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.
Boston Scientific Corp. and Target Therapeutics, Inc,
Third Party Defendants.

No. C 03-05669 JW

Aug. 17, 2007.

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SECOND SUPPLEMENTAL CLAIM CONSTRUCTION ORDER;

ORDER DENYING MOTION FOR SUMMARY JUDGMENT OF INVALIDITY BASED ON LACK WRITTEN DESCRIPTION;

ORDER FINDING CLAIM ARGUABLY INVALID AND REQUESTING FURTHER BRIEFING

JAMES WARE**, United States District Judge.**

I. INTRODUCTION

Plaintiff The Regents of the University of California ("The Regents" or "Plaintiff") brings this action against Defendants Micro Therapeutics Inc. ("MTI") and its wholly owned subsidiary Dendron GmbH (collectively, "Defendants") for infringement of twelve of The Regents' patents which relate to devices for occluding vascular cavities for the treatment of brain aneurysms.

Presently before the Court is Defendants' Motion for Summary Judgment of Invalidity of the Patents-In-Suit

for Failure to Comply with 35 U.S.C. s. 112, para.para. 1 and 2. The Court conducted a hearing on June 5, 2007. On July 9, 2007, the Court issued an order addressing Defendants' motion for summary judgment on the grounds of failure to disclose the best mode requirement and indefiniteness. (*See* Docket Item No. 789.) This Order addresses Defendants' ground of invalidity based on failure of the patents to satisfy the written description requirement. (Defendants' Motion for Summary Judgment for Invalidity of the Patents in Suit for Failure to Comply with 35 U.S.C. s. 112, para.para. 1 and 2, hereafter, "Motion," filed under seal; redacted version at Docket Item No. 610.)

Defendants move for summary judgment of invalidity of Claims 1-4 of the '136 Patent on the ground that those claims encompass methods of occlusion other than electrothrombosis and are therefore, invalid for lack of written description. FN1 In its consideration of the motion, the Court has determined that further construction of claims is required. This Order gives the Court's additional claim construction, in which it finds a claim arguably indefinite. With respect to the motion for summary judgment, the motion is DENIED, without prejudice to being renewed. The Court gives instructions on the matters which must be addressed if the motion is renewed.

FN1. Defendants move for summary judgment with respect to Claims 1-12. However, Claims 7, 8, 9, 10, 11 and 12 include electrothrombosis. Therefore, the Court finds the motion inapplicable to those claims. In addition, because Claims 4 and 5 disclose a method for using electricity to detach the tip from the guidewire, and do not disclose any isolation of the tip from the electricity, the Court will not consider Claims 4 and 5 to be included in the motion. The parties may file motions at their option addressing this aspect of Claims 4 and 5.

II. STANDARDS

A. *The Principles of Claim Construction*

The Court applies the legal standards recited in its previous Claim Construction Orders.

B. *The Written Description Requirement*

Title 35 U.S.C. s. 111 provides that an application for a patent must include a "specification," which complies with the requirement of s. 112. Section 112 requires, *inter alia,* the specification to conclude with the recitation of one or more claims:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. s. 112, para. 2.

In addition, s. 112 requires that the specification satisfy three separate, but related, requirements: (1) it must contain a "written description" of the invention; (2) enable a person of skill in the art to make and use the invention; and (3) if the inventor contemplates one, set forth the best mode for carrying out the invention:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth

the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. s. 112, para. 1; *See* Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed.Cir.2004).

Although the three requirements are related, the "written description" requirement is distinct and independent from the "enablement" and "best mode requirement." Univ. of Rochester, 358 F.3d at 922. There have been cases in which the courts have held that a specification met the written description requirement, but nevertheless found that the description was not "enabling." *Id*. (citing In re Alton, 76 F.3d 1168, 1172 (Fed.Cir.1996)). Similarly, there have been cases holding a specification "enabling" of the invention as disclosed, but holding that it did not contain an adequate "written description" of other parts of the invention. *Id*. (citing In re DiLeone, 58 C.C.P.A. 925, 436 F.2d 1404, 1405 (C.C.P.A.1971)).

The written description requirement applies to the specification which is included with the original patent application and continues to apply if the claims are amended during prosecution of the patent. 35 U.S.C. s. 112, para.para. 1 and 2. To comply with the written description requirement, the applicant must describe elsewhere in the specification the invention claimed at the end of the specification, with all its essential elements. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed.Cir.1997). The failure of the specification to describe expressly or inherently a single essential element is sufficient to invalidate a claim. *See e.g*. Bilstad v. Wakaloupoulos, 386 F.3d 1116 (Fed.Cir.2004).

Whether a specification complies with the written description requirement is a question of fact. Lizardtech Inc. v. Earth Resource Mapping, Inc., 433 F.3d 1373 (Fed.Cir.2006); Union Oil v. Atl. Richfield Co., 208 F.3d 989, 996 (Fed.Cir.2000). The factual issue is whether the disclosure in the specification reasonably conveys to a person skilled in the art that the inventor had possession of the claimed invention at the time the application was filed. Thus, the factual analysis begins with the claim, properly construed. The claim determines the scope of the claimed invention. To satisfy the written description requirement, the inventor must "describe" the claimed invention, using such descriptive means as words, structures, figures, diagrams, formulas, etc., sufficiently to convey to a skilled artisan what is claimed. Lockwood, 107 F.3d at 1572.

