United States District Court,
D. Minnesota.

MEDTRONIC, INC,
Plaintiff.
v.
BOSTON SCIENTIFIC CORPORATION, and SciMed Life Systems, Inc,
Defendants.

No. 99-1035 RHK/FLN

Aug. 31, 2001.

A. James Anderson and Marla R. Butler, Robins, Kaplan, Miller & Ciresi, L.L.P., Atlanta, Georgia, and Celeste P. Grant, Robins, Kaplan, Miller & Ciresi, L.L.P., Minneapolis, Minnesota, for Plaintiff.

John A. Bauer and John E. Lynch, Fulbright & Jaworski, L.L.P., New York, New York, and Paul Robbennolt and Sean Solberg, Dorsey & Whitney, L.L.P., Minneapolis, Minnesota, for Defendants.

MEMORANDUM OPINION AND ORDER

KYLE**, J.**

Introduction

Plaintiff Medtronic, Inc. ("Medtronic") owns two patents that encompass the use of shape memory alloys, United States Patent Nos. 5,067,957 (hereinafter "the '957 patent") and 5,597,378 (hereinafter "the '378 patent"). Medtronic claims that Defendants Boston Scientific Corporation and SciMed Life Systems, Inc., (collectively "BSC") are infringing on these patents by producing and selling the RADIUS TM stent. Currently before the Court are the parties' proposed claim constructions. Having reviewed the parties' submissions and held a hearing on the matter, the Court construes the disputed terms as follows:

Background FN1

FN1. For purposes of construing the claims-at-issue, the parties do not dispute the following facts.

I. Shape Memory Alloys

This case involves patents for the use of shape memory alloys ("SMAs"). SMAs have the capability of "remembering" an original or "parent" shape after being deformed. Under the right conditions, an SMA independently reverts back from its deformed shape to its original shape-this is referred to as "shape memory." SMAs are used in medical devices because they permit a physician to implant a device in the human body that is in a deformed, and often constricted, shape. Once the device is in place, either the temperature of the body will cause a reversion in the SMA to its original shape or the removal of a restraint will cause the reversion. As the device begins to transform into its original shape its medical purpose is achieved, i.e, moves bones or opens arteries.

One example of an SMA medical device is the tracheal catheter. A tracheal catheter must be inserted into the body through a small hole in the front of the neck, which requires that the catheter be straight for easy insertion. Once the catheter enters the trachea, however, it must curve so that the flow of air or oxygen passes axially down the trachea. The SMA in the catheter allows it to be both straight and curved as needed. The catheter's original shape is curved, it is then deformed into a straight device, allowing for insertion into the body through the front of the neck. Once inserted into the neck, the SMA in the catheter responds to the higher temperature of the body, or the removal of a restraint, and reverts to its original curved shape.

The science of SMAs involves two different states of the alloy: the austenitic state and the martensitic state. The austenitic state is present when the SMA is said to be in its original shape-the alloy is not capable of being reversibly deformed in this state. When the SMA is in its martensitic state it is capable of being reversibly deformed. It is the transformation between these two states that make shape memory possible. An SMA's original heat-stable configuration is called austenite, and its heat-unstable configuration is call martensite. In order to achieve shape memory, an alloy in its austenitic state must first be converted to martensite, either by temperature control or the application of stress. When temperature is used to transform austenite into martensite, the result is called thermal-induced martensite. If stress is used for this transformation, the martensite that forms is referred to as stress-induced martensite. Likewise, martensite can be transformed back into austenite either by heating it up if it was thermally induced or, if stress-induced, by releasing stress.

If temperature is used to transform austenite into martensite, four temperature points in the transformation of an SMA become important: martensite start ("M_s"), martensite finish ("M_f"), austenite start ("A_s"), and austenite finish ("A_f"). M_s is the temperature at which the high temperature austenite starts to transform to the low temperature martensite. M_f is the temperature at which the transformation from austenite to martensite is complete and the alloy is fully martensite. A_s represents the temperature at which the martensite, upon heating, starts to form back into austenite; A_f represents the temperature at which the SMA is again fully austenite. These four temperature points are constant if the alloy is not subjected to stress-stress causes the alloy's temperature points to shift depending on the amount of force applied. A fifth temperature point is the maximum point at which martensite can form from the application of stress; this point is expressed as M_d.

