect to Claim 15.

6. Claim 22 of the '385 Patent

Claim 22 provides:

The improvement of claim 15 where **said deformable object is adapted to mechanically form said occlusion within said cavity.**

For the reasons recited with respect to Claim 16, the Court defers consideration of Claim 22 pending further proceeding with respect to Claim 15.

7. Claim 38 of the '385 Patent

[14] Claim 38 provides:

In a method for forming an occlusion in a body cavity having a fluid flowing therein by disposing a wire at least adjacent to said body cavity, the improvement comprising:

disposing **a deformable object** into said cavity having no preferred geometric form when disposed into said cavity, said deformable object capable of being multiply folded upon itself, said deformable object substantially impeding movement of said fluid in said cavity to thereby form said occlusion, whereby said cavity is occluded by said object.

The parties dispute the construction of the phrase, "deformable object." All of the highlighted phrases are limitations on the "object" which must be used to practice the claimed method. Two of these phrases have been previously construed by the Court.

In *Boston v. Cordis,* the Court construed the subject phrase and for convenience, repeats its analysis here.FN20 In the written description, the inventors discuss the phrase "a deformable object" in the context of a description of an embodiment and depict in Figure 1 of the drawings a "coil" which is "easily deformed:"

FN20. The Court construed the phase in its October 7, 2003 Order as well as in its January 18, 2008 Order. (Docket Item No. 1105, hereafter, " *Boston v. Cordis,* January 18, 2008 Order".) In the January 18, 2008 Order, the Court construed additional phrases in Claim 38 of the '385 Patent. The parties have not requested construction of those phrases in this case. If those additional phrases become relevant, the parties are invited to request construction of them for purposes of this case.

Although prebiased to form a cylindrical or conical envelope, secondary coil 28 is extremely soft and its overall shape is **easily deformed.** When inserted within the microcatheter (not shown), secondary coil 28 is **easily straightened** to lie axially within the microcatheter. Once disposed out of the tip of the microcatheter, secondary coil 28 **forms the shape shown in FIG. 1 and may similarly be loosely deformed** to the

interior shape of the aneurysm.
('385 Patent, Col. 7:54-61.)
The Court finds nothing in the specification, including the claims, which indicates explicitly or implicitly that the inventors intended to impart a novel meaning to "deformable." The record contains no evidence that "deformable" has a peculiar meaning in the field of art encompassed by the '385 Patent. The Court concludes that the meaning which would have been attributed to this word by those of ordinary skill in the relevant art at the time of invention is its ordinary and customary meaning. The ordinary and customary meaning attributed to "deformable" is capable of being changed in shape as by pressure or stress. *See* WEBSTER'S NEW TWENTIETH CENTURY DICTIONARY, 477 (2d ed.1983).

Accordingly, the Court construes the phrase **"a deformable object,"** as it is used in Claim 38 of the '385 Patent to mean: **a flexible object, which is capable of being made to assume a different shape by pressure or stress.**

B. *Boston Scientific*'s '498 Patent

Claim 1 provides:

An apparatus for forming an occlusion within a body cavity comprising:

a **catheter;**

a wire; and

a detachable elongate tip portion coupled to a distal portion of said wire which is retrievable until detached, **said tip portion being adapted to be positioned in said body cavity to form an occlusion** in said body cavity using one or more implantations of detachable elongate tip portions from corresponding wires, said wire having a radiopaque marker disposed thereon proximal on said wire from a detachment point of said elongate tip portion from said wire by a predetermined distance, said catheter having two radiopaque markers disposed thereon and spaced apart from each other, wherein one of said two markers on said catheter is provided at a distal end of said catheter and said other marker is positioned proximally thereof,

wherein said radiopaque markers are disposed on said wire and said catheter so that when said marker at said distal end of said catheter is disposed adjacent to an opening of said body cavity and when said wire is telescopically disposed in said catheter to approximately align said wire's radiopaque marker with said more proximal catheter marker, said detachable elongate tip portion then is fully disposed in said body cavity.

1. "catheter"

[15] The parties dispute the construction of the word, "catheter."