The issue of whether the specification satisfies the written description requirement is frequently raised in interference or infringement actions in which an inventor has disclosed a species in the original specification and has later amended the claim to cover a genus. FN2 *See* In re Smythe, 480 F.2d 1376, 1382 (C.C.P.A.1973). However, there is no general proposition in patent law that the written description requirement is violated if the original description is narrower than a broad claim. *Id*. Each case must be decided on its own facts. However, when a narrow disclosure is made in the original written description of the invention, and the claim is amended to broaden the scope of the claim, upon challenge, courts examine the written description to determine if a skilled artisan in that particular field would find from what is stated in the specification that the inventor was in possession of the broader claim at the time of the original application. *See In re John P. Curtis,* 354 F.3d at 1355-1356. Disclosure of a species in the original written description may be sufficient or insufficient to support a later amendment to broaden the claim to cover the genus depending on the facts of the case. *Id.;* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed.Cir.1997); Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 93 F.3d 1572, 1582 (Fed.Cir.1996).

FN2. The issue of whether the written description requirement has been met can also arise when a genus claim is amended to claim a specific species. In such a case, the issue is whether the written description of a genus which includes thousands of species would convey to a person of skill in the art that the inventor has

possession of the specific species sought to be captured by the amendment. *See* In re John P. Curtis, 354 F.3d 1347 (Fed.Cir.2004).

Some of the factors which courts have used to decide if the written description requirement has been met are the following:

1. Whether the written description provides that it is because of their **properties and functions** that particular elements or steps are disclosed under circumstances which would immediately convey to a person skilled in the art that the invention includes the broader group which the inventor seeks to capture in the amended claim. *See* In re Smythe, 480 F.2d at 1384. (Disclosure of the properties and functions of "air or other gas" as a segmentizing medium held sufficient to suggest to skilled artisan that invention includes "inert fluid" broadly.)

2. Whether the original narrow written description, lists **members of a group** and a skilled artisan would know from the list that the invention would apply equally to other undisclosed, **well-known** members of the group which the inventor is seeking to capture by an amendment. *See* Bilstad, 386 F.3d at 1117.

3. Whether the subject matter for which inclusion is being sought under a broad amended claim includes species which were regarded by skilled artisans as being **unpredictable in performance** as compared to those which were disclosed in the narrow original written description. *See* In re Curtis, 354 F.3d at 1355.

4. Whether the original written description attributes **unique properties** to the listed embodiments which are different from the properties of other members of the genus. Id. at 1357.

5. Whether in the original application the inventor **embraced or criticized** the process for which inclusion is being sought under an amendment. *See* Tronzo v. Biomet, 156 F.3d 1154, 1159 (Fed.Cir.1998).

C. *Summary Judgment of Invalidity Under* s. 112***, para.para. 1 and 2***

As set out above, compliance with the written description requirement is a question of fact. Lizardtech Inc., 433 F.3d at 1375; Union Oil, 208 F.3d at 996. Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). The purpose of summary judgment "is to isolate and dispose of factually unsupported claims or defenses." Celotex v. Catrett, 477 U.S. 317, 323-24, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). The moving party "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying the evidence which it believes demonstrates the absence of a genuine issue of material fact." Id. at 323. The non-moving party must then identify specific facts "that might affect the outcome of the suit under the governing law," thus establishing that there is a genuine issue for trial. Fed.R.Civ.P. 56(e).

When evaluating a motion for summary judgment, the court views the evidence through the prism of the evidentiary standard of proof that would pertain at trial. Anderson v. Liberty Lobby Inc., 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). The court draws all reasonable inferences in favor of the non-moving party, including questions of credibility and of the weight that particular evidence is accorded. *See, e.g.* Masson v. New Yorker Magazine, Inc., 501 U.S. 496, 520, 111 S.Ct. 2419, 115 L.Ed.2d 447 (1992).

The court determines whether the non-moving party's "specific facts," coupled with disputed background or contextual facts, are such that a reasonable jury might return a verdict for the non-moving party. *T.W. Elec. Serv.,* 809 F.2d at 631. In such a case, summary judgment is inappropriate. Anderson, 477 U.S. at 248. However, where a rational trier of fact could not find for the non-moving party based on the record as a whole, there is no "genuine issue for trial." *Matsushita,* 475 U.S. at 587.

Generally, an issued patent enjoys a presumption of validity that can be overcome only by clear and convincing evidence of invalidity. U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1563 (Fed.Cir.1997). Thus, a party seeking to invalidate a patent by a motion for summary judgment must submit clear and convincing evidence of invalidity. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 962 (Fed.Cir.2001). Further, summary judgment of invalidity of a patent claim on the ground that the patent specification fails to satisfy the written description requirement is appropriate when there is no genuine dispute about the material facts, and on the basis of those facts, the specification is inadequate as a matter of law. Fed. Rule Civ.P. 56(c); Enzo Biochem v. Gen-Probe Inc., 323 F.3d 956, 963 (Fed.Cir.2002).

