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. C 03-05669 JW

June 26, 2007.

Charles Furlonge Robinson, James E. Holst, P. Martin Simpson, Rita A. Hao, University of California, Oakland, CA, Lynn Harold Pasahow, Patrick Eugene Premo, Carolyn Chang, Chien-Ju Alice Chuang, Henry Zuzueta Carbajal, III, Wendy Lynn Bjerknes, Fenwick & West LLP, Mt. View, CA, Michael Jeffrey Shuster, Fenwick & West LLP, San Francisco, CA, for Plaintiff.

Charles G. Curtis, Jr., David J. Harth, Gabrielle E. Bina, Lissa Rose Koop, Michelle M. Umberger, Sarah C. Walkenhorst, Autumn Noelle Nero, David L. Anstaett, John S. Skilton, Heller Ehrman LLP, David Edwin Jones, Madison, WI, Colin G. Sandercock, Proskauer Rose LLP, Washington, DC, Michael Kenneth Plimack, Heller, Ehrman, LLP, San Francisco, CA, for Defendants and Third Party Plaintiffs.

### THIRD CLAIM CONSTRUCTION ORDER

## JAMES WARE, District Judge.

## I. INTRODUCTION

Plaintiff The Regents of the University of California ("The Regents") bring this action 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.

On March 2, 2007, the Court issued a Supplemental Claim Construction Order. (hereafter, "Supplemental Order," Docket Item No. 482.) Before the Court is Defendants' Motion for Reconsider of the Supplemental Claim Construction Order. (*See* Docket Item No. 625.) Defendants move the Court to reconsider its construction with respect to two phrases: "occlusion" and "core wire." This Order addresses those phrases.

## **II. DISCUSSION**

The Court adopts the claim construction standards articulated in the Supplement Claim Construction Order.

### A. "Occulsion"

Defendants request reconsideration of the construction of Claim 1 of the '136 Patent with respect to the words "occlusion" and "occluded." Defendants object to the part of the Court's construction which states, "The vascular cavity does not have to be completely occupied by the blockage to be occluded." (Supplemental Order at 10.) Defendants contend that given the nature of the medical problem which the invention is designed to remedy, a person of ordinary skill in the art would understand that when the inventors used the word "occlusion," they meant "closed off" or "complete blockage." In addition, Defendants point to statements in the written description to support a contention that the inventors intended "occlusion" to mean "complete occlusion." For the reasons stated below, the Court has been persuaded to modify its construction.

Claim 1 of the '139 Patent provides: FN1

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. The principles of claim construction require construction of the claim language "as issued."

As part of the reconsideration motion, Defendants submitted the prosecution history of the '136 Patent. However, as previously stated, claim construction does not begin with the prosecution history, but with the words of the claim. The Court construes the words of a claim in accordance with how they would be understood by a person of ordinary skill in the relevant art at the time of the invention. The Court considers that the words should be given their ordinary and customary meanings, unless the patent documents support giving to them a different meaning.

The Court emphasizes that claim construction construes patent claims **as issued.** This principle is particularly important with respect to Claim 1 because there are significant differences between the language of the claim as originally filed and the language of the issued claim.

#### 2. The method of Claim 1, as issued, is broader than the invention claimed in the original application.

As originally filed on March 13, 1990, as Application No. 07/492,717, Claim 1 stated:

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 form 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.

(Declaration of Gabrielle E. Bina in Support of 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, Ex. 20 at E20, Prosecution History of '717 Application, hereafter, "Bina Decl.," Docket Item No. 612)

The difference between the original language and the issued language is significant to how the Court construes the words in dispute. The original Preamble disclosed the method as one for forming **a** thrombus. The "whereby" clause listed the objective as forming a thrombus endovascularly.

As issued, Claim 1 states a broader method and a different objective. Claim 1 claims a method for "forming **an occlusion,**" which is a broader objective than one limited to forming a thrombus. In addition, the "whereby" clause of Claim 1, as issued, states a different intended result of the process: occluding a vascular cavity by a tip and any thrombus formed by use of the tip.

Subsequent amendments of the original claim language are also significant. On April 12, 1991, Claim 1 of the '717 Application was amended to delete the step of "applying a first electrical signal:"

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 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 form said guidewire to leave said distal tip within said vascular cavity and said thrombus electrically formed within said vascular cavity,

whereby formation of a thrombus is completely endovascularly formed.

(Bina Delc. Ex. 20 at E57, Preliminary Amendment of '717 Application.)

