IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	James E. Jervis
U.S. Patent No.:	6,306,141
Issue Date:	October 23, 2001
Serial No.:	08/483,291
Filing Date:	June 7, 1995
Title:	MEDICAL DEVICES INCORPORATING SIM ALLOY ELEMENTS

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Mail Stop PATENT BOARD
Patent Trial and Appeal Board
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P.O. Box 1450
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PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NUMBER 6,306,141 UNDER 35 U.S.C. §§ 311-319

Lombard Medical Technologies PLC ("Lombard" or "Petitioner") hereby requests *Inter Partes* Review ("IPR") of Claims 1-10 and 18-22 in U.S. Patent Number 6,306,141 ("141 patent") (**Exhibit 1001).** A detailed statement supporting the petition follows.

The requisite fee accompanies this request. If any additional fee is necessary the Director is authorized to charge Deposit Account No. 16–0605. This document, together with all exhibits referenced herein, has been served on the patent owner at the address of record for the 141 patent, as well as on the counsel of record for the 141 patent, as reflected in the accompanying Certificate of Service.

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1004	U.S. Patent No. 4,503,569 to Dotter
1005	A. Cragg *et al*., *Nonsurgical Placement of Arterial Endoprostheses: A New Technique Using Nitinol Wire*, Radiology, Vol. 147: 261-263 (April 1983)
1006	Japanese Patent Publication No. S58-46923 (filed Sept. 12, 1981; disclosed Mar. 18, 1983) to Miyauchi et al.
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1018 C. Dotter et al., *Transluminal Expandable Nitinol Coil Stent Grafting: Preliminary Report*, Radiology, Vol. 147: 259 (April 1983)

1019 Otsuka et al., *Pseudoelastiticy*, 4 Metals Forum No. 3, 142 (Aus. Inst. of Metals 1981)

1020 Delaey, et al., *Thermoelasticity, pseudoelasticity and the memory effects associated with martensitic transformations. Part 1: Structural and microstructural changes associated with the transformations*, 9 Journal of Materials Science 1521 (1974)

1021 Krishnan, et al., *Thermoplasticity, pseudoelastiticy and the memory effects associated with martensitic transformations. Part 2: The macroscopic mechanical behavior*, 9 Journal of Materials Science 1536 (1974)

1022 U.S. Patent No. 3,890,977 to Wilson

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1024 Canadian Patent No. 1001034 to McWhorter

1025 U.S. Patent No. 4,401,433 to Luther

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1027 Kauffman et al., *The Story of Nitinol: The Serendipitous Discovery of the Memory Metal and Its Applications*, Vol. 2, No. 2 The Chemical Educator 1, 4-6

1028 Ling et al., *Phase Transitions and Shape Memory in NiTi*, 11A Metallurgica Transactions A 77, 77-79 (1980)

1029 Schetky, *Shape-Memory Alloys*, 241:5 Scientific American 74-82 (November 1979)

1030 Patel et al., *Criterion for the Action of Applied Stress in the Martensitic Transformation*, 1 Acta Metalurgica 531-538 (1953)

1031 Otsuka et al., *Stress and Strain Induced Martensitic Transformations*, Proceedings of the Int'l Conference on Martensitic Transformations: ICOMAT 1979, Cambridge, MA Jun 1979, 607.

1032 Miyazaki, *et al*., *Transformation Pseudoelasticity and Deformation Behavior in a Ti-50.6at%Ni Alloy*, 15 Scripta Metallurgica 287, Fig. 1 (1981)

I. REAL PARTY IN INTEREST UNDER 37 C.F.R. § 42.8(b)(1)

The real party in interest for Petitioner is LOMBARD MEDICAL TECHNOLOGIES PLC.

II. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)

Petitioner certifies that the 141 patent is available for IPR and that Petitioner is not barred or estopped from requesting an IPR challenging the patent claims on the grounds identified herein.

III. RELATED MATTERS UNDER 37 C.F.R. § 42.8(b)(2)

Petitioner is not aware of any current judicial or administrative matters that would affect, or be affected by, a decision in this proceeding.

IV. DESIGNATION OF COUNSEL UNDER 37 C.F.R. § 42.8(b)(3) and 42.10(a)-(b)

Lead counsel for the Petitioner is Steven D. Hemminger of Alston & Bird LLP, USPTO Reg. No. 30,755. Backup counsel for the Petitioner is Christopher B. Kelly of Alston & Bird LLP, USPTO Reg. No. 62,573. Pursuant to 37 C.F.R § 42.10(b), a Power of Attorney accompanies this petition.

V. SERVICE INFORMATION UNDER 37 C.F.R. § 42.8(b)(4)

Petitioner's lead counsel may be reached by phone at 650-838-2029, by email at steve.hemminger@alston.com, and by facsimile at 650-838-2001. Petitioner may be served as follows:

Steven D. Hemminger
ALSTON & BIRD LLP
275 Middlefield Road, Suite 150
Menlo Park, CA 94025-4008

VI. STATEMENT OF PRECISE RELIEF REQUESTED UNDER 37 C.F.R. §§ 42.22(a)(1) and 42.104(b)(1)-(2)

For the reasons presented herein, Petitioner seeks the following relief:

(Ground #1) Invalidation of Claims 1-10 and 18-22 of the 141 patent (the IPR Claims) under 35 U.S.C. § 103(a) as being obvious in view of U.S. Patent No. 4,512,338 to Balko et al. ("Balko," **Exhibit 1002**); Schetky, *Shape Memory Alloys*, 20 Kirk-Othmer Encyclopedia of Chemical Technology 726-736 (3d Ed. 1982) ("Kirk-Othmer," **Exhibit 1003**); and U.S. Patent No. 4,485,805 to Foster ("Foster," **Exhibit 1014**).

(Ground #2) Invalidation of The IPR Claims under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 4,503,569 to Dotter ("Dotter," **Exhibit 1004**) or—alternatively—under 35 U.S.C. § 103(a) as being obvious in view of Dotter.

(Ground #3) Invalidation of Claims 1-5 and 18-22 of the 141 patent under 35 U.S.C. § 102(a) as being anticipated by Cragg *et al*., *Nonsurgical Placement of Arterial Endoprostheses: A New Technique Using Nitinol Wire*, 147 Radiology No. 1, 261-263 (April 1983) ("Cragg," **Exhibit 1005**);

(Ground #4) Invalidation of Claims 1-5 and 18-22 of the 141 patent under 35 U.S.C. § 103(a) as being obvious in view of Japanese Patent Publication No.

S58-46923 to Miyauchi et al. ("Miyauchi," original **Exhibit 1006,** and certified English translation **Exhibit 1007**) and Cragg.

(Ground #5) Invalidation of Claims 6-10 of the 141 patent under 35 U.S.C. § 103(a) as being obvious in view of Dotter and Miyauchi.

(Ground #6) Invalidation of The IPR Claims under the doctrine of obvious-type double patenting over the claims of U.S. Patent No. 5,597,378 to Jervis, filed October 2, 1992 and issued on January 28, 1997 ("the '378 Patent", **Exhibit 1008**).

VII. HOW THE CHALLENGED CLAIMS ARE TO BE CONSTRUED UNDER 37 C.F.R. § 42.104(b)(3)

The IPR Claims should be accorded their "broadest reasonable construction" in light of the specification of the 141 patent. 37 C.F.R. § 42.100(b).

VIII. REASONS FOR THE RELIEF REQUESTED UNDER 37 C.F.R. § 42.22(a)(2) and 42.104(b)(4) SHOWING THAT THERE IS A REASONABLE LIKELIHOOD THAT THE PETITIONER WILL PREVAIL UNDER 35 U.S.C. § 314(a)

The 141 patent claims priority to U.S. Appl. No. 06/541,852 ("852 Application"), filed in October of 1983. As a result of terminal disclaimers based on obviousness type double patenting rejections, the other 4 patents issuing from that application all expired on the same date as the first patent issuing from the 852 Application, May 4, 2004. As a result, the 141 patent claims represent the last gasp of its owner Medtronic, Inc. to exclude others in the medical device industry from using technology known in the art for more than 30 years.

In fact, as explained further below, the only reason the 141 patent claims issued is because the PTAB relied on a declaration of an "expert" in stress induced martensite, who has since admitted that he is not and never was an expert in that field. In addition, the IPR Claims are unpatentable over various prior art references that were not before the USPTO during prosecution.

A. Subject Matter of the 141 Patent

The IPR Claims are generally directed to a medical device that includes **(i)** a shape memory alloy (SMA) element, capable of displaying stress-induced martensite (SIM) at body temperature, and **(ii)** a placement device for delivery of the SMA element into a mammal. 141 patent, 2:59 to 3:4, 10:59 to 14:23. All SMA elements, such as Nitinol, include a "martensite" phase and an "austenite" phase. These phases refer to different crystalline structures of the SMA, each of which has different inherent properties. Just as water can transform between various phases (e.g., vapor, liquid, ice), all SMAs are capable of transforming between the austenite phase and the martensite phase; the former a comparatively rigid solid (useful for maintaining the patency of a blood vessel) and the later a more malleable solid (useful for delivery through a catheter).

The transformation between these phases can occur as a result of a change in temperature or stress. For example, just like when H_2O is in its liquid phase (water) and is sufficiently cooled, it transforms to its solid state (ice); if when an

SMA is in its austenite phase and it is sufficiently cooled, it transforms to its martensite phase. This transformation as a result of temperature is often referred to as "thermally induced martensite" or "TIM." Likewise, if an SMA can change state as a result of temperature, the application of sufficient stress to the SMA when in its austenite phase, will transform the SMA to its martensite phase. This transformation as a result of stress is often referred to as "stress induced martensite" or "SIM." 141 patent, 1:52-53. An important inherent property of every SMA that can transform to martensite thermally, is that it can transform to martensite through the application stress—i.e., if TIM then SIM. This inherent property was never disclosed in the application. More importantly for this petition, Medtronic, in the appeal during prosecution of the 141 patent application, Medtronic not only did not disclose this inherent property, but misled the board in to reaching the conclusion that not all SMAs that exhibit TIM exhibit SIM, and on that basis allowed the claims.

SMAs also have a "shape memory" property that enables them to memorize their austenitic shape. This is exhibited in two ways: thermal shape memory and mechanical shape memory (also referred to as "pseudoelasticity"). Thermal shape memory generally refers to when one cools austenite to form martensite, deforms the martensite, and then heats the alloy so that it reverts back to its undeformed austenitic state. Mechanical shape memory refers to the same process, but wherein

martensite is formed by the application of stress, rather than by cooling, and the release of stress allows the austenite phase to be restored without any change in temperature. tin this is an inherent property of Nitinol, one of the SMAs used in most medical devices in the late 1970's and early 1980's.

To assist the Board in understanding these SMA properties, Petitioners have submitted the declaration of Mr. Scott M. Russell—an expert in shape memory alloys—providing a detailed explanation of the inherent properties of SMAs ("Expert Report" or "ER," **Exhibit 1009**), as well as a video presentation by Mr. Russell providing further explanation of these inherent properties ("Inherent Properties Video," **Exhibit 1016**). Mr. Russell focuses on the properties of "Nitinol," a shape memory alloy formed of nickel and titanium. Nitinol is the most widely used shape memory alloy in medical applications, is referenced throughout the 141 patent, and is the SMA disclosed in all of the prior art references discussed herein. 141 patent, 9:14 to 10:7. As discussed in detail below, an understanding of the inherent properties of Nitinol will be important in assessing validity of the IPR Claims.

B. Prosecution History Of The 141 Patent: Issuance Based On a False Representation Of The Properties Of Nitinol

The 141 patent characterizes the improvement of its claimed medical device as "the substitution of an alloy element *which displays stress-induced martensite at*

body temperature." *Id*. at 3:1-4 (emphasis added). In particular, the 141 patent suggests that the known shape memory elements in medical devices only exhibited TIM, which rendered them more difficult to deliver into the body due to the requirement for temperature control. *Id*. at 1:26 to 2:54; 9:14 to 10:7. In particular the specification identifies the desirability of "a way to in which the advantageous property of shape memory alloys, i.e., their ability to return to an original shape after relatively substantial deformation, could be used in the 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. at 2:48-54. This passage incorrectly states that the Nitinol SMA devices in the prior art listed in the Background did not already possess those properties – they did. The statement that by "substituting" an alloy element exhibiting SIM for one that exhibits TIM, the shape memory alloy element is more easily deliverable and therefore a significant improvement over the prior art (*Abstract* & 2:59 to 3:4) is at best misleading.

During prosecution, the Examiner issued a Final Office Action rejecting the IPR Claims as being obvious in view of Balko, Kirk-Othmer, and Foster. Prosecution History of 141 patent ("141 History," **Exhibit 1012**), Final OA, Sept. 15, 1997, pp. 2-3. The Examiner found that Balko disclosed every feature of independent Claims 1, 6, and 18—a shape memory alloy in the form of a Nitinol

wire graft (22) and a hollow placement device in the form of a sheath (50)—but lacked specific disclosure that its Nitinol wire was pseudoelastic and capable of exhibiting stress-induced martensite.[1] The Examiner recognized that Kirk-Othmer discloses that Nitinol is inherently capable of exhibiting pseudoelastic behavior, that it was therefore obvious that Balko's Nitinol device has pseudoelastic properties, because it was well known in the art that pseudoelastic Nitinol could inherently exhibit a stress-induced martensite state at body temperature. *Id*. at 2.