III. DISCUSSION

Defendants move for summary judgment of invalidity on the ground that the specification does not satisfy the written description requirement with respect to Claims 1-4 of the '136 Patent. Defendants make the following contentions: Originally, the inventors applied for a patent for an apparatus and method for endovascular electrothrombosis. Each of the claims in the original application related to electrothrombosis. The written description submitted with the '717 Application described a method for forming a thrombus using electrothrombosis. Approximately one year later, the inventors amended Claim 1 to broadened it to cover "occlusion" by "thrombus," which includes every process for forming a thrombus. Still later, the inventors amended Claim 1 to broaden it to cover "occlusion," thus removing any requirement that the occlusive object be a thrombus. However, the written description was never amended. Thus, the claims at issue cover the genus "occlusion" while the written description only discloses methods for the species "electrothrombosis." Defendants contend that this divergence between the narrow written description and the broad Claim 1, and dependent Claims 2-4, invalidates these claims. In addition, Defendants contend that the only process of which Plaintiff had possession was electrothrombosis.

As stated above, an analysis of whether a specification meets the written description requirement begins with the claim, properly construed. Accordingly, the Court proceeds to reexamine its construction of Claim 1 of the '136 Patent.

A. ***Modification of the Court's Previous Construction of Claim 1 of the '136 Patent***

On March 2, 2007 and on June 26, 2007, the Court construed certain words and phrases of Claim 1 of the '136 Patent. FN3 The contentions made by the parties in support and opposition to Defendants' motion for summary judgment have persuaded the Court that further construction of Claim 1 is necessary. The contentions made by the parties highlight a dispute over the proper construction of the following claim element: "disposing a distal tip of said guide wire into said vascular cavity to form said occlusion within said vascular cavity about said distal tip." Specifically, there is a dispute over the word "disposing a distal tip" and the phrase "about said distal tip." In addition, there is a dispute over the meaning of the phrase "any thrombus" in the "whereby" clause and whether the "whereby" clause is limiting in that it requires forming a thrombus as a necessary element of the method.

FN3. (*See* Supplemental Claim Construction Order, Docket Item No. 482; Third Claim Construction Order,

Docket Item No. 751.)

Claim 1 of the '136 Patent provides: FN4

FN4. 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. "disposing"

The method of Claim 1 is disclosed as comprising three steps, two of which use the word "disposing:" (1) endovascularly disposing a guide wire near an endovascular opening; (2) disposing a tip into the vascular cavity; and (3) detaching the distal tip. The word "disposing" is a commonly used word with many definitions, the applicability of each definition depends on the context in which it is used. In Claim 1, the word "disposing" is used to disclose the steps of placing guidewire near an opening to a vascular cavity and the step of inserting the tip into a vascular cavity for the purpose of forming an occlusion within the cavity about the tip:

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

From the use of the word in Claim 1, one of ordinary skill in the art would understand that the inventors are using the word "disposing" with one of its common meanings, i.e., a manipulative step of placing an object in a location or position.

Further, in dependent Claim 2, the inventors also use "disposing" to mean a manipulative step of "substantially occupying" the vascular cavity, i.e., to put more of the tip or a longer or larger tip into the cavity:

The step of **disposing** the distal tip in the vascular cavity further comprises the step of substantially occupying the vascular cavity with the distal tip.

Accordingly, the Court construes the word, **"disposing"** as it is used in Claims 1-4 FN5 to mean **"a**

manipulative step in which an object is placed in a particular location or position."FN6

FN5. The word "disposing" is also used in Claim 8. However, the Court does not apply this construction to Claim 8 because the Court will discuss Claim 8's arguable indefiniteness in Section C.

FN6. Elsewhere in the specification, the inventors use the related term "disposed" in their description of an embodiment:
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.

('136 Patent, Col. 6:44-47.)

They also use "disposed" to describe a prior art reference:
O'Reilly places a tip into an aneurysm by means of an endovascular microcatheter. The tip is adhesively bonded to a optic fiber **disposed through the microcatheter.**

('136 Patent, Col. 3:23-25.)

2. "about said distal tip"

In the second step, "said occlusion" is formed "about said distal tip." Nothing in the specification, including the claims, indicates explicitly or implicitly that the inventors intended to impart a novel meaning to "about said tip." There is no evidence that "about said tip" has a peculiar meaning in the field of art encompassed by the '136 Patent. Therefore, the Court concludes that the ordinary and customary meaning attributed to this term by those of ordinary skill in the art at the time of the invention is a widely accepted meaning. Phillips v. AWH Corp., 363 F.3d 1207, 1314 (Fed.Cir.2004).

Accordingly, the Court construes the phrase **"about said distal tip"** to mean **"on or around the distal tip."**

3. "to form said occlusion"

The "disposing into" step requires that an occlusion be formed. The step does not state what object constitutes the occlusion, only that it be formed "about" the distal tip. Thus, the occlusion which is "formed" cannot be the tip itself, because it cannot "form" on or about itself.

A person of skill in the art would understand from the "whereby" clause that the occlusion is the tip and "any thrombus." Previously, the Court has found that the whereby clause is limiting in that it supplies an essential element, namely, the occlusion consists of two things: (1) the tip and (2) "any thrombus ."

Accordingly, the Court finds that forming an occlusion on or around the tip is a necessary element of the method.

