

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

BOSTON SCIENTIFIC CORP. and Target Therapeutics, Inc,
Plaintiffs.

v.

CORDIS CORP,
Defendant.

No. C 02-01474 JW

Aug. 21, 2006.

Michael Francis Kelleher, Folger Levin & Kahn LLP, San Francisco, CA, Amanda Marie Kessel, Christopher T. Holding, J. Anthony Downs, Paul F. Ware, Jr., Roland Schwillinski, Goodwin Procter, LLP, Sean Paul Cronin, Boston, MA, Julie Lynn Fieber, Folger Levin & Kahn LLP, San Francisco, CA, for Plaintiffs.

David T. Pritikin, Hugh A. Abrams, Lisa Anne Schneider, Marc A. Cavan, Tara C. Norgard, Stephanie Pauline Koh, Sidley Austin LLP, Chicago, IL, Edward V. Anderson, Georgia K. Van Zanten, Teague I. Donahey, Matthew T. Powers, Susan E. Bower, Tracy J. Phillips, Sidley Austin, LLP, San Francisco, CA, for Defendant.

ORDER RE: CLAIM CONSTRUCTION OF THE "MULTIPLY FOLDED" TERM

JAMES WARE, District Judge.

I. INTRODUCTION

Boston Scientific Corp. and Target Therapeutics, Inc. ("Plaintiffs") filed this action against Cordis Corp. ("Defendant") alleging infringement of a number of patents relating to methods and devices for treating aneurysms. On June 27, 2006, the Court granted Defendant's Motion for Claim Construction of Additional Claim Terms. That same day, the Court held a hearing at which the parties presented proposed definitions of the "multiply folded" claim term. Subsequent to the hearing, the parties submitted supplemental briefs on the matter. This Order construes the "multiply folded" claim term.

II. BACKGROUND

Plaintiffs have alleged that Defendant's Trufill DCS Detachable Coil System infringes numerous claims of U.S. Patents 5,895,385 ("the '385 patent"), 6,010,498 ("the '498 patent"), and 6,238,415 ("the '415 patent"). On September 19, 2003, 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. On October 7, 2003, the Court issued a *Markman* Order construing certain terms of the '385, '498, and '415 patents. (*See* Order Following Claims Construction Hearing, " *Markman* Order," Docket Item No. 177.) A complete

background of the technology and patents-in-suit is provided in that *Markman* Order.

On October 1, 2004, Defendant filed an *Ex Parte* Reexamination Request with the U.S. Patent and Trademark Office ("USPTO") with respect to the '498 patent. FN1 (Declaration of Matthew T. Powers in Support of Defendant Cordis' Brief in Support of Claim Construction of Term "Multiply Folded," "Powers Decl.," Docket No. 892, Ex. 3.) Among other things, Defendant argued that claims 3 and 9 of the '498 patent, which describe the distal tip structure of the vascular catheter as "adapted to be multiply folded upon itself," were obvious in light of U.S. Patents 5,261,916 ("the '916 patent") and 4,994,069 ("the '069 patent"). (Powers Decl., Ex. 3 at 12.) Specifically, Defendant argued the '069 patent disclosed a coil that is "capable of being multiply folded upon itself to occlude the body cavity." (Powers Decl., Ex. 3 at 12 .)

FN1. A request for reexamination of the '385 patent was filed concurrently with this request.

In February 2006, the USPTO mailed a Notice of Intent to Issue *Ex Parte* Reexamination Certificate ("NIRC") with respect to the '498 patent. (Powers Decl., Ex. 4.) The USPTO examiner rejected all of Defendant's arguments. (Powers Decl., Ex. 4 at 2.) With respect to Defendant's arguments regarding the '916 and '069 patents, the examiner stated in part:

[The] Engelson '916 [patent] respectfully to the request does not disclose a coil capable of being multiply folded upon itself to fill the cavity of an aneurysm. Instead, Engelson '916 and the Ritchart '069, which is incorporated by reference by Engelson '916, coils are coils having a predetermined shape when no forces are applied to said coils and after the proper amount of force is placed on the coils in order for said coils to fit inside the catheter to be pushed therethrough, said coils returned to the predetermined shapes that are generally dictated in the figures of Ritchart '069 once released by the catheter.

