United States District Court,
N.D. Georgia, Atlanta Division.

**CALMEDICA, LLC,**
Plaintiff.
v.
**BEST VASCULAR, INC,**
Defendant.

Civil Action No. 1:04-CV-2646-RWS

**June 19, 2008.**

Kathleen A. Lyons, Keith V. Rockey, Rockey, Depke, Lyons & Kitzinger, LLC, Maurice E. Teixeira, Wallenstein, Wagner & Rockey, Ltd., Chicago, IL, Lawrence K. Nodine, Robin L. Gentry, Needle & Rosenberg, Atlanta, GA, for Plaintiff.

Devin Howard Gordon, Arnall Golden & Gregory, Atlanta, GA, John W. Bateman, Michael M. Shen, Kenyon & Kenyon, Washington, DC, for Defendant.

***CLAIM CONSTRUCTION ORDER***

RICHARD W. STORY**, District Judge.**

## I. Procedural History

Calmedica, LLC ("Calmedica") initiated this action on June 9, 2003, in the United States District Court for the Northern District of Illinois alleging that Novoste Corporation ("Novoste") infringed U.S. Patent Nos. 5,302,168 (the "'168 Patent") and 5,411,466 (the "'466 Patent"). On January 29, 2004, the Illinois court granted Novoste's Motion to Transfer the action to this Court. In August 2005, Calmedica amended its Complaint to withdraw the allegations of infringement of the '466 Patent. An application for reissue of that patent had been pending since May 1997, and Calmedica had learned that issuance of a reissue patent had been delayed.

In July 2006, the '466 Patent underwent reissue and was issued as the RE 39,157 (the "RE '157Patent"). In November 2006, Calmedica was permitted to amend its Complaint to include allegations of infringement of the reissue patent. In December 2006, Calmedica was permitted to amend its Complaint to substitute Best Vascular, Inc. ("Best Vascular") for Novoste as the Defendant in this action.

The case is presently before the Court for claim construction. After considering the papers filed by the parties, arguments of counsel presented at the May 19, 2008 hearing, and applicable law, the Court enters the following Order.

## II. The Field of the Invention

The invention of the patents relates to a method for preventing restenosis after angioplasty or other stenosis treatment ('168 Patent, col. 1, ll. 5, et seq.). Angioplasty and other stenosis treatments are commonly used to widen a portion of a blood vessel that has been narrowed-stenosed-by the buildup of atherosclerotic plaque. A problem encountered in a significant number of patients treated by such stenosis procedures is a condition known as restenosis, which is the subsequent narrowing of the artery at the site of the original expansion treatment ('168 Patent, col. 1, ll. 38, et seq.). Restenosis, if left untreated, will eventually renarrow the blood vessel thus making the prior stenosis treatment ineffective.

To appreciate how and why restenosis occurs, it is helpful to understand how stenosis has been typically treated in the first instance. In the usual percutaneous transluminal coronary angioplasty or percutaneous transluminal angioplasty procedure, a guiding catheter is introduced into the vascular system of a patient through an artery and advanced until the tip of the guiding catheter is appropriately positioned. A dilation catheter with a balloon on its distal end and a guide wire are introduced through the guiding catheter. The guide wire is first advanced through the tip of the guiding catheter until the end of the guide wire crosses the lesion to be dilated. The dilation catheter is then advanced over the guide wire until the dilation balloon on the dilation catheter is properly positioned inside the lesion ('168 Patent, col. 1, ll. 16, et seq.).

Once the device is properly positioned within the blood vessel, the balloon portion of the dilation catheter is inflated to a predetermined size to reduce the annular stenosed area by radially compressing the atherosclerotic plaque of the lesion against the inside of the artery wall. After a period of time, the balloon can be deflated, thereby resuming blood flow and allowing the dilation catheter to be removed ('168 Patent, col. 1, ll. 31, et seq.).