4. "any thrombus"

The issue now becomes whether the phrase "any thrombus" means "with or without a thrombus." The word "any" is a common term which variously means: "One or some, regardless of kind, quantity or number; one or another selected at random, one or another without restriction or exception; the whole amount of; all [I will turn over any profit]; an indeterminate number or amount." *See Webster's New Twentieth Century Dictionary,* 83 (2d ed.1983). Since formation of an occlusion is required by the "disposing into" step, and because the "whereby' clause requires that "any thrombus" be included in the occluding objects, the Court concludes that the phrase **"any** thrombus**"** means **"a** thrombus **irrespective of its size."**

However, there is still the issue of the difference between the broad language of the "disposing into step" ("said occlusion ... about said tip") and the narrow language of the "whereby" clause ("any thrombus").FN7 On the one hand, the broad language of the "disposing into step" would permit any form of occlusion. For example, the invention could be practiced using any embolizing agent, which forms about the inserted tip. Thus, balloon embolization, thermal coagulation of blood, isobutylcyanoacrylate (ICBA) polymerization, as well as thrombosis would all be occlusions which could satisfy the step, as long as each could be formed "about" the tip. On the other hand, the "whereby" clause only discloses "any thrombus" as part of the occlusion. However, although the Court has found that the "whereby" clause is limiting in one respect, the Court does not find that the "whereby" clause limits the method of occlusion to a thrombus.

FN7. The Court notes that during prosecution, the inventors amended the claim to eliminate "thrombus" from the Preamble and steps of the Claim, but left "any thrombus" in the "whereby" clause.

Accordingly, the Court now construes the phrase "disposing a distal tip of said guidewire into said vascular cavity to form said occlusion within said vascular cavity about said distal tip" to mean: **"placing the distal tip of a guidewire into a vascular cavity to form a blockage in the vascular cavity. The blockage is formed on or around the distal tip."**

Having now construed the words and phrases of Claim 1, the scope of the claim is clear from its language. The inventors claim as their invention a method for occluding a vascular cavity by a blockage formed on or around a distal tip. The claim is broad enough to cover a thrombus formed from the mere presence of the distal tip, i.e., mechanical thrombosis or from using the distal tip in some manipulative step, e.g., electrothrombosis.FN8 In other words, as construed by the Court, Claim 1 covers all processes for endovascular occlusion, including all processes for endovascular thrombosis formation in which the occlusion is formed on and around a detachable distal tip.

FN8. The Claim does not cover mechanical object occlusion, such as a balloon, because in the processes described in the specification, the mechanical object **is** the occlusion and nothing is "formed" about the tip.

The issue becomes whether the written description adequately describes that invention. Defendants contend that it does not. Defendants point to the narrow written description and a statement made by the inventors to the examiner that other occlusions were "possible" as proof of inadequacy. The Court proceeds to examine whether the original claim, the subsequent amendment, and the current written description support a broad reading of Claim 1 of the '136 Patent.

B. ***Analysis of Claim 1 of the '136 Patent***

1. The Original '717 Application

On March 13, 1990, the inventors filed the '717 Application which was later issued as the '136 Patent. With respect to matters pertinent to this motion FN9, the "claim" was a method for using "an electrical signal" to form a thrombus within a vascular cavity:

FN9. The Claim covered other aspects to the invention such as endovascular disposing of a guidewire and detaching the distal tip. Whether these other aspects were supported by the written description is not being considered in this Order.

I claim:

(1) A method for forming a thrombus 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 guidewire into said vascular cavity;

applying a first electrical signal to said distal tip within said vascular cavity to form a thrombus within said vascular cavity about said distal tip; and

electrolytically detaching said distal tip from said guidewire to leave said distal tip within said vascular cavity and said thrombus electrically formed within said vascular cavity,

whereby electrical formation of a thrombus is completely endovascularly formed.

(Exhibit UCR 6254.)

Although the inventors described other prior art methods for occluding vascular cavities, electrothrombosis was the only method for forming a thrombus described in the original claims and the original written description of the invention. Significantly, electrothrombosis was described in each embodiment of the invention.FN10

FN10. FIG. 1 is an enlarged view of a first embodiment ... after placement of secondary coil 28 within the interior of the aneurysm, a direct current is applied ... The positive charge on the secondary coil 28 within the cavity of the aneurysm causes a thrombus to form within the aneurysm by electrothrombosis.
* * *

FIG. 2 illustrates an enlarged partially cross-sectional view a second embodiment of the invention ... The embodiment of FIG. 2 is utilized in exactly the same manner as described above in connection with FIG. 1 to form a thrombic mass within an aneurysm or other vascular cavity.

* * *

Turn now to the third embodiment of the invention as shown in FIG. 3 ... A positive electric current of approximately 0.01 to 2 milliamps at 0.1-6 volts is applied to guidewire 42 to form the thrombus.
The Court finds that the original claims and written description limited Claim 1 to electrothrombosis.

2. The April 12, 1991 Preliminary Amendment to the '717 Application

On April 9, 1991, the applicants submitted a "Preliminary Amendment" to the ' 717 Application as follows: FN11

FN11. Symbols and punctuation are from the original.