The temperature at which austenite begins its change to martensite does not correlate with the temperature at which martensite begins its change to austenite. Stated another way, M_s is generally not the same temperature as A_s. The temperature difference between M_s and A_s is called "hystersis." The hystersis can be as high as several tens of degrees Celsius. For example, if an SMA achieves M_s at zero degrees Celsius, achieving A_s may take heating the SMA up to twenty degrees Celsius. It is this large hystersis and the requirement of precise temperature control that the patents-in-suit attempted to improve upon with the introduction of stress-induced martensite for medical devices.

II. The Jervis Patents

On November 26, 1991, the '957 patent entitled "Method of Inserting Medical Devices Incorporating

[Stress-Induced Martensite] Alloy Elements," was issued to James E. Jervis ("Jervis"), and subsequently acquired by Medtronic. (Am. Compl. at para. 10.) The independent claim-at-issue in the '957 patent is for

[a] method of medical treatment of a mammal which comprises the steps of:

(a) providing a device comprising an element which comprises a shape memory alloy which displays stress-induced martensite behavior at body temperature of the mammal, the element being restrained in a deformed configuration, the restraining means stressing the element thereby inducing stress-induced martensite in the alloy;

(b) positioning the device so that the shape memory alloy element is within a mammalian body or in such proximity to a mammalian body that the element and the restraining means are substantially at body temperature; and

(c) at least partially removing the restraining means from the element thereby transforming the element from the deformed configuration, the transformation occurring with the element and the restraining means being substantially at body temperature.

(Robbennolt Aff. Ex. 1 (the '957 patent, col. 10, Ins. 42-51).)

On January 28, 1997, the '378 patent entitled "Medical Devices Incorporating [Stress-Induced Martensite] Alloy Elements," was issued to Jervis. (Am. Compl. at para. 6.) The '378 patent claim-at-issue provides for

[a] medical device which comprises: (a) an element for use within a human body that the device is substantially at human body temperature, the element comprising a shape memory alloy which displays a stress-induced martensite behavior at body temperature; and (b) a restraint holding the shape memory alloy element in a deformed configuration at a temperature less than the body temperature of the human for positioning the shape memory alloy element within or in proximity to the human body in its deformed configuration, the deformation occurring through the formation of stress-induced martensite.

(Lehmann Aff. Ex. B (the '378 patent, at col. 10, lns. 35-48).) Medtronic also holds all right, title, and interest in the '378 patent. (Am. Compl. at para. 7.) The '957 patent is a method patent while the '378 patent deals with the actual medical devices.

Jervis did not invent stress-induced martensite-this alternative to thermal-induced martensite was well-known in the prior art. Jervis instead discovered that there were multiple benefits to using stress-induced martensite in lieu of thermal-induced martensite in medical devices. The use of thermal-induced martensite in medical devices required that an SMA device be cooled below the SMA's M_s temperature and kept at that temperature until inserted in the body. This caused logistical problems with shipping and storing these devices. More problematic was that keeping the device cool meant that the surgeon would have to insert the device quickly into the body before it heated up and reverted to its original shape. If the device were to heat up and revert to its original shape before the physician placed it where intended, the device could cause damage to the body. In addition to these difficulties, the large hysteresis in many SMAs made them unsuitable for use within the human body because the body cannot withstand extreme temperature variations.

Jervis solved these problems by proposing the use of SMAs that display stress-induced martensite behavior at body temperature. By using stress instead of temperature to convert an SMA from austenite to martensite, there was no longer a need to control the temperature. A device consisting of stress-induced martensite could be shipped and stored without concern of temperature, the only requirement being that the SMA remain restrained until deployment. For stress-induced martensite, the temperature becomes significant at the time the stress is released. If the stress is released at a temperature above the SMA's A_f temperature, determined at zero stress, the SMA will revert, or attempt to revert, into its original shape because the SMA is transforming from martensite into austenite. If the SMA is released between its A_s and A_f temperature it will partially recover its original shape, and if released at a temperature below A_s it will remain in its deformed shape because it remains martensite by virtue of the cool temperature.