Medtronic Appealed to the Board and submitted with its arguments a declaration by Dr. Middleman, whom Medtronic represented was "an expert in the field of stress-induced martensite (SIM) alloy elements." 141 History, Appeal Brief, Jun. 18, 1998, p. 18 and Middleman Dec. Dr. Middleman stated:

> Although nitinol can exhibit properties of an SIM material, it can do so *only if it undergoes a treatment process to make it exhibit the properties of an SIM material*. This process requires an extensive, time consuming, and expensive procedure. Where is the suggestion in Balko or any of the other references to use nitinol exhibiting SIM behavior rather than less expensive conventional Nitinol? There is no such suggestion . . . . *Id*. at Middleman Dec, p. 4 (emphasis added).

[1] The Examiner also felt Balko lacked sufficient disclosure of a guide wire, and pointed to Foster for disclosure of this feature. *Id*. at 3.

In its Decision, the Board reversed the Examiner's rejections, relying principally on Dr. Middleman's declaration.

> As shown by Kirk-Othmer and the Middleman declaration, *nitinol does not exhibit SIM properties unless it receives additional treatment*, of which there is no suggestion in Balko. We therefore conclude that the examiner has not made out a prima facie case that the SMAs disclosed by Balko would inherently display SIM properties. *Id*. at Decision on Appeal, Feb. 26, 2001, p. 6 (emphasis added).

While the Board understandably accepted Dr. Middleman's representations because in the ex parte appeal process Medtronic represented he was an expert in SIM with knowledge of Nitinol processing, the reality is that Dr. Middleman has since admitted that he is not an expert in SIM.

In 2007, Medtronic sued AGA Medical Corp. ("AGA") for infringement of, *inter alia*, the 141 patent. *Medtronic, Inc. et al. v. AGA Medical Corporation*, Case No. C07 00567 MMC (N.D.C.A.) (settled and dismissed in 2010). During the course of litigation, Dr. Middleman was deposed. Deposition of Dr. Middleman, Dec. 10-10, 2008 ("Middleman Deposition," **Exhibit 1015**). Contrary to Medtronic's representation to the Board that Dr. Middleman was an expert in the field of SIM, Dr. Middleman testified that, not only was he not an expert in SIM, but that he could not even recall the meaning of SIM.

Middleman Deposition, p. 100:

Q. Did you ever consider yourself to be an expert in the use of stress-induced martensite materials?
A. No.
Q. Did you ever consider yourself to be an expert in the use of stress-induced martensite materials in medical devices?
A. I would not have characterized myself as an expert, no.

Middleman Deposition, p. 29:

Q. When did you first learn about a characteristic called SIM?
A. SIM? Remind me --
Q. You don't know what SIM is as you sit here now?
A. I don't.

Middleman Deposition, p. 29:

Q. If you'll look at column 2 of the '989 patent, line 52. If you'll read those two paragraphs beginning at line 52.
A. Okay.
Q. Do you recall whether there was any special work that needed to be done to get the nitinol that could exhibit the superelastic effects described in the paragraph at column 2, lines 57 through 60?
A. No, I don't.

Middleman Deposition, p. 34:

Q. So your entire experience with shape-memory alloy products was in the 1989 through 1991 time frame?
A. I believe so. I mean, as I said to you, I was exposed to nitinol before that, but it was just one of many Raychem technologies.
Q. When you said you were exposed to nitinol before that, that was just kind of playing around with the wires --
A. Yes.

Middleman Deposition, p. 229:

Q. Well, if you believed it was true, correct?
A. Yes.
Q. And you have admitted you are not an expert in the manufacturing of stress-induced martensite.
A. Correct.

Middleman Deposition, p. 100:

Q. Isn't it true that you believed you had expertise in the use of nitinol in medical devices?
A. I was definitely not an expert in nitinol.
Q. You were not an expert in stress-induced martensite?
A. Absolutely not.

Middleman Deposition, p. 146-148:

Q. Sure. When you were working at Raychem, did you ever do any investigation to determine how costly, how expensive it is to create an alloy that had a stress-induced martensite effect at about body temperature in the 30 to 40 degrees C range?
A. No.
Q. Did you ever gather up any knowledge as to how expensive it is to create shape-memory alloys that have a stress-induced martensite effect at all regardless of the temperature range?
A. I was aware that it was a complex process, that it was an expensive process. But that's all.
Q. Where did you get that information?
A. People like Jack Harrison and Tom described in general terms. I've seen the equipment that they were using to heat the metals. I saw the quantities they produced.
Q. Do you know whether it was more expensive to create a shape-memory alloy with stress-induced martensite as opposed to a shape-memory alloy?
A. I don't.
Q. Did you ever know that?
A. I don't think so.
Q. Ever did any studies with regard to that?
A. No.
Q. So all your knowledge about the cost and complexity and everything, that's just hearsay that you heard from people in the metals division at Raychem?
MS. ESPINOSA: I'll object to the extent you made a legal characterization.
THE WITNESS: Yeah, I think that's true.

Middleman Deposition, p. 29:

Q. Stress-induced martensite is sometimes referred to as superelasticity, correct?
A. I don't know.

Id. at pp. 29, 34, 100, 146-148, 229.[2]

As explained by Mr. Russell, an actual expert in SMAs, ***all Nitinol alloys that can exhibit thermally-induced martensite (TIM) can inherently also exhibit stress-induced martensite (SIM)***. ER, pp. 11-16. This follows fundamental thermodynamic principles and, in fact, ***no special treatment is required for a Nitinol alloy that exhibits TIM to also exhibit SIM***. *Id*. As such, the Examiner was correct that Balko's Nitinol wire—which exhibits TIM—would inherently be capable of exhibiting SIM. *See* Balko, 3:30 to 4:47 (thermal transformation from martensite to austenite). The requirement for "special treatment" set forth by Dr. Middleman—and upon which the Board based its Decision on Appeal—is quite simply false. *Id*. at 11-16 and 27-31.

Given that the Board's reliance on the Middleman Declaration was misplaced, the IPR Claims should be invalidated as being obvious under § 103(a) in view of the references relied on by the Examiner—Balko, Kirk-Othmer, and Foster. In addition, other references disclose all of the features of Claims 1-10 and 18-22, some of which—Dotter and Miyauchi—were not considered during prosecution of the 141 patent.

[2] Statements indicated "A" were made by Dr. Middleman; statements indicated "Q" were made by AGA's counsel Mr. Steve Hemminger.

All of the prior art reference discussed below use a Nitinol alloy element in a medical device. In considering them, it is important to bear in mind three inherent properties of Nitinol alloys in assessing the validity of the IPR Claims:

- Nitinol alloys that exhibit TIM also inherently exhibit SIM.
- In such Nitinol alloys, martensite is martensite and there is no difference between martensite formed by changing temperature and martensite formed by changing stress.
- Any Nitinol material that can exhibit TIM will be pseudoelastic if stressed between A_S and M_D temperatures.

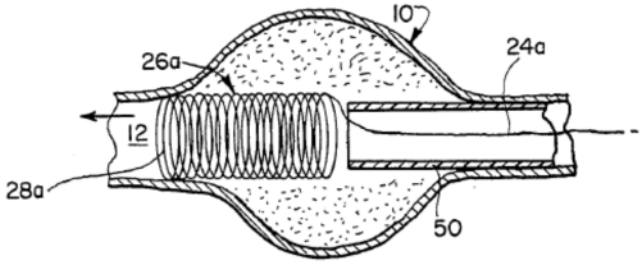
The scientific basis for each of these inherent properties is described in detail in Petitioner's Expert Report and Inherent Properties Video.

C. The IPR Claims are Obvious in view of Balko, Kirk-Othmer, and Foster[3] under § 103(a)

Balko discloses various embodiments of a Nitinol coil (24) configured for insertion into a human body. As shown in Fig. 6 below, the Nitinol coil (24) is configured to be deformed to a martensitic state in which it is a "relatively straight length of wire" for delivery into a human body through a sheath. Balko, 3:54-63.

[3] Balko was filed on Jan. 25, 1983 and issued on Apr. 23, 1985, and thus qualifies as prior art under § 102(e). Kirk-Othmer was published in 1982 and thus qualifies as prior art under § 102(a). Foster was filed on Aug. 24, 1982 and issued on Dec. 4, 1984, and thus qualifies as prior art under § 102(e).

Upon extrusion out of the sheath and into a blood vessel, the Nitinol wire (24) reverts back to its austenitic coil configuration to maintain the patency of the vessel. *Id*. at 3:54-63; Figs. 1-8.



Balko Figure 6

Balko's Nitinol coil (24) is inherently capable of exhibiting the same behavior as the memory alloy element and stent recited in the IPR Claims. For example, Balko teaches that its Nitinol coil (24) is capable of thermal transformation between its austenitic and martensitic states (i.e., the coil exhibits TIM). *Id*. at 3:30 to 4:12. Because any Nitinol alloy that exhibits TIM is inherently capable of exhibiting SIM, Balko's Nitinol coil (24) can inherently exhibit SIM. *See* ER, pp. 11-16. Moreover, Balko teaches that its coil can be alloyed to have an A_F temperature below body temperature. Balko, 3:54 to 4:12. As discussed in the Expert Report, an alloy's A_F temperature is inherently above its A_F temperature. ER, pp. 16-20. Accordingly, the coil (24) inherently can form SIM at and below body temperature. Balko, 3:54 to 4:12; *see also* ER, pp. § 2. As taught in Kirk-Othmer and explained in Russell's Expert Report, Balko's Nitinol

coil (24) is inherently capable of exhibiting pseudoelastic behavior. K-O, 727-28, 731, Table 1; *see also* ER, pp. 16-22.

A detailed chart showing where each feature of the IPR Claims is disclosed in Balko, Kirk-Othmer, and Foster follows. For the each of the claim charts below, Petitioner notes that reference can be made to the corresponding claim charts in the attached Expert Report (Exhibit 1009) for the opinions of Mr. Scott M. Russell.

Kirk-Othmer discusses properties of shape memory alloys, while Foster discloses a guide wire to insert a medical device into a human body. Thus, a person of ordinary skill would have found motivation to look to and utilize their respective teachings with Balko's teachings of the benefits of a shape memory medical device.

141 Patent: Claims 1-10 & 18-22	**Balko (Exh. 1002) + Kirk-Othmer (Exh. 1003) + Foster (Exh. 1014)**
1. A medical device for insertion into a mammalian body, the device comprising	Non-limiting preamble. However, Balko discloses a Nitinol wire coil (24) configured for insertion into a human vessel, such as an artery. Abstract; 2:27 to 6:16; Figs. 1-8.[4]
(a) a hollow placement device;	Balko discloses a hollow placement device in the form of a sheath (20). 3:4-29.
(b) a memory alloy element	Balko discloses a memory alloy element in the form of a Nitinol wire coil (24/24a/26/26a, collectively "24"). 3:30 to 6:7; Figs. 1-8.
formed at least partly	Balko discloses a Nitinol coil (24) having a transition

[4] Column, line, page numbers and the like in each claim chart refer to a respective chart's lead reference unless otherwise indicated.

from pseudoelastic shape-memory alloy,	temperature (A_F) at which the coil will thermally transform from martensite to austenite. 3:30 to 4:47. Above A_F, Balko's Nitinol coil (24) is inherently pseudoelastic. Expert Report (herein "ER"), § II. Kirk-Othmer also recognizes the inherent pseudoelasticity of Balko's Nitinol coil. Kirk-Othmer ("K-O"), 727-28, 731, Table 1.
the alloy displaying reversible stress-induced martensite at about body temperature such that it has a stress-induced martensitic state and an austenitic state,	Balko's Nitinol coil can be thermally transformed between austenite and martensite (i.e., the coil can exhibit TIM). 3:30 to 4:12. All Nitinol alloys that exhibit TIM inherently can exhibit SIM. ER, § II. Balko's coil (24) is alloyed such that it will thermally transform from martensite to austenite at a transformation temperature (A_F) that is "somewhat below the normal body temperature." 3:54 to 4:12. Accordingly, at body temperature (above A_F), the Nitinol coil (24) can inherently be transformed to its martensitic state by stress (i.e., stress-induced martensitic state). *Id*. At body temperature and absent stress, the Nitinol coil (24) will inherently revert to back to its austenitic state (i.e., reversible transformation). ER, § II; K-O, 726-29, 731. For Balko's Nitinol coil (24), martensite is martensite and there is no difference between martensite formed by applying stress and martensite formed by adjusting temperature. ER, § II.
the memory alloy element having (i) a deformed shape when the alloy is in its stress induced martensitic state and (ii) a different unstressed shape when the alloy is in its austenitic state; and	Balko discloses that its Nitinol coil (24) can be deformed in its martensitic state to a "relatively straight length of continuous wire" (deformed shape) and returns to a continuous coil shape (unstressed shape) when in its austenitic state. 3:54-63, Figs. 1-8. As discussed above, the transformation between these shapes can be caused by stress or temperature and—for Balko's coil—there is no difference between martensite formed by changing stress and martensite formed by changing temperature. ER, § II; K-O, 726-27, 731.
(c) a guide wire;	Balko discloses a guide wire in the form of its member (52), which is a "wire" element configured to help a surgeon manipulate the sheath (20). 4:38-47.