(Powers Decl., Ex. 4 at 3.)

In light of this statement, Defendant filed a motion for claim construction of "multiply folded upon itself," a term which appears in both the '385 and '498 patents. (*See* Defendant Cordis' Motion for Claim Construction of Additional Claim Terms, Docket Item No. 858.) Plaintiffs opposed Defendant's motion on numerous grounds. (*See* Plaintiffs' Opposition to Defendant Cordis' Motion for Claim Construction of Additional Claim Terms, Docket Item No. 875.) Despite the arguments Plaintiffs advanced as to why the Court should not order claim construction of the "multiply folded" term, the Court granted Defendant's motion. (*See* Order Granting Defendant's Motion for Claim Construction of Additional Claim Terms, Docket Item No. 884.) The Court found the issue as to whether the claims and specification of the '385 and '498 patents indicate the claimed coils may have a prebiased shape was something that should be resolved through further construction of the claim terms. Additionally, the Court found its previous construction of "relaxed coil" in the '385 patent did not obviate the need to construe the "multiply folded" term, which appears in both the '385 and '498 patents.

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). 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). To determine the meaning of the claim terms, the Court initially must look to intrinsic

evidence, that is, the claims, the specification, and, if in evidence, the prosecution history. *Autogiro v. United States*, 384 F.2d 391 (Ct.Cl.1967). The Court must look first to the words of the claims themselves. *See Vitronics Corp. v. Conceptor, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). These words are to be given their ordinary and customary meaning unless it is clear from the specification and prosecution history that the inventor used the term with a different meaning. *Id.* The claims should be interpreted consistently with the specification. *See Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed.Cir.1998).

Where intrinsic evidence alone resolves any ambiguity in a disputed claim term, it is improper to rely on evidence which is external to the patent and file history. *Vitronics*, 90 F.3d at 1583, 1585. However, extrinsic evidence may be considered in the rare instances where the intrinsic evidence is insufficient to enable the court to construe disputed claim terms. *Id.* at 1585. Common sources of extrinsic evidence include expert testimony, inventor testimony, dictionaries, and technical treatises and articles. *Id.* at 1584.

III. DISCUSSION

The "multiply folded" term appears in certain claims of the '385 and '498 patents. Independent claims 7, 15, 32, and 38 of the '385 patent each refer to either a "relaxed coil capable of being multiply folded upon itself" FN2 or a "deformable object capable of being multiply folded upon itself." Dependent claims 3 and 9 of the '498 patent each describe the "detachable elongate tip portion" as a "substantially pliable segment adapted to be multiply folded upon itself." While Defendant has requested construction of the phrase "multiply folded," (*see* Defendant Cordis's Brief in Support of Claim Construction of Term "Multiply Folded," "Def.'s Br.," Docket Item No. 891, at 1), Plaintiffs seek construction of the phrases "capable of being multiply folded upon itself" and "adapted to be multiply folded upon itself," (*see* Plaintiffs' Brief Regarding Claim Construction of the "Multiply Folded" Claim Term, "Pls.' Br.," Docket Item No. 893, at 1). The Court finds it appropriate to take this latter approach, but for convenience will continue to refer to these phrases collectively as the "multiply folded" term.

FN2. Although the Court construed the term "relaxed coil" in the '385 patent in its October 7, 2003 *Markman* Order, the phrase following that term, "capable of being multiply folded upon itself," was not construed by the Court. (*See Markman* Order at 17-18.)

Defendant contends the "multiply folded" term should be construed to mean "a coil that is not prebiased, so that there is no restriction on its ability fold on itself multiple times in the body cavity being treated." (Def.'s Br. at 1.) Plaintiffs urge the Court to construe the term to mean having "an overall shape that is capable of being folded upon itself more than one time to conform to the shape of the cavity." (Pls.' Br. at 1.)

