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

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,
Plaintiff.
v.
MICRO THERAPEUTICS, INC. and Dendron GmbH,
Defendants and Third Party Plaintiffs.
v.
Boston Scientific Corp. and Target Therapeutics, Inc,
Third Party Defendants.

No. C03-05669 JW

March 2, 2007.

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SUPPLEMENTAL CLAIM CONSTRUCTION ORDER

JAMES WARE**, J.**

INTRODUCTION

Plaintiff The Regents of the University of California ("The Regents") bring this action suit against Defendants Micro Therapeutics Inc. ("MTI") and its wholly owned subsidiary Dendron GmbH ("Dendron") (collectively, "Defendants") for infringement of twelve of its patents which relate to devices and apparatus for occluding vascular cavities. The inventions disclosed in the patents are useful for treatment of brain aneurysms.

On March 4, 2005, the Court held 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 disputed words and phrases of the asserted claims. On August 25, 2005, the Court issued a Claim Construction Order. (hereafter, "August 2005 Markman Order," Docket Item No. 270.). On September 20, 2006, the Court held another hearing to construe additional disputed words and phrases. This Order addresses those additional words and phrases.

BACKGROUND

The Regents of the University of California is the sole assignee and the exclusive owner of the patents-in-suit. The named inventors of the patents-in-suit are Dr. Guido Guglielmi, who was at the time of the invention a professor at the University of California Los Angeles Medical Center, and Ivan Sepetka, who at the time of the invention was an employee of Target Therapeutics, Inc.

Defendant MTI develops, manufactures, and markets medical devices for the treatment of neuro and peripheral vascular diseases. Defendant Dendron, is a German company which was acquired by MTI in 2002. Dendron is in the business of manufacturing and distributing detachable coil delivery systems both in Europe and the United States.

The Regents allege that Dendron and MTI are currently engaged, or are completely prepared to engage, in the manufacture, importation, distribution and sale in the United States of the Sapphire line of detachable coil delivery systems, which are used for the treatment of brain aneurysms, and which allegedly infringe the patents-in-suit.

During the claim construction process, The Regents withdrew five of its asserted patents. The Regents presently assert the following seven patents against Defendants: 5,122,136 ("the '136 patent"), 5,855,578 ("the '578 patent"), 5,947,962 ("the '962 patent"), 5,947,963 ("the '963 patent"), 5,925,037 ("the '037 patent"), 5,976,126 ("the '126 patent"), and 6,066,133 ("the '133 patent").

Defendants deny infringement of the patents-in-suit and have raised affirmative defenses and asserted counterclaims for invalidity. In addition, Defendants have filed a Third Party Complaint against Target Therapeutics, Inc. ("Target") and Boston Scientific Corporation ("Boston Scientific") for declaratory relief of invalidity and non-infringement. FN1

FN1. Defendants also asserted an Amended Counterclaim as well as an Amended Third Party Complaint for antitrust violations based on Defendants' claim that, by obtaining and enforcing its patents, The Regents, together with its exclusive licensee, Target, and Target's parent corporation, Boston Scientific, engaged in anti-competitive and monopolistic behavior. Defendants' counterclaims relate to all twelve of The Regents' originally asserted patents. The five additional patents that remain in the counterclaims are the 5,354,295 ("the '295 patent"), 5,540,680 ("the '680 patent"), 5,895,385 ("the '385 patent"), 6,010,498 ("the '498 patent"), and 6,083,220 ("the '220 patent").

STANDARDS AND PROCEDURES FOR CLAIM CONSTRUCTION

A. *General Principles of Claim Construction*

Claim construction is purely 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 meanings of a word or phrase 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 proposed construction. 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 word or phrase. The Court's construction becomes legally operative meaning which governs further proceedings in the case. Vitronics Corp. v. Conceptronic. Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996).

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

An invention is defined by the language of the claim. Phillips v. AWH Corp., 415 F.3d 1303, 1322 (Fed.Cir.2005). In construing the meaning of claim language, the Court does so from the viewpoint of person of ordinary skill in art at the time of the invention. Thus, the Court seeks to construe the patent claim in accordance with what a person of ordinary skill in the art would understand the claim to mean at the time of the invention. The time of the invention is as of the effective filing date of the patent application. Id., at 1312.

The Court proceeds from an understanding that a person of ordinary skill in the art would come to an understanding of the meaning of the language of the claim by interpreting the language in the context of the intrinsic record. The instinsic record includes the language of the claim itself, and any surrounding claims, the written description, the drawings and the prosecution history-if they are in evidence. Teleflex, Inc. v. Fisosa N. Am. Corp., 299 F.3d 1313, 1324 (Fed.Cir.2002).

The Court approaches claim construction with an understanding that a person of ordinary skill in the art reading the intrinsic evidence would give consideration to whether the disputed word is one commonly used in lay language, a technical word or is a word coined by the inventor.

C. ***Commonly Used Words or Phrases***

If the disputed word or phrase is one which is commonly used in ordinary language, the Court considers that a person of ordinary skill in the art would give to it its ordinary and customary meaning, unless a specialized definition is stated in the patent specification or was stated by the inventor during prosecution of the patent. In articulating the ordinary and customary definition of a word which is commonly used in the English language, the Court may consult a general purpose dictionary. Phillips, 415 F.3d at 1314.

However, an inventor is free to act as his own lexicographer. Thus, acting as a lexicographer, the inventor may use a word or phrase differently than with its ordinary and customary meaning. Vitronics Corp., 90 F.3d at 1582. The Court examines the claim and other parts of the patent specification to determine if the inventor used the word with a specialized meaning.

A statement made by the inventor in the prosecution of the patent application as to the scope of the invention may be considered as evidence of what meaning to give to a word or phrase of a claim. Microsoft Corp. v. Multi-Tech Systems, Inc., 357 F.3d 1340, 1349 (2004). If it is in evidence, the Court examines the prosecution history of the patent for any specialized definition of a word or phrase used in a claim. A specialized definition clearly stated in the specification or during prosecution of a particular word or phrase is regarded by the Court as highly persuasive of the meaning of the word or phrase when it is used in a claim. Phillips, 415 F.3d at 1322.

D. ***Technical Words or Phrases***

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

the technical word or phrase. *Id*.

E. *Coined Words or Phrases*

If the disputed word or phrase is coined by the inventor, the definition must be clearly stated in the patent documents. Vitronics Corp., 90 F.3d at 1582. If a definition of a coined word or phrase is not clearly stated or cannot be reasonably inferred, the Court may decline to construe the word pending further proceedings.

The Court recognizes that in the claim construction process, the Court is able to consider a number of extrinsic sources in any sequence it desires so long as it does not adopt a construction based on extrinsic evidence which contradicts the unambiguous meaning of a claim given in the intrinsic evidence. Phillips, 415 F.3d at 1324.

DISCUSSION

In the August 2005 Markman Order, the Court construed the following words as they were used in the '136 and '578 Patents: "wire," "guidewire," "tip," "distal tip," "connecting segment," "detach," "detaching," "detachment," and "detachable." In the course of considering additional claim language and additional patents from the September, 2006 hearing, the Court has decided to modify some of the constructions given in the August 2005 Markman Order. To the extent a construction given in this Order to a particular word or phrase as it is used in a particular claim conflicts with the construction given in the August 2005 Markman Order, the construction in this Order controls as to that claim.

The Court examines the patents-in-suit in the order of the filing dates of the respective underlying applications.

I. THE '136 PATENT

The '136 Patent is entitled: "Endovascular Electrolytically Detachable Guidewire Tip for the Electroformation of Thrombus in Arteries, Veins, Aneurysams, Vascular Malformations and Arteriovenous Fistulas." The '136 Patent is the parent patent of the patents-in-suit. The application which led to its issuance was filed on March 13, 1990. The '136 Patent issued on June 16, 1992. The following claims of the '136 Patent are being asserted in this case: 4-6, 21, 22 and 23. The Court will only address the claims containing words or phrases about which there is a dispute.

With respect to the '136 Patent, Claim 1 is not being asserted against Defendants in this case. However, Claim 4, which is being asserted, is a dependent claim to Claim 1. The parties dispute the proper construction of language in Claim 4 which depends upon antecedent words contained in Claim 1. Therefore, before beginning its construction of Claim 4, the Court considers the antecedent language of Claim 1.