Robert Hess, the inventor of the patents, explained in his deposition how restenosis occurs (Calmedica's Opening Br. [151], Ex. 3 at 28):

"As described in the patent, restenosis occurs due to trauma of the artery by the interventional device, and then the-the proliferation of smooth muscle cells in response to that trauma, and in coronary arteries-commonly known as scarring, if you will, the-the response to trauma in the arteries, however, seems to be extremely prolific in terms of these smooth muscle cells and creates a renarrowing of the artery, commonly known as restenosis, but, in fact, it is not a reoccurrence of the original stenosis; it is a stenosed region of the artery consisting of these smooth muscle cells."

Thus, if not properly treated, the restenosis of an artery after a procedure such as angioplasty will create a renarrowing of the artery, rendering the prior stenosis treatment completely ineffective.

At the time that the application for the '168 patent was filed, roughly one third of all patients treated for stenosis developed restenosis post-treatment ('168 Patent, col. 1, ll. 63-64). Numerous methods were employed to try to prevent restenosis, including multiple inflations of the balloon during the original procedure, atherectomy, hot balloons, lasers and the installation of permanent stents. None of those methods were successful in reducing the rate of occurrence of restenosis to any significant degree ('168 Patent, col. 1, ll. 41, *et seq.*).

## III. The Patents-In-Suit

The patents-in-suit are directed to treating restenosis by applying a radioactive dose to the area of reduced

stenosis following an angioplasty or like-intended procedure ('168 Patent, col. 2, ll. 5, *et seq*.). The '168 patent issued on April 12, 1994 on an application filed in September of 1991. The second patent, the '466 patent issued in May of 1995 on an application filed March 28, 1994. The latter application was a continuation of the application that issued as the '168 patent. The RE '157 patent, the reissue of the '466 patent, issued on July 4, 2006 on an application filed May 2, 1997.

At the time of the filing of the application for the '168 Patent, radiation was used in nuclear medicine in such fields as oncology (Calmedica's Opening Br., Ex. 3 at 90-91). The patent included a method of treating restenosis using radiation. Because radiation was to be delivered inside an artery, this new technology addressed problems that had not been addressed before.

The '168 patent includes one independent claim, Claim 1. That claim encompasses a method for treatment and post-treatment of a stenosed area of an artery using radiation ('168 Patent, col. 5, ll. 10, *et seq*.) The '168 Patent includes 5 dependent claims. The RE '157 patent contains 41 claims, each directed to apparatus for the treatment of stenosed regions of an artery (RE ' 157 Patent, col. 5, ll. 2, *et seq*.). Claims 1-5 of the RE '157 patent are the same as the original claims in the '466 patent; claims 6-41 were added by way of reissue.

## IV. Applicable Law

The interpretation of claim terms is a question of law for the Court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 391, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). In construing a claim, the Court may consider "both intrinsic evidence (e.g., the patent specification and file history) and extrinsic evidence (e.g., expert testimony)." Viatronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1986). The Court first looks "to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." *Id*. Words in a claim are "generally given their ordinary and customary meaning," but the "patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." *Id*.

The Court must always review the specification "to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." *Id*. "[T]he court may also consider the prosecution history of the patent, if in evidence." *Id*.

An analysis of intrinsic evidence is usually sufficient to construe a disputed claim term. *Id*. at 1583. If the intrinsic evidence is sufficient to resolve disputed claim terms, "reliance on any extrinsic evidence is improper." *Id*.

Special rules of construction apply to means-plus-function terms. 35 U.S.C. s. 112, para. 6. "A presumption applies that a claim limitation that includes the word 'means' is intended to invoke means-plus-function treatment. However, that presumption may be rebutted (1) if the claim limitation recites no function corresponding to the means or (2) if the claim limitation itself recites sufficient structure for performing the recited function." Aristocrat Tech. Australia Pty Ltd. v. Multimedia Games, Inc., No.2007-1375, 2008 WL 484449 (Fed.Cir. Feb. 22, 2008)(internal citations omitted). "[W]hen an element of a claim does not use the term 'means,' treatment as a means-plus-function claim element is generally not appropriate. However, when it is apparent that the element invokes purely functional terms, without the additional recital of specific structure or material performing that function, the claim element may be a means-plus-function element

despite the lack of express means-plus-function language." *Al-* Site Corp. v. VSI Intern'l, Inc., 174 F.3d 1308, 1318 (Fed.Cir.1999) (citations omitted).

