United States District Court,
N.D. California.

MEDTRONIC, INC., et al,
Plaintiffs.
v.
W.L. GORE & ASSOCIATES, INC,
Defendant.

No. C 06-04455 JSW

Oct. 19, 2007.

Joshua Christian Walsh-Benson, Dechert LLP, Mountain View, CA, for Plaintiffs.Gerard Haddad, Christopher K. Hu, David H. Pfeffer, Jennifer Bianrosa, John T. Gallagher, Morgan & Finnegan, L.L.P., New York, NY, Hillary Noll Kalay, Sonnenschein Nath & Rosenthal LLP, San Francisco, CA, for Defendant.Ellen J. Wang, James J. Elacqua, Noemi C. Espinosa, Dechert LLP, Mountain View, CA, for Plaintiffs/Counter-defendants.

CLAIM CONSTRUCTION ORDER

JEFFREY S. WHITE**, United States District Judge.**

Plaintiffs, Medtronic, Inc., Medtronic USA, Inc., and Medtronic Vascular, Inc. (collectively "Medtronic"), filed this suit in which they allege that Defendant W.L. Gore & Associates, Inc. ("Gore"), infringes U.S. Patent Nos. 5,067,957 ("the '957 Patent"), 5,190,546 ("the '546 Patent"), and 6,306,141 ("the '141 Patent") (collectively, "the Jervis Patents"). Plaintiffs also allege that Gore infringes U.S. Patent Nos. 4,886,062 ("the '062 Patent"), 6,656,219 ("the '219 Patent"), and 6,923,828 ("the '828 Patent") (collectively, "the Wiktor Patents").

On August 14, 20007, pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), the Court held a claim construction hearing to construe disputed claim terms from the patents-in-suit. Having carefully considered the parties' papers, including their supplemental briefs, having heard the parties' arguments, and having considered the relevant legal authorities, the Court construes the disputed terms and phrases as set forth in the remainder of this Order.

BACKGROUND

This case involves alleged infringement of two patent families, the Jervis Patents and the Wiktor Patents, each of which are directed, in general, to medical devices or methods for implanting such medical devices into a human body.

A. The Jervis Patents.

The Jervis Patents are directed to medical devices, or methods for implanting such devices, that utilize shape memory alloys ("SMAs"). FN1 As Jervis acknowledges in his patents, it was well known that certain materials are capable of possessing shape memory. Jervis also explains that:

FN1. Gore submits an article from a 1979 issue of *Scientific American,* which contains a useful discussion about the austenitic and martensitic states of shape memory alloys. (*See* Declaration of Jennifer Bianrosa ("Bianrosa Decl."), Ex. 4.)

An article made of [a material capable of possessing shape memory] can be deformed from an original, heat-stable configuration to a second, heat-unstable configuration. The article is said to have shape memory for the reason that, upon the application of heat alone, it can be caused to revert, or to attempt to revert, from its heat-unstable configuration to its original, heat-stable configuration, *i.e.* it "remembers" its original shape.
Among metallic alloys, the ability to possess shape memory is a result of the fact that the alloy undergoes a reversible transformation from an austenitic state to a martensitic state with a change in temperature. This transformation is sometimes referred to as a thermoelastic martensitic transformation. An article made from such an alloy, ... is easily deformed from its original configuration to a new configuration when cooled below the temperature at which the alloy is transformed from the austenitic state to the martensitic state. The temperature at which this transformation begins is usually referred to as M_S and the temperature at which it finishes M_f. When an article thus deformed is warmed to the temperature at which the alloy starts to revert back to austenite, referred to as A_S (A_f being the temperature at which the reversion is complete) the deformed object will begin to return to its original configuration.

(Bianrosa Decl., Ex. 1 ('957 Patent, 1:23-49).) FN2 Thus, there are two key phases involved in taking advantage of the properties of SMAs: (1) the *formation* of martensite from austenite; and (2) the *reversion* of martensite to austenite.
FN2. The Court cites to references within the patents-in-suit in the following format: "column:line" or "column:line-column:line."

Jervis also notes that there are disadvantages associated with using SMA devices for medical purposes, including the fact that "it is difficult to control the transformation temperatures of shape memory alloys with accuracy, as they are usually composition-sensitive[.]" (*Id.,* 2:32-35.) Jervis also notes that "there is a large hysteresis as the alloy is transformed between austenitic and martensitic states, so that reversing of the state of an SMA element may require a temperature excursion of several tens of degrees Celsius." (*Id.,* 2:39-43.)

Jervis concludes his discussion of the Background of the Invention as follows:

The combination of these factors with the limitation that (a) it is inconvenient to have to engage in any temperature manipulation, and (b) human tissue cannot be heated or cooled beyond certain relatively narrow limits ... without suffering temporary or permanent damage is expected to limit the use of SMA medical devices. It would thus be desirable to develop a way in which the advantageous properties of shape memory alloys, i.e. their ability to return to an original shape after relatively substantial deformation, could be used in medical devices without requiring the delicacy of alloying control and/or the temperature control of placement or removal needed by present shape memory alloy devices. (*Id.,* col. 2, ll. 51-58.)