	Foster discloses use of a guide wire in the form of a stylette (16) configured for guiding a medical device into a body cavity. Foster, 3:62 to 4:51, 5:21-46.
the memory alloy element being within the hollow placement device, and	Balko discloses that its Nitinol wire coil (24) (memory alloy element) is configured for placement in its sheath (20) (hollow placement device). 4:4-36; col. 5:13-47; Figs. 5-8.
the placement device being guidable by the guide wire,	The sheath (20) is inserted by "conventional techniques," which one of ordinary skill would know includes guiding by a guide wire. 3:4-13; Fig. 1. Balko also states the wire member (52) enables positioning of the sheath (20). 4:38-47. Foster discloses its stylette (16) enables positioning of a medical device in a body cavity. Foster, 3:62 to 4:51, 5:21-46.
the hollow placement device stressing the memory alloy element at a temperature greater than the A_S of the alloy so that the memory alloy element is in its deformed shape,	The Nitinol coil (24) in its coiled shape has a diameter sufficient to maintain the patency of a blood vessel, while the sheath (20)—through which the coil (24) is fed—has a smaller diameter for insertion into a blood vessel. 3:4-29; 4:13-57. When positioned within the sheath (20) and delivered into the body, the coil (24) heats to body temperature (just above the coil's A_F and inherently above A_S) and thus inherently attempts to revert from its deformed martensitic shape back to its larger austenitic state. K-O, 726-27, 729; ER, § II. The coil remains in its deformed shape because the sheath (20) constrains it by applying stress as the coil attempts to expand. *Id*.
wherein the memory alloy element can be extruded from the hollow placement device by the guide wire at a temperature greater than the A_S of the alloy to transform at least a portion of the alloy from its stress-induced martensitic state so that the memory alloy	As noted above, it would have been obvious to a person of ordinary skill to use a guide wire to extrude the Nitinol coil (24) from the sheath (20), and Balko discloses the coil (24) can be extruded by the wire member (52) or "further wire." 4:13 to 5:40; *see also* Foster, 3:62 to 4:51, 5:21-46. In Balko's A_F = below body temperature embodiment, the Nitinol coil (24) since it is restrained in the sheath (20) is still held in a martensitic state by stress as it is passed through the sheath (20) at body temperature. 3:54 to 4:57; K-O, 726-731. When the coil (24) is extruded from the sheath (20) into the blood vessel, the coil (24) stays at

element transforms from its deformed shape to its unstressed shape,	body temperature (above A_S), the stress applied by the sheath (20) is removed, and the coil transforms from its deformed martensitic shape to its unstressed austenitic shape. K-O, 727-28, 731, Table 1 (pseudoelasticity); ER, § II.
and wherein the alloy is selected so that the transformation can occur without any change in temperature of the placement device or the memory alloy element.	As Balko discloses A_F is just below body temperature, the coil (24) will be above A_F when it is in the sheath (20) in the blood vessel. When the coil is extruded from the catheter (24) (i.e., the stress is removed), the coil inherently transforms from its stressed, martensitic state to its unstressed, austenitic shape without a change in temperature of the coil or the sheath (20). K-O, p. 727-28, 731; ER, § II.
2. The device of claim 1 wherein the memory alloy element is a stent.	Balko discloses that its Nitinol coil is configured for use as a stent in maintaining the patency of a blood vessel, such as the aorta. 4:13-57.
3. The device of claim 2, including a guide wire for endarterial placement of a stent graft.	Balko discloses that its Nitinol coil may be secured to a fabric graft (22) and it would have been obvious to a person of ordinary skill to the place the resulting stent graft using a guide wire. 3:4-53. Foster also discloses use of a guide wire (16) for guiding a medical device into a body cavity. Foster, 3:62 to 4:51, 5:21-46.
4. The invention of claim 1 wherein the transformation occurs without any change in the state of the placement device.	As detailed above, the aforementioned transformation of Balko's coil (24) from its martensitic state to its austenitic state occurs through a change in stress; no change in state of the sheath (20) is required. K-O, p. 731; ER, § II.
5. The device of claim 1, wherein the hollow placement device is a catheter.	Balko discloses a catheter in the form of its sheath (20). 3:4 to 4:57.
6. A medical device which comprises:	Non-limiting preamble. Balko discloses an apparatus for delivering a Nitinol wire coil (24) into a human vessel. Abstract; 2:27 to 6:16; Figs. 1-8.
(a) a stent for endarterial placement within a human body so that the	Balko discloses a stent in the form a Nitinol wire coil (24) configured for endarterial placement in a blood vessel, such as an artery. 2:55-59; 3:30-39 to 5:26.

stent is substantially at human body temperature,	Upon insertion into the blood vessel, the Nitinol coil (24) will be at human body temperature.
the stent comprising a shape memory alloy which displays stress induced martensite behavior at body temperature; and	Balko's Nitinol coil can be thermally transformed between austenite and martensite (i.e., the coil can exhibit thermally-induced martensite, or "TIM"). 3:30 to 4:12. All Nitinol alloys that exhibit TIM inherently can exhibit "stress-induced" martensite, or "SIM." ER, § II. Balko's coil (24) is alloyed such that it will thermally transform from martensite to austenite at a transformation temperature (A_F) that is "somewhat below the normal body temperature." 3:54 to 4:12. Accordingly, at body temperature (above A_F), the Nitinol coil (24) can inherently be transformed to its martensitic state by stress (i.e., stress-induced martensitic state). *Id*. For Balko's Nitinol coil (24), martensite is martensite and there is no difference between martensite formed by applying stress and martensite formed by adjusting temperature. ER, § II.
(b) a restraint holding the stent in a deformed configuration at a temperature less than the body temperature of the human for endarterial positioning of the stent within the human body in its deformed configuration, the deformation occurring through stress induced martensite;	Balko's sheath (20) (restraint) is used for endarterial positioning of the Nitinol coil (24) in a human blood vessel. 3:4 to 5:40. Balko discloses that the Nitinol coil (24) can have an A_F below body temperature and—as discussed above in relation to Claim 1—the sheath (20) is capable of holding the coil (24) in a deformed, martensitic state with the coil at A_F (below body temp). 3:54 to 4:12; ER, § II. Moreover, it would have been obvious to a person of ordinary skill in view of Nitinol's known pseudoelasticity to configure the coil with a room temperature A_F. K-O, 731, 733; ER, § II. In such an embodiment, when the Nitinol coil (24) is inserted into the sheath (20) at room temperature (below body temp) for delivery into the body, the sheath (20) would deform the coil from its austenitic state to its martensitic state through stress and hold the coil in this configuration as it is delivered to the body (below body temp until the coil reaches the blood vessel).

wherein the stent is sufficiently deformed that when the stent is at human body temperature removal of the restraint of the stent, without change in temperature of the device, releases at least a portion of the stent from its deformed configuration.	When the deformed Nitinol coil (24) is extruded from the sheath (20) in the blood vessel at body temperature (above the coil's A_F), the coil (24) inherently reverts to its unstressed, austenitic coil configuration due to the release of the stress applied by the sheath (20). 3:54 to 5:40, Figs. 1-8; K-O, 731, 733; ER, § II. This occurs without a change in temperature as the coil (24) is inherently at body temperature when positioned in the sheath (20) in the vessel, and remains at body temperature when extruded into the blood vessel.
7. A device as claimed in 6, in which the restraint is hollow, and the stent is positioned at least partially within the restraint.	Balko's sheath (20) is hollow (hollow restraint) and its Nitinol coil (24) is configured for delivery through the sheath (20) (stent partially within restraint). 3:4 to 5:40; Figs. 1-8.
8. A device as claimed in claim 6 or 7, in which the restraint is a catheter.	Balko's sheath (20) is a catheter. 3:4 to 4:57.
9. A device as claimed in claim 6 or 7, in which the stent has a transverse dimension and a longitudinal dimension, wherein the stent is deformed by its transverse dimension being reduced, and wherein the restraint prevents transverse expansion of the stent.	Balko's Nitinol coil (24) has a transverse dimension and a longitudinal dimension. Figs. 1-8. The coil (24) is deformed by its transverse dimension being reduced (from a continuous coil in its austenitic state to a straight length of wire in its martensitic state). 3:54 to 4:57. As discussed above, Balko's sheath (20) is dimensioned to prevent transverse expansion of the Nitinol coil (24) from its martensitic state to its austenitic state when the coil (24) is positioned within the sheath (20). Figs. 1-8; s*ee discussion of Claim 1*.
10. The device of claim 6, wherein the shape memory alloy is sufficiently deformed that removal of the restraint from the shape memory alloy releases at least a portion of the	When the deformed Nitinol coil (24) is extruded from the sheath (20) in the blood vessel at body temperature (above the coil's A_F), the coil (24) inherently reverts to its unstressed coil configuration due to the release of the stress applied by the sheath (20). 3:54 to 5:40, Figs. 1-8; K-O, 731, 733; ER, § II. This transformation occurs at body temperature due to a change in stress applied to the coil (24) without

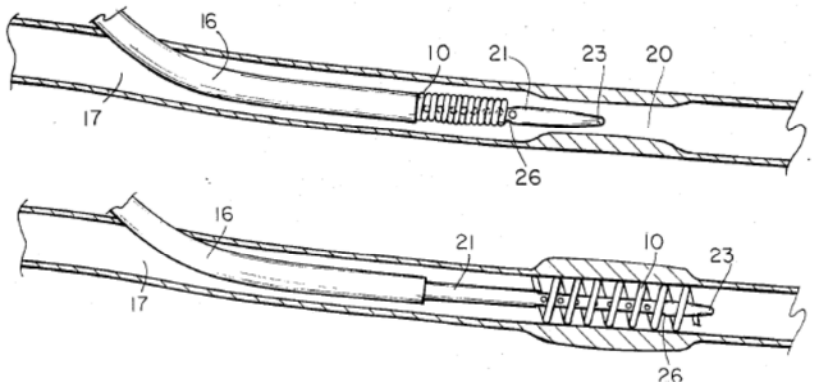
shape memory alloy element from its deformed configuration without change in state of restraint.	any need for a change in state of the sheath (20). *See discussion of Claim 6*.
18. A medical device comprising:	Non-limiting preamble. Balko discloses an apparatus for delivering a Nitinol wire coil (24) into a human vessel. Abstract; 2:27 to 6:16; Figs. 1-8.
(a) a wire stent	Balko discloses a wire stent in the form of a Nitinol wire coil (24). 2:55-59; 3:30-39 to 5:26.
formed at least partly from a pseudoelastic shape memory alloy,	Balko discloses its Nitinol coil (24) has a transition temperature (A_F) at which the coil will thermally transform from martensite to austenite. 3:30 to 4:47. Above A_F, Balko's Nitinol coil (24) is inherently pseudoelastic. Expert Report (herein "ER"), § II. Kirk-Othmer also recognizes the inherent pseudoelasticity of Balko's Nitinol coil. Kirk-Othmer ("K-O"), 727-28, 731, Table 1.
the alloy displaying reversible stress-induced martensite at about human body temperature such as it has a deformed shape when the alloy is in its stress induced martensitic state and a different unstressed shape when the alloy is in its austenitic state; and	Balko's Nitinol coil can be thermally transformed between austenite and martensite (i.e., the coil can exhibit TIM). 3:30 to 4:12. All Nitinol alloys that exhibit TIM inherently can exhibit SIM. ER, § II. Balko's coil (24) is alloyed such that it will thermally transform from martensite to austenite at a transformation temperature (A_F) that is "somewhat below the normal body temperature." 3:54 to 4:12. Accordingly, at human body temperature (above A_F), the Nitinol coil (24) can inherently be transformed to its martensitic state by stress (i.e., deformed stress-induced martensitic state). *Id*. At body temperature and absent stress, the Nitinol coil (24) will inherently revert to back to its austenitic state (i.e., reversible transformation). ER, § II; K-O, 726-29, 731. As noted above, for Balko's Nitinol coil (24), martensite is martensite and there is no difference between martensite formed by applying stress and martensite formed by adjusting temperature. ER, § II.
(b) a restraint stressing the wire stent at a temperature greater than	Balko discloses a restraint in the form a sheath (20). 3:4-29. The Nitinol coil (24) in its coiled shape has a diameter sufficient to maintain the patency of a blood

the A_S of the alloy so that the wire stent is in its deformed shape,	vessel, while the sheath (20)—through which the coil (24) is fed—has a smaller diameter for insertion into a blood vessel. 3:4-29; 4:13-57. When positioned within the sheath (20) and delivered into the body, the coil (24) heats to body temperature (just above the coil's A_F and inherently above A_S) and thus inherently attempts to revert from its deformed martensitic shape back to its larger austenitic state. K-O, 731, 733; ER, § II. The coil remains in its deformed shape because the sheath (20) constrains it by applying stress as the coil attempts to expand. *Id*.
wherein the stent can be disengaged from the restraint upon placement in a human so that the stent transforms from its deformed shape to its unstressed shape, and	As shown in Figs. 1-8, the Nitinol coil (24) can be extruded from the sheath (20) and placed into a human blood vessel. 3:54-5:40. As noted above, upon extrusion from the sheath (20), the coil (24) will inherently transform from its deformed relatively straight shape back to its unstressed coil shape. ER, § II; *see discussion of Claim 1*.
wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraint or the wire stent.	As discussed above, in the blood vessel the coil (24) heats to body temperature (above A_F) and is inherently constrained in its deformed martensitic state by stress applied by the sheath (20). 3:30 to 4:47. Upon extrusion from the sheath (20), the stress is removed and the coil (24) inherently transforms back to its austenitic shape. Figs. 1-8; K-O, 731, 733; ER, § II. No change in the temperature of the sheath (20) or the coil (24) is required as the transformation is caused by changing stress. ER, § II.
19. The device of claim 6, 11, 15, 16 or 18, including a guide wire for endarterial placement of the stent.	Balko discloses the coil (24) can be positioned in the blood vessel by the wire member (52) or "further wire." 4:13 to 5:40. Moreover, it would have been obvious to a person of ordinary skill to use a guide wire for endarterial placement of the coil (24). Foster also discloses use of a guide wire (16) for guiding a medical device into a body cavity. Foster, 3:62 to 4:51, 5:21-46.
20. The device of claim 15, 16, or 18, wherein the transformation of the alloy occurs without any	As detailed above, the aforementioned transformation of Balko's coil (24) from its martensitic state to its austenitic state occurs by changing stress; no change in state of the sheath (20) is required. K-O, p. 731;

change in state of the restraint.	ER, § II.
21. The device of claim 1, 15, 16, or 18, wherein the restraint is a catheter.	Balko discloses a catheter in the form of its sheath (20). 3:4 to 4:57.
22. The device of Claim 1, 11, 15 or 18 wherein the stent is a coil stent.	Balko discloses a Nitinol wire coil (24) for use as a stent. 3:30 to 6:7; Figs. 1-8.