Construction of a means-plus-function limitation involves two steps. First, the court must identify the claimed function. The court must construe the function of a means-plus-function limitation to include the limitations contained in the claim language, and only those limitations....

After identifying the claimed function, the court must then determine what structure, if any, disclosed in the specification corresponds to the claimed function. In order to qualify as corresponding, the structure must not only perform the claimed function, but the specification must clearly associate the structure with performance of the function. This inquiry is undertaken from the perspective of one of ordinary skill in the art. Alternative embodiments may disclose different corresponding structure, and the claim is valid even if only one embodiment discloses corresponding structure. If, however, this inquiry reveals that no embodiment discloses corresponding structure, the claim is invalid for failure to satisfy the definiteness requirement of s. 112, para. 2.

Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 296 F.3d 1106, 1113-14 (Fed.Cir.2002) (citations omitted).

## V. CLAIM CONSTRUCTION

### A. AGREED CLAIM TERMS

**1.** '168 Patent

The parties have agreed to construction of the following terms and phrases in the '168 Patent:

**(1) "advancing"**

The term "advancing" in Claim 1 of the '168 patent means moving forward.

**(2) "positioning means"**

The parties agree that the phrase "positioning means" is a means-plus-function clause governed by 35 U.S.C. s. 112, para. 6. However, the parties do not agree as to the function recited in the claim nor the structure which corresponds to the claimed function.

**2. RE '157 Patent**

The parties have agreed upon construction of the following terms and phrases in the RE '157 Patent:

**(1) "Preambles"**

The parties agree that the preambles of Claims 1, 10, 35, 37, 39 and 41 of the RE '157 patent are not limitations so no construction is needed.

**(2) "the positioning means further including an** angioplasty balloon"

The phrase "the positioning means further including an angioplasty balloon" means that the positioning means includes an angioplasty balloon.

**(3) "a radiation source"**

The phrase "a radiation source" in Claim 10 of the Re '157 patent means a source of radiation.

**B. DISPUTED CLAIM TERMS**

**1.** '168 Patent

The Court finds that the following disputed claim terms in the '168 Patent shall have the meanings set out below.

**(1) "radioactive dose means"**

Calmedica argues that "radioactive dose means" should not be governed by s. 112, para. 6. Acknowledging that the presence of the word "means" raises the presumption that this is a means-plus-function clause, Calmedica asserts that the presumption is rebutted because the phrase contains sufficient structure to perform the recited function. (Pl.'s Opening Br. [92] at 15). However, the Court finds that the claim itself discloses no structure. Therefore, the Court concludes that "radioactive dose means" is a means-plus-function clause governed by s. 112, para. 6.

The recited function of the claimed "radioactive dose means" is to provide a radioactive dose. Calmedica asserts that the structures disclosed for performing the claim function as described in the specification include any radioactive material whether incorporated into a solid, liquid, or gaseous form. In support of this contention, Calmedica cites the following language in the '168 patent:

"radioactive dose" means bombardment by particles emitted from radioactive materials including, but not limited to, materials such as Radon 222 Gold 198, Strontium 90, Radium 192, and Iodine 125. These materials may be incorporated into or delivered in a solid, liquid, or gaseous forms, and the delivery of such forms is considered to be within the scope of the subject invention.

('168 Patent, col. 4, ll 4-12). The Court finds that the description of the materials as "a solid, liquid, or gaseous form" is a reference to the "radioactive dose," not the "radioactive dose means."

The Court concludes that the structures described in the specification that correspond to this function are (1) radioactive material that is either a single piece of solid material not in any container or, if the material is confined, its form or shape is restricted within its container; (2) the radioactive portion of a stint; and (3) radioactive material attached to an angioplasty balloon.