(*Id.,* 2:43-58.)

Jervis then summarizes the invention and notes that "if, in a medical device containing a shape memory alloy element which uses the shape memory property of that alloy, an element which shows the property of stress-induced martensite is used instead, an improved device results." (*Id.,* 2:62-66; *see also id.,* 3:1-6.)

B. The Wiktor Patents.

The Wiktor Patents are directed to intravascular stents. According to Medtronic, "[t]he Wiktor invention addresses the problem of distortions in the length and shape of a helically-coiled wire device when it is expanded from a small diameter to a larger diameter." (Medtronic Br. at 3:27-28.) Wiktor purportedly resolved this problem through the use of "zig-zag" bends, which permit a device to be sized and shaped more predictably when it expands. (*Id.* at 3:27-4:9.)

Wiktor describes his invention in the specification as comprising "an open-ended wire formed device of basically cylindrical shape and made of a softer-then [*sic*] spring type metal and fitted over an inflatable element of a typical balloon type catheter.... The wire formed device is intended to act as a permanent prosthesis stent and is implanted transluminarely." (*See, e.g.,* Bianrosa Decl., Ex. 5 ('062 Patent, 1:14-22).)

ANALYSIS

A. Legal Standard.

"It is a bedrock principle of patent law that the 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 Sys., Inc., 381 F.3d 1111, 1115 (Fed.Cir.2004). The interpretation of the scope and meaning of disputed terms in patent claims is a question of law and exclusively within the province of a court to decide. Markman, 517 U.S. at 372. The inquiry into the meaning of the claim terms is "an objective one." Innova/Pure Water, 381 F.3d at 1116. As a result, when a court construes disputed terms, it "looks to those sources available to the public that show what a person of skill in the art would have understood the disputed claim language to mean." *Id.* In most cases, a court's analysis will focus on three sources: the claims, the specification, and the prosecution history. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). However, on occasion, it is appropriate to rely on extrinsic evidence regarding the relevant scientific principles, the meaning of technical terms, and the state of the art at the time at the time the patent issued. Id. at 979-81.

The starting point of the claim construction analysis is an examination of the specific claim language. A court's "claim construction analysis must begin and remain centered on the claim language itself, for that is the language that the patentee has chosen to particularly point out and distinctly claim the subject matter which the patentee regards as his invention." Innova/Pure Water, 381 F.3d at 1116 (internal quotations and citations omitted). Indeed, in the absence of an express intent to impart a novel meaning to a term, an inventor's chosen language is given its ordinary meaning. York Prods., Inc. v. Cent. Tractor Farm & Family Center, 99 F.3d 1568, 1572 (Fed.Cir.1996). Thus, "[c]laim language generally carries the ordinary meaning of the words in their normal usage in the field of the invention." Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1367 (Fed.Cir.2003); *see also* Renishaw v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed.Cir.1998) (recognizing that "the claims define the scope of the right to exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim"). A court's final construction, therefore, must accord with the words chosen by the patentee to mete out the boundaries of the

claimed invention.

The claims do not stand alone. Rather, "they are part of 'a fully integrated written instrument.' " Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed.Cir.2005) (en banc) (quoting Markman, 52 F.3d at 978). The written description, the drawings, and, if included in the record, the prosecution history, each provide context and clarification regarding the intended meaning of the claim terms. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324-25 (Fed.Cir.2002). The specification "may act as a sort of dictionary, which explains the invention and may define terms used in the claims." Markman, 52 F.3d at 979. The specification also can indicate whether the patentee intended to limit the scope of a claim, despite the use of seemingly broad claim language. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed.Cir.2001) (when the specification "makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question").

Intent to limit the claims can be demonstrated in a number of ways. For example, if the patentee "acted as his own lexicographer," and clearly and precisely "set forth a definition of the disputed claim term in either the specification or prosecution history," a court will defer to that definition. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002). In order to so limit the claims, "the patent applicant [must] set out the different meaning in the specification in a manner sufficient to give one of ordinary skill in the art notice of the change from ordinary meaning." Innova/Pure Water, 381 F.3d at 1117. In addition, a court will adopt an alternative meaning of a term "if the intrinsic evidence shows that the patentee distinguished that term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention." CCS Fitness, 288 F.3d at 1367. Likewise, the specification may be used to resolve ambiguity "where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone ." Teleflex, 299 F.3d at 1325.

Limitations from the specification (such as from the preferred embodiment) may not be read into the claims, absent the inventor's express intention to the contrary. Id. at 1326; *see also* CCS Fitness, 288 F.3d at 1366 ("[A] patentee need not 'describe in the specification every conceivable and possible future embodiment of his invention.' ") (quoting Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed.Cir.2001)). To protect against this result, a court's focus should remain on understanding how a person of ordinary skill in the art would understand the claim terms. Phillips, 415 F.3d at 1323.