D. The IPR Claims are Anticipated by Dotter under § 102(e)

Dotter was considered during prosecution of the 141 patent. Dotter was filed on Mar. 3, 1983 and issued on Mar. 12, 1985, and qualifies as prior art under § 102(e). Dotter discloses a Nitinol coil (10) configured for delivery through a catheter (16) and into a blood vessel lumen (17). Dotter, 3:15 to 5:20, Figs. 1-6. As shown in Dotter's Figures 4 and 6 below, the Nitinol coil (10) has a deformed, narrow coil shape in its martensitic state for delivery through the catheter (16). *Id*. at 3:44-66; Figs. 1 and 5. Upon extrusion out of the catheter (16) and into the blood vessel lumen (17), the Nitinol coil (10) reverts back to its austenitic state and its undeformed wider coil shape. *Id*. at 3:44-66; Figs. 2 and 6.



Dotter Figures 4 & 6

Dotter's Nitinol coil (10) is inherently capable of exhibiting the same behavior as the memory alloy element and stent recited in the IPR Claims. For example, Dotter discloses that its Nitinol coil (10) is capable of thermal transformation between its austenitic and martensitic states (i.e., the coil exhibits TIM). *Id*. at 3:15 to 4:40. Because any Nitinol alloy that exhibits TIM is inherently capable of exhibiting SIM, Dotter's Nitinol coil (10) can inherently exhibit SIM. *See* ER, pp. 11-16. Moreover, Dotter teaches that its coil's A_F temperature can be adjusted over a wide range depending on the desired application (i.e., a design choice) and identifies body temperature as one example. Dotter, 3:15-28 and 5:14-21. As such, the coil (10) would inherently be capable of exhibiting SIM can be alloyed to exhibit SIM below body temperature as well (e.g., at room temperature) depending on the application. *See* ER, pp. 18-19. Finally, as discussed in Russell's Expert Report, Dotter's Nitinol coil is inherently capable of exhibiting pseudoelastic behavior. *See* ER, pp. 16-22, 40-42.

A detailed chart showing where each limitation of the IPR Claims is taught in Dotter follows.

141 Patent: Claims 1-10 & 18-22	**Dotter (Exh. 1004)**
1. A medical device for insertion into a mammalian body, the	Non-limiting preamble. However, Dotter is directed to a "graft prosthesis which is useful for placement within a body passageway." 2:36-38.

device comprising	
(a) a hollow placement device;	Dotter discloses a hollow placement device in the form of a catheter (16) configured for insertion into a blood vessel lumen (17). 4:8-24; Figs. 3-6.
(b) a memory alloy element	Dotter discloses a memory alloy element in the form of a prosthesis (10), a coil of wire formed from a "shape memory Nitinol alloy." 3:17-21 and 2:44-46.
formed at least partly from pseudoelastic shape-memory,	Dotter teaches that the Nitinol alloy forming the coil (10) can be thermally transformed from martensite to austenite at a transformation temperature (A_F). 3:49-54. Above its A_F temperature, Dotter's Nitinol coil (10) is inherently pseudoelastic. ER, § II.
the alloy displaying reversible stress-induced martensite at about body temperature such that it has a stress-induced martensitic state and an austenitic state,	Dotter teaches that its Nitinol coil (10) can be thermally transformed between austenite and martensite (i.e., the coil can exhibit TIM). 3:15 to 4:40. All Nitinol alloys that exhibit TIM inherently can exhibit SIM. ER, § II. The coil (10) transforms thermally from martensite to austenite at a transition temperature (A_F), which in one embodiment is 98.6° F (i.e., body temp). 5:14-21. Accordingly, at body temperature (A_F), the Nitinol coil (10) can inherently be transformed to its martensitic state by stress (i.e., stress-induced martensitic state). ER, § II. At body temperature and absent stress, the Nitinol coil (10) will inherently revert to back to its austenitic state (i.e., the transformation is reversible). ER, § II. For Dotter's Nitinol coil, martensite is martensite and there is no difference between martensite formed by stress and martensite formed by temperature. *Id*.
the memory alloy element having (i) a deformed shape when the alloy is in its stress induced martensitic state and (ii) a different unstressed shape when the alloy is in its austenitic state; and	Dotter discloses that the Nitinol coil (10) has a deformed shape in its martensitic state (narrow coil). 3:44-66; Figs. 1 and 5. Again, martensite is martensite and there is no difference between martensite formed by stress and martensite formed thermally. ER, § II. In its austenitic state, the Nitinol coil (10) has a different unstressed shape (wider coil). 3:44-66; Figs. 2 and 6.
(c) a guide wire;	Dotter discloses a guide wire in the form of an inner guide catheter (21). 4:16-24 and Figs. 4-5.

the memory alloy element being within the hollow placement device, and	Dotter's Nitinol coil (10) (memory alloy element) is placed within and fed through the catheter (16) (hollow placement device) for delivery into a blood vessel. 4:8-24; Figs. 3-4.
the placement device being guidable by the guide wire,	Dotter discloses that the catheter (16) is "percutaneously inserted into blood vessel lumen 17 . . . using normal catheterization techniques" and shows that the catheter (16) is guidable by the inner guide catheter (21). 4: 8-16; Figs. 3-6.
the hollow placement device stressing the memory alloy element at a temperature greater than the A_S of the alloy so that the memory alloy element is in its deformed shape,	Dotter discloses that the Nitinol coil (10) in its austenitic state has a large diameter approximately equal to that of the blood vessel, while the catheter (16)—through which the Nitinol coil (10) is fed—has a diameter less than that of the coil (10) in its austenitic state. 3:32-63; 4:8-24. Accordingly, the catheter (16) stresses the Nitinol coil (10) when the coil is positioned therein at or above A_F (98.6° F in the aforementioned embodiment). 5:14-21; ER, § II. At A_F (which is above A_S), the Nitinol coil (10) would inherently attempt to revert from its deformed martensitic shape back to its large diameter, austenitic state and only remains in its deformed shape because of the stress applied by the catheter (16). *Id*. This occurs when the Nitinol coil (10) is fed through the catheter (16) within the blood vessel and heats to body temperature.
wherein the memory alloy element can be extruded from the hollow placement device by the guide wire at a temperature greater than the A_S of the alloy to transform at least a portion of the alloy from its stress-induced martensitic state so that the memory alloy element transforms from its deformed shape to its	The Nitinol coil (10) is "passed by external manipulation of the guide catheter 21 [guide wire] through and beyond catheter 16 to the desired site of placement in the . . . blood vessel lumen 17 [extruded from]." 4:17-24; Fig. 3. In the A_F = 98.6° F embodiment, the Nitinol coil (10) since it is restrained in the catheter (16) is still held in a martensitic state by stress as it is passed through the catheter (16) at body temperature. When the coil (10) is extruded from the catheter (16) into the blood vessel, the coil (10) remains at body temperature (above A_S) and transforms from its deformed martensitic shape to its unstressed austenitic shape. ER, § II.

unstressed shape,	
and wherein the alloy is selected so that the transformation can occur without any change in temperature of the placement device or the memory alloy element.	In the Nitinol coil's A_F = 98.6° F embodiment, the coil (10) will be at A_F when it is in the catheter (16) in the blood vessel. Therefore, when the coil is extruded from the catheter (16) (i.e., the stress is removed), the coil will transform from its stressed, martensitic state to its unstressed, austenitic shape without a change in temperature of the coil or catheter. 5: 21-30;ER, § II.
2. The device of claim 1 wherein the memory alloy element is a stent.	The Nitinol coil (10) can be used as a stent for "expanding partially occluded segments of a blood vessel passageway" or as a "stent supportive graft placement within blocked arteries." 5: 29-47.
3. The device of claim 2, including a guide wire for endarterial placement of a stent graft.	The Nitinol coil (10) is "passed by external manipulation of guide catheter 21 [guide wire] through and beyond catheter 16 to the desired site of placement in the narrowed segment 20 of blood vessel lumen 17 [endarterial placement]." 4:16-24. Dotter's coil (10) is a "graft prosthesis." 3:15-28.
4. The invention of claim 1 wherein the transformation occurs without any change in the state of the placement device.	As explained above, the Nitinol coil (10) can transform from its martensitic state to its austenitic state by changing stress and without any change in the state of the catheter (16) (placement device). *See discussion of Claim 1*.
5. The device of claim 1, wherein the hollow placement device is a catheter.	As discussed above, Dotter discloses a hollow catheter (16) configured for insertion into a blood vessel lumen (17). 4:10-20; Figs. 3-6.
6. A medical device which comprises:	Non-limiting preamble. Petitioner notes that Dotter discloses a graft prosthesis medical device as discussed above. 2:36-38.
(a) a stent for endarterial placement within a human body so that the stent is substantially at human body temperature,	Dotter discloses a Nitinol coil (10) for use as a stent for "expanding partially occluded segments of a blood vessel passageway" (endarterial placement within a human body), where the coil (10) would be at body temperature. 3:15-43; 5:29-47.
the stent comprising a shape memory alloy	Dotter's coil (10) is formed from a "shape memory Nitinol alloy." 3:17-21; 5:5-20.

which displays stress induced martensite behavior at body temperature; and	Dotter discloses various transition temperatures for its Nitinol coil, discloses that the transition temperature "can be manipulated over a wide range," and that such manipulation is well known to those skilled in the art. 3:15-28; 4:65 to 5:20; ER, § II. Room temperature may be selected as the A_F so Dotter's Nitinol coil (10) will be austenitic at room temperature. *Id*. In such an embodiment, the Nitinol coil (10) can inherently exhibit stress-induced martensite behavior at body temperature (above A_F) upon application of stress. 5: 21-30; ER, § II; *see discussion of Claim 1*. For Dotter's coil, martensite is martensite and there is no difference between martensite formed by changing temperature and martensite formed by changing stress. ER, § II.
(b) a restraint holding the stent in a deformed configuration at a temperature less than the body temperature of the human for endarterial positioning of the stent within the human body in its deformed configuration, the deformation occurring through stress induced martensite;	Dotter's catheter (16) (restraint) is used for endarterial positioning of the Nitinol coil (10) in the human body. 4:18-24; Figs. 3-6. As discussed above, Dotter teaches that the transition temperature of its Nitinol coil "can be manipulated over a wide range" and so the coil may inherently have an A_F of room temperature. 3:21-28; ER, § II. In such an embodiment, the Nitinol coil (10) is inserted into the catheter (16) at room temperature (i.e., below body temp) in its austenitic shape (wide diameter coil) for delivery into the body. 3:8-24; Fig. 3; ER, § II. The catheter (16) deforms the coil (10) through stress from its austenitic shape to its martensitic shape and holds the coil (10) in this deformed configuration. 5:5-20 (discussion of inserting coil (10) into catheter (16) at room temp).
wherein the stent is sufficiently deformed that when the stent is at human body temperature removal of the restraint of the stent, without change in temperature of the device, releases at least a portion of the	When the deformed Nitinol coil (10) is extruded from the catheter (16) at body temperature (above the coil's room temp A_F), the coil (10) reverts to its undeformed coil configuration without a change in temperature due to the release of the stress applied by the catheter (16). *See discussion of Claim 1*; ER, § II.

stent from its deformed configuration	
7. A device as claimed in 6, in which the restraint is hollow, and the stent is positioned at least partially within the restraint.	Dotter's catheter (16) is hollow (hollow restraint) and its Nitinol coil (10) is configured for delivery through the catheter (16) (stent partially within restraint). 4:8-24; Figs. 3-4.
8. A device as claimed in claim 6 or 7, in which the restraint is a catheter.	Dotter discloses a restraint in the form of a catheter (16) as detailed above. 4:8-24; Figs. 3-6.
9. A device as claimed in claim 6 or 7, in which the stent has a transverse dimension and a longitudinal dimension, wherein the stent is deformed by its transverse dimension being reduced, and wherein the restraint prevents transverse expansion of the stent.	Dotter's Nitinol coil (10) has a transverse dimension and a longitudinal dimension. Figs. 1-2. The coil (10) is deformed by its transverse dimension being reduced (transforming from a large diameter coil in the austenitic state to a narrower profile in the martensitic state). 3:29-63. As detailed above, Dotter's catheter (16) is dimensioned to prevent transverse expansion of the Nitinol coil (10) from its martensitic state to its austenitic state when the coil (10) is positioned within the catheter (16). *See also discussion of Claim 1*.
10. The device of claim 6, wherein the shape memory alloy is sufficiently deformed that removal of the restraint from the shape memory alloy releases at least a portion of the shape memory alloy element from its deformed configuration without change in state of restraint.	In embodiments where the Nitinol coil (10) has an A_F equivalent to room temperature, the coil (10) will inherently be held in its deformed martensitic state by stress as it passes through the catheter (16) at body temperature. Upon extrusion from the catheter (16) (i.e., removal of restraint), the coil (10) will revert back to its unstressed austenitic state. *See discussion of Claim 6*; ER, § II. This transformation occurs without any change in state of the catheter (16) (restraint).
18. A medical device comprising:	Non-limiting preamble. Petitioner notes that Dotter discloses a graft prosthesis medical device as discussed above. 2:36-38.
(a) a wire stent	Dotter discloses a wire coil (10) for use as a stent for