Defendant contends its definition-which excludes prebiased coils-is consistent with the claims, specification, and prosecution history, including the recent statements made by the USPTO examiner in the reexamination proceedings of the '498 patent. With respect to the claim language, Defendant contends Plaintiffs' proposed construction cannot be adopted because "it would mean that a 'relaxed coil' and a coil 'capable of being multiply folded upon itself' are one and the same, even though both phrases are used in the claims." (Def.'s Br. at 3.) With respect to the specification, Defendant contends that while the specification does not specifically define the "multiply folded" term, "the context in which that phrase is used makes clear that the phrase was intended to encompass only a coil without prebias, so that there is no restriction on the ability of the coil to fold." FN3 (Def.'s Br. at 4.) With respect to the prosecution history, Defendant makes two arguments. First, Defendant contends the USPTO, in the reexamination proceedings of the '498 patent,

construed the "multiply folded" term to exclude prebiased coils.FN4 (Def.'s Br. at 6-8.) Second, Defendant contends that during the prosecution of patent application number 07/840,211 ("the '211 application"), which was one of a series of continuation applications from which the '385 and '498 patents issued, the applicants repeatedly distinguished prior art on the ground that it was prebiased. (Def.'s Br. at 10-11.)

FN3. The context to which Defendant refers is a sentence in the "Detailed Description" section of specification which states "[t]he tip may be elongate and flexible so that it packs the cavity by being folded upon itself a multiple number of times." (Declaration of Roland H. Schwillinski in Support of Plaintiffs' Brief Regarding Claim Construction of the "Multiply Folded" Claim Term, "Schwillinski Decl.," Ex. B, '498 patent, col. 6, lns. 57-59.)

FN4. Defendant also contends the patent owner (the Regents of the University of California) was obligated to file an objection during the reexamination proceedings and that silence in the face of the examiner's statement precludes Plaintiffs from making contrary arguments now. (Def.'s Br. at 8-10.)

Plaintiffs disagree with each of Defendant's contentions. Regarding the claim language, Plaintiffs contend the claims of the '385 and '498 patents say nothing about whether the coil has a prebiased shape or not. (Pls.' Br. at 3.) Rather than having anything to do with prebias, Plaintiffs contend the "multiply folded" term "concerns the coil's ability to fold upon itself multiple times to conform to the interior shape of the aneurysm being occluded." (Pls.' Br. at 3.) With respect to the specification, Plaintiffs contend the specification not only emphasizes a coil may either be prebiased or not prebiased but also discloses various prebiased shapes that the coils may have, including a "spiral" or "helix" shape. (Pls.' Br. at 4.) With respect to the prosecution history, Plaintiffs contend the USPTO examiner in the reexamination of the '498 patent did "not state that all coils that multiply fold upon themselves cannot have any prebiased shape." (Pls.' Br. at 5.) Additionally, during the prosecution of the '211 application, Plaintiffs contend the applicants continued to emphasize the coils could be prebiased. (Pls.' Br. at 6.)

The Court is not convinced there is a basis for construing the "multiply folded" term so as to exclude prebiased coils. The language of the claims does not provide any context from which it can be determined whether such an exclusion results from the "multiply folded" term. The Court also does not read in such a limitation given the disclosure of both prebiased and non-prebiased coils in the specification. *See* Vitronics, 90 F.3d at 1583 (implying that excluding one of the disclosed embodiments from the claim scope is rarely, if ever, correct). The first embodiment described in the specification is a coil that is "prebiased to form a cylindrical or conical envelope...." (Schwillinski Decl., Ex. B, '498 patent, col. 7, lns. 60-61.) The third embodiment is a coil that is "not prebiased, nor does it contain any internal reinforcement, but is a free and open coil...." (Schwillinski Decl., Ex. B, '498 patent, col. 9, lns. 2-4.) Additionally, the specification states "it must be understood that the shape of the tip or distal platinum coil used in combination with the wire according to the invention may be provided with a variety of shapes and envelopes." (Schwillinski Decl., Ex. B, '498 patent, col. 12, lns. 27-29.) The Court does not find the claim language or specification support Defendant's proposed definition of the "multiply folded" term.