Returning to the tracheal catheter example, the advantage of using a catheter containing stress-induced martensite is that it eliminates the requirement that the catheter be stored at a temperature below the SMA's A_s temperature. It also eliminates the practice of flushing a patients throat with a cold solution in order to get the temperature in the throat below or near the SMA's A_s. A catheter made of stress-induced martensite is simply restrained within a sheath until it enters the body. Once there, the sheath is removed, releasing the stress and allowing the catheter to revert back to its original curved shape. For this to work, however, the SMA must display stress-induced martensite behavior at body temperature.

In addition to the advantages gained while inserting the catheter, stress-induced martensite allows for easy removal of the catheter. Trying to remove a catheter made of thermal-induced martensite required that the trachea again be flushed with a cold solution to achieve martensite in the catheter. FN2 Once in the martensitic state the catheter could be deformed and removed. The use of stress-induced martensite allows the catheter to be stressed by a restraint producing stress-induced martensite in the catheter without having to cool the catheter below M_s by flushing the trachea with a cold solution.

FN2. Because of the hystersis, the temperature needed to keep the catheter from heating above A_s while being inserted into the body, may not be the same temperature needed to cool the catheter below M_s in order to remove it. The hystersis can be as high as several tens of degrees Celsius-temperature changes in which the human body is not accustomed.

III. The Suit

The parties are engaged in the business of manufacturing, promoting, and selling medical devices, including stents. (Am. Compl. at para.para. 2-3.) Medtronic filed this suit claiming that BSC manufactured, sold, offered for sale, and distributed devices within the United States which infringed one or more claims of the patents-in-suit. (Id. at para.para. 11 & 15.) Medtronic further contends that BSC continues to offer infringing products, primarily the RADIUS TM-which consists of a stent for implantation in the body and a delivery catheter for restraining it. As alleged by Medtronic, this device infringes claims 1, 2, and 3 of the '957 patent, and claims 1-3, 7-12, and 33 -34 of the '378 patent.

Analysis

Prior to addressing the issue of infringement, the term "stress-induced martensite" must be defined. The meaning of the words and the construction of the claims are questions of law for this Court to decide. *See* Markman v. Westview Instruments, Inc ., 52 F.3d 967, 979 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 391 (1996).

In determining which reading of the words is accurate, the Court first looks to the plain meaning of "stress-induced martensite." *See* Thermalloy, Inc. v. Aavid Eng'g, Inc., 121 F.3d 691, 693 (Fed.Cir.1997) ("Nonetheless, throughout the interpretation process, the focus remains on the meaning of claim language.") The parties agree that stress-induced martensite is martensite that forms from austenite due to the application of stress. The parties further agree that for stress-induced martensite to form, the temperature must be above the SMA's M_s temperature, determined at zero stress, or the transformation is thermally-induced. This is where the agreement ends. The primary dispute between the parties concern two issues, (1) whether the patents-in-suit teach that M_s is determined at zero stress, and (2) whether the formation of stress-induced martensite must occur "without cooling" the SMA.

Medtronic contends that the definition of stress-induced martensite is "Martensite that forms from austenite due to the presence of stress, applied while the alloy is above its M_s temperature, where M_s is determined at zero stress." (Medtronic's Proposed Order on Claim Construction.) BSC defines that term as "Martensite obtained from the application of stress to austenite, *without cooling,* resulting in transformation of the austenite to stress-induced martensite." (BSC's Proposed Order on Claim Construction (emphasis added).)

I. M_s Temperature at Zero Stress

Medtronic argues that the patents-in-suit teach that M_s must be determined at zero stress, because with the addition of stress M_s shifts and is no longer a constant temperature. BSC contends that this is too broad a reading as it includes austenite that is stressed, raising the temperature of M_s, and then cooled to below the new M_s temperature. Therefore, according to BSC, the martensite that formed was thermally, not stress, induced. BSC would have the Court read into the term stress-induced martensite the words "without cooling" or, as later argued by BSC, isothermal.