	"expanding partially occluded segments of a blood vessel passageway." 3:15-43; 5:29-47.
formed at least partly from a pseudoelastic shape memory alloy,	Dotter discloses that the Nitinol alloy forming the coil (10) can be thermally transformed from martensite to austenite at a transformation temperature (A_F). 3:49-54. Above its A_F temperature, Dotter's Nitinol coil (10) is inherently pseudoelastic. ER, § II.
the alloy displaying reversible stress-induced martensite at about human body temperature such as it has a deformed shape when the alloy is in its stress induced martensitic state and a different unstressed shape when the alloy is in its austenitic state; and	Dotter discloses that its Nitinol coil (10) can be thermally transformed between austenite and martensite (i.e., the coil can exhibit TIM). 3:15 to 4:40. All Nitinol alloys that exhibit TIM inherently can exhibit SIM. ER, § II. The coil (10) transforms thermally from martensite to austenite at a transition temperature (A_F), which in one embodiment is 98.6° F (i.e., body temp). 5:14-21. Accordingly, at body temperature (A_F), the Nitinol coil (10) can inherently be transformed to its martensitic state by stress (i.e., stress-induced martensitic state). ER, § II. In particular, Dotter notes that its coil may have a small diameter in this martensitic state. 3:29-66. At body temperature and absent stress, the Nitinol coil (10) will inherently revert to back to its unstressed, larger diameter (different) austenitic state (i.e., the transformation is reversible). ER, § II. For Dotter's coil, martensite is martensite and there is no difference between martensite formed by changing stress and martensite formed by adjusting temperature. *Id*.
(b) a restraint stressing the wire stent at a temperature greater than the A_S of the alloy so that the wire stent is in its deformed shape,	As discussed above, Dotter's catheter (16) is necessarily dimensioned to stress the Nitinol coil (10) when it is positioned in the catheter (16) and reaches body temperature (inherently above A_S in the A_F=98.6 F embodiment). 4:10-20; 5:5-20; Figs. 3-6; ER, § II. At body temperature, the Nitinol coil (10) inherently attempts to revert back to its larger-diameter, austenitic state and is held in its deformed position by stress applied by the catheter (16). *Id*.
wherein the stent can be disengaged from the restraint upon placement	As discussed above, when the Nitinol coil (10) is extruded from the catheter (16) at body temperature, it will inherently revert to its undeformed, large-

in a human so that the stent transforms from its deformed shape to its unstressed shape, and	diameter coil configuration due to the release of stress on the coil (10). ER, § II; *see discussion of Claim 1*.
wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraint or the wire stent.	As discussed above, the transformation of the coil from martensite to austenite is caused by changing stress and occurs without any necessary change in temperature of the catheter (16) or Nitinol coil prosthesis (10). 5: 21-30; ER, § II; *see discussion of Claim 1*.
19. The device of claim 6, 11, 15, 16 or 18, including a guide wire for endarterial placement of the stent.	Dotter discloses that its Nitinol coil (10) is "passed by external manipulation of guide catheter 21 [guide wire] through and beyond catheter 16 to the desired site of placement in the narrowed segment 20 of blood vessel lumen 17 [endarterial placement]." 4:1 6-24.
20. The device of claim 15, 16, or 18, wherein the transformation of the alloy occurs without any change in state of the restraint.	As discussed above, the aforementioned transformation occurs without any necessary change in state of the catheter (16). 5: 21-30; ER, § II; *see discussion of Claim 1*.
21. The device of claim 1, 15, 16, or 18, wherein the restraint is a catheter.	As discussed above, Dotter discloses a catheter (16) configured for insertion into a blood vessel lumen (17). 4:10-20; Figs. 3-6.
22. The device of Claim 1, 11, 15 or 18 wherein the stent is a coil stent.	Dotter discloses a wire coil (10) for use as a stent for "expanding partially occluded segments of a blood vessel passageway." 3:15-43; 5:29-47.

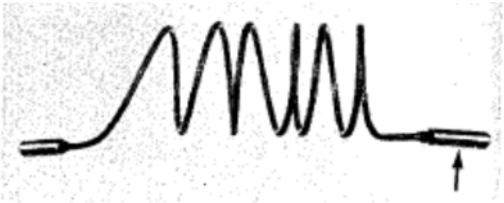
E. Claims 6-10 are Obvious in view of Dotter under § 103(a)

As described above, Petitioner believes that Claims 6-10 are anticipated by Dotter. To the extent the Board believes that Dotter fails to disclose that its Nitinol coil (10) has an A_F of about room temperature and/or that Dotter fails to disclose a restraint holding the stent in a deformed configuration at a temperature less than

the body temperature, Petitioner respectfully asserts that it would have been an obvious design choice to a person of ordinary skill to select room temperature as the A_F so the Nitinol coil (10) will be austenitic at room temperature as taught by Dotter. Dotter, 3:15-28; 4:65 to 5:20; *see also* ER, pp. 16-22, 40-42. In such an embodiment, a person of ordinary skill would readily appreciate that the catheter (16) would hold the stent in a deformed configuration at a temperature less than the body temperature. Accordingly, in the alternative Claims 6-10 are obvious in view of Dotter.

F. Claims 1-5 and 18-22 are Anticipated by Cragg under § 102(a)

Cragg discloses a Nitinol coil configured for delivery into a human body using a catheter. Cragg, 261-26, Fig. 1. Cragg was published at least as early as Mar. 22, 1983, and qualifies as prior art under § 102(a). Cragg discloses that its Nitinol coil can be transformed to a deformed martensitic state where it is straight and pliable and placed in a catheter. *Id*. Upon extrusion out of the catheter, the Nitinol coil is transformed back to an undeformed austenitic state where it has a coil profile for maintaining the patency of a vessel. *Id*.



Cragg Figure 1

Cragg's Nitinol coil is inherently capable of exhibiting the same behavior as the medical devices recited in the IPR Claims. For example, Cragg discloses that its Nitinol coil has an A_F temperature "at or near body temperature" (in one embodiment 36° C). *Id*. Cragg also discloses that its Nitinol coil is placed within a blood vessel by extruding the Nitinol coil from the catheter. Once the coil is in place in the human body, it will be at body temperature, i.e., above the A_F , and in its austenitic state. If after deployment into the body, the position of the coil needs to be adjusted, Cragg teaches pulling the body temperature coil back into the catheter by "withdrawing the guide wire" (which is still attached to the coil) and re-extruding it in the proper position. *Id*. at 261. As the coil is drawn back into the catheter, the coil is at body temperature (above A_F) and hence in its austenitic state. Thus, when it is pulled back into the catheter it is stressed by the catheter into its deformed, martensitic shape. *Id*. Upon extrusion back out of the catheter, the stress applied by the catheter is removed, and the coil, still at body temperature, reverts back to its austenitic state. *See* ER, § II. Accordingly, Cragg inherently discloses using a restraint, i.e., the catheter to stress induce martensite by pulling the Nitinol Coil into the catheter in the body for repositioning. As discussed in Russell's Expert Report, Cragg's Nitinol coil is also inherently capable of exhibiting pseudoelastic behavior. *See* ER, pp. 16-22, 49-51.

A detailed chart showing where each limitation of the IPR Claims is disclosed in Cragg follows.

141 Patent: Claims 1-5 & 18-22	**Cragg (Exh. 1005)**
1. A medical device for insertion into a mammalian body, the device comprising	Non-limiting preamble. However, Cragg discloses a Nitinol (Ti-Ni alloy) wire coil graft designed for insertion into a human blood vessel. 261-262.
(a) a hollow placement device;	Cragg discloses a hollow placement device in the form of a catheter. 261.
(b) a memory alloy element	Cragg discloses a memory alloy element in the form of a wire coil graft made from Nitinol, which Cragg discloses has shape memory properties. 261-62.
formed at least partly from pseudoelastic shape-memory alloy,	Cragg discloses that its Nitinol coil can be thermally transformed from a deformed shape to its original shape at a transformation temperature (A_F). 261-62. Above its A_F temperature, Cragg's Nitinol coil is inherently pseudoelastic. ER, § II.
the alloy displaying reversible stress-induced martensite at about body temperature such that it has a stress-induced martensitic state and an austenitic state,	Cragg's Nitinol coil has a transformation temperature (A_F) "at or near body temperature" and, in one embodiment, the coil has an A_F of 36° C. 261-62; ER, § II. Cragg also discloses that its Nitinol coil is precisely placed within a blood vessel by extruding the Nitinol coil from the catheter and, where the position of the coil needs to be adjusted, "withdrawing the guide wire" such that the coil is pulled back into the catheter for repositioning within the vessel. 261. As the coil is drawn back into the catheter for repositioning, the coil is at body temperature (above A_F) and is stressed by the catheter into its deformed, martensitic shape (stress-induced martensitic state). *Id*. Upon extrusion back out of the catheter, the coil remains at body temperature, the stress applied by the catheter is removed, and the coil inherently reverts back to its austenitic state (i.e., reversible transformation). ER, § II.
the memory alloy element having (i) a deformed	Cragg's Nitinol coil has a deformed shape where it is straight and pliable (a deformed martensitic shape).

shape when the alloy is in its stress induced martensitic state and (ii) a different unstressed shape when the alloy is in its austenitic state; and	261-62. For Cragg's coil, martensite is martensite and there is no difference between martensite formed by changing stress and martensite formed changing temperature. ER, § II. Nevertheless, as discussed above, Cragg discloses that its coil is deformed by stress to its martensitic shape. 261. Cragg's coil also has an original, memorized coil (a different, unstressed austenitic shape). 261-62.
(c) a guide wire;	Cragg discloses that its Nitinol coil is "fastened to a threaded guiding wire." 261.
the memory alloy element being within the hollow placement device, and	Cragg discloses that its Nitinol coil is positioned within the catheter (hollow placement device) for delivery into a blood vessel. 261-62.
the placement device being guidable by the guide wire,	Cragg discloses a guide wire threaded through the catheter, thereby enabling the guide wire to guide the catheter through a blood vessel. 261.
the hollow placement device stressing the memory alloy element at a temperature greater than the A_S of the alloy so that the memory alloy element is in its deformed shape,	Cragg's Nitinol coil in its austenitic state has a diameter large enough to maintain vessel patency (e.g., 11mm), while a standard 10-F catheter (diameter 3.3mm) is used to permit insertion into the blood vessel. 261-62. Accordingly, Cragg's catheter is dimensioned to stress the Nitinol coil where it is pulled back into the catheter from the blood vessel and deformed to its martensitic state. 261; ER, § II. As discussed above, this occurs at body temperature, just above the coil's A_F and inherently above the coil's A_S. ER, § II.
wherein the memory alloy element can be extruded from the hollow placement device by the guide wire at a temperature greater than the A_S of the alloy to transform at least a portion of the alloy from its stress-induced martensitic state so that the memory alloy element transforms from its	Cragg's Nitinol coil is "fastened to a threaded guiding wire to allow accurate placement after being deposited in the aorta" (i.e., the coil is extruded from the catheter by the guide wire). 261. As discussed above, Cragg discloses that the coil is stressed into its deformed martensitic state as it is withdrawn into the catheter for repositioning in the blood vessel. *Id*. Upon extrusion back out of the catheter in the blood vessel at body temperature (above A_S), the stress of the catheter is removed and the coil transforms back to its unstressed austenitic state. *Id*.; ER, § II.

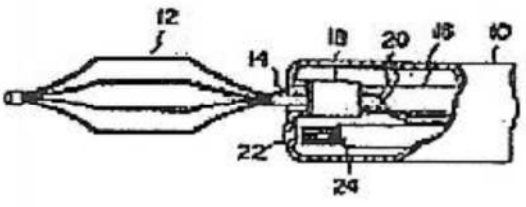
deformed shape to its unstressed shape,	
and wherein the alloy is selected so that the transformation can occur without any change in temperature of the placement device or the memory alloy element.	As discussed above, Cragg's Nitinol coil will be above its A_F (36° C) when it is in the catheter in the blood vessel. As the coil is extruded from the catheter (i.e., the stress is removed) for repositioning, the coil will transform from its stressed, martensitic state to its unstressed, austenitic shape without a change in temperature of the coil or catheter (the coil remains at body temperature). 261; ER, § II.
2. The device of claim 1 wherein the memory alloy element is a stent.	Cragg discloses that its Nitinol wire coil graft "could be used as [a] stent[] to maintain vessel patency." 262.
3. The device of claim 2, including a guide wire for endarterial placement of a stent graft.	As noted above, Cragg discloses that its Nitinol coil is "fastened to a threaded guiding wire to allow accurate placement" 261.
4. The invention of claim 1 wherein the transformation occurs without any change in the state of the placement device.	As described above, Cragg's Nitinol coil is transformed from its martensitic state to its austenitic state by stress. The coil remains at or above its A_F and no change in state of the catheter (placement device) is required to cause the transformation. ER, § II.
5. The device of claim 1, wherein the hollow placement device is a catheter.	As detailed above in regard to Claim 1, Cragg discloses a hollow placement device in the form of a catheter. P. 261-62.
18. A medical device comprising:	Non-limiting preamble. However, Petitioner again notes that Cragg discloses a Nitinol wire coil graft designed for insertion into a human blood vessel. 261-262.
(a) a wire stent	Cragg discloses a Nitinol wire coil configured for use as a stent. 261-62.
formed at least partly from a pseudoelastic shape memory alloy,	The Nitinol alloy used to form Cragg's coil is a known pseudoelastic shape-memory alloy, as recognized in the Expert Report. ER, § II.
the alloy displaying reversible stress-induced martensite at about	Cragg's Nitinol coil has a transformation temperature (A_F) "at or near body temperature" and, in one embodiment, the coil has an A_F of 36° C. 261-62;