Aside from the claim language and specification, Defendant also relies on the USPTO examiner's statement in the NIRC as support for its proposed definition. Contrary to what Defendant contends, however, the examiner did not state that all coils which multiply fold upon themselves cannot be prebiased. Rather, the examiner merely states the '069 patent discloses coils which return to predetermined shapes and that these

particular coils are not capable of being multiply folded upon themselves. (*See* Schwillinski Decl., Ex. F at 3.) Accordingly, the Court finds the examiner's statement does not support a definition of the "multiply folded" term that excludes prebiased coils. FN5

FN5. As the examiner's statements do not bear on the definition of the "multiply folded" term, the Court does not reach the question of whether the patent owner had an obligation to respond to the examiner's statement. *See supra* note 4.

Finally, the Court considers whether statements made by the applicants during the prosecution of the '211 application support a construction of the "multiply folded" term that excludes prebiased coils. According to Defendant, in an attempt to distinguish the coils disclosed in the '069 patent, the applicants repeatedly relied on the fact the '069 coils were prebiased. (Def.'s Br. at 10.) Defendant cites the following statement made by the applicants in an information disclosure statement submitted to the USPTO:

Essential to the operation of [the '069 coil] is that the wire have a memory which returns it from its stretched to its relaxed condition as the wire is released from the catheter into the vascular cavity....

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

(Powers Decl., Ex. 5 at 9-10.) Defendant also cites the following statement made by the applicants as part of their explanation for certain claim amendments:

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

(Powers Decl., Ex. 6 at 5.) This statement, Defendant contends, further shows that the applicants believed prebiased coils could not multiply fold on themselves. (Def.'s Br. at 11.) Defendant contends the public was entitled to rely on these distinctions drawn during the prosecution of the patent.

The Court recognizes the public has a right to rely on statements made by an applicant during the prosecution of a patent application. *See* Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc., 222 F.3d 951, 957 (Fed.Cir.2000) ("The prosecution history constitutes a public record of the patentee's representations concerning the scope and meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct, such as designing around the claimed invention."). Nevertheless, "[t]o balance the importance of public notice and the right of patentees to seek broad patent coverage, [the Federal Circuit has] thus consistently rejected prosecution statements too vague or ambiguous to qualify as a disavowal of claim scope." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314,

1325 (Fed.Cir .2003). In other words, for prosecution history disclaimer to attach, "precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." Id. at 1326.

The Court does not find the applicants' statements cited above clearly distinguished the prior art on the basis that it was prebiased. Rather, in these statements, the applicants appear to have been emphasizing that the '069 coils were different because they had a "preferred or memorized shape" or "predisposition configuration." (*See Powers Decl., Ex. 5 at 9.*) The applicants certainly could have drawn a distinction based on the prebiased nature of these coils-a prebias that coincidentally enabled the coils to take on a memorized or predisposed configuration-but they did not do this. The emphasis instead was placed on the '069 coils' memory-i.e., their ability to return to a particular shape. As the applicants explicitly stated, "[e]ssential to the operation of [the '069 coils] is that the wire have a memory which returns it from its stretched to its relaxed condition as the wire is released from the catheter into the vascular cavity." (*Powers Decl ., Ex. 5 at 9.*) Accordingly, the Court does not find the statements cited by Defendant distinguish the prior art on the basis of prebias.

IV. CONCLUSION

The Court construes (i) "capable of being multiply folded upon itself" to mean "capable of being folded upon itself more than one time" and (ii) "adapted to be multiply folded upon itself" to mean "adapted to be folded upon itself more than one time." The Court invites the parties to stipulate as to whether there is a difference between the terms "capable of" and "adapted to." If the parties do not file a stipulation within thirty (30) days of this Order, the Court will set a hearing for further construction of these terms.

N.D.Cal.,2006.

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