**(2) "operatively connected"**

Calmedica's proposed construction for this term is: "The phrase 'operatively connected' means that the radioactive dose means and the positioning means are connected or associated with each other so that the radioactive dose means moves only when the positioning means is moved." (Rev'd Claim Constr. St. [142] Ex. B2 at 2). The Court finds that the requirement that the radiation dose means moves only when the positioning means is moved is not supported by the specification. The embodiment illustrated in figures 2, 3,

and 4 allows the radioactive dose means, which is found on the surface of the balloon, to move without any movement of the catheter shaft which is the positioning means.

Best Vascular's proposed construction is: "The phrase 'operatively connected' means physically joined, linked or attached such that when the positioning means moves, the radioactive dose means moves." ( Id.). The Court finds that Best Vascular's construction ignores the term "operatively" and simply focuses on "connected." The Court finds that the appropriate construction of the claim term is a combination of the proposed constructions of the parties. The Court finds that the phrase "operatively connected" means that the radioactive dose means and the positioning means are connected or associated with each other so that when the positioning means moves, the radioactive dose means moves.

**(3) "positioning means"**

The parties agree that the phrase "positioning means" is a means-plus-function clause governed by 35 U.S.C. s. 112, para. 6. "Calmedica contends that the function of the 'positioning means' is to advance the radioactive dose means within the artery and to remove the radioactive dose means from the artery." ( Id.). Calmedica asserts that the "structure set forth in the specification of the '168 patent for performing this function is described in a number of different embodiments, including the use of catheters to position the radioactive dose means ('168 Patent, Fig. 1, Col. 3, ll 17, *et seq*.), the use of angioplasty balloons ('168 Patent, Fig. 2-4, Col. 3, ll 41, *et seq*.), the use of motion wires ('168 Patent, Fig. 5, Col. 4, ll 17, *et seq*.). the use of a cannister at the end of a shaft portion ('168 Patent, Fig. 6, Col. 4, ll 27, *et seq*.), and the use of inflatable stent delivery balloon systems ('168 Patent, Fig. 7-9, Col. 4, ll 34, *et seq*.)." (Rev'd Claim Constr. St. Ex. B2 at 2-3).

Calmedica further contends that the meaning of "positioning means" is not limited to the above-described embodiments. "The specification clearly states that the radioactive materials 'may be incorporated into or delivered in a solid, liquid, or gaseous form, and the delivery of such forms is considered to be within the scope of the subject invention' ('168 Patent, Col. 4, ll 8, *et seq*.). Plaintiff thus contends that the phrase 'positioning means' means the use of a solid, liquid, or gas to advance or remove the radioactive dose means within the artery and equivalents thereof." (Rev'd Claim Constr. St. Ex. B2 at 3-4).

Best Vascular contends that the "recited function of the 'positioning means' is to position the radioactive dose means, to advance the radioactive dose means within the artery to the area of the reduced stenosis, and to remove the radioactive dose means from the artery. The structures described in the specification that correspond to this function are a catheter shaft or a motion wire." ( Id.).

The Court finds that the recited function of the "positioning means" is to position the radioactive dose means, to advance the radioactive dose means within the artery to the area of reduced stenosis, and to remove the radioactive dose means from the artery. The Court further finds that Calmedica's contentions regarding the structures performing these functions in the specification of the '168 Patent are overly broad. As stated above, the incorporation of the radioactive materials into a solid, liquid, or gaseous form is a reference to the dose. It is not a reference to the positioning means. The structures described in the specification that correspond to this function are a catheter shaft, angioplasty balloons, motion wires, a cannister at the end of a shaft portion, and an inflatable stent delivery balloon system. Thus, the Court finds that the phrase "positioning means" is a means-plus-function clause governed by 35 U.S.C. s. 112, para. 6. The recited function of the 'positioning means' is to position the radioactive dose means, to advance the radioactive dose means within the artery to the area of reduced stenosis, and to remove the radioactive dose

means from the artery. The structures described in the specification that correspond to this function are a catheter shaft, angioplasty balloons, motion wires, a cannister at the end of a shaft portion, and an inflatable stent delivery balloon system.