human body temperature such as it has a deformed shape when the alloy is in its stress induced martensitic state and a different unstressed shape when the alloy is in its austenitic state; and	ER, § II. Cragg also discloses that its Nitinol coil is precisely placed within a blood vessel by extruding the Nitinol coil from the catheter and, where the position of the coil needs to be adjusted, "withdrawing the guide wire" such that the coil is pulled back into the catheter for repositioning within the vessel. 261. As the coil is drawn back into the catheter for repositioning, the coil is at body temperature (above A_F) and is stressed by the catheter into its deformed, martensitic shape (stress-induced martensitic state). *Id*. Upon extrusion back out of the catheter, the coil remains at body temperature, the stress applied by the catheter is removed, and the coil inherently reverts back to its different, unstressed coil austenitic state (i.e., reversible transformation). *Id*.; ER, § II.
(b) a restraint stressing the wire stent at a temperature greater than the A_S of the alloy so that the wire stent is in its deformed shape,	Cragg discloses a restraint in the form of a catheter. 261-62. Cragg's Nitinol coil in its austenitic state has a diameter large enough to maintain vessel patency (e.g., 11mm), while a standard 10-F catheter (diameter 3.3mm) is used to permit insertion into the blood vessel. 261-62. Accordingly, Cragg's catheter is dimensioned to stress the Nitinol coil where it is pulled back into the catheter from the blood vessel and deformed to its martensitic state. 261; ER, § II. As discussed above, this occurs at body temperature, just above the coil's A_F and inherently above the coil's A_S. ER, § II.
wherein the stent can be disengaged from the restraint upon placement in a human so that the stent transforms from its deformed shape to its unstressed shape, and	Cragg discloses that the coil is stressed into its deformed martensitic state as it is withdrawn into the catheter for repositioning in the blood vessel. 261. Upon extrusion back out of the catheter in the blood vessel at body temperature (above A_S), the stress of the catheter is removed and the coil inherently transforms back to its unstressed austenitic state. *Id*.; ER, § II.
wherein the alloy is selected so that the transformation can occur without any change in	As discussed above, Cragg's Nitinol coil will be above its A_F (36° C) when it is in the catheter in the blood vessel. As the coil is extruded from the catheter (i.e., the stress is removed) for repositioning,

temperature of the restraint or the wire stent.	the coil will transform from its stressed, martensitic state to its unstressed, austenitic shape without a change in temperature of the coil or catheter (the coil remains at body temperature). 261; ER, § II.
19. The device of claim 6, 11, 15, 16 or 18, including a guidewire for endarterial placement of the stent.	As noted above, Cragg discloses "the Nitinol coils were fastened to a threaded guiding wire to allow accurate placement" within a blood vessel (endarterial placement of the coil stent). Cragg, pp. 261.
20. The device of claim 15, 16, or 18, wherein the transformation of the alloy occurs without any change in state of the restraint.	As described above, Cragg's Nitinol coil is transformed from its martensitic state to its austenitic state by stress. The coil remains at or above its A_F and no change in state of the catheter (placement device) is required to cause the transformation. ER, § II.
21. The device of claim 1, 15, 16, or 18, wherein the restraint is a catheter.	Cragg discloses that the restraint may be a 10-F catheter. Cragg, p. 262.
22. The device of Claim 1, 11, 15 or 18 wherein the stent is a coil stent.	Cragg discloses a Nitinol wire coil configured for use as a stent. Cragg, 261-62.

G. Claims 1-5 and 18-22 are Obvious In View of Miyauchi & Cragg under § 103(a)

Miyauchi was **not** considered during prosecution of the 141 patent. Miyauchi was publicly disclosed on Mar. 18, 1983 and qualifies as prior art under § 102(a). Miyauchi discloses a Nitinol manipulation tool (12) for insertion into a human body through an endoscope sheath (10). Miyauchi, p. 1, Fig. 1. In its martensitic state, the Nitinol tool (12) has a deformed shape "long in the lengthwise direction" for movement through the sheath (10). *See id*. at 3. In its unstressed austenitic state, the Nitinol tool (12) reverts to a basket forceps configuration for removing body calculi. *Id*. at 2-3, Fig. 1.



Miyauchi Figure 1

Miyauchi's Nitinol tool (12) is inherently capable of exhibiting the same behavior as the medical device recited in Claims 1-10 and 18-22. Miyauchi specifically discloses that its Nitinol tool's martensitic state can be reached by changing temperature or stress. *Id*. at 1-3. The Nitinol tool (12) can be stress-induced to its martensitic state at body temperature by being pulled into its sheath (10) when inside a body cavity, and returned to its original, austenitic state upon extrusion from the sheath (10) within the body cavity. *Id*. at 3. Accordingly, the Nitinol tool is clearly capable of exhibiting stress-induced martensite at body temperature.

Both Miyauchi and Cragg relate to shape memory alloy elements used in body cavities. A person of ordinary skill would have found it obvious to utilize the teachings of Miyauchi for the placement of a coil stent disclosed in Cragg. A detailed chart identifying where each limitation of the IPR Claims is disclosed in Miyauchi and Cragg follows. Page numbers referenced in this claim chart refer to the English translation of Miyauchi unless otherwise indicated.

141 Patent: Claims 1-5 & 18-22	**Miyauchi (Exh. 1006) + Cragg (Exh. 1005)**
1. A medical device for insertion into a mammalian body, the device comprising	Non-limiting preamble. However, Miyauchi is directed to a manipulation tool (12) for insertion into a human body cavity through an endoscope sheath (10). P. 1.
(a) a hollow placement device;	Miyauchi discloses a hollow placement device in the form of a hollow cylindrical sheath (10). P. 2, Fig. 1.
(b) a memory alloy element	Miyauchi discloses a memory alloy element in the form of a manipulation tool (12) made from a shape-memory alloy, such as Nitinol (Ti-Ni). P. 2-3; Fig. 1.
formed at least partly from pseudoelastic shape-memory,	Miyauchi teaches that the Nitinol forming the manipulation tool (12) exhibits "pseudoelasticity." P. 3.
the alloy displaying reversible stress-induced martensite at about body temperature such that it has a stress-induced martensitic state and an austenitic state,	Miyauchi teaches that the Nitinol tool's martensitic state can be reached by changing temperature or stress. P. 1-3. The Nitinol tool (12) can be stress-induced to its martensitic state at body temperature by being pulled into its sheath (10) when inside a body cavity. P. 3. The Nitinol tool (12) can then be returned to its original, austenitic state upon extrusion from the sheath (10) within the body cavity (i.e., reversible transformation). *Id*.; Fig. 1.
the memory alloy element having (i) a deformed shape when the alloy is in its stress induced martensitic state and (ii) a different unstressed shape when the alloy is in its austenitic state; and	In its martensitic state, the Nitinol tool (12) has a deformed shape "long in the lengthwise direction." P. 3. Miyauchi discloses that this deformed, martensitic shape can be reached by applying stress (i.e., stress-induced). *Id*. The Nitinol tool (12) has a different shape—basket forceps—in its unstressed, austenitic state. *Id*; Fig. 1.
(c) a guide wire;	Miyauchi shows that the Nitinol tool (12) is guided through the sheath (10) and it would have been obvious to use a guide wire. Fig. 1. For example, Cragg discloses use of a guiding wire for guiding an intraluminal Nitinol coil. Cragg, 261.
the memory alloy element being within the	Miyauchi's Nitinol tool (12) is positioned within the sheath (10) for insertion into a body cavity. P. 2-3;

hollow placement device, and	Fig. 1.
the placement device being guidable by the guide wire,	Cragg discloses use of a guiding wire and it would have been obvious to a person of ordinary skill to use such a guiding wire to place Miyauchi's endoscope sheath (10) in a blood vessel. Cragg, 261; P. 2-3.
the hollow placement device stressing the memory alloy element at a temperature greater than the A_S of the alloy so that the memory alloy element is in its deformed shape,	As discussed above, Miyauchi's Nitinol tool (12) can be pulled into the sheath (10) within a body a cavity such that the sheath (10) will apply stress to the Nitinol tool (12) and transform it to its longer martensitic state. Miyauchi also discloses that the Nitinol tool (12) has a transformation temperature in one embodiment of 30° C (A_F = 30° C). P. 3. When the Nitinol tool (12) is stressed by the sheath (10) to its deformed martensitic state within a body cavity, the transformation inherently occurs at body temp above the tool's A_F (and above A_S). ER, § II.
wherein the memory alloy element can be extruded from the hollow placement device by the guide wire at a temperature greater than the A_S of the alloy to transform at least a portion of the alloy from its stress-induced martensitic state so that the memory alloy element transforms from its deformed shape to its unstressed shape,	When Miyauchi's Nitinol tool (12) is extruded from the sheath (10) within the body cavity, the stress applied to the tool (12) by the sheath (10) is removed and the tool (12) transforms from its deformed martensitic state (stress-induced by the sheath (10) above A_S) to its unstressed, austenitic shape. P. 3. This transformation back to austenite occurs above the tool's A_S (e.g., at body temperature) and Miyauchi makes clear the tool (12) can withstand this manipulation "any number of times, so it has a long life." *Id*.
and wherein the alloy is selected so that the transformation can occur without any change in temperature of the placement device or the memory alloy element.	As described above, the Nitinol tool's transformation from its martensitic state within the sheath (10) to its austenitic state within the body cavity occurs without any change in temperature of the sheath (10) or the tool (12). P. 3. Both the Nitinol tool (12) and sheath (10) remain at body temperature during the tool's transformation.

2. The device of claim 1 wherein the memory alloy element is a stent.	Cragg discloses that its Nitinol wire coil graft "could be used as [a] stent[] to maintain vessel patency." Cragg, 262. It would have been obvious to a person of ordinary skill to modify Miyauchi's apparatus for use with a Nitinol stent as disclosed in Cragg.
3. The device of claim 2, including a guide wire for endarterial placement of a stent graft.	Cragg discloses that its Nitinol coil is "fastened to a threaded guiding wire to allow accurate placement" in blood vessel (endarterial placement). Cragg, 261. Cragg further discloses a Nitinol wire coil graft. *Id*.
4. The invention of claim 1 wherein the transformation occurs without any change in the state of the placement device.	As described above, transformation of Miyauchi's Nitinol tool from its martensitic state within the sheath (10) to its austenitic state within the body cavity occurs due to a change in stress applied to the tool (12) and does not require a change in state of the sheath (10).
5. The device of claim 1, wherein the hollow placement device is a catheter.	Miyauchi discloses a catheter in the form of its sheath (10), which is a cylindrical, hollow sheath having open ends and is composed of plastic. P. 2.
18. A medical device comprising:	Non-limiting preamble. However, Miyauchi is directed to a manipulation tool (12) for insertion into a human body cavity through an endoscope. P. 1
(a) a wire stent	Miyauchi discloses a Nitinol manipulation tool (12) for insertion into a body cavity. P. 2-3; Fig. 1. Cragg discloses a Nitinol wire coil configured for use as a stent. Cragg, 261-62. It would have been obvious to one of ordinary skill to modify Miyauchi's apparatus for use with a wire stent as disclosed in Cragg.
formed at least partly from a pseudoelastic shape memory alloy,	Miyauchi discloses that its Nitinol manipulation tool (12) exhibits "pseduoelastiticy." P. 3. Cragg's coil is also formed from Nitinol. Cragg, 261.
the alloy displaying reversible stress-induced martensite at about human body temperature such as it has a deformed shape when the alloy is in its stress induced martensitic state and a	Miyauchi states that the Nitinol tool's martensitic state can be reached by changing temperature or stress. P. 1-3. The Nitinol tool (12) can be stress-induced to its martensitic state at body temperature by being pulled into its sheath (10) when inside a body cavity. P. 3. The Nitinol tool (12) can then be returned to its original, austenitic state upon extraction from the sheath (10) within the body cavity

different unstressed shape when the alloy is in its austenitic state; and	(i.e., reversible transformation). *Id*.; Fig. 1. Cragg's Nitinol coil inherently exhibits the same behavior and Cragg discloses deforming the coil to its martensitic state via stress. Cragg, 261; *see discussion of Claim 1*.
(b) a restraint stressing the wire stent at a temperature greater than the A_S of the alloy so that the wire stent is in its deformed shape,	Miyauchi discloses a restraint in the form of an endoscope sheath (10). P. 2, Fig. 1. Miyauchi discloses pulling its Nitinol tool (12) into the sheath (10) within a body a cavity such that the sheath (10) stresses the Nitinol tool (12) and transforms it to its longer martensitic state. Miyauchi also discloses that the Nitinol tool (12) has a transformation temperature in one embodiment of 30° C (A_F = 30° C). P. 3. When the Nitinol tool (12) is stressed by the sheath (10) to its deformed martensitic state within a body cavity, the transformation inherently occurs at body temp above the tool's A_F (and above A_S). ER, § II. The sheath (10) would obviously function in the same way when used with Cragg's Nitinol coil.
wherein the stent can be disengaged from the restraint upon placement in a human so that the stent transforms from its deformed shape to its unstressed shape, and	When Miyauchi's Nitinol tool (12) is extruded from the sheath (10) within the body cavity, the stress applied to the tool (12) by the sheath (10) is removed and the tool (12) transforms from its deformed martensitic state (stress-induced by the sheath (10) above A_S) to its unstressed, austenitic shape. P. 3. The same transformation would obviously take place with Cragg's Nitinol coil. ER, § II
wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraint or the wire stent.	As described above, the Nitinol tool's transformation from its martensitic state within the sheath (10) to its austenitic state within the body cavity occurs without any change in temperature of the sheath (10) or the tool (12). P. 3. Both the Nitinol tool (12) and sheath (10) remain at body temperature during the tool's transformation, and the same would be obviously be true in transforming Cragg's Nitinol coil. ER, § II
19. The device of claim 6, 11, 15, 16 or 18, including a guide wire for endarterial placement of the stent.	Cragg discloses use of a guiding wire and it would have been obvious to a person of ordinary skill to use such a guiding wire to place Miyauchi's endoscope sheath (10) in a blood vessel. Cragg, 261; P. 2-3.