The word "catheter" is commonly used in the medical device field to refer to a variety of tubular instruments designed to allow passage of something into or out of a body cavity or blood vessel. *See* STEDMAN'S MEDICAL DICTIONARY, 326-327 (28th ed.2006). In the written description, the inventors discuss a "catheter" or "microcatheter" with radiopaque markers as a device used to guide the "wire" through blood vessels and to assist in placing the tip in a position for insertion into the cavity.FN21 The words "catheter" and "microcatheter" are used interchangeably.FN22 Therefore, one skilled in the art reading the patent documents would understand the inventors to use "catheter" in its plain ordinary meaning

within the medical device field: **a tubular medical device.**

FN21. An artery, vein, aneurysm, vascular malformation or arterial fistula is occluded through endovascular occlusion by the endovascular insertion of a platinum tip into the vascular cavity. The vascular cavity is packed with the tip to obstruct blood flow or access of blood in the cavity such that the blood clots in the cavity and an occlusion if formed. The tip may be elongate and flexible so that it packs the cavity by being folded upon itself a multiple number of times, or may pack the cavity by virtue of a filamentary or fuzzy structure of the tip. The tip is then separated from the wire mechanically or by electrolytic separation of the tip from the wire. The wire and **the microcatheter** are thereafter removed leaving the tip embedded in the thrombus formed within the vascular cavity. Movement of wire in the microcatheter is more easily tracked by providing a radiopaque proximal marker on the microcatheter and a corresponding indicator marker on the wire. Electrothrombosis is facilitate by placing the ground electrode on the distal end of the microcatheter and flowing current between the microcatheter electrode and the tip. ('498 Patent, Col. 6:52-7:4.)

FN22. **Microcatheter 144** is positioned so that its distal end 162 within vessel 66 is positioned at the opening aneurysm 64. Microcatheter 144 is provided with radiopaque marker 108 at distal tip 162, a tip marker. Moving toward the proximal end of microcatheter 144 is a second radiopaque marker 110, a proximal marker. Radiopaque markers 108 and 110 are, for example, in the form of radiopaque rings made of platinum, approximately 1-3 mm in longitudinal length along the axis of microcatheter 144. Rings 110 and 108 are typically separated by about 3 cm on microcatheter 144. Similarly, wire 10 has a radiopaque marker 112 defined on it such that marker 112 on wire 10 is approximately aligned with marker 110 on microcatheter 14 when coil 56 is fully deployed into aneurysm 64. Typically, full deployment will place the solder or connection point 54 of the order of 2-3 mm past opening 68 of aneurysm 64. Distal marker 108 on microcatheter 144 is used to facilitate the location of the microcatheter tip, which can often be obscured by the coils which have been previously deployed. The coils are a varying lengths depending on the application or size of the aneurysm or vascular cavity being treated. Coil lengths of 4-40 cm are common. Therefore, even though the thinness of coil 56 may make it difficult to see under standard fluoroscopy and even though the fineness of wire 10 may similarly be obscured or partly obscured, radiopaque markers 108, 110 and 112 are clearly visible. Manipulation of wire 10 to proximal marker 110 can then easily be observed under conventional fluoroscopy even when there are some loss of resolution or fluoroscopic visual obstruction of the coil. ('498 Patent, Col. 11:38-6.7.)

2. "said tip portion being adapted to be positioned in said body cavity to form an occlusion"

[16] The parties dispute the construction of the phrase, "adapted to." The dispute is whether the phrase should be construed to mean a particular adaptation.FN23

FN23. The Defendant contends that "adapted to" should mean adding a plurality of filaments or conducting electricity. (*See* Joint Claim Construction Statement at 13, Docket Item No. 79.)

In Claims 1, 3, 7, and 9 and in the written description, the inventors use the phrase "adapted to:"

The invention is also a wire for use in formation of an occlusion within a vascular cavity used in

combination with a microcatheter comprising a core wire, and a detachable elongate tip portion extending the core wire for a predetermined lineal extent. The tip portion is **adapted to be packed into the vascular cavity** to form the occlusion in the vascular cavity and coupled to the distal portion of the core wire. As a result, endovascular occlusion of the vascular cavity can be performed.

('498 Patent, Col. 5:3-11.)

In one embodiment, the elongate tip portion is a long and substantially pliable segment **adapted to be multiply folded upon itself** to substantially pack said vascular cavity.

In another embodiment, the elongate tip portion is a segment adapted to be disposed in said vascular cavity and having a plurality of filaments extending therefrom to substantially pack said vascular cavity when disposed therein.

('498 Patent, Col. 5:12-18.)