If the analysis of the intrinsic evidence fails to resolve any ambiguity in the claim language, a court then may turn to extrinsic evidence, such as expert declarations and testimony from the inventors. Intel Corp. v. VIA Techs., Inc., 319 F.3d 1357, 1367 (Fed.Cir.2003) ("When an analysis of *intrinsic* evidence resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence to contradict the meaning so ascertained.") (emphasis in original). When considering extrinsic evidence, a court should take care not to use it to vary or contradict the claim terms. Rather, extrinsic evidence is relied upon more appropriately to assist in determining the meaning or scope of technical terms in the claims. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583-84 (Fed.Cir.1996).

Dictionaries also may play a role in the determination of the ordinary and customary meaning of a claim term. In *Phillips,* the Federal Circuit reiterated that "[d]ictionaries or comparable sources are often useful to assist in understanding the commonly understood meanings of words...." Phillips, 415 F.3d at 1322. The

Phillips court, however, also admonished that district courts should be careful not to allow dictionary definitions to supplant the inventor's understanding of the claimed subject matter. "The main problem with elevating the dictionary to ... prominence is that it focuses the inquiry on the abstract meaning of the words rather than on the meaning of claim terms within in the context of the patent." *Id*. at 1321. Accordingly, dictionaries necessarily must play a role subordinate to the intrinsic evidence.

In addition, a court has the discretion to rely upon prior art, whether or not cited in the specification or the file history, but only when the meaning of the disputed terms cannot be ascertained from a careful reading of the public record. Vitronics, 90 F.3d at 1584. Referring to prior art may make it unnecessary to rely upon expert testimony, because prior art may be indicative of what those skilled in the art generally understood certain terms to mean. *Id*.

B. Claim Construction.

1. "Stress-induced martensite"

The parties agree that "stress-induced martensite," is martensite that is formed from austenite by the application of stress. The crux of the dispute is whether martensite must form by the application of stress alone or whether temperature also is a factor in the process. Gore urges the former, and the Court shall refer to Gore's proposed inclusion of this requirement as the "isothermal limitation."

Medtronic correctly notes that the disputed claim term does not contain an "isothermal limitation." When the Court looks at all the claims in which the term is used, it appears that when Jervis included an "isothermal" limitation, he either did so expressly or did so in connection with the reversion of the stress-induced martensite to austenite. (*See, e.g.,* '957 Patent, 11:26-36, 12:14-25; '546 Patent, 11:62-66, 13:10-13; '141 Patent, 11:12-20 .) FN3

FN3. The '546 and '141 Patents are attached as Exhibits 2 and 3, respectively, to the Bianrosa Declaration.

The Court also considers the claim language in light of the specification of which it is a part. *See* Markman, 52 F.3d at 979. In the Background of the Invention section of the specification, Jervis states:

Many [SMAs] are known to display stress-induced martensite (SIM). When an SMA sample exhibiting stress-induced martensite is stressed at a temperature above M_S (so that the austenitic state is initially stable), but below M_d (the maximum temperature at which martensite formation can occur even under stress) it first deforms elastically and then, at a critical stress, begins to transform by the formation of stress-induced martensite. Depending on whether the temperature is above or below A_s, the behavior when the deforming stress is released differs. If the temperature is below A_s, the stress-induced martensite is stable; but if the temperature is above A_s, the martensite is unstable and transforms back to austenite, with the sample returning (or attempting to return) to its original shape. This effect is seen in almost all alloys which exhibit a thermoelastic martensitic transformation, along with the shape memory effect. However, the extent of the temperature range over which SIM is seen and the stress and strain ranges for the effect vary greatly with the alloy.

('957 Patent. 1:50-2:2.) This portion of the specification supports Medtronic's assertion that temperature will be a factor in the *formation* of stress-induced martensite. Similarly, there are references in the specification

that suggests the "isothermal" limitation referred to the reversion process. (*See, e.g., id.,* 4:1-2 ("the alloy reverts to austenite without requiring a change in temperature").)

Gore contends that the prosecution history of the Jervis Patents demonstrates that Jervis "repeatedly disclaimed use of temperature change as part of his invention." (Opp. Br. at 7:13-14.) For example, Gore refers to a Response to Office Action, dated January 27, 1996, in which Jervis states, "[s]trictly speaking the Applicant is taking advantage of the shape memory effect ... [t]he difference is that the material transforms isothermally instead of over a temperature range." (Bianrosa Decl., Ex. 8 at p. 3.) FN4 The paragraph immediately preceding this statement demonstrates that Jervis was responding to the Examiner's concern that "while Applicant is claiming a device and method whereby a shape memory alloy is utilized it appears that the shape memory effect is not utilized." It also is directed to the Examiner's request for clarification of the invention. (*Id.*) Jervis responds by noting that he was, in fact, taking advantage of the shape memory effect, albeit through the use of an alloy that displays stress-induced martensite at body-temperatures. (*Id.* at pp. 3-6.)

FN4. This response was submitted to the USPTO during the prosecution of an application, subsequently abandoned, that was a predecessor to the application that issued as the '957 Patent.