Jervis taught in the '957 patent that "[w]hen 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 ... it first deforms elastically and them at a critical stress, begins to transform by the formation of stress-induced martensite." (the '957 patent, col. 1, lns. 51-58.) An SMA's M_s temperature is constant only at zero stress because with the application of stress the M_s temperature rises. Thus, in order for a person skilled in the art to know what the M_s temperature is, if it is not at zero stress, the patent would have to disclose the amount of stress that is being applied to the SMA-which it does not. Moreover, in the '378 patent, Jervis lists a number of alloys and gives one M_s temperature for each alloy, without addressing the issue of stress. Accordingly, the Court concludes that the M_s temperature referred to in the patents-in-suit represents the temperature at which martensite will begin to form at zero stress.

II. Without Cooling

BSC relies on the following language from the patents themselves and their file histories in support of its reading "without cooling" into the term stress-induced martensite:

If a [stress-induced martensite] pseudoelastic wire is used to form the coil, which is then *isothermally* deformed by loading into a catheter, then the need for temperature control is avoided. The wire remains straight when in the catheter, but re-forms the coil spontaneously when it is extruded from the catheter. Accurate placement is thus readily obtainable, since there is no urgency as might be required with a conventional shape memory effect element.

(Robbennolt Aff. Ex. 1 (the '957 patent, col. 9, lns. 39-47) (emphasis added).) "[I]f an [stress-induced martensite] pseudoelastic wire is used, it can exert a relatively constant force.... The load may be applied mechanically, and is thus more readily established, and *no precise temperature control of the alloy is needed* as would be required for the shape memory effect." (Id. at col. 9, Ins. 10-17 (emphasis added).) Both of these statements are taken from examples of uses for stress-induced martensite under the preferred embodiment section of the '957 patent. It is unclear how the use of the word isothermal in one of eight examples limits the definition of stress-induced martensite. Moreover, the statement "no precise temperature control of the alloy is needed" does not lead to a finding that temperature control of an SMA prevents any resulting martensite from being termed stress-induced.

In addition, Jervis argued to the PTO, in order to overcome prior art, that "[s]trictly speaking, the Applicant is taking advantage of the shape memory effect since there is a transformation between austenite and martensite when the material acts pseudoelastically. The difference is that the material transforms *isothermally instead of over a temperature range*." (Lehmann Aff. Ex. E (Jervis '852 Appl. filed October 14, 1983; Jan. 13, 1986 Response to Office Action, p. 3)(emphasis added).) FN3 Again, the Court is not persuaded that an isolated statement made to the PTO distinguishing stress-induced martensite from martensite that forms over a temperature range, that is cooling below M_s, limits stress-induced martensite to martensite created without any temperature variation.

FN3. The '957 patent is a continuation of co-pending commonly assigned application No. 047,824, filed May 8, 1987, which is a continuation of application No. 865,703, filed May 21, 1986, now United States patent No. 4,665,906, which is a continuation of application serial No. 541,852, filed October 14, 1983. (Lehmann Aff Ex. A, the '957 patent file history).)

BSC also claims that Jervis should be bound by the term "without cooling" because this is how he was able to distinguish his patents from the prior art. In support of this argument BSC quotes portions of the following language from the prosecution history of the '378 patent:

By way of background, there are two techniques available for transforming an appropriate alloy into the martensitic state. *The first technique ... is cooling the material so that martensite forms at M_s under no stress. By the second technique, the same material, martensite can form above M_s if stress is applied, thereby forming stress-induced martensite*. The present invention is directed to use of the unique properties of stress-induced martensite, not martensite formed by cooling.

(Robbennolt Aff. Ex. 13 (November 24, 1993 Amen. at 13) (emphasis added).) The underlined language was omitted by BSC. BSC argues that the last sentence supports its addition of "without cooling" to the definition of stress-induced martensite. The Court disagrees. Instead of using the terms stress-induced martensite and thermal-induced martensite, Jervis referred to the two techniques as one that required cooling below M_s at zero stress and one that will form above the M_s temperature at zero stress if stress is applied. Accordingly, he distinguishes the two techniques by calling thermal-induced martensite, the first technique, martensite formed by cooling. This does not translate into a finding that stress-induced martensite must form without cooling.

