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

Aug. 25, 2005.

#### ORDER FOLLOWING CLAIMS CONSTRUCTION HEARING; SETTING CASE MANAGEMENT CONFERENCE

#### JAMES WARE, District Judge.

## I. INTRODUCTION

Plaintiff, The Regents of the University of California ("Regents" or "Plaintiff"), initiated this suit against Defendants Micro Therapeutics Inc. ("MTI") and its wholly owned subsidiary Dendron GmbH ("Dendron") (collectively "Defendants") asserting that Defendants willfully infringed, and continue to infringe, twelve of its patents which relate to the treatment of brain aneurysms (collectively "the patents-in-suit"). Through the claim construction process. The Regents eliminated five of its asserted patents, and presently assert the following seven patents against Defendants: 5,122,136 ("'136 Patent") 5,855,578 ("'578 Patent") 6,066,133 ("133 Patent") 5,976,126 ("126 Patent") 5,947,962 ("'962 Patent"), 5,947,963 ("'963 Patent"), and 5,925,037 ("037 Patent"). Defendants deny infringement of the patents-in-suit and raised affirmative defenses of invalidity, non-infringement and failure to join Target Therapeutics, Inc. and Boston Scientific Corporation as necessary parties. Defendants asserted counterclaims for declaratory judgment of invalidity and noninfringement against The Regents. In addition, Defendants filed a Third Party Complaint against third party defendants Target Therapeutics, Inc. ("Target") and Boston Scientific Corporation ("Boston Scientific") for declaratory relief of invalidity and non-infringement. FN1 Defendants' counterclaims of invalidity and noninfringement still relate to all twelve of The Regents' originally asserted patents. The five extra patents that remain in the counterclaims are the 5,354,295 ("'295 Patent"), 5,540,680 ("'680 Patent"), 5,895,385 ("'385 Patent"), 6,010,498 ("'498 Patent"), and 6,083,220 ("'220 Patent"). On March 4, 2005, the Court held a hearing in accordance with Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), to construe the disputed terms and phrases of the asserted claims.

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.

## II. BACKGROUND

Plaintiff Regents 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 third party defendant Target. Target is now wholly owned by third party defendant Boston Scientific. The Regents have an exclusive license agreement with Target. Boston Scientific is the exclusive distributor of products manufactured pursuant to the patents.

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

The inventions claimed in these patents, among others, enabled the development of the Guglielmi Detachable Coil or "GDC Coil," a detachable coil device for the treatment of aneurysms. Plaintiff alleges 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 is used for the treatment of brain aneurysms, thereby infringing the patents-in-suit.

On March 4, 2005, the Court conducted a hearing to construe the disputed terms and phrases contained in the patents-in-suit. As conveyed to the parties at the hearing, the Court is disposed to providing constructions to the parties incrementally. This Order sets forth the Court's construction of those terms and phrases it has deemed to be central to the dispute between the parties.

## III. STANDARDS

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 (1996). "[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude ." Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed.Cir.2004). Claims are construed from the perspective of a person of ordinary skill in the art at the time of the invention. Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed.Cir.1995).

The specification "is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." Vitronics Corp. v.. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996); Phillips v. AWH Corp., 2005 WL 1620331, at (Fed.Cir. Jul. 12, 2005). The specification must describe the claimed invention in "full, clear, concise, and exact terms." 35 U.S.C. s. 112, para. 1. "In light of the statutory directive that the inventor provide a "full" and "exact" description of the claimed invention, the specification necessarily informs the proper construction of the claims." Phillips, 2005 WL 1620331, at \*8. The inventor can act as lexicographer in defining claim terms in the specification. *Id*.

Generally, extrinsic evidence is less reliable than the patent and its prosecution history and therefore given less deference in determining the meaning of the claim terms. Id. at \* 11. However, "because extrinsic evidence can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean, it is permissible for the district court in its sound discretion to admit and use such evidence." Id. Yet, the court must always weigh the usefulness of the extrinsic evidence in light of the intrinsic evidence and also recognize the flaws in using extrinsic evidence. Id. "The sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law." Id. at \* 16.