Please amend the claims as follows:

1. (once amended) A method for forming a thrombus 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 guidewire into said vascular cavity[; applying a first electrical signal to] said distal tip within said vascular cavity to form a thrombus within said vascular cavity about said distal tip; FN12 and

FN12. The Court notes that as amended the "disposing step" provides: "disposing a distal tip of said guidewire into said vascular cavity said distal tip within said vascular cavity to form a thrombus within said vascular cavity about said distal tip." On April 15, 1991, the inventors made a Revised Preliminary Amendment. However, the "disposing step" was left unchanged. On August 12, 1991, the inventors filed an Amendment; the Amendment removed the duplicative language. The "disposing step" as amended, provides: "disposing a distal tip of said guidewire into said vascular cavity [said distal tip within said vascular cavity] to form [a thrombus] *said occlusion* within said vascular cavity about said distal tip ."

electrolytically detaching said distal tip from said guidewire to leave said distal tip within said vascular cavity and said thrombus electrically formed within said vascular cavity,
whereby [electrical] formation of a thrombus is completely endovascularly formed.

In the submission, the inventors eliminated the "applying a first electrical signal" step altogether. As amended, "disposing a distal tip" became the only step recited as necessary "to form a thrombus ... about said distal tip." It is clear that the amendment broadened Claim 1 from a claim limited to electrothrombosis to a claim for any thrombosis formed on or around a distal tip. Although there were subsequent amendments, the same broad scope is present in Claims 1-4, as issued. Accordingly, the Court finds that the

April 12, 1991 Preliminary Amendment, while continuing to rely on the original written description, broadened the scope of Claim 1 when the inventors eliminated electrothrombosis as a limitation.

3. The Prosecution of the '136 Patent

In the prosecution of the '136 Patent, the inventors amended Claim 1 to encompass occlusion forming processes that did not depend upon electricity. For a claim to be valid, the written description must describe the process or processes which would convey to a person of skill in the art that at the time of the original application, the inventors were in possession of such a process.

The written description clearly describes electrothrombosis. In addition, in their discussion of prior art, the inventors discuss other occlusion processes known in the art. The Court finds that except for a description of prior art methods, the specification only describes electrothrombosis in the description of the invention. The issue becomes whether the disclosure of electrothrombosis in the description of the invention and of other occlusion processes in the prior art, would convey to a person of skill in the art that the invention includes the prior art process or any other unnamed process. Before discussing the evidence with respect to what the prior art would convey to a person of skill in the art, the Court describes and categorizes the prior art processes.

In the "Background" section of the specification, the inventors list four types of occlusion processes; the Court examines them in turn:

a. Mechanical Object Occlusion

The Court defines "mechanical object occlusion" as a method for occluding a vascular cavity by inserting into the cavity an object or tool. 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.

Under the section of the application entitled "Background of the Invention," the inventors describe methods for "mechanical object occlusion" by mechanically tying off the cavity:

The extravascular approach is comprised of surgery or microsurgery of the aneurysm or treatment site for the purpose of preserving the parent artery. This treatment is common with intracranial berry aneurysms. The methodology comprises the step of **clipping the neck of the** aneurysm**, performing a sutureligation of the neck, or wrapping the entire** aneurysm**.** Each of these surgical procedures is performed by intrusive invasion into the body and performed from outside the aneurysm or target site. General anesthesia, craniotomy, brain retraction and arachnoid dissection around the neck of the aneurysm and placement of a clip are typically required in these surgical procedures. Surgical treatment of vascular intracranial aneurysm can expect a mortality rate of 4-8% with a morbidity rate of 18-20%. Because of the mortality and morbidity rate expected, the surgical procedure is often delayed while waiting for the best surgical time with the result that an additional percentage of patients will die from the underlying disease or defect prior to surgery. For this reason the prior art has sought alternative means of treatment.

Another "mechanical object occlusion" method described in the background section is using a balloon to occlude a vascular cavity:

In the endovascular approach, the interior of the aneurysm is entered through the use of a microcatheter.

Recently developed microcatheters, such as those shown by Engleson, "Catheter Guidewire", U.S. Pat. No. 4,884,579 and as described in Engleson, "Catheter for Guidewire Tracking", U.S. Pat. No. 4,739,768 (1988), allow navigation into the cerebral arteries and entry into a cranial aneurysm.

In such procedures **a balloon** is typically attached to the end of the microcatheter 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.** While endovascular balloon embolization of berry aneurysms is an attractive method in situations where an extravascular surgical approach is difficult, inflation of a balloon into the aneurysm carries some risk of aneurysm rupture due to possible over-distention of portions of the sac and due to the traction produced while detaching the balloon.

While remedial procedures exist for treating a ruptured aneurysm during classical extravascular surgery, no satisfactory methodology exists if the aneurysm breaks during an endovascular balloon embolization.

Furthermore, an ideal embolizing agent should adapt itself to the irregular shape of the internal walls of the aneurysm. On the contrary, in a balloon embolization the aneurysmal wall must conform to the shape of the balloon. This may not lead to a satisfactory result and further increases the risk of rupture.