A. The '136 Patent-Claims 1

Claim 1 provides: FN2

FN2. Unless otherwise indicated, all bold typeface is added by the Court for emphasis.

A method for forming an occlusion within a vascular cavity having blood disposed therein comprising the

steps of:
endovascularly disposing a guidewire near an endovascular opening into said vascular cavity;

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

detaching said distal tip from said guidewire to leave said distal tip within said vascular cavity and said occlusion being formed within said vascular cavity, whereby said vascular cavity is occluded by said distal tip, and any thrombus formed by use of said tip.

1. "forming an occlusion within a vascular cavity"

The Preamble to Claim 1 provides:

A method for forming an occlusion within a vascular cavity having blood disposed therein ...

The parties dispute the proper construction of the phrase "forming an occlusion within a vascular cavity."

The field of the invention includes a knowledge of vascular medicine. In the field of vascular medicine, a person of ordinary skill would understand the word "occlusion" to be a technical word which means a blockage of a blood vessel usually by thrombosis. *See Stedman's Medical Dictionary,* 1355 (28th ed.2006). Some areas of vascular medicine are concerned with methods and devices for removing an occlusion, such as when a blockage has formed as a result of a disease. For example, percutaneous transluminal coronary angioplasty is used to open an occlusion of a coronary artery. *Id.,* 88-89.

In contrast to procedures for removing an occlusion, the inventions of the '136 Patent are methods and devices for deliberately forming an occlusion to treat malformations within the vascular system.

The "Background of the Invention" section of the patent states that creation of an "occlusion" to block off vascular malformations was known at the time of the invention. The "Background" discusses intracranial aneurysms as examples of a vascular malformations which physicians sought to treat by "occluding" them in various ways. The "Background" discusses endovascular and extra-intravascular prior art methods for "occluding" intracranial aneurysms by inserting objects such as balloons or injecting coaggulants within them:

In such [endovascular] procedures a balloon is typically attached to the end of the microcather and it is possible to introduce the balloon into the aneurysm, inflate it, and detach it, leaving it to occlude the sac and neck with preservation of the parent artery.

('136 Patent, Col. 1:51-55.)

In the extra-intravascular approach, an aneurysm is surgically exposed or stereotaxically reached with a probe. The wall of the aneurysm is then perforated from the outside and various techniques are used to occlude the interior in order to prevent it from rebleeding.

('136 Patent, Col. 2:11-16.)

The "Background" also discusses prior art methods for forming a thrombus in an aneurysm as a means for occluding the aneurysm:

In the use of electrothrombosis for extra-intravascular treatement the tip of a positively charged electrode is inserted surgically into the interior of the aneurysm. An application of the positive charge attracts white blood cells, red blood cells, platelets and fibrinogen which are typically negatively charged at the normal pH of the blood. The thrombic mass is then formed in the aneurysm about the tip. Thereafter, the tip is removed.

('136 Patent, Col. 2:19-26.)

The disputed language under consideration appears in the Preamble of Claim 1, which states that the invention is a method "for forming an occlusion within a vascular cavity." The Summary of the Invention section of the '136 Patent discloses that the method is practiced by forming a thrombus in the vascular cavity:

A method for forming a thrombus within a vascular cavity comprising the steps of endovascularly disposing a guidewire near an endovascular opening into the vascular cavity. A distal tip of the guidewire is disposed into the vascular cavity. A electrical signal is applied to the distal tip within the vascular cavity to form a thrombus within the vascular cavity about the distal tip. The distal tip is detached from the guidewire to leave the distal tip within the vascular cavity and the thrombus electrically formed within the vascular cavity.

As a result, electrical formation of a thrombus is completely endovascularly formed.

('136 Patent, Col. 4:1-14.)

However, the language of Claim 1 does not limit "formation of an occlusion" only to formation of a thrombus. The Claim discloses that the vascular cavity is occluded by a thrombus and the distal tip:

whereby FN3 said vascular cavity is occluded by said distal tip, and any thrombus formed by use of said tip.

FN3. This language is taken from a "whereby clause." As discussed in Discussion Section I.A.3, below, the "whereby clause" of Claim 1 is limiting because it imposes a limitation on the composition of the occlusion.

Therefore, construction of the subject phrase must be broad enough to cover occlusion by the distal tip and any associated thrombus.

In the area of vascular medicine concerned with removal of an occlusion formed due to disease, a vessel may be described as "occluded" if it is partially blocked. An additional aspect of the dispute over the construction of the subject phrase is whether the inventors intended the word "occlusion" to mean a blockage which *completely obstructs* the vascular cavity or whether a *partial obstruction* was intended to be included in the definition of "occlusion."

On its face, Claim 1 does not state what amount or degree of blockage is meant by "formation of an occlusion." In general, if a claim does not contain a limitation on the extent of a disclosed parameter, the Court should not add such a limitation. *See* Modine Manufacturing Co. v. U.S. International Trade

Commission, 75 F.3d 1545, 1551 (Fed.Cir.1996).

The written description discloses three embodiments of the invention. With respect to the first embodiment, the inventors discuss that in using that embodiment of the invention, a thrombus or blood clot is formed, but they do not specify any extent to which the thrombus occludes the aneurysm:

The positive charge on secondary coil 28 within the cavity of the aneurysm causes a thrombus to form within the aneurysm by electrothrombosis.

('136 Patent, Col. 6:52-55.) Similarly with respect to the second embodiment, no specification of an extent of occlusion is disclosed:

The embodiment of FIG. 2 is utilized in exactly the same manner as described above in connection with FIG. 1 to form a thombic mass with an aneurysm or other vascular cavity.

('136 Patent, Col. 7:12-15.)

However, in a discussion of a third embodiment the inventors disclose circumstances under which the method results in the vascular cavity being "completely occluded:"

Turn now to the third embodiment of the invention as shown in FIG. 3.

* * *

After the thrombus has been formed and the aneurysm completely occluded, tip 58 and coil 56 are detached from guidewire 42 by electrolytic disintegration of at least one portion of stainless steel coil 46.

* * *

After separation by electrolytic disintegration, guidewire 42, microcatheter 44 and the remaining portion of coil 46 still attached to guidewire 42 are removed from vessel 66, leaving aneurysm 64 completely occluded as diagrammatically depicted in FIG. 5 by thrombus 74.

('136 Patent, Col. 7:42-43; 8:16-19, 26-30.)

There is no discussion in the extrinsic evidence that only complete occlusion would fulfill the medical purpose of the invention. Thus, in light of the inventors' choice of words, i.e., using "completely occluded" with only one embodiment, the Court declines to adopt a construction of "an occlusion" which requires that it completely block the vascular cavity because the construction arguably would not read on the first two embodiments. *See* SanDisk Corp. v. Memorex Products, Inc., 415 F.3d 1278, 1285 (Fed.Cir.2005).

The Court construes "forming an occlusion within a vascular cavity" as it is used in the Preamble to Claim 1 of the '136 Patent to mean:

forming a blockage within a vascular cavity. The vascular cavity does not have to be completely occupied by the blockage to be occluded.

2. "detaching said distal tip from said guidewire to leave said distal tip within said vascular cavity and said occlusion being formed within said vascular cavity"

The parties dispute the proper construction of the phrase "detaching said distal tip from said guidewire to leave said distal tip within said vascular cavity and said occlusion being formed within said vascular cavity," as disclosed in Claim 1.

Before turning to the specifics of the dispute with respect to this phrase, the Court's attention is drawn to the fact that the subject phrase includes the words "guidewire" and "distal tip." Supplemental materials and oral arguments from the parties in connection with the September 2006 hearing has led the Court to conclude that it should modify the definitions of the words "guidewire," and "distal tip."

Previously, the Court construed "guidewire and "wire" as having the same meaning for all claims.FN4 Based on additional consideration in light of the September 2006 proceedings, the Court now finds that each of these words should be defined in each claim in accordance with how it is used in that particular claim.FN5

FN4. "A thin, flexible, continuous length of metal, usually of circular cross-section that collectively includes both guidewires and tips and simply wires without distinct tip structures." (*See* August 2005 Markman Order.)

FN5. In the written description of the '578 Patent, the inventors expressly define "wire" and guidewire:
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. The wire may include a distinguishable structure at its distal end, which is termed a tip, in which case the remaining portion of the wire may be termed a guidewire. 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.