**(4) "advancing step being performed by moving the positioning means"**

The Court finds that the phrase "advancing step being performed by moving the positioning means" requires no further definition and means that the advancing step is performed by moving the positioning means.

**(5) "applying a radioactive dose to the area of reduced stenosis by exposing"**

Calmedica contends that this phrase means exposing the area of reduced stenosis to the effects of radiation from the radioactive dose. ( Id. at 4). Best Vascular contends that the phrase means causing a radioactive dose to reach the area of reduced stenosis by means of causing there to be no part of the apparatus used to carry out the claimed method between the area of reduced stenosis and the radioactive dose means. ( Id. at 4-5). The Court finds that Calmedica's definition more closely comports with the ordinary meaning of the words. Thus, the Court concludes that the phrase "applying a radioactive dose to the area of reduced stenosis by exposing" means exposing the area of reduced stenosis to the effects of radiation from the radioactive dose.

**(6) "removing the dose means from the artery by moving the positioning means"**

The Court finds that these terms should be given their ordinary meaning. Thus, the Court finds that the phrase "removing the dose means from the artery by moving the positioning means" means moving the radioactive dose means out of the artery by moving the positioning means.

**(7) "containing a source of radioactive dose before and after exposure to said area of reduced stenosis"**

The dispute between the parties is whether the term "containing" means "holding or to hold" as contended by Calmedica or "shielding a source of radioactive dose from the body" as contended by Best Vascular. ( Id. at 5). This phrase is contained in Claim 6 of the '168 Patent. The Court finds that construing "containing" to mean "holding or to hold" would render Claim 6 redundant. The Court finds that the term "containing" means shielding a source of radioactive dose from the body. Thus, the Court finds the phrase "containing a source of radioactive dose before and after exposure" means shielding a source of radioactive dose from the body in the time before and the time after the area of reduced stenosis is exposed to the radioactive dose.

**2. RE '157 Patent**

The Court finds that the following disputed terms in the RE '157 Patent shall have the meanings set out below.

**(1) "radioactive dose means for emitting radiation"**

The Court finds that the phrase "radioactive dose means" is a means-plus-function clause governed by 35 U.S.C. s. 112, para. 6 with the recited function and corresponding structures as set out with regard to Claim 1 of the '168 Patent. The remainder of the phrase "for emitting radiation" should be given its ordinary meaning, that is, releasing radioactive particles.

**(2) "positioning means operatively connected to said dose means for advancing said dose means and positioning said dose means within the stenosed region of an artery that has been reduced by** angioplasty **or other means, said positioning means also being operatively connected to said dose means for withdrawing said dose means from the artery, the positioning means further including an** angioplasty balloon**, said radioactive dose means being connected to said balloon and moveable into contact with the stenosed region by expansion of said balloon"**

The constructions of "positioning means" and "operatively connected" are the same as those previously set forth in relation to Claim 1 of '168 Patent and for the same reasons. The phrase "for withdrawing" refers to removing the dose means from the artery. The phrase "said radioactive dose means being connected to said balloon and moveable into contact with the stenosed region by expansion of said balloon" means that the radioactive dose means and angioplasty balloon are connected with each other so that the radioactive dose means moves into contact with the region being treated by the balloon expanding.