A final method for occluding a vascular cavity which is discussed in the background section of the specification is liquid adhesive polymerization. Although the occlusive mass is described as being formed on contact with blood, it is the polymer mass which occludes the cavity, not a chemical change in the blood caused by the adhesive:

The prior art has also devised the use of a liquid adhesive, isobutylcyanoacrylate (IBCA) which polymerizes rapidly on contact with blood to form a firm mass. The **liquid adhesive is injected into the** aneurysm by puncturing the sac with a small needle. In order to avoid spillage into the parent artery during IBCA injection, blood flow through the parent artery must be momentarily reduced or interrupted. Alternatively, an inflated balloon FN13 may be placed in the artery at the level of the neck of the aneurysm for injection. In addition to the risks caused by temporary blockage of the parent artery, the risks of seepage of such a polymerizing adhesive into the parent artery exists, if it is not completely blocked with consequent occlusion of the artery.

FN13. Although this prior art method uses a balloon, it is different from using a balloon in "Mechanical Object Occlusion" because the balloon is not being used to fill the vascular cavity and thus occlude it. The balloon is being used to stop blood flow in the vessel in order to limit the polymerization to the blood in the vascular cavity.

Mechanical object occlusion does not involve formation of a thrombus.

b. Catalytic thrombosis

The Court is using the phrase "catalytic thrombosis" to describe methods for occluding a vascular cavity by using a catalyst to cause or to accelerate formation of a thrombus. The inventors describe two procedures which the Court characterizes as "catalytic thrombosis." The first is electrothrombosis:

In the use of **electrothrombosis** for extra-intravascular treatment 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. See Mullan, "Experiences with Surgical Thrombosis of Intracranial Berry Aneurysms and Carotid Cavernous Fistulas", J. Neurosurg., Vol. 41, December 1974; Hosobuchi, "Electrothrombosis Carotid-Cavernous Fistula", J. Neurosurg., Vol. 42, January 1975; Araki et al., "Electrically Induced Thrombosis for the Treatment of Intracranial Aneurysms and Angiomas", Excerpta Medica International Congress Series, Amsterdam 1965, Vol. 110, 651-654; Sawyer et al., "Bio-Electric Phenomena as an Etiological Factor in Intravascular Thrombosis", Am. J. Physiol., Vol. 175, 103-107 (1953); J. Piton et al., "Selective Vascular Thrombosis Induced by a Direct Electrical Current; Animal Experiments", J. Neuroradiology, Vol. 5, pages 139-152 (1978). However, each of these techniques involves some type of intrusive procedure to approach the aneurysm from the exterior of the body.

The second catalytic thrombotic process described by the inventors is ferro-magnetic thrombosis:

Ferromagnetic thrombosis in the prior art in extra-intravascular treatments comprises the stereotactic placement of a magnetic probe against the sac of the aneurysm followed by **injection into the** aneurysm **by an injecting needle of iron microspheres. Aggregation of the microspheres through the extravascular magnet is followed by interneuysmatic** thrombus**.** This treatment has not been entirely successful because of the risk of fragmentation of the metallic thrombus when the extravascular magnet is removed. Suspension of the iron powder in methyl methymethacrylate has been used to prevent fragmentation. The treatment has not been favored, because of the need to puncture the aneurysm, the risk of occlusion of the parent artery, the use of unusual and expensive equipment, the need for a craniectomy and general anesthesia, and the necessity to penetrate cerebral tissue to reach the aneurysm.

c. Thermal Coagulation

The inventors differentiate methods which cause the blood to form a thrombus from those using heat which cause the blood to coagulate. Therefore, the Court characterizes any methods using heat as "thermal coagulation:" FN14

FN14. Although this prior art method uses a balloon, this is different from the balloon used in "Mechanical Object Occlusion" because the balloon is not being used to treat the vascular cavity be occluding it. The balloon is being used to stop blood flow in the vessel in order to allow the tip to reach an effective temperature.

Endovascular **coagulation of blood** is also well known in the art and a device using **laser optically generated heat** is shown by O'Reilly, "Optical Fiber with Attachable Metallic Tip for Intravascular Laser Coagulation of Arteries, Veins, Aneurysms, Vascular Malformation and Arteriovenous Fistulas", U.S. Pat. No. 4,735,201 (1988). See also, O'Reilly et al., "Laser Induced Thermal Occlusion of Berry Aneurysms: Initial Experimental Results", Radiology, Vol. 171, No. 2, pages 471-74 (1989). O'Reilly places a tip into an aneurysm by means of an endovascular microcatheter. The tip is adhesively bonded to a optic fiber disposed through the microcatheter. Optical energy is transmitted along the optic fiber from a remote laser at the proximal end of the microcatheter. **The optical energy heats the tip to cauterize the tissue surrounding the neck of the** aneurysm **or other vascular opening to be occluded.** The catheter is provided with a balloon located on or adjacent to its distal end to cut off blood flow to the site to be cauterized and

occluded. Normally, the blood flow would carry away the heat at the catheter tip, thereby preventing cauterization. The heat in the tip also serves to melt the adhesive used to secure the tip to the distal end of the optical fiber. If all goes well, the tip can be separated from the optical fiber and left in place in the neck of the aneurysm, provided that the cauterization is complete at the same time as the hot melt adhesive melts.
d. Mechanical Thrombosis

The Court is using the phrase "mechanical thrombosis" to describe methods for occluding a vascular cavity by inserting a thrombogenic material, which, because of its presence, causes formation of a thrombus. In the background section, the inventors discussed a method which the Court places in this category:

Still further, the prior art has utilized an air gun to **inject hog hair through the** aneurysm **wall to induce internal** thrombosis**.** The success of this procedure involves exposing the aneurysm sufficiently to allow air gun injection and has not been convincingly shown as successful for thrombic formations.