The invention is also a wire for use in formation of an occlusion within a vascular cavity used in combination with a microcatheter. The invention comprises a core wire and a detachable elongate tip portion extending the core wire for a predetermined lineal extent. The core wire is **adapted to being packed into the vascular cavity** to form the occlusion in the vascular cavity and is coupled to the distal portion of the core wire. The tip portion includes a first segment for disposition into the cavity and a second segment for coupling the first portion to the core wire. The second segment is **adapted to be electrolysized** upon application of current. An insulating coating is disposed on the first segment. The second segment is left exposed to permit selective electrolysis thereof. As a result, endovascular occlusion of the vascular cavity can be performed.

('498 Patent, Col. 6:1-15.)

It is clear from the specification, including the claims, that the inventors are using the phrase "adapted to" with its plain and customary meaning, i.e., "to be made suitable for." *See* WEBSTER'S NEW TWENTIETH CENTURY DICTIONARY, 21 (2d ed.1983). A person of ordinary skill in the art reading the patent documents would understand that the inventors are using the phrase "adapted to" in Claim 1 to mean that the detachable elongate tip portion is configured in a manner which makes it suitable for being placed in the body cavity for the purpose of forming an occlusion, with no limitation on the mechanism of occlusion.FN24

FN24. It is not clear to the Court whether the dispute is over the word "occlusion." In the "Background" section of the specification, the inventors discuss prior art processes for "occlusion" of a body cavity. An occlusion is a blockage. The specification discusses the following categories of processes for "occlusion:" (1) "Mechanical object occlusion," methods for occluding a vascular cavity by inserting an object or tool into the cavity. The cavity is blocked, occupied or otherwise closed off primarily by the mechanical object, itself, as opposed to some chemical change in the body brought about from using the tool; (2) "catalytic thrombosis," methods for occluding a vascular cavity by using a catalyst to cause or to accelerate formation of a thrombus; (3) "thermal coagulation," causing an occlusion by using heat to cause the blood to coagulate; and (4) "mechanical thrombosis," methods for occluding a vascular cavity by inserting a thrombogenic material, which, because of its presence, causes formation of a thrombus.

Accordingly, the Court construes the phrase **"said tip portion being adapted to be positioned in said body cavity to form an occlusion,"** as it is used in Claim 1 of the '498 Patent to mean: **a detachable elongate tip configured to make it suitable for being placed in a body cavity for the purpose of being an occlusion of or forming an occlusion in the cavity.**

C. *Micrus*' '*558 Patent*

Claim 1 provides:

An occlusive device comprising at least one strand of a flexible material movable between an inoperable substantially linear configuration for insertion into and through **a means for delivering the device to a desired portion of a vesicle,** and an operable, **substantially spherical configuration** being substantially hollow for occluding at least a portion of said vesicle, **said substantially spherical configuration assuming a substantially minimal energy configuration for said strand.**

1. "a means for delivering the device to a desired portion of a vesicle"

[17] The parties dispute the proper construction of the phrase, "means for delivering the device to a desired portion of a vesicle." The parties have stipulated that the phrase is written in means-plus-function format and that it should be construed under 35 U.S.C. s. 112 para. 6, which provides:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The statutory language makes s. 112 para. 6 applicable to a claim if an "element in [the] claim for a combination" is expressed as a means for performing a specified function without the recital of structure. Claim 1 recites a structure, i.e., "at least one strand of flexible material." The "means for" limitation is a limitation on the "at least one strand of flexible material." A threshold issue is whether s. 112 para. 6 is applicable to the subject phrase, the resolution of which turns on the meaning of the statutory language "element in a claim for a combination."

a. "element in a claim for a combination"

In patent law, the word "element" is used in multiple ways.

While not an absolute rule, all claim terms are presumed to have meaning in a claim. The words of a claim describe and point out the invention by a series of limiting words or phrases-limitations. * * * It is said to be elementary patent law that all limitations are material.

References to 'elements' can be misleading. The term is often used to refer to structural parts of the accused device or of a device embodying the invention. It is also used in the phrase, in 35 U.S.C. s. 112, 'elements of a claim.' An element of an embodiment of an invention may be set forth in the claim. But it is the limitation of a claim that counts in determining both validity and infringement. Because claims are composed of a number of limitations, the limitations have on occasion been referred to as claim elements or elements of a claim, but clarity is advanced when sufficient wording is employed to indicate when 'element'is intended to

mean a component of an accused device or of an embodiment of an invention and when it is intended to mean a feature set forth in or as a limitation in a claim.