Similarly, when Jervis distinguished the Shreck reference, he noted that martensite can be formed by cooling or by the application of stress. However, the discussion does not suggest that temperature plays no factor in the formation of stress-induced martensite. Other references cited actually support Plaintiff's position that the "isothermal" reference pertains to the reversion of martensite to austenite, rather than to its formation from austenite in the first instance. (*See, e.g.,* Bianrosa Decl., Ex. 12 at p. 4.) Having considered the references in the prosecution history upon which Gore relies, the Court finds that they do not support a conclusion that, in order to distinguish his invention over prior art, Jervis limited the term "stress-induced martensite" to martensite that is formed solely by the application of stress.

Accordingly, the Court construes the term "stress-induced martensite" to mean: **"martensite that forms from austenite due to stress."**

2. "Shape memory alloy element" and "Memory alloy element"

The primary dispute between the parties is whether these terms must be construed to require that the "shape memory alloy element" be placed in a deformed shape, *i.e.* its martensitic state, solely by the application of stress. For the reasons set forth above, the Court rejects Gore's arguments on this point.

Accordingly, the Court construes the term "shape memory alloy element" to mean: **"a device or device component made of an alloy that can be caused to revert, or to attempt to revert, from its unstable deformed shape to its stable, original state."**

3. "Restraining means" "Restraining member" and "Restraint"

With respect to these terms, the parties dispute (1) whether they should be construed to include the location at which the restraining means is positioned, and (2) whether the construction should include an isothermal limitation. For the reasons previously set forth, the Court rejects Gore's proposed construction to the extent it includes the isothermal limitation.

With respect to the position of the restraining means, the asserted claims generally are silent on this point. (*See, e.g.,* '957 Patent, claims 1-3, 5-7.) In other claims, Jervis expressly provides for a specific position. Furthermore, as Medtronic notes, one such claim expressly contradicts Gore's proposed construction. (*Compare* '957 Patent, claim 10 (memory alloy element is within restraining member) *with* '957 Patent, claim 14 (restraining means is within hollow memory alloy element).) Similarly, where Jervis required that the temperature be above the austenite start temperature, he expressly included such a requirement in the claims. (*See, e.g.,* '957 Patent, claims 10, 18.) Medtronic thus argues that the presumption of claim differentiation should apply to these claims.

In general, the doctrine of claim differentiation recognizes "that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1369 (Fed.Cir.2007) (quoting Karlin Tech. Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 971-72 (Fed.Cir.1999)). Thus, there is a presumption that "[t]o the extent the absence of such difference in meaning and scope would make a claim superfluous, ... the difference between claims is significant." *Id.* (quoting Tandon Corp. v. U.S. Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed.Cir.1987)). That presumption may be overcome, however, by the written description of the patent or its prosecution history. *Id.* Here, Gore has offered no argument in opposition to Medtronic's claim differentiation argument. Furthermore, although the position of the restraining means and the austenite start temperature are not the only differences in the claims, the Court has examined the claims in light of the specification, and finds no reason why the presumption of claim differentiation should not apply.

The Court also has reconsidered its tentative construction of these terms, as they are used in the '141 Patent, and concludes that Medtronic's proposed construction should be adopted as to all patents in which the terms are used.

Accordingly, the Court construes the terms "restraining means," "restraining member," and "restraint" to mean: **"a device that prevents the transformation of the shape memory alloy element back into its original shape."**

4. "Wherein the memory alloy element can be extruded from the hollow placement device by the guide wire"

This disputed phrase appears in independent claim 1 and in dependent claims 2, 3, 4, 5 and 22 of the '141 Patent.FN5 Claim 1 reads, in pertinent part:

FN5. Claims 2-5 and Claims 22 each depend from Claim 1.

A medical device for insertion into a mammalian body, the device comprising (a) a hollow placement device; (b) a memory alloy element formed at least partly from pseudo-elastic shape memory alloy, ...; and (c) a guide wire;
the memory alloy element being within the hollow placement device, and the placement device being guidable by the guide wire, ..., wherein the memory alloy element can be extruded from the hollow placement device by the guide wire ....

(*See* '141 Patent, 10:6-11:20.)
The parties agree that this disputed phrase should be construed to require that "the device or memory alloy

element is forced out of the hollow placement device by a guide wire." The crux of the dispute is over the meaning of "guide wire," which derives its antecedent basis from subsection (c) of the claim. The plain language of the claim suggests that the term "a guide wire" should mean what it says, *i.e.,* a wire that is used to guide a device. Medtronic, however, argues that the specification and prosecution history demonstrate that Jervis did not intend for the term to be restricted to a "wire," but rather that he intended the term to be construed broadly enough to encompass a catheter. As support for this argument, Medtronic notes that Jervis describes Figure 7 as disclosing "a guide catheter, a transport catheter, and compacted wire coil stent according to the present invention." ('141 Patent, 3:21-22.)