The inventors stated that the reason for the amendment was to claim a method for formation of thrombus which is not dependent on the mechanism of electrothrombic formation. "It is possible that the mechanical presence FN2 of the distal tip may be enough to **initiate formation of** thrombus." (*Id.* at E59.) FN3

### 3. The Court applies the rules of English grammar when construing the words used in a claim.

On August 7, 1991, Claim 1 of the '717 Application was further amended FN4 to change the language of a step in the method from one in which a "thrombus was electrically formed" to a claim of "an occlusion being formed:"

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 guidewire into said vascular cavity said distal tip within said vascular cavity to form a thrombus within said vascular cavity about said distal tip; and

detaching said distal tip form 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.

(Prosecution History, UCR402.) The Court finds the August 7, 1991 amendment significant because of its abandonment in the detaching step of the pre-amendment past tense verb, "formed," which signifies a completed action. The post-amendment phrase "being formed" indicates an on-going action.FN5 Thus, one of ordinary skill reading the patent documents would conclude that the inventors intended to claim "forming an occlusion" as a process which is on-going at the time of detaching.FN6 The Court now turns its attention to the object being formed.

# 4. A word which has multiple definitions must be construed as it would be understood by a person of ordinary skill in the field of the invention.

Defendants ask the Court to give further consideration to the construction of the word "occlusion" in terms of medical science. The word "occlusion" has multiple definitions in the field of medicine. Excerpts from *Stedman's Medical Dictionary* illustrate the variety of definitions:

**occlude.** 1. To close or bring together. 2. To enclose, as in an occluded virus. occluder: In dentistry, a name given to some articulators.

**occlusal.** 1. Pertaining to occlusion or closure. 2. In dentistry, pertaining to the contacting surfaces of opposing occlusal units (teeth or occlusioin rims) or the masticating surfaces of the posterior teeth.

**occlusion.** Do not confuse this word with atresia or stenosis. 1. The act of closing or the state of being closed. 2. In chemistry, the absorpton of a gas by a metal or the inclusion of one substance within another (as in a gelatinous precipitate). 3. Any contact between the incising or masticating surfaces of the upper and lower teeth. 4. The relationship between the occlusal surfaces of the maxillary and mandibular teeth when they are in contact.

\* \* \*

coronary o[clusion], blockage of a coronary vessel, usually by thrombosis or atheroma, often leading to

myocardial infarction.

\* \* \*

**mesenteric artery o[clusion],** obstruction of arterial flow in the mesenteric circulation by an embolus or thrombus; usually refers to o[clusion] of the superior mesenteric artery, although atherosclerotic narrowing may involve all three major splanchnic branches (celiac, superior, and inferior mesenteric).

See Stedman's Medical Dictionary 1355 (28th ed.2006).

It is clear that medical practitioners use the word "occlusion" in a variety of contexts. In dentistry, "occlusion" means closing or bringing dental surfaces together. In viral medicine "occlusion" is used synonymously with "inclusion," FN7 meaning one material engulfing another. In vascular medicine, "occlusion" means a blockage or obstruction FN8 of a vascular passage:

**coronary o[clusion],** blockage of a coronary vessel, usually by thrombosis or atheroma, often leading to myocardial infarction.

\* \* \*

**mesenteric artery o[clusion],** obstruction of arterial flow in the mesenteric circulation by an embolus or thrombus; usually refers to o[clusion] of the superior mesenteric artery, although atherosclerotic narrowing may involve all three major splanchnic branches (celiac, superior, and inferior mesenteric).

See Stedman's Medical Dictionary 1355 (28th ed.2006).

The Court finds that a person of ordinary skill in the art would understand that in the '136 Patent, the inventors are using "occlusion" in the context of vascular medicine, namely a blockage. Before giving a definitive construction, the Court considers the effect of the "whereby" clause.

## 5. The "whereby" clause of Claim 1 is limiting.

The Court affirms its previous finding that the "whereby' clause is limiting. The language of the "whereby" clause imposes a limitation that the occlusion "is by the distal tip and any thrombus formed from using the distal tip."

## 6. The method of Claim 1 does not require complete occlusion as an element of the claim.

The Court turns to the remaining issue: whether the word "occlusion" should be construed to require "complete" blockage. The parties have introduced extrinsic evidence in the form of expert reports and published medical journal articles with respect to how practitioners used the word "occlusion" in treating aneurysms:

This 60-year-old woman presented with a recent memory deficit and severe headaches. \* \* \* This aneurysm was considered inoperable due to its size and location. \* \* \* Several platinum coils (a total of 8.5 ft) were then delivered and detached within the sac of the aneurysm by electrothrombosis and electrolysis. approximately 80% of the aneurysm was filled with coils; and aneurysm neck was preserved in order to spare the origin of both posterior cerebral arteries and both superior cerebellar arteries. \* \* \* An angiogram

performed 6 day post embolization demonstreted progressive thrombosis around the coils within the aneurysm with **approximately 80% occlusion of the** aneurysm **volume**.