Robert L. Harmon, *Patents and the Federal Circuit,* 362-363 (8th ed.2007).

As used in s. 112 para. 6, the word "element" means a "limitation of a patent claim:"

The statute [s. 112 para. 6] refers to a claim "element," but this court [the Federal Circuit] has moved towards the custom of referring to claim "limitations," reserving the word "elements" for describing the parts of the accused device, though the court on occasion continues to use the words interchangeably.

Dawn Equipment Co. v. Kentucky Farms, Inc., 140 F.3d 1009, 1014 fn. 1 (Fed.Cir.1998).

[18] The phrase, "in a claim for a combination," has also been interpreted by the Federal Circuit. The "claim for a combination" phraseology requires a patent claim, which is drafted in means-plus-function format, to recite a combination of limitations. In other words, s. 112 para. 6 may not be used in a "single means claim:"

The language [of the final paragraph of s. 112] does not go so far as to permit a so-called single means claim, that is a claim which recites merely one means plus a statement of function and nothing else. Attempts to evade this by adding purely nominal elements to such a claim will undoubtedly be condemned.

In re Hyatt, 708 F.2d 712, (Fed.Cir.1983).

[19] [20] It is established law that it is permissible for an inventor to use a limitation to disclose the invention of a device by reciting its function or by disclosing the relationship between the device and some "other structure." FN25 This remains true whether or not the "other structure" is a component of the device itself.FN26 Therefore, the Court finds as a matter law that, in disclosing the relationship between the device and some other structure, the inventor is permitted to describe the "other structure" in means-plus-function format. Here, the means-plus-function limitation is a structure which limits the "occlusive device." The Court also notes that Claim 1 is not a single means claim because it recites multiple limitations. Thus, Claim 1 meets the criteria for having a limitation expressed in means-plus-function format.

FN25. A patentee is free to claim features of an apparatus using either structural or functional language. In re Schreiber, 128 F.3d 1473, 1478 (Fed.Cir.1997). In certain circumstances, the functional language will be regarded as a claim limitation. *See, e.g.,* DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1021 (Fed.Cir.2006).

FN26. *Cf.* In re Wakefield, 57 C.C.P.A. 959, 422 F.2d 897, 904 (C.C.P.A.1970) (rejecting a finding by the Patent Office Board of Appeals that the use of a negative limitation excluding the characteristics of prior art products causes a claim to be indefinite).

Accordingly, the Court accepts the parties' stipulation and proceeds to construe the subject phrase under 35 U.S.C. s. 112 para. 6.FN27

FN27. The Court notes that the "means for delivering" is not claimed as an invention in Claim 1. The invention is an "occlusive device" capable of insertion into and through the "means for delivery" even if it is not delivered using that "means."

b. the recited function

[21] In construing the meaning of a limitation in means-plus-function format, the Court must first identify the claimed function. *See* Micro Chem., Inc. v. Great Plains Chem. Co., 194 F.3d 1250, 1258 (Fed.Cir.1999). Typically, the words and phrases following the phrase "means for" indicate the function which is performed by the means. *See, e.g.,* Lockheed Martin Corp. v. Space Systems/Loral, Inc., 249 F.3d 1314, 1324 (Fed.Cir.2001). If there is a dispute over the meaning of the words and phrases which express the function of the means, their meaning must be decided by the court, using the standard principles of claim construction. Id.

The function of the "means" limitation of Claim 1 is "**for delivering** the [occlusive] device to a desired portion of a vesicle." Claim 1 recites that the "strand of flexible material" must be capable of being **inserted into and moved through** the "means for delivery." The Court finds that the function of "delivering" includes: inserting the strand into the means, moving the strand through the means, and placing the "strand" in a desired location in a vesicle.

c. corresponding structure

After the function of the means is defined, the Court must look to the specification to identify corresponding structure which performs that function. *See* Micro Chem., Inc., 194 F.3d at 1258. The means limitation must be construed "to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1308 (Fed.Cir.1998).