**(3) "a catheter having at least one lumen adapted to deliver said radiation source within the stenosed region of an artery that has been reduced by** angioplasty **or other procedure, said catheter also being adapted to at least partially reposition relative to the radiation source for treatment when positioned within the stenosed region of an artery, the catheter being adapted to at least partially reposition to withdraw said radiation source from the artery"**

The term "catheter" means a tubular medical device for insertion into canals, vessels, passageways, or body cavities. A "catheter having at least one lumen adapted to deliver said radiation source within the stenosed region of an artery that has been reduced by angioplasty or other procedure" means a catheter having at least one passageway to deliver the radiation source to the stenosed region of the artery that has been reduced by angioplasty or other procedure. The phrase "said catheter also being adapted to at least partially reposition relative to the radiation source for treatment when positioned within the stenosed region of an artery" requires (i) that the catheter be adapted to at least partially reposition relative to the radiation source, and (ii) that this repositioning occur after both the catheter and the radiation source have been positioned within the stenosed region of an artery. The phrase "the catheter being adapted to at least partially reposition to withdraw said radiation source from the artery" means that the catheter is adapted to reposition to cause the withdrawal of the radiation source from the artery.

**(4) "a radioactive dose for emitting radiation, wherein the radiation dose is incorporated into a liquid for delivery"**

The specification provides:

With regard to all embodiments of the subject invention, "radioactive dose" means bombardment by particles emitted from radioactive materials including, but not limited to, materials such as Radon 222, Gold 198, Strontium 90, Radium 192, and Iodine 125. These materials may be incorporated into or delivered in a solid, liquid, or gaseous form, and the delivery of such forms is considered to be within the scope of the subject invention.

(RE '157 Patent, Col. 4, ll 1-8). Calmedica contends that "the phrase 'wherein the radioactive dose is incorporated into a liquid for delivery' refers to use of a liquid to deliver the radioactive dose to the stenosed region of the artery." (Rev'd Claim Constr. St. at 11). Best Vascular contends that the phrase "means that the radioactive dose is in the form of a liquid." ( Id.). The Court does not agree with either construction. The

Court finds that the phrase simply requires that the radioactive dose be in a liquid. The dose itself need not be in a liquid form. Further, the phrase does not require that the dose be delivered by the liquid. Accordingly, the Court finds the phrase "wherein the radioactive dose is incorporated into a liquid for delivery" means that the radioactive dose is included in a liquid at the time the dose is delivered to the stenosed region of the artery.

**(5) "a catheter"**

The term "catheter" shall have the same meaning for the same reasons as set forth above.

**(6) "positioner"**

The parties disagree as to whether "positioner" is a means-plus-function clause governed by 35 U.S.C. s. 112, para. 6. Calmedica relies on the presumption that the phrase is not a means-plus-function clause because the term "means" is not used. (Calmedica's Resp. Br. [174] at 4). Further, Calmedica asserts that the claim history supports its position. When Claims 35 and 37 were originally filed, they included the term "positioning means" instead of "positioner." In October 2003, after the claims had been allowed over the prior art, Calmedica's patent attorney amended those claims by replacing the term "positioning means" with the term "positioner." To explain this amendment, the attorney stated: "The claims have been amended throughout to remove the 'means' language for improved clarity of the claims." Calmedica asserts that the "improved clarity" sought by the amendment to the claims was to remove the clause from the purview of s. 112, para. 6 and that the purpose of the Amendment was to broaden the claims. ( Id. at 5).

In response, Best Vascular contends that "positioner" is governed by s. 112 para. 6 because the claim language defining the "positioner" is functional language rather than structural language. (Best Vascular's Suppl. Br. [152] at 7). Best Vascular further asserts that "positioner" does not have a reasonably well understood structural meaning in the relevant art. ( Id. at 8). The term is not found in any of the prior art patents cited during the prosecution of the RE '157 Patent, or any of the 12 patents listing Mr. Hess as an inventor other than the RE '157 patent, or in any of the 35 patents assigned to Calmedica or Best Vascular other than the RE '157 Patent. The word "positioner" does not appear at all in the specification. ( Id. at 7-8). Best Vascular acknowledges that because the claim term does not use the word "means," there is a presumption that it is not a means-plus-function term. However, Best Vascular asserts that the aforestated facts overcome that presumption. ( Id. at 7).