('578 Patent, Col. 4:3-13.)
The Court construes "guidewire" as it is used in Claim 1 of the '136 Patent to mean:

Part of an apparatus of the invention which is a thin, flexible, continuous length of metal, of circular cross-section which has a detachable tip.

The Court construes "distal tip" as it is used in Claim 1 of the '136 Patent to mean:

a detachable portion or segment of the guidewire furthest away from the physician.

The Court now returns to the disputed phrase, "detaching said distal tip from said guidewire to leave said distal tip within said vascular cavity and said occlusion being formed within said vascular cavity." Specifically, there is a dispute over whether the "detaching" step is performed *after* the occlusion is completely formed, or whether "detaching" takes place after the formation of the occlusion has been initiated but before it is completely formed. The plain language of the Claim discloses that the "detaching"

step takes place while the occlusion is "being formed," i.e., after formation has been initiated but before it has been completed. If formation of an occlusion is actually finished at the time of detachment, the "being formed" limitation would be unnecessary.

In the written description, the inventors describe an embodiment in which the thrombus continues to form after detachment:

It has further been discovered that thrombus 74 continue to form even after detachment from guidewire 42. It is believed that a positive charge is retained on or near coil 56 which wherefore continues to attract platelets, white blood cells, red blood cells and fibrinogen with aneurysm 64.

('136 Patent, Col. 8:42-47.) There are other embodiments in which the inventors state that detachment takes place after the vascular cavity is completely occluded:

After the thrombus has been formed and the aneurysm completely occluded, tip 58 and coil 56 are detached from guidewire 42 by electrolytic disintegration of at least one portion of stainless steel coil 46.

* * *

After separation by electrolytic disintegration, guidewire 42, microcatheter 44 and the remaining portion of coil 46 still attached to guidewire 42 are removed from vessel 66, leaving aneurysm 64 completely occluded as diagrammatically depicted in FIG. 5 by thrombus 74.

('136 Patent, Col. 8:16-19, 26-30.)

It is apparent that the inventors distinguished between detachment after an aneurysm is "completely occluded" and detaching "to leave" "said occlusion being formed." The latter is claimed in Claim 1. Therefore, in the following element of Claim 1 of the '136 Patent: "detaching said distal tip from said guidewire to leave said distal tip within said vascular cavity and said occlusion being formed within said vascular cavity," the Court construes the phrase, "being formed" to mean:

detaching the distal tip after the formation of an occlusion has started under circumstances where continuation of formation of the occlusion can take place after detachment.

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

Claim 1 concludes with a "whereby" clause:

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

('136 Patent, Col. 9:17-19.)

The parties dispute the proper construction of the "whereby" clause. A "whereby" clause in a method claim may express the intended result of a process. *See* Minton v. Nat'l Ass'n of Securities Dealers, Inc., 336 F.3d 1373, 1381 (Fed.Cir.2003). The "whereby" clause may also express a limitation on the method and thus be part of the method itself. Hoffer v. Microsoft Corp., 405 F.3d 1326, 1330 (Fed.Cir.2005). In this case, the

Court finds that with respect to Claim 1, the "whereby" clause imposes a limitation. The "whereby" clause requires that the occlusion be composed of both the distal tip and any thrombus formed by use of the distal tip.

The Court construes "whereby said vascular cavity is occluded by said distal tip, and any thrombus formed by use of said tip" to mean:

As a consequence of the method, a vascular cavity is blocked by the detached distal tip and any thrombus formed by use of the distal tip

B. The '136 Patent-Claim 5

Claim 5 provides:

The method of claim 4 where said step of electrolytically detaching said distal tip from said guidewire comprises the step of electrolytically disintegrating at least one portion of a connecting segment extending between said guidewire and said distal tip.

Claim 5 is a dependent claim of Claim 4. Thus, before construing Claim 5, the Court must examine the claim from which it depends.

Claim 4 is a limitation on the "detaching" step of Claim 1. Claim 4 discloses that the detaching step of Claim 1 comprises "electrolytically detaching." Claim 5 discloses limitations on the "electrolytically detaching" step of Claim 4, namely that the electrolytically detaching comprises "electrolytically disintegrating as least a portion of a connecting segment extending between said guidewire and said distal tip." The parties dispute the proper construction of two phrases of Claim 5: "connecting segment" and "extending between."

1. "connecting segment"

In the August 2005 Markman Order, the Court construed "connecting segment" to mean "a distinct portion of the device, capable of detaching the distal tip from the guidewire." (August 2005 Markman Order at 7.) This Order modifies that definition.

The phrase "connecting segment" is a coined phrase. The Court looks to the specification for a clear statement of the meaning of coined phrases. Vitronics Corp., 90 F.3d at 1582.

In the written description and in various claims of the patents-in-suit, the inventors use the words "segment" and "portion" interchangeably to indicate discreet parts of their invention. For example, with respect to an embodiment of the "guidewire," the written description states that it has a "core wire," (a phrase which will be considered later in this Order) which has a distal "portion" which is a stainless steel "segment:"

The distal portion is an exposed stainless steel segment.

The stainless steel segment comprises a coil connected at its proximate end to the core wire and connected at its distal end to the tip portion of the guidewire.

('136 Patent, Col. 4:63-69.) As a further example, in describing the tip, the written description uses the words "portion" and "segment" interchangeably:

The tip portion is a long and substantially pliable segment and is comprised of a material not susceptible to electrolytic disintegration within blood.

('136 Patent, Col. 5:8-10.)

With respect to the subject phrase, "connecting segment," the written description provides:

The step of electrolytically detaching the distal tip from the guidewire comprises the step of electrolytically disintegrating at least one portion of a connecting segment extending between the guidewire and the distal tip.

The step of electrolytically disintegrating the connecting segment comprises the step of electrolytically corroding away at least a portion of a coil segment.

('136 Patent, Col. 4:25-32.)

The Court finds that a person of ordinary skill would understand that the "connecting segment" is a distinct segment of the guidewire which functions to connect other portions or segments. It would also be clear to one of skill in the art reading the patent documents that another function of the connecting segment is to perform the function of "detaching." In the plain language of Claim 5, the distal tip is detached from the guidewire by electrolytically disintegrating at least one portion of the connecting segment. Thus, the construction of "connecting segment" must be one which includes the "detaching" function. Before giving a construction to this part of the subject phrase, the Court considers the other disputed phrase.

2. "extending between said guidewire and said distal tip"

With respect to the "connecting segment," the parties dispute the proper construction of the phrase "extending between said guidewire and said distal tip" as it is used in Claim 5. The dispute is whether the phrase should be construed to mean "located between" or whether it should be construed to include both "located between and connecting spatially."

It is clear from the language of the Claim that the phrase "extending between" is a limitation on the relationship among three components: the "connecting segment;" the "guidewire" and the "distal tip."

One of ordinary skill in the art would understand the phrase "extending between" to be composed of non-technical words which have ordinary and customary meanings. The phrase "extending between" uses the common preposition, "located between," meaning "in or through the space that separates two things." *See Webster's New Twentieth Century Dictionary,* 177 (2d ed.1983). A common definition of "extending" is "stretched out." *Id.,* 649. The Court finds that one of ordinary skill in the art would understand the phrase "extending between" to mean that the connecting segment is not only "between" the guidewire and the distal tip but that it also "extends" from the guidewire to the distal tip. In other words, a person of ordinary skill in the art would conclude that the connecting segment is attached at one of its ends to the guidewire and at its other end to the distal tip. This construction of the claim language is supported by a statement in the written description, describing an embodiment with these connections:

The stainless steel segment comprises a coil connected at its proximate end to the core wire and connected at its distal end to the tip portion of the guidewire.

('136 Patent, Col. 4:65-68.)

The Court construes "connecting segment" as it is used in Claim 5 to mean:

A segment of the guidewire that is attached at one of its ends to the core wire and is attached at its other end to the distal tip. The connecting segment is capable of being operated on to detach the distal tip from the remainder of the guidewire." FN6

FN6. The same definition applies to the phrase as it is used in Claims 5 and 14 of the '578 patent, which provides: "The method of claim 11 where said step of electrolytically detaching said distal tip of said wire electrolytically disintegrates a connecting coupling between said wire and said distal tip to effect separation."