To fulfill the "delivering" function, the specification must recite a structure which is capable of receiving insertion of the occlusive device **into it** and capable of moving the device **through it** for placement in a desired location in the body. The Court examines the specification for corresponding structure. In the "Summary of the Invention," the inventor states that the occlusive device is introduced into a "catheter," which is pre-positioned with its distal opening within the mouth of the body cavity and describes a "pusher" as a structure used to move the device to that position for its emanation into the vascular cavity:

The device is used simply by temporarily straightening the device into the inoperable configuration and **introducing it into a suitable catheter,** the catheter already having been situated so that its distal opening is within the mouth of the vascular crevice or opening to be filled. **The device is then pushed through the catheter** and, upon its emanation at the distal end of the catheter into the vascular cavity, assumes its relaxed operable configuration.

('558 Patent, Col. 2:56-63.)

The "Detailed Description of the Invention" also describes the use of a pusher for delivering the device:

Although the device may be used with a flexible pusher without connection to the vasoocclusive device described here, much more desirable is the use of a mechanically detachable coupling on the vasoocclusive

device and the pusher.

('558 Patent, Col. 7:22-26.)

Accordingly, the Court construes the phrase **"a means for delivering the device to a desired portion of a vesicle,"** as it is used in Claim 1 of the '558 Patent to mean: **the catheter and pusher, as described in the specification, and equivalent structures.**

2. "substantially spherical configuration"

[22] Claim 1 claims an occlusive device comprising at least one strand of a flexible material movable to an operable, substantially spherical configuration. The parties dispute the construction of the phrase, "substantially spherical configuration."

In the specification, the inventor defined the phrase "substantially spherical:"

By the term "substantially spherical" is meant a shape which includes spherical as well as other distorted shapes, such as ovate, ovoid, or ellipsoid, but in any event having two orthogonal cross sections which are closed shapes having no substantially straight sides.

('558 Patent, Col. 4:5-10.)

The ordinary and customary meaning of "configuration" is "the external form figure or shape of a thing as resulting from the predisposition and shape of its parts, contour, or outline." *See* WEBSTER'S NEW TWENTIETH CENTURY DICTIONARY, 382 (2d ed.1983). A person or ordinary skill in the art at the time of the invention reading the patent documents would understand that the inventor used the phrase "substantially spherical configuration" to mean "substantially spherical shape." Moreover, a skilled artisan would also understand that the inventor meant for the phrase in Claim 1, "being substantially hollow," to be a limitation on the configuration.FN28

FN28. The inventor is critical of three-dimensional devices which did not maintain their shape: "These prior vasoocclusive devices do not maintain a three-dimensional conformation for a satisfactory period of time; the coils collapsing in upon themselves to form mere rings. A useful substantially spherical vasoocclusive device has heretofore not been made available." ('558 Patent, Col. 1:34-40.)

Accordingly, the Court construes the phrase **"substantially spherical configuration,"** as it is used in Claim 1 of the '558 Patent to mean: **capable of assuming a substantially hollow, three-dimensional, spherical shape, such as ovate, ovoid, or ellipsoid, having two orthogonal cross sections which are closed shapes having no substantially straight sides.**

3. "said substantially spherical configuration assuming a substantially minimal energy configuration for said strand"

[23] The parties dispute the meaning of the phrase, "said substantially spherical configuration assuming a substantially minimal energy configuration for said strand." The subject claim language is not used elsewhere in the specification.

Claim 1 is a device claim, which discloses an "occlusive device" by reciting defining limitations. A skilled artisan would understand that the phrase "assuming a substantially minimal energy configuration" means a strand which is *capable* of assuming that configuration. Moreover, a skilled artisan would understand that the limitation requires that the strand be capable of assuming that configuration when it is in a "substantially spherical configuration." Thus, the issue becomes what the inventors meant by "assuming a substantially minimal energy configuration."

In the "Summary of the Invention," the inventor states that "the invention" comprises a strand of flexible material which would be "wound" during the manufacturing process and which would form a spherical shape that is "relaxed:"

This invention is a vasoocclusive device comprising one or more strands, or vasoocclusive members, which are wound to form a generally **spherical or ovoid shape when relaxed.** The strand is made of a flexible material movable between an inoperable substantially linear configuration for insertion into and through a means for delivering the device to a cavity, and **an operable, substantially spherical configuration** for occluding at least a portion of said cavity.

('558 Patent, Col. 2:29-36.) A skilled artisan would understand that the inventor is using the phrase "generally spherical or ovoid shape when relaxed" with an ordinary and customary meaning, i.e., a device which must be capable of assuming a spherical or ovoid shape when free of external stress or restriction.