## **IV. DISCUSSION**

The terms addressed in this Order are contained in claim 1 of the '578 patent and claims 1 and 5 of the '136 patent, which are set forth immediately below:

## Claim 1, '578 Patent

1. An apparatus for forming an occlusion within a body cavity having an ionic fluid therein 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

an electrolytically detachable connecting segment coupling said distal tip and said wire.

## Claim 1, '136 Patent

1. 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.

## Claim 5, '136 Patent

5. 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.

The constructions of the terms and phrases that follow are intended to broadly apply to each occurrence of the terms in the asserted claims of all of the patents-in-suit:

A. "Wire" and "Guidewire"

The parties have agreed that the terms "guidewire" and "wire" should be construed synonymously for purposes of claim construction. This Court construes the term "wire" to mean "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."

An inventor can act as a lexicographer in defining claim terms in the specification. Phillips, 2005 WL 1620331, at \*8. As such, the specification is controlling when an explicit definition for a term is given. The specifications of eleven of the Regents' patents set forth an explicit definition of the term "wire"-"the term 'wire' should be understood to collectively include both guidewires and tips and simply wires without distinct tip structures." '578 Patent, 4:8-10. Following the *Phillips* decision, the Court finds that the proper construction of the term "wire" would necessarily include the definition of the term as set forth in the specification.

Further, both parties agree that the definition of "wire" should include "a thin, flexible, continuous length of metal, usually of circular cross-section." This additional language is consistent with the term's use in the specifications, the claims and the prosecution histories of the patents-in-suit. Therefore, this Court adds the parties' agreed-upon language to the explicit definition set forth in the specification.

## B. "Distal tip" and "Tip"

It is clear from the language of the claims that "distal tip" and "tip," as used in the patents-in-suit, are synonymous. *See e.g.* '136 patent, claim 1 ("whereby said vascular cavity is occluded by said distal tip, and any thrombus formed by use of said tip."). Accordingly, this Court construes the terms "distal tip" and "tip" synonymously. Seeking guidance once again from the specifications of the patents-in-suit, the Court defines the terms "distal tip" and "tip" to mean "a piece of the guidewire furthest away from the physician that is capable of being detached."

The specifications of the patents-in-suit describe the tip to be any part of the distal end of the guidewire that is intended to be placed in the vascular area to occlude it. *See e.g.* '136 patent, 4:10-12 ("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."); '133 patent, 4:58-61 ("The distal tip of the wire is detached from the wire to leave the distal tip of the vascular cavity. As a result, the vascular cavity is occluded by the distal tip, and by any thrombus formed by use of the tip."). The Court's construction is thus consistent with these teachings in the specifications of the patents-in-suit.

The Court rejects Plaintiff's contention that the distal tip be defined, in part, as "a fixed and distinct piece." Plaintiff's proposed construction would exclude at least one preferred embodiment of the invention:

A portion of the guidewire connected between the tip and the body of the guidewire is comprised of stainless steel and exposed to the bloodstream so that upon continued application of a positive current to the exposed portion, the exposed portion is corroded away *at least at one location* and the tip is separated from the body of the guidewire. The guidewire and the microcatheter are thereafter removed leaving the guidewire tip embedded in the thrombus formed within the vascular cavity.

'136 patent, 5:47-53 (emphasis added). The Court notes that the phrase "at least at one location" in the above description of a preferred embodiment of the invention implies that the detachable portion (the tip) of the device is not fixed, but rather can be lengthened or shortened as need be. In general, "a claim

interpretation that excludes a preferred embodiment from the scope of the claim 'is rarely, if ever, correct.' " Globetrotter Software, Inc. v. Elan Computer Group, Inc., 362 F.3d 1367, 1381 (Fed.Cir.2004) (citing Vitronics Corp., 90 F.3d at 1583). Thus, the Court declines to include Plaintiff's proposed language in its construction.