(Bina Decl. Ex. 26 at MTI2785-86.)

In the same article a case was discussed in which:

A follow-up angiogram obtained 6 day postembolization deminstrated progressive thrombisis of the aneurysm sac with approximately **95% occlusion**.

(*Id.*)

In a third case the authors stated:

An immediate postembolization angiogram (Fig. 6 right) and a follow-up angiogram 4 days after the procedure both demonstrated **complete occlusion of the** aneurysm.

## (*Id*.)

As illustrated by these references, the word "occlusion" is used as a noun to indicate the thing which is blocking or the state of containing a blockage. While it is appears that some practitioners recognize the difference between partial occlusion and complete occlusion, a vascular cavity which is partially obstructed is described as being occluded or having an occlusion.

# 7. The Court construes the words "occlusion" and "occluded" as they are used in various parts of Claim 1.

The Preamble to Claim 1 of the '136 Patent provides: "A method for forming an occlusion within a vascular cavity having blood disposed therein" As used in the Preamble, the Court construes the phrase "**a method** for forming an occlusion within a vascular cavity" to mean:

# a method for creating a blockage or an obstruction in a vascular cavity by using a distal tip of the invention and by forming a thrombus in the cavity by use of the tip.

A step of the method of Claim 1 of the '136 Patent provides: disposing a distal tip of said guide wire into said vascular cavity to form said occlusion within said vascular cavity about said distal tip." As used in this step, the Court construes **"to form said occlusion"** to mean:

## for the purpose of using the distal tip to form a thrombus in and around the distal tip

A further step of the method of Claim 1 of the '136 Patent provides: "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 used in this step, the Court construes "**said occlusion being formed**" to mean:

the distal tip and the thrombus being formed about and around the distal tip as it exists at the time of detaching the distal tip. At the time of detaching the distal tip, the thrombus may partially or completely fill the vascular cavity.

The "whereby" clause of Claim 1 of the '136 Patent provides: "whereby said vascular cavity is occluded by said distal tip, and any thrombus formed by said tip." The word "occluded" refers not to the occlusion, but to the state of the vascular cavity. The Court construes the phrase "vascular cavity is occluded," as it is used in this clause, to mean:

# the vascular cavity is filled, blocked or obstructed by the distal tip and any thrombus formed by the distal tip.

#### B. "Core Wire"

The Court has reconsidered its construction of the phrase "core wire" in its August 25, 2005 Order and declines to modify its construction. To the extent the Court has highlighted instances in which the Court's construction of "core wire" creates arguable invalidity of a particular claim, the parties are invited to file appropriate motions.

#### **III. CONCLUSION**

In this Order, the Court has reconsidered its previous construction. Any modifications made in this Order supersede previous claim construction Orders for claims being construed.

FN1. Unless otherwise indicated, all bold typeface is added by the Court for emphasis.

FN2. The Court defers consideration of whether a claim to mechanical formation of a thrombus is supported by the written description until it addresses a pending motion directed to that issue.

FN3. The Court notes that the April 12, 1991, language continued to include the phrase "electrically formed" in the "detaching step." The inclusion of this phrase is inconsistent with the stated objective of deleting the limitation of applying electricity to form a thrombus. This inconsistency was eliminated in a subsequent amendment, which deleted the phrase "electrically formed."

FN4. The Court notes that on April 15, 1991, Claim 1 of the '717 Application was amended to change the reference in the Preamble from forming a "thrombus" to forming an "occlusion:" 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 guidewire into said vascular cavity said distal tip within said vascular cavity to form a thrombus within said vascular cavity about said distal tip; and

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

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

(Bina Decl. Ex 20 at E60, Revised Preliminary Amendment of '717 Application.)

FN5. Verb tense and aspect are commonly used to indicate whether the action will take place, is taking place or has taken place. The phrase "being formed" is a compound verb, which combines the word "being," a progressive form of the verb "to be," with the verb "formed" to describe an action already in progress at the moment in focus within the sentence.

FN6. In the Preamble the method is one for "forming an occlusion." The word "forming" is an active verb. The active voice can be either transitive (acting on a direct object) or intransitive (being acted upon and not taking a direct object). In its transitive voice, it means "to give form or shape to" a direct object. The object subjected to "forming" is an occlusion. The Court recognizes that "to form" can be used in an intransitive voice, meaning "to become formed or shaped." In the Preamble, the inventors use the verb with a direct object.

FN7. See Stedman's Medical Dictionary 961 (28th ed.2006).

FN8. An "obstruction" is commonly understood in medicine to mean: Blockage, clogging, or impeded flow, e.g., by occlusion or stenosis. *See* Stedman's Medical Dictionary 1354 (28th ed.2006).

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