This conclusion is supported by a further description in the Summary:

The device is used simply by temporarily straightening the device into the inoperable configuration and introducing it into a suitable catheter, the catheter already having been situated so that its distal opening is within the mouth of the vascular crevice or opening to be filled. The device is then pushed through the catheter and, upon its emanation at the distal end of the catheter into the vascular cavity, assumes its **relaxed operable configuration.**

('558 Patent, Col. 2:56-63.) Thus, a skilled artisan would understand that the inventor is describing a strand which must be fabricated to be generally spherical or ovoid, capable of being "temporarily straightened" during delivery, and capable of resuming its generally spherical or ovoid shape when deployed into a vascular cavity. A skilled artisan would understand that when such a strand is straightened and placed in a catheter, external stresses are imposed on the strand. When the strand is deployed into a vascular cavity, the strand "relaxes," meaning it assumes its prior spherical or ovoid shape, unless of course new stresses are imposed upon it by the cavity. For instance, it may be deformed by the walls of the cavity.

Accordingly, the Court construes the phrase **"said substantially spherical configuration assuming a substantially minimal energy configuration for said strand,"** as it is used in Claim 1 of the '558 Patent to mean: **a flexible strand which assumes a substantially spherical configuration when it is subjected to minimal or no external stress.**

D. *Micrus*' '*219 Patent*

1. Claim 9 of the '219 Patent

[24] Claim 9 provides:

The device of claim 1, wherein said **strand of flexible material further comprises a first portion and a second portion,** said first portion forming a cavity in the substantially spherical configuration, and said second portion being disposed within said cavity.

The parties dispute construction of the phrase, "strand of flexible material further comprises a first portion and a second portion." The issue is what the inventor meant by the word "portion" of "said strand." FN29

FN29. The Court notes that the Preamble of Claim 9 uses the phrase "further comprises." Normally, this phrase is used to add an additional limitation to an antecedent "comprising" limitation. Claim 1 does not recite any "comprising" limitation for a strand. Claims 7 and 8 do contain a "comprising" limitation for "said flexible material," which implicitly is a limitation of the "strand." However, Claim 9 does not depend from Claims 7 or 8. Unless a party raises the issue, the Court will regard the wording of Claim 9 as inartfully drafted, with no affect on validity.

The ordinary and customary meaning of "portion" is a part of a whole. The Court examines the patent documents to determine if a person of skill in the art would understand that the inventor used the word with its widely accepted meaning.

Claim 9 depends from Claim 1. Claim 1 discloses an occlusive device comprising "at least one strand of a flexible material." A person of ordinary skill in the art would understand that the occlusive device could be comprised of one strand or of multiple strands. Thus, the limitations of Claim 9 would be understood to apply to "at least one strand" or to multiple strands. In either event, the limitations of Claim 9 would be understood to apply to a strand. Moreover, a skilled artisan would understand Claim 9 to recite a strand that has a first portion which forms a spherical cavity and a second portion which is positioned inside of the cavity.

Although the precise language of Claim 9 is not discussed elsewhere in the specification, the written description discusses drawings of embodiments of a strand which have a portion or portions which "nest" within another portion:

FIG. 6A shows a cross-section of such an alternative embodiment of the invention, wherein **two vasoocclusive strand portions** (142, 144) are provided to nest concentrically with each other in the operable configuration. The **larger** vasoocclusive **strand portion** (142) can serve as a cavity in which to concentrically house the other **smaller** vasoocclusive **strand portion** (144). When the device (140) is unwound in the inoperable configuration, each vasoocclusive strand portion (142, 144) is aligned longitudinally in tandem. Such a vasoocclusive device (140) with a plurality of concentric vasoocclusive portions can be made **from the same metallic strand along different portions thereof, or separate strands can be prepared and then fused together at their ends in longitudinal tandem.** FIG. 6B shows this alternative embodiment in a partially unwound position to demonstrate that the spheres are arranged in tandem along the same strand. The aligned vasoocclusive strand portions (142, 144) can each be wound on the same or slightly different sized mandrel in order to form a multiple-layered sphere when positioned in the wound, operable configuration.

The invention, as shown in FIG. 6C, contemplates that **a plurality of concentrically nesting occlusive strand portions (143) may be employed.** Each spherical occlusive strand portion may have a unique size, so that the device is capable of concentric nesting with the other occlusive members.

('219 Patent, Col. 6:3-28.)