C. The '136 Patent-Claim 6

Claim 6 of the '136 patent provides:

The method of claim 5 where said step of electrolytically disintegrating said connecting segment comprises the step of electrolytically corroding away at least a portion of a coil segment.

Claim 6 introduces a new phrase, namely, "coil segment." The parties dispute the proper construction of that phrase. Claim 6 depends from Claim 5. Thus, Claim 6 is a further limitation on the "electrolytically disintegrating" step of Claim 5.

By its language, Claim 6 requires that the step of Claim 5 of "electrolytically disintegrating of at least one portion of a connecting segment" be performed by "electrolytically corroding away at least a portion of a coil segment." There is no limitation in Claim 5 or 6 disclosing the connecting segment of Claim 6 *as* a coil.FN7 Without such a limitation, Claim 6 is arguably indefinite because there is no disclosure that "said connecting segment" is a "coil."

FN7. It is permissible for an inventor, who has disclosed a device in general terms in an antecedent claim, to state in a subsequent dependent claim that the device is made in a particular configuration as a limitation on the device already disclosed. For example, in a claim, an inventor may specify a "connecting segment." The inventor may introduce in a dependent claim "where said connecting segment is a coil." Claim 6 refers to the "connecting segment" of Claim 5 as "said connecting segment" but does not state that the "connecting segment" is a "coil."

In general, a claim ought to be construed to sustain its validity. Liebel-Flarsheim Co. v. Medrad, 358 F.3d 898, 911 (Fed.Cir.2004). In this case, to preserve the validity of Claim 6, the Court interprets "coil segment" of Claim 6 to be a limitation on the "connecting segment" of Claim 5. This is because without the two phrases referring to the same element, there is no logical way for the corrosion of the "coil segment" to

electrolytically disintegrate the "connecting segment."

The Court construes "coil segment" as it is used in Claim 6 of the '136 Patent the to mean:

a connecting segment that is a coil, at least a portion of which can be corroded electrolytically

D. The '136 Patent-Claim 21

Claim 21 of the '136 patent provides:

A guidewire for use in formation of an occlusion used in combination with a microcatheter comprising:

a core wire, said core wire having a distal portion susceptible to electrolytic disintegration in blood; and

an elongate tip portion extending said core wire for a predetermined lineal extent and coupled to said distal portion of said core wire, said tip portion for endovascular insertion within a vascular cavity, said elongate tip portion not being susceptible to electrolytic disintegration in blood,

wherein said elongate tip portion is a long and substantially pliable segment and is comprised of a metal [mental] FN8 not susceptible to electrolytic disintegration within blood, and

FN8. A Certificate of Correction was filed on June 16, 1992 correcting the word from "mental" to "metal."

wherein said long and pliable segment is prebiased to form a helix when extended from said microcatheter, whereby endovascular occlusion of said vascular cavity can be performed.

1. "core wire"

The parties dispute the proper construction of the phrase "core wire." This phrase is neither a phrase of common use in the English language nor is it a commonly used technical term. The phrase "core wire" was coined by the inventors to describe a part of the invention.

On the face of Claim 21, the phrase was coined by the inventors to describe a segment of the guidewire. Earlier in this Order, the Court gave its modified construction of the word "guidewire." It is also clear from the language of Claim 21 that the core wire has a "distal portion," and that "coupled to" the "distal portion" of the core wire is an "elongated tip portion:"

The Summary of the Invention of the '136 Patent discusses all of these portions:

The invention is also a guidewire for use in electrothrombosis and used in combination with a microcatheter comprising a core wire. The core wire has a distal portion susceptible to electrolytic disintegration in blood. A tip portion is coupled to the distal portion of the core wire.

('136 Patent, Col. 4:54-59.) This description in the Summary is significant because it is not limited to a particular embodiment. Therefore, the Court considers that unless a particular claim states otherwise, the phrase "core wire" should be construed to provide that its distal portion is susceptible to electrolytic disintegration in blood. Significantly, this excerpt from the Summary also makes it clear that the "tip

portion," which is "coupled to the distal portion of the core wire," is not a part of the "core wire."

In a description of Figure 1, "stainless steel guidewire 10," "reduced diameter section 16," and "threadlike section 18," are collectively included in the definition of a "core wire" of that embodiment:

The stainless steel guidewire 10, comprised of that portion disposed within the microcatheter body, tapered section 12, reduced diameter section 16 FN9 and threadlike section 18, is collectively referred to as a core wire which typically is 50-300 cm. in length.

FN9. Figure 1 has no reduced diameter section 16. The Court assumes that the written description was intended to read, "reduced diameter section 14." This apparent mistake does not affect the Court's claim construction.

In the illustrated embodiment the portion of the core wire extending from tapered section 12 to second bonding location 22 is collectively referred to as the grinding length and may typically be between 20 and 50 cm. in length.
('136 Patent, Col. 6:3-12.)
Figure 1 shows a component other than those which are listed "collectively" as the core wire, namely, stainless steel coil 26. The issue becomes whether the inventors meant the phrase "core wire" to include this additional component. Before addressing that issue, the Court considers how, if at all, the phrase "core wire" is used in descriptions of other embodiments of the invention.

With respect to the "second embodiment of the invention, illustrated by Figure 2, the written description states:

FIG. 2 illustrates in enlarged partially cross-sectional view a second embodiment of the invention. Stainless steel core 32 terminates in a conical distal portion 34. Stainless steel coil 36, shown in cross-sectional view, is soldered to distal portion 34 of guidewire 32 at bonding location 38. The opposing end of the stainless steel coil 36 is provided with a soldered, rounded platinum tip 40. In the illustrated embodiment, stainless steel core wire 32 is approximately 0.010 inch in diameter with the length of stainless steel coil 36 being approximately 8 cm. With the longitudinal length of platinum tip 40 being between 3 and 10 mm. The total length of guidewire 32 from tip 40 to the proximate end is approximately 150 cm.

The embodiment of FIG. 2 is utilized in exactly the same manner as described above in connection with FIG 1 to form a thombic mass within an aneurysm or other vascular cavity. The embodiment of FIG. 2 is distinguished from that shown in FIG 1 by the absence of the extension of stainless core 32 through coil 36 to tip 40. In the case of the embodiment of FIG. 2 no inner core or reinforcement is provided within stainless steel coil 36. Threadlike portion 18 is provided in the embodiment of FIG 1 to allow increased tensile strength of the guidewire. However, a degree of flexibility of the guidewire is sacrificed by the inclusion even of threadlike tip 18, so that the embodiment of FIG 2 provides a more flexible tip, at least for that portion of the microguidewire constituting the stainless steel coil 36.

('136 Patent, Col. 6:66-7:26.) In their description of the second embodiment, the inventors use "stainless steel core" and "stainless steel core wire" interchangeably.

The "third embodiment" of the invention, illustrated in Figure 3, does not use the phrase "core wire."

However, the description of the third embodiment refers to components which have the same names and descriptions FN10 as the components which are included in the definition of "core wire" in the first embodiment:

FN10. "Threadlike section 18" of the first embodiment is included in "core wire." The third embodiment discloses "thin threadlike extension 52." The Court finds that a skilled artisan would conclude that the components are the same for purposes of defining "core wire."

Turn now to the third embodiment of the invention as shown in FIG 3. FIG 3 shows an enlarged side view of a guidewire, generally denoted by reference numeral 42, disposed within a microcatheter 44 shown in crossectional view. Like the embodiment of FIG 1, a stainless steel coil 46 is soldered to guidewire 22 FN11 at a first bonding location 50. A thin threadlike extension 52 is then logitudinally disposed within stainless steel coil 46 to a second bonding location 54 where stainless steel guidewire 46 FN12 and threadlike portion 52 are soldered to a soft platinum coil 56. 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 stainless steel coil 36 of the embodiment of FIG. 2.
FN11. Figure 3 does not contain a drawing labeled "guidewire 22." The Court considers this reference to be an erroneous reference to guidewire 42.

FN12. Figure 3 does not contain a drawing labeled "guidewire 46." The Court considers this reference to be an erroneous reference to guidewire 42.

('136 Patent, Col. 7:42-55.)