Medtronic's argument also is supported by the prosecution history of the '141 Patent, during which Jervis appealed a final rejection and in his appeal brief referred to element 104 of Figure 7 as a "guide wire." (Declaration of Ellen J. Wang in Support of Medtronic's Claim Construction Brief ("Wang Decl."), Ex. F at 11.) The specification of the '141 Patent refers to element 104 as a "transport catheter." ('141 Patent, 9:28.) Thus, these references support Medtronic's argument that "a guide wire" need not be construed to literally encompass a "wire," and that it should be construed more broadly.

Gore argues that this term should be construed to include a reference to the fact that the guide wire "is also used to guide the hollow placement device into a mammalian body." However, the clause that immediately precedes the disputed "wherein" phrase provides that "the memory alloy element being within the hollow placement device, and the placement device being guidable by the guide wire...." This clause therefore explains that the guide wire is used to guide the hollow placement device. The Court concludes there is no need to include such a limitation in the disputed phrase.

Accordingly, the Court construes the phrase "wherein the memory alloy element can be extruded from the hollow placement device by the guide wire," to mean: **"the device or memory alloy element is forced out of the hollow placement device by the guide wire, which is a device that assists in positioning another device."**

5. "Catheter at least partly formed from a pseudoelastic shape-memory alloy"

This phrase is found in independent claim 18 of the '957 Patent, and the crux of the dispute is over the proper construction of the term "catheter." The parties agree that, however "catheter" is construed, it must be made, at least in part, of a pseudoelastic shape-memory alloy. (*See* Amended Joint Claim Construction Statement, Ex. A at 3.)

The claim language suggests that the term catheter should be given its ordinary meaning in the field, namely "a hollow, flexible tube for insertion into a body cavity, duct or vessel to allow the passage of fluids or distend a passage way." (*See, e.g.,* Wang Decl., Ex. G.) Medtronic, however, argues that Jervis acted as his own lexicographer and defined the term "catheter" to include "cannulas," which do not necessarily transport fluids. (*See* '957 Patent, 5:59-62 ("Wilson ... discloses a catheter or cannula (both being included hereinafter in the word 'catheter')...."); Wang Decl., Ex. H (cannula, in surgical field, means "a tube to be inserted into a cavity or duct").)

Dependent claim 21 of the '957 Patent, however, claims "[t]he method of claim 18 wherein the catheter is a cannula." The use of the term "cannula," is the only significant difference between the two claims. Thus, if the Court construes the term "catheter" to include a "cannula," it could be argued that dependent claim 21 is superfluous. If, however, the Court determined that a "catheter" could not include a cannula, independent

claim 1 would be narrower than dependent claim 21. In this situation, the Court concludes that the doctrine of claim differentiation is overcome by the specification and concludes that Jervis acted as his own lexicographer and defined the term "catheter" to include "cannulas."

Gore's construction, which includes a reference to the catheter's function, is offered primarily out of a concern that the term not be construed so as to encompass a stent. (*See* Gore Br. at 18.) However, the specification of the ' 957 Patent sets forth examples of medical devices unitizing SMAs. One such example discusses catheters and cannulas. ('957 Patent, 5:59-6:57.) Another such example discusses coil stents and filters. (*Id.,* 9:20-57.) Because of this distinction, the Court concludes that a person of ordinary skill in the art would understand from the specification that the term "catheter" is intended to be something different than a stent. As such, the Court concludes that phrase should not be construed to include a reference to the function of the "catheter."

Accordingly, the Court construes the term "catheter at least partly formed from a pseudoelastic shape-memory alloy" to mean: **"a tube inserted into a cavity or duct that is made of, at least in part, a pseudoelastic shape-memory alloy."**

6. "Stent"

The term "stent" is used in both the '141 Patent and each of the Wiktor Patents. Medtronic argues for a construction of this term that would be applied uniformly to each of the patents. Gore contends that the term "stent" in the Jervis '141 Patent should be construed differently from the term "stent" in the Wiktor Patents. The Court concurs with Gore that the terms have different meanings in the '141 Patent and the Wiktor Patents. The Court, however, is not persuaded by many of the limitations Gore seeks to include in the construction of the term.

a. The '141 Patent.

Gore argues that the term "stent" in the '141 Patent means "a wire, typically in the shape of a tubular coil, used to keep a body vessel open." To the extent Gore is seeking a construction that includes a reference to the material from which the stent is made, the claims expressly note that the stent is composed of a memory alloy or a shape memory alloy. (*See* '141 Patent, 11:22-23 ("The device of claim 1 wherein the memory alloy element is a stent."); *id.,* col. 11:32-36 ("... the stent comprising a shape memory alloy ...").) Furthermore, independent claim 18 specifically claims a "*wire* stent," and dependent claim 22 specifically claims "[t]he device of claim 1, 11, 15 or 18 wherein the stent is a *coil* stent. (*Id.,* 13:22, 14:22-23 (emphasis added).)

As previously noted, the doctrine of claim differentiation recognizes "that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." Andersen Corp., 474 F.3d at 1369 (quoting Karlin Tech. Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 971-72 (Fed.Cir.1999)); *see also* Accumed LLC v. Stryker, Inc., 483 F.3d 800, 806 (Fed.Cir.2007) (quoting Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed.Cir.2004)) ("[T]he presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim.' ") The presumption of claim differentiation "is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." SunRace Roots Enter. Co. v. SRAM Crop., 336 F.3d 1298, 1303 (Fed.Cir.2003). The Court has considered Gore's arguments but finds that the specification and prosecution history submitted do not overcome the presumption that the

dependent claims differ in scope from the independent claims.