A person of ordinary skill in the are reading the written description would understand that the inventor uses the phrase "strand portions" to refer to two parts of a single strand. The inventor discusses embodiments which can be fabricated in such a manner that one part of the strand will form an outermost sphere and the other portion of the strand will form an innermost sphere FN30 which will nest concentrically inside of the other. The inventor also discloses an embodiment in which a strand can be fabricated by fusing together "separate strands" which, acting as a single unit, will perform concentric nesting in the operable configuration. The Court's conclusion that the inventor meant the word "portions" to refer to parts of a single strand is supported by the language of Claim 13:

FN30. There is no limitation in Claim 9 which requires the "second portion" be spherical.

The device of Claim 9, further comprising a plurality of additional strand portions disposed within said cavity.
Further, a person of skill in the art would understand that by the phrase, "plurality of strand portions," the inventor means separate, unconnected strand portions. In the written description, the inventor draws a distinction between a strand with a nesting "portion" and a separate "strand portion" which is nested:

The invention, as shown in FIG. 6D, also contemplates that a plurality of substantially spherical **strand portions** (145), or other known vasoocclusive devices, can be inserted in a nonconcentric manner inside a substantially spherical cavity created by the **first strand portion.** To protect flowing blood from a thrombogenic surface, the outermost coils may be bare, or unfibered. Providing naturalor synthetic fibers (146) to the innermost **strand portion** (144) increases the thrombogenicity therein and protects the vesicle from flowing blood. In this way, blood clotting begins in the center of the vasoocclusive device and proceeds outward, stopping at the arterial lumen.

('219 Patent, Col. 28-40.) A person of skill in the art would understand from the written description and Figure 6D that the innermost nonconcentric strand portion which the inventor is discussing is not connected to the "first strand portion." The inventor does not use the claim phrase "second portion" to refer to these separate additional unconnected strand portions.

Accordingly, the Court construes the phrase **"strand of flexible material further comprises a first portion and a second portion,"** as it is used in Claim 9 of the '219 Patent to mean: **A single strand of flexible material comprising two distinct parts.**

2. Claim 22 of the '219 Patent

Claim 22 provides:

A vesicle-occlusion device for repairing a vessel having a vesicle to restore physiologically normal flow to the vessel, the device comprising **at least one strand of a flexible material having a substantially linear configuration that winds into a three-dimensional cage** within the vesicle for occluding at least a portion of the vesicle, said three-dimensional cage assuming a substantially minimal energy configuration for said strand.

[25] The parties dispute the construction of the phrase, "three-dimensional cage" as used in Claim 22.

In the specification, the inventor uses the word "cage" synonymously with "a strand wound so as to have multiple loops spaced to form a spherical cavity:"

The strand (102) shown is **wound in a tertiary substantially spherical structure so as to have multiple loops spaced generally equally to form a cavity, or cage-like structure.** The rear side strand (102) loops are shown as dotted lines for clarity, however, these would be visible through the open areas of the **cage.** It is clearly not necessary that the tertiary shape be precisely a sphere, but it is desirable from a mechanical point of view that such a spacing be approached. The invention contemplates that the occlusive device (100) is wound into and is self-forming into a substantially spherical or distorted spherical form.

In one embodiment, it is intended that the device (100) in the operable configuration be in a **roughly spherical cavity or cage-like structure** where at least 90-95% of the strand (102) is in the outer 10-15% of the diameter of the device (100). The precise number of loops of the strand will vary and depends upon the type of vesicle or cavity to be filled, and upon the length of catheter tubing necessary for deployment in the extended, linear position.

('219 Patent, Col. 3:41-55.)

Accordingly, the Court construes the phrase **"at least one strand of a flexible material having a substantially linear configuration that winds into a three-dimensional cage,"** as it is 32 used in Claim 22 of the '219 Patent to mean: **At least one strand of flexible material wound so as to have multiple loops spaced so as to enclose a substantially spherical cavity.**

3. Claim 44 of the '219 Patent

[26] Claim 44 provides:

A vesicle-occlusion device for repairing a vessel having a vesicle to restore physiologically normal flow to the vessel, the device comprising at least one strand of a flexible material having a substantially linear configuration that winds into **a three-dimensional configuration approximating the shape of the vesicle** into which the device is inserted to occlude at least a portion of the vesicle, said **three-dimensional configuration having about 90% of said strand in about the outer 15% of the diameter of said three-dimensional configuration.**

a. "a three-dimensional configuration approximating the shape of the vesicle"

The parties dispute the phrase, "a three-dimensional configuration approximating the shape of the vesicle."