Finally, Best Vascular asserts that the prosecution history supports a means-plus-function construction. Best Vascular argues that Calmledica's patent attorney never represented to the PTO that the replacement of "positioning means" with "positioner" was intended to broaden the claims. Rather, the representation was that the amendment was "for improved clarity." Best Vascular asserts that if the intent was to broaden the claims, after the claims had been allowed over the prior art, "it was incumbent on Calmedica's patent attorney to make that clear to the PTO." ( Id. at 10).

The Court agrees with Best Vascular. The claim language defining "positioner" describes functions and offers no structural language. Calmedica has pointed to no evidence that "positioner" has a well understood structural meaning in the art. In fact, the term does not appear to have previously been used in the art. The timing of the amendment of the claim before the PTO suggests that the amendment was not intended to change the scope of the claim. Therefore, the Court concludes that "positioner" is a means-plus-function term governed by s. 112, para. 6.

The Court finds that the recited function of the positioner is to advance a radioactive dose to a stenosed region of the artery, to position the radioactive dose for treating at least a portion of the stenosed region, and to withdraw a radioactive dose from the artery. The structures described in the specification that correspond to these functions include a catheter shaft, a motion wire, an angioplasty balloon, a sheath, and a remotely actuated window.

**(7) "wherein in the first position the dose is positioned within the artery in a non-deployed configuration and a second position wherein the dose in in a deployed configuration for treating at least a portion of the stenosed region of the artery"**

The Court finds that "in a non-deployed configuration" means that the dose is in a position relative to the stenosed region of the artery where it cannot treat that region. "A deployed configuration" means that the dose is in a position with relation to the stenosed region of the artery that permits the dose to treat at least a portion of the stenosed region of the artery.

**(8) "said positioner being operatively connected to said dose for withdrawing said dose from the artery after said radioactive dose is exposed"**

The terms "operatively connected" and "exposed" shall have the same meanings as provided in Claim 1 of the '168 Patent. "Withdrawing" shall have the same meaning as provided in Claim 1 of the RE '157 Patent.

**(9) "a radioactive dose for emitting radiation, wherein the radioactive dose is incorporated into a liquid for delivery"**

These terms shall have the same meanings as provided in Claim 35 of the RE ' 157 Patent.

**(10) "a catheter movable with respect to the dose"**

The term "catheter" shall have the same meaning as already determined. The phrase "movable with respect to the dose" refers to the ability to change the physical location of the catheter in relation to the radioactive substance. The remaining terms of Claim 37 shall have the meanings already determined.

**(11) "move the radioactive dose from a non-deployed and shielded position to a deployed and unshielded position"**

Calmedica urges the following construction of this phrase:

The reference to the "shielded" position and "unshielded" position refers to the ability to move the radioactive source from a position in which radioactivity is prevented from reaching the area of reduced stenosis, in which position of the radioactive source is "shielded." When the radioactive source is moved to a position in which radiation can reach the area of reduced stenosis, that position is referred to as the "unshielded" position.

(Rev'd Claim Constr. St. at 18-19).

The Court finds that this construction does not sufficiently distinguish these terms from "non-deployed" and "deployed." Accordingly, the Court adopts the construction proposed by Best Vascular. The phrase "configured to move the catheter and the radioactive dose with respect to one another to move the

radioactive dose from a non-deployed and shielded position to a deployed and unshielded position" means configured to move the catheter and the radioactive dose with respect to one another so as to move the radioactive dose from a position where part of the claimed apparatus is located between the radioactive dose and the stenosed region (i.e ., a non-deployed and shielded position) to a position where no part of the apparatus is located between the radioactive dose and the stenosed region (i.e., a deployed and unshielded position).

**(13) "for a period of time sufficient to inhibit** restenosis **of the stenosed region"**

The phrase means exposure for a period of time for restenosis to be impaired.

**(14) Claim 41**

The terms of Claim 41 shall have the meanings previously determined by the Court.

## VI. SUMMARY OF CONCLUSIONS

Attached hereto as an Appendix to this Order is a summary of the Court's constructions of the terms of the patents-in-suit.

**SO ORDERED.**

N.D.Ga.,2008.
Calmedica, LLC v. Best Vascular, Inc.