The specification does not describe the hog hair method any further. It is described as a method which has not been convincingly shown as effective for thrombic formation.

4. Applying the Evidence to the Four Types of Occlusion Processes

To determine whether Defendants have proved by clear and convincing evidence that the written description is inadequate to convey to a person of skill in the art that the invention covers one or more of the prior art processes or to an unlisted process, the Court applies the evidence submitted to the four types of occlusion processes discussed above.

Defendants have addressed some but not all of the processes. For example, Defendants have submitted the declaration of Dr. Donald Larsen which provides:

For many years prior to the filing of the application for the '136 patent in 1990, investigators had embolized vascular cavities with a variety of embolic materials, including straight and coiled wires. Using both invasive and relatively noninvasive (e.g., endovasular) approaches, occlusion was effected through both mechanical and electrothrombotic means ... Platinum wires were used because of their thrombogenicity ... Thrombogenicity of metal can be enhanced by using an electrical current, by combining the wire with fabric strands, or by "packing" multiple wires into the vascular structure.FN15

FN15. (Declaration of Gabrielle E. Bina, In Support of Defendants' Motion for Summary Judgment of Invalidity, Ex. 25, Expert Report of Donald Larsen, M.D., quoting in part from *Yang* reference, Docket Item No. 611.)

This excerpt appears to describe what the Court has characterized as mechanical object occlusion and mechanical thrombosis. However, it is unclear to the Court whether Dr. Larsen is stating that skilled artisans would understand the specification to include the variety of embolic materials and associated processes.

In response, Plaintiffs have submitted the declaration of Dr. Gary Nesbit, which provides, *inter alia:*

... [I]t is my opinion that a person of ordinary skill would recognize that filling or substantially filling a cavity (such as an aneurysm) with a long and pliable distal tip such as is shown in originally-filed figures 4 and 5 would necessarily result in mechanical occlusion of the vascular cavity. This is so because a person of

ordinary skill would know that by putting these types of materials into a cavity such as an aneurysm, the flow of blood into the cavity would slow. thus, for example, if one were to place the coil described and depicted in the specification in an aneurysm, but did not apply current to it, it would still slow the flow of blood.FN16

FN16. (Declaration of Dr. Gary Nesbit in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment of Invalidity for Failure to Comply With 35 s. 112 para.para. 1 and 2 para. 13, Docket Item No. 646.)

It is unclear to the Court whether Dr. Nesbit is stating that a skilled artisan would understand that the specification and drawings describe mechanical object occlusion or mechanical thrombosis. The Court would find Dr. Nesbit's declaration more helpful if it were to categorize the occlusion processes in the same way the Court has.

In sum, the Court finds that the reference to mechanical thrombosis in the "background" section of the specification creates a genuine factual dispute as to whether one skilled in the art would understand from that reference that mechanical thrombosis was being included in the subject matter of the invention. Accordingly, the Court DENIES Defendants' motion for summary judgment of invalidity based on lack of written description without prejudice.

However, if the parties are inclined to bring this written description issue back before the Court, the evidence, expert declarations and arguments should be organized in a fashion which addresses the following: FN17

FN17. If the parties choose not to bring the issue back to the Court, they are advised that the Court will include these factors in its instructions to the jury on deciding invalidity on the ground of inadequate written description.

(1) Would a person of skill in the art conclude or not conclude that a process, which is covered by a broad claim but which is not described in the written description, is nevertheless supported by the written description because the written description conveys that the reason a process is described in the written description is due to its **properties and functions** and a skilled artisan would immediately know from the listed process that an unlisted process is also covered?
(2) Is the process which is described in the written description a **member or not a member of a well-recognized group** such that a skilled artisan would know from the listed process that the invention applies equally to another member of the group?

(3) Is a process which is not described in the written description but which an inventor seeks to have included in the claim regarded by skilled artisans as being **equally predictable or not in performance** as compared to a process which is disclosed in the written description?

(4) Does the original written description attribute or not attribute **unique properties** to the process which is described, and would a person of skill in the art conclude that the undescribed process shares those same unique properties?

(5) Is the undescribed process which the inventor seeks to include in the invention a prior art which the inventor **criticized** in a manner which would lead a skilled artisan to conclude that the inventor intended or did not intend to include the process in the coverage of the invention?

(6) If the inventor admits that at the time of the original application he or she was **not aware** of a later realized species FN18 (but one which is known in the art generally), and they only describe species of which they are personally aware in the written description, what significance, if any, does such an admission have on a person of ordinary skill in the art whether the later realized species should be considered as part of the invention if upon realization of the species the inventor later broaden his or her claim to capture a genus which includes all species? FN19

FN18. Defendants have produced evidence that in 1991, at the time of the amendment, the inventors speculated that their method could be practiced using mechanical thrombosis:
Claim 1, 8 and 12 have been amended to claim an apparatus and method for formation of thrombus which is not dependent on the mechanism of electrothrombic formation. **It is possible that the mechanical presence of the distal tip may be enough to initiate formation of thrombus.** The amendment does not affect the election which has been made.