20. The device of claim 15, 16, or 18, wherein the transformation of the alloy occurs without any change in state of the restraint.	As described above, transformation of Miyauchi's Nitinol tool from its martensitic state within the sheath (10) to its austenitic state within the body cavity occurs due to a change in stress applied to the tool (12) and does not require a change in state of the sheath (10). The same would be obviously be true in transforming Cragg's Nitinol coil. ER, § II
21. The device of claim 1, 15, 16, or 18, wherein the restraint is a catheter.	Miyauchi discloses a catheter in the form of its sheath (10), which is a cylindrical, hollow sheath having open ends and is composed of plastic. P. 2. Cragg also discloses use of a catheter. 261-62.
22. The device of Claim 1, 11, 15 or 18 wherein the stent is a coil stent.	Cragg discloses a Nitinol wire coil configured for use as a stent. Cragg, 261-62.

H. Claims 6-10 are Obvious in view of Dotter & Miyauchi under § 103(a)

As discussed above, Dotter discloses a Nitinol coil (10) having an A_F temperature that "can be manipulated over a wide range." Dotter, 3:21-28. In view of Miyauchi's teaching of using stress to transform a medical device for use in a human body, i.e., its Nitinol tool (12), between its austenitic and martensitic states, a person of ordinary skill would have found it obvious to alloy Dotter's coil (10) to have an AF of room temperature such that it would exhibit stress-induced martensite at a temperature below body temperature. *Id*. at 5:5-20 (discussion of insertion of coil (10) into catheter (16) at room temp); Miyauchi, p. 3 (discussion of SIM).

A detailed chart identifying where each feature of Claims 6-10 is disclosed in Dotter and Miyauchi follows.

141 patent: Claims 6-10	**Dotter (Exh. 1004) + Miyauchi (Exh. 1006)**
6. A medical device which comprises:	Non-limiting preamble. Petitioner notes that Dotter discloses a graft prosthesis medical device as discussed above. 2:36-38.
(a) a stent for endarterial placement within a human body so that the stent is substantially at human body temperature,	Dotter discloses a Nitinol coil (10) for use as a stent for "expanding partially occluded segments of a blood vessel passageway" (endarterial placement within a human body), where the coil (10) would be at body temperature. 3:15-43; 5:29-47.
the stent comprising a shape memory alloy	Dotter's coil (10) is formed from a "shape memory Nitinol alloy." 3:17-21; 5:5-20.
which displays stress induced martensite behavior at body temperature; and	Dotter teaches that the transition temperature of its Nitinol coil "can be manipulated over a wide range" and that such manipulation is well known to those skilled in the art. 3:21-28; ER, § II. It would have been an obvious design choice to select a room temperature A_F so the Nitinol coil (10) will be austenitic at room temperature. In such an embodiment, it would have been obvious to a person of ordinary skill in view of Miyauchi that Dotter's Nitinol coil (10) can inherently exhibit stress-induced martensite behavior at body temperature (above A_F) upon application of stress. 5: 21-30; Miyauchi, p. 3 (discussion of SIM); ER, § II; *see also discussion of Claim 1*.
(b) a restraint holding the stent in a deformed configuration at a temperature less than the body temperature of the human for endarterial positioning of the stent	Dotter's catheter (16) (restraint) is used for endarterial positioning of the Nitinol coil (10) in the human body. 4:18-24; Figs. 3-6. In Dotter's A_F = room temperature embodiment, the Nitinol coil (10) is inserted into the catheter (16) at room temperature (i.e., below body temp) in its austenitic shape (wide diameter coil) for delivery into the body. 3:8-24; Fig.

within the human body in its deformed configuration, the deformation occurring through stress induced martensite;	3; ER, § II. It would have been obvious to a person of ordinary skill in view of Miyauchi that the catheter (16) can deform the coil (10) through stress from its austenitic shape to its martensitic shape and inherently hold the coil (10) in this deformed configuration by stress. 5:5-20 (discussion of insertion of coil (10) into catheter (16) at room temp); Miyauchi, p. 3 (discussion of SIM); ER, § II.
wherein the stent is sufficiently deformed that when the stent is at human body temperature removal of the restraint of the stent, without change in temperature of the device, releases at least a portion of the stent from its deformed configuration	When the deformed Nitinol coil (10) is extruded from the catheter (16) at body temperature (above the coil's room temp A_F), the coil (10) reverts to its undeformed coil configuration without a change in temperature due to the release of the stress applied by the catheter (16). Miyauchi, p. 3; ER, § II; *see also discussion of Claim 1*.
7. A device as claimed in 6, in which the restraint is hollow, and the stent is positioned at least partially within the restraint.	Dotter's catheter (16) is hollow (hollow restraint) and its Nitinol coil (10) is configured for delivery through the catheter (16) (stent partially within restraint). 4:8-24; Figs. 3-4.
8. A device as claimed in claim 6 or 7, in which the restraint is a catheter.	Dotter discloses a restraint in the form of a catheter (16) as detailed above. 4:8-24; Figs. 3-6.
9. A device as claimed in claim 6 or 7, in which the stent has a transverse dimension and a longitudinal dimension, wherein the stent is deformed by its transverse dimension being reduced, and wherein the restraint prevents transverse expansion of the stent.	Dotter's Nitinol coil (10) has a transverse dimension and a longitudinal dimension. Figs. 1-2. The coil (10) is deformed by its transverse dimension being reduced (transforming from a large diameter coil in the austenitic state to a narrower profile in the martensitic state). 3:29-63. As detailed above, it would have been obvious to a person of ordinary skill in view of Miyauchi that Dotter's catheter (16) is dimensioned to prevent transverse expansion of the Nitinol coil (10) from its martensitic state to its austenitic state when the coil (10) is positioned within the catheter (16). Miyauchi p.3; *discussion of Claim 1*

10. The device of claim 6, wherein the shape memory alloy is sufficiently deformed that removal of the restraint from the shape memory alloy releases at least a portion of the shape memory alloy element from its deformed configuration without change in state of restraint.	In embodiments where the Nitinol coil (10) has an A_F equivalent to room temperature, the coil (10) will inherently be held in its deformed martensitic state by stress as it passes through the catheter (16) at body temperature. *See discussion of Claim 6*; 5:21-30; Miyauchi, p. 3; ER, § II Upon extrusion from the catheter (16) (i.e., removal of restraint), the coil (10) will revert back to its unstressed austenitic state. *Id*. This transformation occurs without any change in state of the catheter (16) (restraint).

I. The IPR Claims are Invalid For Obvious-Type Double Patenting

As indicated above, the Petitioner also requests invalidation of The IPR Claims for obviousness-type double patenting in view of claims of the ’378 patent. The term of the ’378 patent ended on May 19, 2004, by operation of a terminal disclaimer. 141 History, Terminal Disclaimer dated Mar. 14, 1995. The 141 patent issued on October 23, 2001. The nominal term of the 141 patent extends for seventeen years from issuance of the patent (October 23, 2018) and has been extended under § 156 for an additional 1,270 days (i.e., until April 15, 2022), based upon regulatory review of a corresponding product by the Food and Drug Administration. Patent Term Extension Certificate, July 5, 2011.

The 141 patent and the ’378 patent are commonly assigned to Medtronic, Inc. and both patents have the same sole inventor, Dr. James Jervis. Because the IPR Claims are obvious variants of claims in the’378 patent, and because the 141

patent claims are not subject to safe harbor under 35 U.S.C. § 121, the term of the 141 patent beyond May 19, 2004 is an unlawful extension of the patentee's exclusive rights, and The IPR Claims are therefore invalid.

i. The IPR Claims Are Obvious Variants of Claims in the '378 Patent

A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obviousness-type double patenting. *Eli Lilly & Co. v. Barr Labs.,* 251 F.3d 955, 968 (Fed. Cir. 2001). Where a later claim is obvious over, or anticipated by, an earlier claim, the later claim is not patentably distinct. *Id*. As detailed in the following claim chart, to the extent the language of the IPR Claims differs from the '378 patent claims, the differences amount to nothing more than obvious variations of the '378 patent claims. In certain instances, the claims are simply obvious variants of two prior art references incorporated by reference in the 141 patent's specification: **(i)** Dotter et al., Transluminal Expandable Nitinol Coil Stent Grafting: Preliminary Report, 147 Radiology 259-260 (herein "Dotter Article," attached as **Exhibit 1018**) and **(ii)** the aforementioned Cragg reference. *See* 141 patent, 9:14-52.

Claim 1 of the 141 patent is an obvious variant of '378 Claim 34; 141 Claims 2 and 3 are obvious variants in view of the Dotter Article and Cragg; 141 Claim 4 is an obvious variant of '378 Claim 20; 141 Claim 5 is an obvious variant of '378 Claim 3; 141 Claim 6 is an obvious variant of '378 Claim 1; 141 Claim 7 is

an obvious variant of ’378 Claim 2; 141 Claim 8 is an obvious variant of ’378 Claim 3; 141 Claim 9 is an obvious variant of ’378 Claim 7; 141 Claim 10 is an obvious variant of ’378 Claim 8; 141 Claim 18 is an obvious variant of ’378 Claim 15; 141 Claim 19 is an obvious variant in view of Cragg; 141 Claim 20 is an obvious variant of ’378 Claim 20; 141 Claim 21 is an obvious variant of ’378 Claim 20; and 141 Claim 22 is an obvious variant in view of the Dotter Article. To assist the Board in assessing the double patenting issues between the 141 patent and the ’378 patent, Petitioners have also provided a video presentation by expert Mr. Russell illustrating the similarities between the devices claimed in each patent. Double Patenting Video Presentation by Scott M. Russell (**Exhibit 1017**).

141 **Claim 1**	**’378 Claim 34**
1. **A medical device** for insertion into a mammalian body, the device comprising: (a) **a hollow** placement device;	34. **A medical device** for treatment of a human body, the device comprising:… (b**) a hollow** tubular restraining member…
(b) **a memory alloy element formed at least partly from pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about body temperature such that it has a stress-induced martensitic state and an austenitic state, the memory alloy element having (i) a deformed shape when the alloy is in its stress-induced martensitic state and (ii) a different unstressed shape** when the alloy is in its austenitic state; and	(a) **a memory alloy element formed at least partly from** a **pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about human body temperature such that it has a stress-induced martensitic state and an austenitic state, the memory alloy element having (i) a deformed shape when the alloy is in its stress-induced martensitic state and (ii) a different unstressed shape**;
(c) a guide wire; **the memory alloy element being**	(b) **a hollow** tubular restraining member with **the memory alloy element being**

within the hollow placement device, and the placement device being guidable by the guide wire, the hollow placement device **stressing the memory alloy element at a temperature greater than the** A_s **of the alloy so that the memory alloy element is in its deformed shape**,	**within** the restraining member, the restraining member engaging and **stressing the memory alloy element at a temperature greater than the** A_s **of the alloy so that the memory alloy element is in its deformed shape**;
wherein the memory alloy element can be extruded from the hollow placement device by the guide wire **at a temperature greater than the** A_s **of the alloy to transform at least a portion of the alloy from its stress-induced martensitic state so that the memory alloy element transforms from its deformed shape to its unstressed shape**, and **wherein the alloy is selected so that the transformation can occur without any change in temperature of the** placement device **or the memory alloy element.**	wherein the memory alloy element is axially slidable within the tube, and **wherein the memory alloy element can be extruded** completely out of the tube for deployment in the mammalian body **to transform at least a portion of the alloy from its stress-induced martensitic state** towards its austenitic state **at a temperature greater than the** A_s **of the alloy so that the memory alloy element transforms from its deformed shape** toward **its unstressed shape**, and **wherein the alloy is selected so that the transformation can occur without any change in temperature of the** restraining member **or the memory alloy element.**
141 **Claims 2 and 3**	**Prior Art: Dotter Article & Cragg**
2. The device of claim 1 wherein the memory alloy element is **a stent**. 3. The device of claim 2, including a **guide wire** for endarterial **placement** of the stent graft.	"A method is described for the percutaneous catheter placement of expandable Nitinol coil **stents** …" Dotter Article, 259. "The Nitinol coils were fastened to a threaded **guiding wire** to allow accurate **placement** after being deposited in the aorta." Cragg, 261