The phrase "core wire" is used in other claims of the '136 Patent. Claim 13 discloses a guidewire comprising a "core wire" with a "distal portion" and an "elongated tip portion." Claim 14 discloses a guidewire as disclosed in Claim 13 in which the "distal portion" of the core wire is a "stainless steel segment." Claim 15 discloses a guidewire as disclosed in Claim 14 in which the "stainless steel segment" of the "distal portion" of the "core wire" is a "coil." FN13

FN13. The language of Claim 14 imposes a limitation on the distal portion of the core wire. The limitation imposed by Claim 14 is that the distal portion of the core wire "is an exposed stainless steel segment." Claim 15 imposes a limitation on the stainless steel segment, namely, that the segment "is a coil." Thus, Claim 15 claims a distal portion of the core wire which is a coil. A potential ambiguity is introduced within Claim 15, however, because it also imposes the limitation that the "coil" be connected to the "core wire." If the distal portion of the core wire "is" a coil, it is arguably ambiguous to say that the coil "is connected to the core wire." It is unnecessary for a dependent claim to claim that a coil is *connected to* the core wire if in that dependent claim the coil *is* a part of the core wire. The Court has chosen to treat the arguable ambiguity as a valid claim in that it is permissible in a dependent claim to define the coil as part of the "core wire" if the dependent claim discloses connecting the coil to the core wire.

Accordingly, the definition of "core wire" must be broad enough to include a coil. However, in every claim, the "elongate tip portion" is excluded from the definition of "core wire." Therefore, the definition of the

"core wire" must exclude the elongate tip portion.

The Court construes "core wire" as it is used in Claim 21 of the '136 Patent to mean:

The guidewire of the invention, except for the elongate distal tip.

2. "a distal portion susceptible to electrolytic disintegration in blood ... elongate tip portion not being susceptible to electrolytic disintegration in blood"

The parties dispute the proper construction of the phrases "susceptible to electrolytic disintegration in blood" and the opposite phrase "not susceptible to electrolytic disintegration within blood" as those phrases are used in Claim 21 of the '136 Patent.

The phrases "susceptible to" and "not susceptible to" are non-technical phrases which are commonly used in the English language. The commonly understood definition of "susceptible to" is "capable of being affected by." *See Webster's New Twentieth Century Dictionary,* 1837 (2d ed.1983). A commonly understood meaning of "not susceptible to" is "being resistant to."

The Court examines the written description for any use of the phrases. The phrase "not susceptible to electrolytic disintegration in blood" is used in the written description to refer to the characteristics of the material out of which the tip portion is constructed:

The tip portion is a long and substantially pliable segment and is comprised of a material not susceptible to electrolytic disintegration within blood.

('136 Patent, Col. 5:8-10.) There is no intrinsic evidence that these phrases are intended to have any specialized meanings. The Court finds that one of ordinary skill in the relevant art would give the phrases "susceptible to" and "not susceptible to" their ordinary and customary definitions.

The written description does contain a discussion of various materials and manufacturing processes which would make an embodiment susceptible or not susceptible to disintegration.FN14 However, the characteristics of a preferred embodiments may not be adopted as limitations on the apparatus as claimed.

FN14. In the Summary of the Invention and elsewhere in the written description, stainless steel is listed as a material which can be electrolytically disintegrated. (*See* '136 Patent, Col. 4:33-35.) A secondary coil 28 is disclosed in the written description made out of platinum, having particular diameter and specially shaped tip. (*See* '136 Patent, Col. 6:23-65.) Platinum is discussed as being resistant to electrolytic disintegration. [citation?]

The Court construes "susceptible to" as it is used in the phrase, "a distal portion susceptible to electrolytic disintegration in blood" in Claim 21 of the '136 to mean:

a distal portion of the core wire which has attributes which make the segment able to electrolytically disintegrate when submersed in blood.

Correspondingly, the Court construes "not being susceptible to" as it is used in the phrase "elongate tip

portion not being susceptible to electrolytic disintegration in blood," in Claim 21 of the '136 Patent to mean:

an elongate tip portion which has attributes which make the portion resistant to electrolytic disintegration when submersed in blood.

II. THE '578 PATENT

The '578 Patent is entitled: "Endovascular Electrolytically Detachable Wire and Tip for the Formation of Thrombus in Arteries, Veins, Aneurysms, Vascular Manformations and Arteriovenous Fistulas." The '578 Patent is a continuation of the '136 Patent. The application which led to the Patent was filed on February 14, 1997. It was issued on January 5, 1999. The following claims of the '578 Patent are being asserted in this case: Claims 1-3, 5, 11-14, 16-20, 23 and 24.FN15

FN15. Claim 8 is not asserted in this case. However, there are counterclaims in the case which challenge the validity of various patents. The Court has not examined whether Claim 8 is the subject of a counterclaim. The Court examined Claim 8 as part of its construction considerations. During its examination, the Court observed that an element of Claim 8 discloses the "tip portion" as *more susceptible* to electrolytic disintegration than the core wire. In another element of Claim 8, the "tip portion" is disclosed as *not as susceptible* to electrolytic disintegration as the core wire. The two elements appear to refer to the same "tip portion" and therefore, would impose inconsistent and conflicting limitations. These conflicting limitations arguably renders Claim 8 invalid. If Claim 8 is at issue in the case, the Court invite the parties to file appropriate motions addressing this issue.

A. The '578 Patent-Claim 17

Claim 17 provides:

A method of using a catheter to form an occlusion comprising:

disposing an electrolyzable core wire near the situs of said occlusion;

disposing a separable elongate tip portion extending from said catheter and coupled to said core wire at said situs of said occlusion, said separable elongate tip portion being more resistant to electrolytic disintegration in fluid than said electrolyzable core wire, and being a long and substantially flexible segment prebiased to form a helix when extended from said catheter; and

detaching said separable elongate tip portion from said core wire by electrolysis.

The parties dispute the proper construction of only one phrase of Claim 17: "elongate tip portion being more resistant to electrolytic disintegration in fluid than said electrolyzable core wire." Specifically, the dispute is over the proper construction of the phrase, "more resistant to electrolytic disintegration."

Claim 17 is a method claim. The method is performed with an apparatus which is comprised of an "electrolyzable core wire" with a "separable elongate tip portion." The language of Claim 17 provides that the "elongate tip portion" is "more resistant to electrolytic disintegration in fluid" than the "electrolyzable core wire."

The phrase "resistant to" is a commonly used non-technical phrase which means "not susceptible to," a phrase construed by the Court with respect to the '136 Patent. The same phrase appearing in different claims in the same patent should be given the same meaning unless it is clear from the specification and prosecution history that the phrases have different meanings. Wilson Sporting Goods Co. v. Hillerich & Bradsby Co., 442 F.3d 1322, 1328 (Fed.Cir.2006). In addition, a phrase should be interpreted consistently if it appears in different claims of different patents but which are of common ancestry, unless the specification or prosecution history suggest otherwise. Epcon Gas Sys. Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1031 (Fed.Cir.2002).

There is no suggestion in the specification that the Court should define the phrase "resistant to" inconsistently from the construction given to "not susceptible to."

The Court construes "more resistant to" as it is used in the phrase "elongate tip portion being more resistant to electrolytic disintegration in fluid than said electrolyzable core wire," in Claim 17 of the '578 Patent to mean:

An elongate tip portion of the invention which has attributes which make that portion more resistant to electrolytic disintegration than the electrolyzable core wire of the invention.

B. 578 Patent-Claim 20

Claim 20 provides:

An apparatus for use in formation of an occlusion within a body cavity comprising:

a core wire having at least a electrolyzable distal portion; and

a separable elongate tip portion of said core wire coupled to and extending from said core wire, said separable elongate tip portion adapted to form said occlusion in said body cavity and being adapted for insertion within said body cavity, said separable elongate tip portion being resistant to electrolysis compared to said distal portion of said core wire, said separable elongate tip portion being coupled to said core wire by said electrolyzable distal portion.

The parties dispute the proper construction of only one phrase of Claim 20: "elongate tip portion being resistant to electrolysis compared to said distal portion of said core wire." The Court has construed the phrase "resistant to" above.

The phrase "compared to" is a common non-technical phrase which means one thing is assessed in relation to another thing. In Claim 20, the apparatus comprises a "core wire," which has an "electrolyzable distal portion," and a "separable elongate tip portion" which is coupled to the core wire by the "electrolyzable distal portion" of the core wire. The Court rests its construction on the plain meaning of the language of Claim 20. The phrase under consideration is a limitation that the "separable elongate tip" be more resistant to electrolysis as "compared to" the distal portion of the core wire, which is "electrolyzable."