## C. "Connecting segment"

The patents-in-suit require a portion of the device to be left in the body. *See e.g.* '136 Patent, 4:10-12 ("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."). In order for a portion of the device to be left in the body, the device must disassociate into at least two separate pieces. When the device is intact (i.e. before electrolytic detachment of the distal tip), the connecting segment is the portion of the device between the segment that is ultimately left in the vascular cavity and the portion that is withdrawn from the body. *See e.g.* '136 Patent, 4:25-29 ("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 "connecting segment" to mean "a distinct portion of the device, capable of detaching the distal tip from the guidewire."

Plaintiff contends that the connecting segment is a "fixed and distinct" detachment segment. The Court is persuaded by the "distinct" nature of the connecting segment. In order to effect detachment of the tip without causing disintegration of the entire device upon application of current, the invention requires that the connecting segment, unlike the tip portion of the device, be susceptible to disintegration. *See e.g.* '136 Patent, 4:49-54 ("The guidewire is then repositioned so the disintegratable portion is exposed to electrolytic disintegration in the blood by application of the same or different level of current for an additional time period to effect detachment."); '136 Patent, 4:56-59 ("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, 5:8-10 ("The tip portion is a long and substantially pliable segment and is comprised of a material not susceptible to electrolytic disintegration within blood."). As such, the Court finds that the specifications of the patents-in-suit make clear that the connecting segment is a distinct portion of the device distal to the tip portion which is susceptible to electrolytic degradation.

There is no basis, however, for Plaintiff's assertion that the connecting segment is "fixed." Neither the specification nor the prosecution history provides support for Plaintiff's position. Nor has Plaintiff demonstrated in its papers or oral argument why such a limitation is necessary. As such, the court declines to include "fixed" in its definition of "connecting segment."

# D. "Detach," "Detaching," "Detachment," "Detachable," etc.

This Court construes the term "detaching" to mean "separating." The various forms of the word "detach," as they are used throughout the patents-in-suit, *e.g.* "detachment," "detachable," are construed to mean essentially the same thing.

Plaintiff contends that the term "detaching" means "separating at a predetermined location without damage." (Plaintiff's Opening Claim Construction Brief at 7:22-23.) Defendants contend that the term "detaching" means "separating, disconnecting, breaking, breaking off or rupturing." (MTI's Opposition at 14;8-12.) The Court declines to limit, or expand, its definition of "detaching" any further and finds that its construction is consistent with the specifications, prosecution histories, and preferred embodiments of the patents-in-suit.

The context of the surrounding words of a claim must be considered in determining the ordinary and customary meaning of a term. ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed.Cir.2003). *See also* Phillips, 2005 WL 1620331, at \*6 ("Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms."). The operative claim language covering the detachment mechanism of the claimed invention is contained in claim 5 of the '136 patent:

5. 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*.

'136 patent, claim 5 (emphasis added). Given the context of the claim, the Court finds that a construction that would define "detaching" as occurring at a predetermined location would be at odds with the phrase, "at least one portion of a connecting segment extending between said guidewire and said distal tip." Because the language of the claim teaches that "detaching" does not occur at a precise location on the connecting segment but rather can occur anywhere along that portion, the Court declines to construe "detaching" as taking place at a predetermined location as Plaintiff proposes.

Also evident from the language of claim 5 above is the requirement of disintegration in order for detachment to occur. As such, the Court rejects Plaintiff's proposed phrase "without damage," and finds that detachment does not occur without damage.

## V. CONCLUSION

The Court has completed claim construction of "wire," "guidewire," "distal tip," "tip," "connecting segment," "detach," "detaching," "detachment," and "detachable." The parties shall meet and confer and submit supplemental or additional briefing addressing the terms and phrases that remain at issue given the constructions set forth above.

The Court notes that the parties have submitted briefing regarding the scheduling of a case management conference. The Court will conduct a case management conference on September 26, 2005. The parties shall develop a joint case management statement, which shall be filed no later than September 12, 2005.

N.D.Cal.,2005. Regents of University of California v. Micro Therapeutics, Inc.

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