141 **Claim 4**	**'378 Claim 20**
4. The invention of claim 1 **wherein the transformation occurs without any change in the state** of the placement device.	20. The invention of claim 10, 13 or 15 **wherein the transformation of the alloy occurs without any change in the state of the restrain**ing member.
141 **Claim 5**	**'378 Claim 3**
5. The device of claim 1, wherein the hollow placement device **is a catheter**.	3. A device as claimed in claim 2, in which **the restraint is a catheter**.
141 **Claim 6**	**'378 Claim 1**
6**. A medical device which comprises**: (a) a stent for endarterial placement **within a human body** so that the stent **is substantially at human body temperature**, the stent **comprising a shape memory alloy which displays stress-induced martensite behavior at body temperature**; and	1. **A medical device which comprises**: (a) an element for use **within a human body** or in such proximity to 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** stent **in a deformed configuration at a temperature less than the body temperature of the human for** endarterial **positioning** of the stent **within the human body in its deformed configuration, the deformation occurring through the formation of stress-induced martensite**;	(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**;
wherein the stent **is sufficiently deformed that when** the stent **is at human body temperature removal of the restraint from** the stent, **without change in temperature of the device, releases at least a**	**wherein the** shape memory alloy element **is sufficiently deformed that when** the shape memory alloy element **is at human body temperature removal of the restraint from** the shape memory alloy element, **without change in**

portion of the stent **from its deformed configuration**.	**temperature of the device, releases at least a portion of the** shape memory alloy element **from its deformed configuration**.
141 **Claim 7**	**'378 Claim 2**
7. **A device as claimed in** 6, **in which the restraint is hollow, and the** stent **is positioned at least partially within the restraint.**	2. **A device as claimed in** claim 1, **in which the restraint is hollow, and the** shape memory alloy element **is positioned at least partially within the restraint.**
141 **Claim 8**	**'378 Claim 3**
8. **A device as claimed in claim** 6 or 7, **in which the restraint is a catheter.**	3. **A device as claimed in claim** 2, **in which the restraint is a catheter.**
141 **Claim 9**	**'378 Claim 7**
9. **A device as claimed in claim** 6 or 7, **in which the** stent **has a transverse dimension and a longitudinal dimension, and wherein the** stent **is deformed by its transverse dimension being reduced, and wherein the restraint prevents transverse expansion of the** stent.	7. **A device as claimed in claim** 2, **in which the** shape memory alloy element **has a transverse dimension and a longitudinal dimension, and wherein the** shape memory alloy element **is deformed by its transverse dimension being reduced, and wherein the restraint prevents transverse expansion of the** element.
141 **Claim 10**	**'378 Claim 8**
10. **The device of claim** 6**, wherein the shape memory alloy element is sufficiently deformed that removal of the restraint from the shape memory alloy releases at least a portion of the shape alloy element from its deformed configuration without change in state of the restraint.**	8. **The device of claim** 1**, wherein the shape memory alloy element is sufficiently deformed that removal of the restraint from the shape memory alloy releases at least a portion of the shape memory alloy element from its deformed configuration without change in state of the restraint.**
141 **Claim 18**	**'378 Claim 15**
18. **A medical device** comprising: (a) a wire stent **formed at least partly from a pseudoelastic shape memory alloy, the alloy displaying**	15. **A medical device** …the device comprising: (i) a restraining member and (ii) a hollow catheter **formed at least party**

reversible stress-induced martensite at about human body temperature such as it has a deformed **shape when the alloy is in its stress-induced martensitic state and a different unstressed shape when the alloy is in its austenitic state**; and	**from a pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about human body temperature such that it has** a stress-induced **martensitic state** and an **austenitic state**, the catheter having (i) an easily inserted **shape when the alloy is in its stress-induced martensitic state and** (ii) **a different unstressed shape when the alloy is in its austenitic state**;
(b) a restraint **stressing the** wire stent **at a temperature greater than the** A_s **of the alloy so that** the wire stent is **in its** deformed **shape**,	The restraining member engaging and **stressing the** catheter **at a temperature greater than the** A_s **of the alloy so that** the catheter **is in its** easily inserted **shape** so that the catheter can be inserted into the mammalian body;
wherein the stent can be **disengage**d from the restraint upon placement in a human **so that the** stent **transforms from its** deformed shape to **its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the** restraint or the wire stent.	wherein **disengage**ment of the restraining member from the catheter at a temperature greater than the A_s of the alloy transforms at least a portion of the alloy from its stress-induced martensitic state to its austenitic state **so that the** catheter **transforms from its** easily inserted shape toward **its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the** restraining member or the catheter.
141 **Claim 19**	**Prior Art: Cragg**
19. The device of claim 6, 11, 15, 16 or 18, including a **guide wire** for endarterial **placement** of the stent.	"The Nitinol coils were fastened to a threaded **guiding wire** to allow accurate **placement** after being deposited in the aorta." Cragg at 261
141 **Claim 20**	**'378 Claim 20**
20. The device of claim 15, 16, or 18, **wherein the transformation of the alloy occurs without any change in state of the restrain**t.	20. The invention of claim 10, 13 or 15 **wherein the transformation of the alloy occurs without any change in the state of the restrain**ing member.

141 **Claim 21**	**'378 Claim 3**
21. The device of claim 1, 15, 16, or 18, wherein **the restraint is a catheter**.	3. A device as claimed in claim 2, in which **the restraint is a catheter**.
141 Claim 22	**Prior Art: Dotter Article**
22. The device of Claim 1, 11, 15 or 18 wherein the stent is a **coil stent**.	"A method is described for the percutaneous catheter placement of expandable Nitinol **coil stent**s …" Dotter Article, 259.

ii. The IPR Claims Are Not Entitled to Safe Harbor

Under 35 U.S.C. § 121, safe harbor is only available for claims in a patent that was issued from a divisional application. *Amgen, Inc. v. F. Hoffmann-La Roche*, LTD, 580 F.3d 1340, 1353 (Fed. Cir. 2009)*, reh'g and reh'g en banc denied*. As explained in detail below, the IPR Claims are not subject to safe harbor from double patenting under § 121 because the 141 patent stems from a continuation, rather than a divisional, application and none of he IPR Claims were ever subject to a final restriction requirement.

On June 7, 1995, Patent Application No. 08/483,291 ("the 141 application") was filed as a continuation application and was accompanied by a Preliminary Amendment amending the specification accordingly.[5] On July 14, 1995, Applicant

[5]141 History, Transmittal dated June 7, 1995 (box for "continuation" is checked) and Preliminary Amendment dated June 7, 1995 (states "This application is a continuation . . ." at p. 1); *see also* '378 History, Amendment dated June 7, 1995

filed a document captioned, "Supplemental Preliminary Amendment," that requested the Examiner to amend the 141 application as a Divisional Application. However, the Applicant failed to amend either the specification or the Preliminary Amendment and failed to inform the Examiner exactly where and how the application should be amended in order to convert the application to a Divisional.[6] In fact, the amendment was never formally entered and subsequent to July 14, 1995, both the Examiner and the Applicant considered the 141 application to be a Continuation Application, and never referred to it as a Divisional Application.[7]

(states at p. 6 "Applicant wishes to advise the Examiner that Applicant may file a continuation application that includes the 'A(90)' claims, as well as a claim comparable to claim 19 that is not limited to humans.").

[6] 141 History, Supplemental Preliminary Amendment dated July 14, 1995; *see* 37 C.F.R. 1.121 ("Amendments in applications . . . are made by filing a paper, in compliance with § 1.52, directing that specified amendments be made"); *see also* MPEP 714 ("When a . . . section of the specification is to be amended, it should be wholly rewritten and the original insertion canceled.").

[7] *See e.g.*, 141 History, Appeal Brief dated June 18, 1998 (states at p. 1 "The application on appeal is a continuation. . . .").

On October 23, 2001, the 141 application issued as the 141 patent, and the patent specification and cover page identify the application as a continuation of the '378 application. Since October 23, 2001, at no time did the Applicant seek a certificate of correction in an attempt to amend the patent to reflect that the application should be converted to a divisional. Moreover, the PTO has not issued a certificate of correction as to the 141 patent. Accordingly, because the 141 patent issued from a continuation application, The IPR Claims are not entitled to safe harbor under 35 U.S.C. § 121. *See Amgen,* 580 F.3d at 1353.

In addition, Petitioner notes that none of Claims 1-10 or 18-22 were ever subject to a final restriction requirement. During prosecution of Patent Application No. 08/483,291("the '378 Application"), the Examiner issued an Office Action that included an election of species requirement stating the following:

> This application contains claims directed to the following patentably distinct species of the claimed invention: where the shape memory alloy is an IUD, a stent graft, a blood filter[,] a catheter and a tracheal catheter. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 12, 19, and 37 are generic. . . . Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise

include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141.

'378 Patent File History, OA Feb. 22, 1993, p. 3 ("'378 History," **Exhibit 1013**).

Under the Feb. 22, 1993 Office Action, '378 application Claims 12, 19, and 37 are generic, as the Examiner noted, because the language in these claims concerning a shape memory alloy element is not limited to a particular type of medical device—such as an IUD, a stent graft, a blood filter, a catheter, or a tracheal catheter. '378 History, Pre. Amend., Oct. 2, 1992, pp. 5-19 and Response to OA Mar. 22, 1993 (Applicant provisionally elects catheter species, arguing no election was required between tracheal catheters and catheters, and stating: "the generic and species claim[s] directed to catheters are: 11-14, 17-21, 24-37, and 41-53."). The election of species requirement was issued pursuant to 37 C.F.R. § 1.146 and contained no restriction requirement pursuant to 37 C.F.R. § 1.142.

Generic Claims 12, 19, and 37, as well as the claims relating to the elected species, were all prosecuted and examined on the merits.[85] As shown in the Index of Claims in the '378 History, application Claims 12 and 37 were rejected by the Examiner, while generic Claim 19 was allowed. *See e.g.,* '378 History, OA's, Jun. 24, 1993; Mar. 7, 1994; and Oct. 31, 1994 and Notice of Allowability, July 25, 1995. Since generic Claim 19 was allowed, all species identified by the Examiner could be prosecuted for examination on the merits and indeed claims to the non-

elected species of IUDs and Blood Filters were examined and allowed as Claims 4 and 5 of the '378 patent.

Upon allowance of generic Claim 19, Medtronic could have pursued its claims directed to the stent graft species. Instead, Applicant authorized an Examiner's Amendment cancelling '378 application generic Claim 37 and species Claim 39, the latter being directed toward the stent graft species, in order to permit the application to issue without delay as the '378 patent. '378 History, Notice of Allowability July 25, 1995, pp. 2-3. Even after the Examiner's Amendment had been entered, the Applicant still had the opportunity to file an Amendment in the '378 application concerning the patentability of Claims 37 and 39, but did not do so. *Id*. at p. 2 ("Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312."). Eschewing these options, Medtronic freely chose to pursue canceled Claims 37 and 39 in a new continuation application by filing corresponding Claims 1 and 2, respectively, in the 141 application.

In the '378 application, the Examiner never issued a restriction requirement that compelled the Applicant to cancel '378 application Claims 37 and 39 and refile them in a subsequent application in order to have them examined on the merits. Because the condition subsequent of the provisional election of species requirement was never satisfied, it was never finalized as a restriction requirement

and therefore no restriction ever occurred as to any of the non-elected species claims. Indeed, the '378 patent was issued with the generic claim that covers medical devices having a shape memory alloy element ('378 patent Claim 1), as well as with claims that cover the species of IUDs ('378 patent Claim 4) and Blood Filters ('378 patent Claim 5) that had not been elected for prosecution in response to the Examiner's election of species requirement. Indeed, none of the iPR Claims resulted from a restriction requirement entered by the PTO during the prosecution of the '378 application.

Even if claims were subject to a restriction requirement in a previous application, and even if those claims reappeared in a divisional application, a line of demarcation must be sufficiently clear from the earlier restriction requirement such that one can determine whether the claims allowed in the later patent maintain consonance with the earlier restricted claims in order to qualify for safe harbor under 35 U.S.C. § 121. *See Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1381 (Fed. Cir. 2003). Because '378 application generic Claim 19 was allowed, there was no restriction requirement as between the identified species, and thus no clear line of demarcation exists.

In view of the above, Petitioner submits that because the 141 patent issued from a continuation application; because the IPR Claims were never subject to a restriction requirement; and because there is no clear line of demarcation

sufficient to establish whether the claims of the 141 patent maintain consonance even if they were subject to a restriction requirement, the IPR Claims are not eligible for safe harbor under § 121. Because the asserted claims of the 141 patent are obvious variants of claims in the '378 applications; and because no safe harbor exists under Section 121, the IPR Claims are invalid.

IX. CONCLUSION

For the foregoing reasons, *inter partes* review of the IPR Claims is respectfully requested, followed by the rejection of the claims on each of the bases detailed in this Request.

Respectfully Submitted,

May 6, 2013
Date

By: /s/ Steven D. Hemminger

Steven D. Hemminger
USPTO Reg. No. 30,755
ALSTON & BIRD LLP
275 Middlefield Road, Suite 150
Menlo Park, CA 94025-4008
Tel: 650-838-2029
Fax: 650-838-2001
Email: steve.hemminger@alston.com

Inter Partes Review of U.S. Patent No. 6,306,141

Certificate of Service

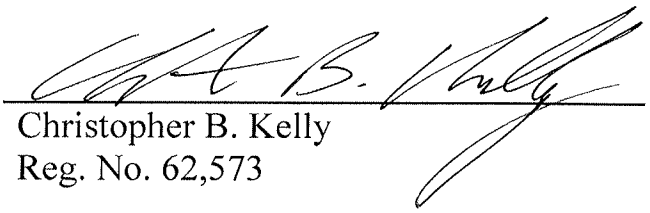
The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b) on the Patent Owner by UPS of a copy of this Petition for *Inter Partes* Review and supporting materials at the corresponding address of record for the '141 Patent:

Medtronic Vascular, Inc.
IP Legal Department
3576 Unocal Place
Santa Rosa, CA 95403

The undersigned further certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b) on the counsel who recorded the most recent assignment of record by UPS of a copy of this Petition for *Inter Partes* Review and supporting materials at the corresponding address:

Jeffrey G. Sheldon
Sheldon Mak & Anderson
100 Corson Street Third Floor
Pasadena, CA 91103-3842

Dated: May 6, 2013



Christopher B. Kelly
Reg. No. 62,573