Accordingly, the Court construes the term "stent," as used in the '141 Patent, to mean: **"a supporting device."**

b. The Wiktor Patents.

With respect to the Wiktor Patents, Gore argues that the term "stent," should be construed to mean "a bare low memory metal wire stent without any attached fabric or graft material that would be obstructive to any supportive vessels." Gore relies on language in the specification that refers to "[t]he stent of this invention is characterized by the low memory level of the relatively easily deformable metal used for the wire." ('062 Patent, 2:51-54.)

Medtronic again relies on the principles of claim differentiation in support of its proposed construction. For example, Medtronic notes that dependent claim 2 of the '828 Patent claims "[t]he intravascular stent of claim 1, wherein said helically coiled wire is a low memory metal." (Bianrosa Decl., Ex. 7 ('828 Patent, 7:53-54); *see also id.,* 8:57-59.) The "low memory metal" limitation is the only meaningful difference between that claim and independent claim 1 of the '828 Patent. It also is the only meaningful difference between independent claim 14 and dependent claim 17 of the '062 Patent. Thus, the presumption of claim differentiation is especially strong. SunRace Roots, 336 F.3d at 1303.

Gore also relies on cases such as Honeywell Int'l Inc. v. ITT Indus., Inc., 452 F.3d 1312 (Fed.Cir.2006), Inpro II Licensing v. T-Mobile USA, Inc., 450 F.3d 1350 (Fed.Cir.2006), and Astrazeneca AB v. Mut. Pharm Co., 384 F.3d 1333 (Fed.Cir.2004) to argue that Wiktor disclosed only balloon-expandable stents in the specification and also disparaged, and thereby disavowed, self-expanding or resilient stents.FN6 It is true that the Wiktor Patents generally discuss balloon-expandable stents, especially in the context of the preferred embodiment. As the Federal Circuit has noted, however, "the applicant's choice to describe only a single embodiment does not mean that the patent clearly and unambiguously disavowed other embodiments." Home Diagnostics, Inc. v. Lifescan, Inc., 381 F.3d 1352, 1357 (Fed.Cir.2004); *see also* Phillips, 415 F.3d at 1323 ("In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment ...."). In addition, Wiktor notes that "other applications not specifically mentioned herein are possible and no limitations in scope for this invention are intended or implied without departing from the basic principles of this invention." (' 062 Patent, col. 4, ll. 8-11.) This language provides further support for the Court's conclusion that Wiktor did not disavow clearly the use of self-expanding or resilient stents. *See, e.g.,* Pfizer, Inc. v. Ranbaxy Labs. Ltd., 457 F.3d 1284, 1289 (Fed.Cir.2006) (rejecting claim construction that would limit claims to disclosed embodiments where specification stated that the examples were illustrative and should be read as limiting the scope of the invention).

FN6. Gore argues, without support, that a person of ordinary skill in the art would understand that a "balloon-expandable stent" would be made of a low memory metal, rather than a resilient or self-expanding metal. Based on the parties' discussion of shape-memory alloys, the Court understands Gore's argument to be that a "low memory metal" is one that does not "remember" its initial shape easily and, thus, requires some additional force to return it to its original shape.

Further, although Wiktor describes the benefits of a low memory level metal wire, and refers to prior art

that used spring devices, Wiktor does not say resilient metal is unsuitable to achieve the object of his invention, namely a stent which expands radially. The Court also does not find Wiktor's reference in the specification to the fact that the stent is "characterized" by the use of low memory metal to be dispositive. *See, e.g.,* Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1326 (Fed.Cir.2003) (concluding that statement that the invention is "uniquely characterized" by a particular feature did not limit the claims where the claim language did not contain such a limitation and where argument was undermined by doctrine of claim differentiation).

Furthermore, during the prosecution history of the '062 Patent, the Examiner suggested that Wiktor include a "low-memory metal" limitation to distinguish his invention over prior art. Wiktor declined to do so, and the Examiner allowed the claims as written. In addition, the '219 and '828 Patents issued with claims directed specifically to low memory metals, a fact which adds further support to Medtronic's argument that the Examiner did not understand the stent of the invention to require a low memory metal in all embodiments. *See, e.g.,* Home Diagnostics, 381 F.3d at 1358 (noting that related patents that issued with specific limitations supported a broader construction of the disputed term which did not contain those limitations). For all of these reasons, the Court cannot find a clear and unambiguous intent to disavow self-expanding or resilient stents, and the Court concludes that the term should not be limited to low memory metals.