The Court construes "elongate portion being resistant to electrolysis compared to said distal portion" as it is used in Claim 20 of the '578 Patent to mean:

In the apparatus of Claim 20 which comprises a core wire, with an electrolyzable distal portion, and a "separable elongate tip portion," the elongate tip portion has attributes which make that portion resistant to electrolysis. The distal portion of the core wire has attributes which make that portion susceptible to electrolysis.

III. THE '037 PATENT

The '037 Patent is a continuation of the '578 Patent. The application leading to its issuance was filed on October 6, 1997. It was issued on July 20, 1999.

The only Claim of the '037 Patent over which there is a dispute is Claim 6, which provides:

A wire for use in formation of an occlusion within a cavity used in combination with a catheter comprising:

a core wire having a tip portion end; and

a detachable elongate tip portion extending said core wire adapted to being packed into said cavity to form said occlusion in said cavity, said detachable elongate tip portion being temporarily coupled to said distal end of said core wire and detachable from said core wire without applying any force by said distal tip to any surface within said body cavity, whereby occlusion of said cavity can be performed.

The parties dispute the proper construction of the phrase "temporarily coupled to." "Temporarily" is a common adverb meaning "for a time only; for the time being." *See Webster's New Twentieth Century Dictionary,* 1878 (2d ed.1983). The phrase "coupled to," is a commonly used non-technical phrase meaning "attached to."

The language of Claim 6 supports giving the phrase "temporarily coupled to" its common meaning. The phrase is used with respect to the relationship between the "elongate tip portion" and the "distal end of the core wire." The two are "temporarily coupled" and are "detachable." Further, except for its use in the claims, the phrase "temporarily coupled to" is not used or otherwise defined in the specification. A person of ordinary skill in the art would give the phrase its plain and commonly understood meaning.

The Court construes "temporarily coupled" as it is used in Claim 6 of the '037 Patent to mean:

attached to until detached from.

IV. THE '962 PATENT

The '962 Patent has the same title as the '578 Patent. It is a continuation of the '578 Patent. The application leading to its issuance was filed on October 6, 1997. It was issued on September 7, 1999.

A. The '962 Patent-Claim 1

Claim 1 provides:

A catheter wire for use in electrothrombosis in combination with a microcatheter comprising:

a core wire having a main body and a distal portion, said distal portion being susceptible to electrolytic

disintegration; and

a detachable coil for insertion within a body cavity, said detachable coil being coupled to said main body via said distal portion, being comprised of material not susceptible to electrolytic disintegration, and being prebiased to a spiral or helical shape such that on its advancement out of the distal end of a microcatheter and into a cavity it will change from being straight to its prebiased spiral or helical shape so that on the application of current to said detachable coil disposed in the cavity, electrothrombosis can be performed and at least one portion of said distal portion electrolytically disintegrated to detach said detachable coil from said main body.

1. "A catheter wire for use in electrothrombosis"

The parties dispute the meaning of the term "a cathether wire for use in electrothrombosis."

With respect to the vascular system, the root word "thrombus" is a technical word with a commonly understood meaning. A "thrombus" is clot in the cardiovascular system formed during life from the constituents of blood. *See Stedman's Medical Dictionary,* 1985 (28th ed.2006). "Thrombosis" is a technical term commonly understood to mean "formation or presence of a thrombus." *Id*. "Electrothrombosis" is a technical term commonly understood by skilled artisans to mean "forming a thrombus using electricity."

The Field of Invention section of the '962 Patent states:

The invention relates to a method and apparatus for endovascular electrothrombic formation of thrombi in arteries, veins, aneurysms, vascular malformations and arteriovenous fistulas.

In introducing embodiments of the invention, the written description states:

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.

('962 Patent, Col. 6:64-67.) Thus, as previously discussed, the Court declines to impose as a limitation on the claim that thrombosis be achieved to any particular degree.

The Court construes "a catheter wire for use in electrothrombosis" as it is used in Claim 1 of the '962 Patent to mean:

a catheter wire used with an electrical current to form a thrombus in a vascular cavity.

2. "a core wire having a main body"

The parties dispute the meaning of the phrase "a core wire having a main body." Specifically, the parties dispute the proper construction of the phrase "main body." On the face of Claim 1, the core wire has a "main body" and a "distal portion" of the core wire. Except for its use in the claims of the '962 Patent, the phrase "main body" does not appear elsewhere in the specification.

The Court previously defined the phrase "core wire" in construing the elements of the '136 Patent. Based on the written description of the '962 Patent, the Court gives the phrase the same meaning here.FN16

FN16. Although the Court gives core wire the same construction, the Court notes the following passage from the written description in the '962 Patent, which if taken literally would render all claims for which it may be used to define the phrase "core wire" arguably indefinite:
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.

('962 Patent, Col.6:1-13.) If this passage is used to define "core wire," it would mean that "core wire" would include the elongate distal tip, which is contrary to the Court's earlier construction. Furthermore, the literal language of this passage has the "core wire" attached to the "core wire." The Court declines to include this passage in its construction of Claim 1 of the '962 Patent. Nor does the Court include this passage in its construction of "core wire" as it is used in the '136 and '578 Patents. Any party contending that the above passage has legal significance may file appropriate motions.
The guidewire comprises a core wire, and an 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. The tip portion is coupled to the distal portion of the core wire.
('962 Patent, Col. 5:30-35.)
In the phrase "a core wire having a main body," as it is used in Claim 1 of the '962 Patent, the Court construes "main body" to mean:

the core wire not including the distal portion of the core wire.

3. "electrothrombosis can be performed"

The parties dispute the proper construction of the phrase "electrothrombosis can be performed." There are three aspects to the dispute. One aspect of the dispute is whether the performance of electrothrombosis is a requirement of Claim 1 or whether Claim 1 is practiced if some other method of forming a thrombus is used.FN17 The second aspect of the dispute is whether, if performance of electrothrombosis is a required element, must it be carried through to complete occlusion or does partial occlusion meet the claim. FN18 Finally, although not raised by the parties, the meaning of the phrase "can be performed" raises a construction issue. The language of the Claim resolves all of these issues.

FN17. In the Supplemental Joint Claim Construction Chart, The Regents' Proposed Construction state, "The '962 patent makes clear that the invention can be practiced to form an occlusion with or without electrothrombosis."

FN18. In the Supplemental Joint Claim Construction Chart, Defendants' Proposed Construction state, "Electrothrombosis can start and carry through to completion."

Claim 1 is an apparatus claim. The apparatus is a catheter wire. The catheter wire comprises two elements. The first element is a core wire and the second element is a detachable coil. Although the language of Claim

1 imposes limitations on these two elements, neither occlusion nor electrothrombosis-partial or complete are limitations on the apparatus disclosed in Claim 1. There is no disclosure in Claim 1 of formation of an occlusion as an element of the claim. Indeed, there is no disclosure in Claim 1 of electrothrombosis being performed.

The disputed phrase appears in a "so that clause:"

a detachable coil for insertion within a body cavity, said detachable coil being coupled to said main body via said distal portion, being comprised of material not susceptible to electrolytic disintegration, and being prebiased to a spiral or helical shape such that on its advancement out of the distal end of a microcatheter and into a cavity it will change from being straight to its prebiased spiral or helical shape so that on the application of current to said detachable coil disposed in the cavity, electrothrombosis can be performed and at least one portion of said distal portion electrolytically disintegrated to detach said detachable coil from said main body

A "so that clause" introduces a functional description of the results from the use of an apparatus. *See* In re Michlin, 45 C.C.P.A. 1028, 256 F.2d 317, 320 (C.C.P.A.1958.) Thus, a "so that clause" is equivalent to a "whereby clause" in a method claim. A "whereby clause" in a method claim that merely states the results of the limitations in the claim adds nothing to the substance of the claim. *See* Lockheed Martin Corp. v. Space Systems/Loral. Inc., 324 F.3d 1308, 1319 (Fed.Cir.2003). To be consistent, the Court finds that in an apparatus claim, a "so that clause" which is followed by a description of the desired results from the use of the apparatus, does not impose a limitation on the apparatus. Accordingly, with respect to Claim 1, the phrase "so that ... electrothrombosis can be performed" merely describes the intended results from use of the apparatus but does not impose a limitation that those results in fact take place.FN19

FN19. A different conclusion might be reached in a method claim which recites the electrothrombosis as a step in the method.