FN19. This may be a mixed question of law and fact. In this case, if the reason the inventors were speculating in April of 1991, about whether the process might work in the absence of electricity is because they were not in possession of a method without electricity, this might require invalidating the claim as a matter of law, unless the patent law allows inventors to claim an invention of greater scope than that of which they are personally aware. In other words, if it were known in the art that a thrombus can be formed in the absence of electricity, but the inventors did not know of such processes when they file their application, and hence did not describe them in the written description. If during prosecution, the inventors began to speculate that these other processes might exist and, based on that speculation the inventors broaden their claim but failed to amend their written description, are the inventors entitled to claim the processes unknown to them but known to the art within the scope of the invention?

C. ***Claim 8 of the '136 Patent***

In construing Claim 1, the Court turned its attention to Claim 8 of the '136 because the word "disposing" is also used in Claim 8. The Court now turns to Claim 8 to examine whether it meets the definiteness requirement.

A determination as to whether a patent claim meets the definiteness requirement is a question of law to be decided by the court in performance of its duty as the construer of patent claims. Bancorp Services, L.L.C. v. Hartford Life Insurance Co., 359 F.3d 1367, 1371 (Fed.Cir.2004).

Claim 8 of the '136 Patent provides:

The method of claim 1 wherein said step of disposing said distal tip comprises **the step of applying an electrical signal** to said distal tip to form said thrombus by applying a positive direct current for a first predetermined time period.

There are two ways to interpret Claim 8, i.e., a modification of the "disposing step," or a substitution of the "applying an electrical signal step"; however, the Court finds that adopting either interpretations would present structural problems.

First, Claim 8 may be interpreted as a step which is **added to** the "disposing step" of Claim 1. Under this interpretation, the phrase in Claim 8, "wherein said step of disposing said distal tip comprises the step of applying an electrical signal" would be interpreted to mean that the elements of the "apply an electrical signal" step of Claim 8 are added to the elements of the "disposing step" of Claim 1. The Court declines to adopt this interpretation at this time. Claim 8 uses the word "comprises," which is commonly used to introduce **new** elements. Claim 8 does not use the phrase "further comprises," which is commonly used to mean that the elements of the dependent claim are being **added to** the elements of the independent claim.FN20

FN20. *See* Claim 2 of the '136 Patent.

Alternatively, the language of Claim 8 may be interpreted as providing that its elements **replace** the elements of the "disposing step." Under this interpretation, the phrase "wherein said step of disposing said distal top comprises the step of applying an electrical signal" would be interpreted to mean that the "disposing step" is eliminated and a new step is added, i.e., applying an electrical signal to the tip to form a thrombus. If adopted, this interpretation would render Claim 8 arguably indefinite because each dependent claim must contain all of the limitations of its associated independent claim. *See* 35 U.S.C. s. 112. In addition, if Claim 8 is interpreted as replacing the "disposing step," Claim 8 would also be arguably indefinite because an essential element, namely, inserting the tip into the cavity, would be eliminated.

In sum, because of the ambiguity created by the use of the word "comprises" and of the alternative interpretation described above, the Court finds Claim 8 arguably indefinite and requests the parties to provide further briefing with respect to the validity of Claim 8.

D. ***Motion to Establish Priority Date of Patents Based on the '211 Application***

On February 24, 1992, the inventors filed the 07/840,211 Application ('211 Application) as a Continuation-in-Part (CIP) Application to the '717 Application. A CIP application is entitled to the parent's filing date as to any common subject matter. 35 U.S.C. s. 121. In their motion, Defendants contend that because the specification in the '717 Application does not support any occlusion other than electrothrombosis, claims issued from the '211 Application FN21 for methods of occlusion other than electrothrombosis are not entitled to the priority date of the '717 Application.

FN21. Defendants' motion address the following claims: Claims 11-14, 16-19 of the '578 Patent; Claims 1, 4, 5, 6, 7, and 10 of the '037 Patent; Claims 1, 2 and 6 of the '963 Patent; Claims 1, 2, 3, 5, 6, 7, and 9 of the '126 Patent; Claims 1-6, 8, 10, 16, 20, 25-30, 35, 37, 38 and 42-47 of the '133 Patent.

First, the Court finds that this part of Defendants' motion is improperly noticed. In a single paragraph, Defendants are attempting to advance a separate motion. Second, the motion is untimely, because it is contingent on the Court's ruling that Claims 1-4 of the '136 Patent are invalid for failure to meet the written

description requirement for any occlusion other than electrothrombosis. Accordingly, this part of the Defendants' motion is DENIED as premature.

IV. CONCLUSION

For the reasons stated above, the construction of Claim 1 of the '136 Patent is modified.

Defendants' Motion for Summary Judgment of Invalidity of Claims 1-4 of the ' 136 Patent is DENIED without prejudice. Any renewed motion based on the identical invalidity ground shall be structured in accordance with the issues outlined in this Order.

Finally, the Court finds Claim 8 of the '136 Patent arguably indefinite and directs the parties to address this finding in pretrial motions.

This Order does not address the two pending issues remaining in Defendants' motion for summary judgment of invalidity of: (1) all claims that encompass body cavities other than vascular cavities and fluids other than blood for lack of written description; (2) Claim 8 of the '133 Patent for lack of written description and enablement.

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