Gore also argues that the "stent" of the Wiktor patent cannot include graft material, *i.e.* it is a "bare" wire stent. Medtronic asserts that the Court should not so limit the claims, because the specification notes that the stent can be used for the repair of aneurysms or to support artificial vessels or liners of vessels. Looking at the claims in which the term stent is used, the claims refer to a stent body comprised of a "wire." There is nothing in the claims that discloses the use of material attached to the wire. Further, with the exception of the reference cited by Medtronic, there is no other reference in the specification of material attached to the wire that forms the stent body. Thus, the Court concludes that the claims, read in light of the specification, do not support a construction that would be so broad as to include the combination of a wire stent with material attached.

Accordingly, the Court construes the term "stent," as used in the Wiktor Patents to mean: **"a supporting device, without any attached fabric or graft material."**

7. "Zig-zag means"

The parties agree that this term is a means-plus-function term that must be construed under 35 U.S.C. s. 112 para. 6, which permits a patentee to define a particular function in the claim and a corresponding structure in the specification. *See* Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352, 1360 (Fed.Cir.2000). Construction of a means-plus-function claim involves a two-step process. Medical Instrumentation & Diagnostics Corp. v. Elektra AB, 344 F.3d 1205, 1210 (Fed.Cir.2003). In the first step, the Court must identify the particular claimed function. *Id.* In the second step, the Court looks to the specification and identifies the structure that corresponds to that function. *Id.* A structure is a "corresponding structure" only if that element is necessary to perform the function recited in the claim and is clearly linked to that function by the disclosure in the specification. Asyst Techs., Inc. v. Empak, Inc., 268 F.3d 1364, 1370 (Fed.Cir.2001). The patentee's "duty to clearly link or associate structure to the claimed function" represents the fair exchange for the convenience of employing means-plus-function claim limitations. Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1377 (Fed.Cir.2001).

Medtronic contends that the Court should construe the functional aspect of this term as: "to allow expansion

of the device radially without substantial change in longitudinal length." Medtronic asks that the Court construe the structural aspect of the term as: "wire elements bent into a pattern of reversing bends that may vary in shape and tightness and their equivalents."

Gore contends that any definition of the function of the zig-zag means must include a requirement that expansion occurs "by externally applied forces." Gore agrees that the structure refers to the wire zig-zags but argues that the Court should construe the structure to require that the wire zig-zags be formed of low memory metal. For the reasons previously stated, the Court rejects Gore's arguments as to both of these proposed restrictions on the claim term.

The claims at issue demonstrate that the zig-zag means allow or permit radial expansion of the stent from a first to a second diameter "without significantly altering body length along the longitudinal axis." (*See* '062 Patent, 6:3-7.) Nothing in this claim language suggests that the zigzag means allow or permit the stent body to expand *solely* by the application of outside forces. For the reasons set forth in connection with the term stent, the Court also concludes that the construction of the term "zig-zag means" should not exclude the possibility of self-expanding or resilient wires.

The Court also has considered Gore's argument that the prosecution history supports its position that the function of the zig-zag means must include a reference to externally applied forces to achieve expansion. (*See* Gore Br. at 20:19-2; Bianrosa Decl., Ex. 14.) Gore's brief, however, omits the portion of the information disclosure statement wherein Wiktor distinguished his invention from the prior art cited on the basis that there was "no teaching in the prior art of a helical stent which expands radially *without reducing the axial length*." (Bianrosa Decl., Ex. 14 at 5 (emphasis added).) This reference does not alter the Court's conclusion that the claims should not be limited to devices that are expanded only by the application of external forces.

Accordingly, the Court construes the term "zig-zag means" to mean:

Function: **to allow expansion of the device radially without a substantial change in longitudinal length.**

Structure: **the wire elements bent into a pattern of reversing bends that may vary in shape and tightness and their equivalents.**

8. "Expand" and variations.

Medtronic contends that the Court should construe this term, and its variations, to mean "enlarge from a first to a second larger dimension." Medtronic's proposed construction is in accord with the plain meaning of the term "expand." *See, e.g., Webster's Ninth New Collegiate Dictionary* at 436 ("to open up; to increase the extent, number, volume or scope of"). Gore, in contrast, argues that the Court should construe this term, and its variations, to require that the device expanded is a "low memory metal stent," which is expanded by a balloon rather than by its own resilience. For the reasons previously stated, the Court rejects Gore's proposed construction.

The Court finds further support for its conclusion from the claims of the '062 Patent, which do not contain the "balloon-expandable" limitation proposed by Gore. In contrast, dependent claim 2 of the '219 Patent does contain such a limitation, whereas independent claim 1 of that patent, does not. (*See* Bianrosa Decl., Ex. 6 ("'219 Patent, 8:2-11.) Similarly, dependent claim 15 of the '828 Patent requires the use of a balloon,

whereas claim 14 of the '828 Patent, from which claim 15 depends, contains no such limitation. ('828 Patent, 8:29-59.) Moreover, the use of the balloon in the dependent claims is the only meaningful distinction from the independent claims. Thus, the presumption of claim differentiation weighs against Gore's proposed construction. *See* SunRace Roots, 336 F.3d at 1303.