The Court declines to construe the claim as requiring an occlusion by electricity or by some other means or as requiring electrothrombosis-initiatiated or carried through to completion. To the extent the dispute is over the word "can," the Court construes it to mean is "able to."

The Court construes "electrothrombosis can be performed" to mean:

electrothrombosis is able to be performed.

B. The '962 Patent-Claim 10

Claim 10 provides:

The catheter wire of claim 1 wherein although prebiased said detachable coil is extremely soft and its overall shape is easily deformed such that, once advanced from a microcatheter into said cavity, it will loosely deform to said interior shape of said cavity.

The parties dispute the proper construction of the phrase "extremely soft." Claim 10 is a dependent claim of Claim 1. The disputed phrase is a limitation on the detachable coil, namely that it be extremely soft.

The word "soft" is a commonly used adjective meaning "giving way easily under pressure, easily shaped, delicate. *See Webster's New Twentieth Century Dictionary,* 1728 (2d ed.1983). The word "extremely" is a commonly used adverb meaning "in the utmost degree; exceedingly." *Id.,* 652. The language of Claim 10 ("overall shape is easily deformed" and "will loosely deform to said interior shape of said cavity") supports construing the phrase in accordance with these commonly understood definitions.

Although the phrase "extremely soft" can be given a commonly understood definition, the issue becomes whether the phrase is so broad and so subjective as to make Claim 10 indefinite under 35 U.S.C. s. 112 para. 2. Because the patent claims perform the fundamental function of delineating the scope of the invention, the purpose of the definiteness requirement is to ensure that the claims use language that adequately notifies the public of the inventor's rights to exclude. Honeywell Int'l., Inc., v. Int'l Trade Commission, 341 F.3d 1332, 1338 (Fed.Cir.2003). In evaluating whether or not a phrase such as "extremely soft" is so broad and so subjective as to make the claim indefinite, FN20 the Court examines the intrinsic evidence for any description which would add meaning to the scope of "extremely soft."

FN20. Consideration of whether a patent claim meets the definiteness requirement is normally a part of later proceedings after the claim has been construed. However, it is an appropriate consideration during claim construction because the Court must construe the claim consistent with the scope of the words used in the claim. The Court may decline to construe a broadly worded, subjective claim if it is so broad as to be ambiguous and its scope cannot be ascertained. The Court examines the written descriptions for definitive language in light of these considerations.

In the written description, one embodiment of a detachable coil is described as "soft" and another embodiment is described as "extremely soft." The coil depicted on Figure 1 is described as "extremely soft:"

The distal end of secondary coil 28 is provided with a platinum soldered tip 30 to form a rounded and smooth termination to avoid puncturing the aneurysm or tearing tissue.

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.

('962 Patent, Col. 7:52-63.)

The coil depicted in Figure 3 is described as "soft:"

Turn now to the third embodiment of the invention as shown in FIG. 3. FIG. 3 shows an enlarged side view of a wire, generally denoted by reference numeral 42, disposed within a microcatheter 44 shown in cross-sectional view. Like the embodiment of FIG. 1, a stainless steel coil 46 is soldered to a conical portion 48 of wire 22 at a first bonding location 50. A thin threadlike extension 52 is then longitudinally disposed within stainless steel coil 46 to a second bonding location 54 where stainless steel wire 46 and threadlike portion 52 are soldered to a soft platinum coil 56. 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 stainless steel coil 36 of the embodiment

of FIG. 2.

('962 Patent, Col. 10:54-67.)

The description of coil 28 as "extremely soft" is accompanied by a description of the composition material, diameter, shape, and length of coil 28:

The distal end of stainless steel coil 26 is soldered to the distal end of threadlike portion 18 of wire 10 and to the proximal end of a platinum secondary coil 28 at second bonding location 22. Secondary coil 28 itself forms a spiral or helix typically between 2 to 10 mm. in diameter. The helical envelope formed by secondary coil 28 may be cylindrical or conical. Like wire 10 and stainless steel coil 26, secondary coil 28 is between approximately 0.010 and 0.020 inch (0.254-0.508 mm) in diameter. The diameter of the wire itself forming stainless steel coil 26 and coil 28 is approximately between 0.001-0.005 inch.

('962 Patent, Col. 7:41-51.)

Similarly, the written description of coil 56, described as "soft" is accompanied with a description of some of its parameters:

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 stainless steel coil 36 of the embodiment of FIG. 2.

However, platinum coil 56 is particularly distinguished by its length of approximately 1 to 50 cm. 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. The distal end of platinum coil 56 is provided with a smooth and rounded platinum tip 58 similar in that respect to tips 30 and 40 of FIGS. 1 and 2, respectively.

('962 Patent, Col. 8:64-9:8.)

Absent any extrinsic evidence to the contrary, the Court concludes that these descriptions would provide a person of ordinary skill in the art with an understanding of what kinds of features were meant by the inventors as making a coil "soft" or "extremely soft."

Notwithstanding the disclosure of features of a preferred embodiment which is called "extremely soft," the stated parameters of the embodiment should not be adopted into a construction of the phrase as a limitation on Claim 1. Ordinarily, if a claim element is stated in general words, even if the written description of a preferred embodiment contains parameters such as a range of values which would add a measure of specifity, unless that embodiment is the only embodiment of the claim, the Court should not read the numerical range into the claim. *See* Modine Manufacturing Co., 75 F.3d at 1551.

The Court construes "detachable coil is extremely soft" to mean: FN21

FN21. The fact that the Court finds the phrase sufficiently specific for definition is not intended by the Court as a final ruling that the phrase meets the definiteness requirement.

The material composition, dimension and other configuration of the coil make it exceedingly deformable to the interior shape of the cavity with substantially no influence from any inherent shape.

V. THE '133 PATENT

The '133 Patent is entitled: "Endovascular Electrolytically Detachable Wire and Tip for the Formation of Thrombus in Arteries, Veins, Aneurysms, Vascular Manformations and Arteriovenous Fistulas." It is a continuation of the '578 Patent. The application leading to its issuance was filed on October 6, 1997. It was issued on May 23, 2000. The following Claims of the '133 Patent are being asserted in this case: Claims 1-6, 8, 10, 16, 20, 25-30, 35, 37, 38, 42-47.

A. The '133 Patent-Claim 1

Claim 1 of the '133 patent provides:

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

a wire adapted to be disposed near an opening into said body cavity;

a separable distal tip of said wire adapted for disposition into said body cavity to form said occlusion within said body cavity about said distal tip; and

a selectively detachable coupling between said distal tip and said wire characterized by detachment of said distal tip from said wire without necessarily displacing either said distal tip or said wire during detachment to leave said distal tip within said body cavity with said occlusion being formed within said body cavity,

whereby said body cavity is occluded by said distal tip, and an occlusion is formed by use of said tip without necessarily altering desired placement of said distal tip during detachment or applying any force by said distal tip to any surface within said body cavity by reason of said detachment.

The parties dispute the meaning of only one phrase of Claim 1: "detachment of said distal tip from said wire without necessarily displacing either said distal tip or said wire during detachment." FN22 The focus of the dispute is the phrase "detachment ... without necessarily displacing."

FN22. The parties have stipulated that they will rely on the construction of this term as a representative of similar terms which appear in the following patents: Claim 25 of the '133 patent (and claims dependent therefrom), Claims 1, 2, 3, 9 of the '126 patent (and claims dependent therefrom), and Claim 1 of the '963 patent (and claims dependent therefrom).

Claim 1 is an apparatus claim. The apparatus comprises a wire, a separable distal tip and a selectively detachable coupling. The disputed phrase is a limitation on the "selectively detachable coupling." The limitation requires that the "selectively detachable coupling" function in a particular manner, namely, detach the distal tip from the wire "without necessarily displacing either said distal tip or said wire during detachment." The Court finds that one of ordinary skill in the art would understand that the phrase "detachment ... without necessarily displacing" is being used with a plain and customary meaning.