The narrowing of the term stress-induced martensite by BSC is not supported by the plain meaning of the claim language, and the Court will not read extraneous terms from the prosecution history or the claim specification into the claim under the guise of term interpretation. *See* Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1053 (Fed.Cir.1989) ("[T]his court has consistently adhered to the proposition that courts cannot alter what the patentee has chosen to claim as his invention, that limitations appearing in the specification will not be read into claims, and that interpreting what is meant by a word in a claim 'is not to be confused with adding an extraneous limitation appearing in the specification, which is improper." ') (quoting E.I. duPont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed.Cir.1988)).

Medtronic's definition of stress-induced martensite represents the plain meaning of that term. Accordingly, the Court construes the term stress-induced martensite to mean: Martensite that forms from austenite due to the presence of stress, applied while the alloy is above its M_s temperature, where M_s is determined at zero stress. Having defined this term the Court concludes that the following additional terms and claims are construed as follows:

III. Shape Memory Alloy

Medtronic defines an SMA as "[a]n alloy capable of undergoing a reversible transformation from an austenitic state to a martensitic state with a change of temperature and capable of displaying stress-induced martensite." (Medtronic's Proposed Order.) While BSC defines it as

[a]n alloy capable of transforming from austenite to thermal-induced martensite by being cooled, and if subsequently deformed, capable of regaining ("remembering") its original shape by being heated, the heat causing the thermal-induced martensite to transform back to austenite; the alloy is also capable of transforming from austenite to stress-induced martensite by being subjected to a deforming stress (without cooling), and transforming back from stress-induced martensite to austenite upon release of the stress.

(BSC's Proposed Order.) The Court adopts Medtronic's definition of SMA. BSC, again, adds the limiting language of "without cooling" to the formation of stress-induced martensite. What BSC omits in its more detailed discussion of SMA is that in order for thermal-induced martensite to form, the temperature of the alloy must be below its M_s temperature. Any martensite formed above M_s resulted from the application of stress. Accordingly, the Court concludes that SMA is defined as an alloy capable of undergoing a reversible transformation from an austenitic state to a martensitic state either by cooling the alloy below its M_s temperature at zero stress or by applying sufficient stress to the austenite above its M_s temperature at zero stress.

IV. Pseudoelastic Shape Memory Alloy

In addition to the above terms BSC requests that the Court interpret pseudoelastic shape memory alloy. BSC's purpose for having the Court define this term is to add the language "without cooling" when discussing how stress-induced martensite is formed. As discussed previously, the Court does not find that such a limitation is warranted by the plain meaning of the term. Accordingly, the Court construes pseudoelastic shape memory alloy to mean an alloy, that when subjected to deforming stress in its austenitic state, first deforms elastically, and then, at a critical stress, deforms by the formation of stress-induced martensite.FN4

FN4. There are additional claims that BSC asks the Court to construe. After reviewing BSC's proposed claim construction, however, it appears that the only substantive difference in BSC's proposed claim construction is its addition of the phrase "without cooling" to stress-induced martensite. The Court, therefore, will not address the claim constructions proposed by BSC.

Conclusion

Based on the foregoing, and all of the files, records and proceedings herein, IT IS ORDERED that

(1) the term stress-induced martensite is defined as martensite that forms from austenite due to the presence of stress, applied while the alloy is above its M_s temperature, where M_s is determined at zero stress;

(2) the term shape memory alloy is defined as an alloy capable of undergoing a reversible transformation from an austenitic state to a martensitic state either by cooling the alloy below its M_s temperature at zero stress or by applying sufficient stress to the austenite above its M_s temperature at zero stress; and

(3) the term pseudoelastic shape memory alloy is defined as an alloy that when subjected to deforming stress in its austenitic state, first deforms elastically, and then, at a critical stress, deforms by the formation of stress-induced martensite.

D.Minn.,2001.
Medtronic, Inc. v. Boston Scientific Corp.