Accordingly, the Court construes the term "expand" (and its variations) to mean: **"to enlarge from a first to a second larger dimension."**

9. Method Claims 9, 10, and 12 of the '062 Patent**.**

The final dispute between the parties pertains to whether method Claims 9, 10 and 12 of the '062 Patent require that the steps recited be performed separately and be performed in the particular order recited. The method claims at issue read as follows:

9. A method of forming a radially expandable stent for implantation within a body vessel comprising: bending a wire in a zig-zag pattern; and winding the wire around a form in a coil.

10. The method of claim **9** wherein the step of bending includes forming the zig-zag pattern in the wire generally in a plane and the step of winding the wire includes winding with the zig-zag pattern flat against the form.

12. A method of forming a radially-expandable stent for implantation within a body vessel comprising: forming a wire into a sinusoidal shape; forming the wire into a coil having a first diameter and a first longitudinal length, so that later radial outward deformation of the cylinder to a second larger diameter does not significantly alter the longitudinal length.

('062 Patent, 6:15-32).

"Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one." Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1342-43 (Fed.Cir.2001). The Federal Circuit has developed a two-part test to determine whether the steps of a method claim "that do not otherwise recite an order, must nonetheless be performed in the order in which they are written." Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1369 (Fed.Cir.2003) (citing Interactive Gift, 256 F.3d at 1342-43). The first step requires a court to examine the "claim language to determine if, as a matter of logic or grammar, [the steps] must be performed in the order written." *Id*. If the claim language does not suggest that a particular order is required, a court "next look[s] to the rest of the specification to determine whether *it* 'directly or implicitly requires such a narrow construction.' ... If not, the sequence in which such steps are written is not a requirement." *Id*. at 1370 (quoting Interactive Gift, 256 F.3d at 1343) (emphasis in original). This same analysis applies to the issue of whether the recited steps must be performed separately. *See* Moba B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1314-15 (Fed.Cir.2003).

Gore concedes that the language of the claims does not require that the steps be performed separately and also concedes that the claim language does not require that the steps be performed in the order in which they are recited. Gore asserts, however, that the specification of the '062 Patent implicitly requires that the wire first be bent into a zig-zag pattern and then wound around a form in a coil. (*See* Gore Br. at 22-24.) Gore finds support for its position in references in the specification wherein Wiktor states that the zig-zag wire is "preformed" and "subsequently" wound around a form. Gore also points the Court to references in the

specification describing Figure 1. (*See, e.g.,* '062 Patent 2:55-62, 3:1-2, 3:11-17, 3:35-38, 4:14-16, 4:52-58.)

Wiktor, however, clearly identifies Figure 1 as the "preferred embodiment." (*Id.,* 3:52, 4:6-11.) In general, a court should not limit a disputed claim term to the preferred embodiment, even when the specification only describes a single embodiment. *See* Phillips, 415 F.3d at 1323 ("In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.... That is not just because Section 112 of the Patent Act requires that the claims themselves set forth the limits of the patent grant, but also because persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments.").

For example, in the *Altiris* case, although the specification only disclosed "a single 'preferred' embodiment," which set forth a particular order, the patentee did not state that the order was important and did not disclaim any other order of the steps. Altiris, 318 F.3d at 1371. Similarly, in this case, the specification also describes a single preferred embodiment. As in the *Altiris* case, however, Wiktor did not state that the order of the steps was an important feature of his invention. There also is not a clear disclaimer of any other order of the steps.

Moreover, the prosecution history submitted to the Court does not suggest that Wiktor disclaimed any other order of the steps. *See, e.g.,* Loral Fairchild Corp. v. Sony Corp., 181 F.3d 1313, 1321 (Fed.Cir.1999) (noting that, in addition to claim language, statements by the inventor during the prosecution history limited process claim to the sequence of the steps set forth in claim language). Finally, after noting that the figures represented the preferred embodiment, Wiktor stated that "it is understood that other applications not specifically mentioned herein are possible and no limitations in scope of this invention are intended or implied without departing from the basic principles of this invention." ('062 Patent, 4:6-11.) This language again suggests that the claims should not be limited to the disclosed preferred embodiment. *See* Pfizer, Inc., 457 F.3d at 1289.FN7

FN7. Gore also relies on LizardTech, Inc. v. Earth Res. Mapping Inc., 424 F.3d 1336 (Fed.Cir.2005) presumably because, as noted, the ' 062 Patent only discloses a single preferred embodiment. In *Lizard Tech,* however, the court resolved an issue related to the validity of the patent and concluded that certain claims were invalid for lack of written description. Gore may, in the future, have an argument in favor of invalidity. Resolution of that issue however, is premature at this time.

Accordingly, the Court adopts Medtronic's proposed construction and concludes that the steps of the method claims in dispute need not be performed separately or in a particular order.

CONCLUSION

Based on the analysis set forth above, the Court adopts the foregoing constructions of the disputed terms and phrases. The parties are ordered to submit a further joint case management report pursuant to Patent Standing Order para. 13 by no later than November 9, 2007.

IT IS SO ORDERED.

N.D.Cal.,2007.
Medtronic, Inc. v. W.L. Gore & Associates, Inc.

Produced by Sans Paper, LLC.