Grammatically, in Claim 44, the word "approximating" is a present participle functioning as an adjective modifying the noun phrase "three-dimensional configuration." The ordinary and customary meaning of the word "approximating" functioning as an adjective is: close, near or approaching. *See* WEBSTER'S NEW TWENTIETH CENTURY DICTIONARY, 92 (2d ed.1983). The Court examines the specification to determine if the inventor used "approximating" with its ordinary and customary meaning or with a specialized meaning.

Although the phrase "a three-dimensional configuration approximating the shape of the vesicle" is not discussed in the written description,FN31 in describing an embodiment of the invention, the inventor states the desirability of the device being "similar" in shape to the anatomical shape of the cavity:

FN31. The same limitation is recited in Claim 19.

In general, it is desirable that the device (104) be constructed in such a way that the resulting relaxed device (104) have a **shape similar to the cavity into which it is placed.** Somewhat less spherical configurations of the device are permissible and, in many instances, even desired, depending upon the anatomical shape of the vesicle or cavity to be occluded.
('219 Patent, Col. 3:67-4:5.) Thus, a skilled artisan would understand that the inventor used the phrase "approximating the shape of the vesicle" to mean similar to the shape of the vesicle.
Accordingly, the Court construes the phrase **"a three-dimensional configuration approximating the shape of the vesicle,"** as it is used in Claim 44 of the '219 Patent to mean: **a three-dimensional configuration similar to the shape of the vesicle.**

b. "three-dimensional configuration having about 90% of said strand in about the outer 15% of the diameter of said three-dimensional configuration"

[27] The parties dispute the proper construction of the phrase, "three-dimensional configuration having about 90% of said strand in about the outer 15% of the diameter of said three-dimensional configuration." The primary language in dispute is the phrase "the outer 15% of the diameter."

The subject language recites a limitation which is based on the diameter of the "three-dimensional configuration" of a strand. In discussing an embodiment of the invention in the written description, the inventor discusses "diameter," with respect to both the strand and the three-dimensional coil formed by the strand:

Generally speaking, when the device (100) is formed of a metal such as platinum or a super-elastic alloy such as nitinol, the **diameter of the wire** used in the production of the coil will be in the range of 0.0005 and 0.006 inches. The wire of such diameter is typically then wound into **a coil having a primary diameter of between 0.005 and 0.018 inches.**

('219 Patent, Col. 2:38-44.) Thus, a skilled artisan reading the patent documents would understand that in Claim 44 the inventor is using the word "diameter" with its ordinary and customary meaning, i.e., the longest measurable straight line between two points on the perimeter of a closed figure. *See* WEBSTER'S NEW TWENTIETH CENTURY DICTIONARY, 503 (2d ed.1983).

Further, a skilled artisan would understand that a three-dimensional configuration of a strand could assume an irregular shape, making it difficult precisely to determine the longest diameter. However, a skilled artisan would understand that determination of a precise diameter is not required in Claim 44. Rather, it is clear from the plain language of the Claim that the inventor is using "about the outer 15% of the diameter" to describe an approximate *aggregation of space* in the outer portion of the configuration in which approximately 90% of the overall length of the strand must be located.

Accordingly, the Court construes the phrase **"three-dimensional configuration having about 90% of said**

strand in about the outer 15% of the diameter of said three-dimensional configuration," as it is used in Claim 44 of the '219 Patent to mean: **a three-dimensional configuration of a strand in which approximately 90% of the length of the strand is located in a space which is, in aggregate, defined by approximately 15% of the outer portion of the diameter of the configuration, the diameter being the length of the longest straight line which could be drawn between two opposite points located on the perimeter of the configuration.**

V. CONCLUSION

In this Order, the Court has given its construction of submitted words and phrases of the patents-in-suit: Boston Scientific's '385 and '498 Patents, and Micrus' '558 and '219 Patents.

The parties shall appear for a Case Management Conference on **May 2, 2008 at 10 a.m.** On or before **April 18, 2008,** the parties shall submit a Joint Case Management Statement. The statement shall include, if applicable, a chart of additional claim terms requiring construction, terms the parties wish the Court to reconsider, a briefing schedule for dispositive motions in light of this Order, and a good faith discovery plan.