The word "detachment" means "separation." *See Webster's New Twentieth Century Dictionary,* 496 (2d ed.1983). "Without necessarily" means "without necessity." *Id.,* 1200. The word "displacement" means "to

move out of its place." *Id.,* 528. There is nothing in the written description to support giving the phrase "detachment ... without necessarily displacing" any specialized meaning.

Although the specific phrase "detachment ... without necessarily displacing" is not used elsewhere in the specification, Claim 1 contains the following "whereby clause:"

whereby said body cavity is occluded by said distal tip, and an occlusion is formed by use of said tip without necessarily altering desired placement of said distal tip during detachment or applying any force by said distal tip to any surface within said body cavity by reason of said detachment.

A "whereby" clause in an apparatus claim may express the intended result from using the apparatus. *See* Minton, 336 F.3d at 1381 (Fed.Cir.2003). Considering the "whereby" clause from the perspective of a person of ordinary skill in the art, the Court finds that the "whereby clause" means that after the distal tip is placed into the vascular cavity, the selectively detachable coupling detaches the tip from the wire. Detachment is accomplished without any change in the position of the tip being necessary to achieve detachment and without requiring the application of any force by the tip on any surface in the vascular cavity.

The Court construes "detachment ... without necessarily displacing," as it is used in the phrase "detachment of said distal tip from said wire without necessarily displacing either said distal tip or said wire during detachment" in Claim 1 of the '133 Patent to mean:

detachment accomplished without necessitating movement of the distal tip to accomplish detachment and without necessitating that force be applied by the distal tip on any surface of the vascular cavity to accomplish detachment.

B. The '133 Patent-Claim 10

Claim 10 patent provides:

The apparatus of claim 1 where said distal tip is detached from said wire by applying a positive direct current to said distal tip for a predetermined time period.

The parties dispute the meaning of only one phrase of Claim 10: "applying a positive direct current to said distal tip for a predetermined time period."

The written description discusses the phrase "predetermined time period" in connection with an embodiment of the invention:

As will be described below in greater detail in connection with the third embodiment of FIG. 3, after placement of secondary coil 28 within the interior of the aneurysm, a direct current is applied to wire 10 from a voltage source exterior to the body. The positive charge on secondary coil 28 within the cavity of the aneurysm causes a thrombus to form within the aneurysm by electrothrombosis. Detachment of the tip occurs either: (1) by continued application of current for a predetermined time when the portion 18 is exposed to blood; or (2) by movement of the wire to expose portion 18 to blood followed by continued current application for a predetermined time. Ultimately, both threadlike portion and stainless steel coil 26 will be completely disintegrated at least at one point, thereby allowing wire 10 to be withdrawn from the

vascular space while leaving secondary coil 28 embedded within the thrombus formed within the aneurysm.

('133 Patent, Col. 7:61-8:10.)

The written description discusses other embodiments in which detachment is achieved by conditions other than applying current for a predetermined time period:

Many alterations and modifications may be made by those having ordinary skill in the art without departing from the spirit and scope of the invention * * * Still further, the diameter of the wire, various of the wire described above and the stainless steel coil immediately proximal to the detachable tip may be provided with differing diameters or cross sections to vary the times and current magnitudes necessary in order to effectuate electrolytic detachment from the tip. Still further, the invention may include conventional electronics connected to the proximal end of the wire for determining the exact instant of detachment of the distal tip from the wire.

('133 Patent, Col. 12:17-35.)

The Court finds that one of ordinary skill in the art would understand the term "applying a positive direct current to said distal tip for a predetermined time period" to have its customary meaning, namely, applying current for a time period that is determined in advance.

The Court construes "predetermined time period," as it is used in the phrase, "applying a positive direct current to said distal tip for a predetermined time period" in Claim 1 of the '133 Patent to mean:

applying a positive direct current to the distal tip for a time period determined in advance of the initiation of the detachment process.

C. The '133 Patent-Claim 25

Claim 25 of the '133 patent provides:

A method for forming an occlusion within a body cavity comprising the steps of:

disposing a wire near an opening into said body cavity;

disposing a separable distal tip of said wire into said body cavity to form said occlusion within said body cavity about said distal tip; and

detaching a coupling between said distal tip and said wire without necessarily displacing either said distal tip or said wire during detachment or applying a force by said distal tip to any surface within said body cavity to leave said distal tip within said body cavity with said occlusion being formed within said body cavity.

1. "wire"

Although not raised by the parties, the Court considers the word "wire" as it appears in Claim 25. The '133 Patent is the first Patent which has come to the Court's attention which uses the word "wire" without a modifier in its claims. FN23

FN23. The parent '136 Patent uses "guidewire" and "core wire." The '578 Patent uses the word "core wire." The '126 Patent also uses the word "wire," however, there were no claims from that patent submitted for construction.

Claim 25 is a method claim. The word "wire" appears in the first step: "Disposing a wire near an opening into said body cavity." In the Summary of the Invention, the word wire is discussed as having multiple meanings, depending upon its use:

The term "wire" should be understood to collectively include both guidewires and tips and simply wires without distinct tip structures.

('133 Patent, Col. 4:9-11.) Although this statement is included in the Summary, the word "guidewire" is not used in any of the claims of '133 Patent nor is the word "guidewire" used in the claims of the '578 Patent from which the '133 Patent is a continuation. The only patent claims which contain the use of the word "guidewire" are claims of the '136 Patent.

As it is used in Claim 25, "wire" is an apparatus with a detachable distal tip which can be disposed into a body cavity. The second step of the method of Claim 25 provides: "disposing a separable distal tip of said wire into said body cavity ..." Thus, "wire" as it is used in Claim 25 of the '133 Patent is defined the same as "guidewire" in the '136 Patent.

The Court construes "wire" as it is used in the '133 Patent to mean:

A part of an apparatus of the invention which is a thin, flexible, continuous length of metal, of circular cross-section which has a detachable tip.

2. "detaching a coupling between said distal tip and said wire"

Claim 25 is a method claim. The parties dispute the proper construction of the phrase: "detaching a coupling between said distal tip and said wire." Specifically, the parties dispute the proper construction of the word "coupling" in the disputed phrase.

The word "coupling" is used in the specification in two different ways. In the following excerpt, "coupling" is used as a verb:

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.

('133 Patent, Col. 5:63-6:1.)

Claim 29 of the '133 Patent uses the word "coupling" as a verb:

The method of claim 28 where said step of detaching said distal tip of said wire electrolytically disintegrates

a connecting segment coupling said wire to said distal tip to effect separation.

In contrast, in the following excerpt, the word "coupling" is a gerund, which is used as a noun:

Depicted in FIG. 6 is an embodiment of the invention wherein such mechanical thrombosis can be achieved. Wire 10 has a tapering end portion 14 covered with a Teflon laminate 24 similar to that described in connection with the embodiment of FIG. 1. Wire 10 is attached by means of a mechanical coupling 100 to a platinum coil 102 which has a plurality of filaments or fine hairs 104 extending therefrom In the illustrated embodiment, hairs 104 have a length as may be determined from the size of the vascular cavity in which coil 102 is to be used.

(133 Patent, Col. 9:67-10:10.)

One skilled in the relevant art would understand "coupling" as used in Claim 25 to be used as a noun.FN24 The commonly understood meaning of the noun "coupling" is "a joining together; a pairing; a device for joining two railroad cars together." *See Webster's New Twentieth Century Dictionary,* 419 (2d ed.1983). Thus, a "coupling" could be a separate device, such as a sleeve which joins two separate objects on either end. Alternatively, a "coupling" could be a description of the condition of two things being joined or "coupled" to each other joint without any separate device, such as the twisting or "coupling" of two wires together. There is nothing in Claim 25 or in the specification which would lead to the conclusion that one definition should be used to the exclusion of the other.

FN24. Grammatically, the noun "coupling" would be the direct object of the verb detaching.

The Court construes the word "coupling," as it is used in the phrase "detaching a coupling between said distal tip and said wire" in Claim 25 of the '133 Patent to mean:

detaching the distal tip from the wire.

CONCLUSION

In this Order, the Court has construed disputed words and phrases of the Patents submitted for construction. The Court invites any party desiring to further consideration of the matters addressed in this Order to file appropriate motions in accordance with the Civil Local Rules of the Court.

N.D.Cal.,2007.
Regents of University of California v. Micro Therapeutics, Inc.