

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC,

Petitioners

v.

Medtronic, Inc.,

Patent Owner

Patent No. 6,306,141  
Issue date: October 23, 2001

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**DECLARATION OF KAUSHIK BHATTACHARYA, PH.D.  
IN SUPPORT OF PETITION FOR *INTER*  
*PARTES* REVIEW OF U.S. PATENT NO. 6,306,141**

Case No. IPR2019-00123

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## **I. INTRODUCTION**

1. My name is Kaushik Bhattacharya. I have been retained to investigate and provide testimony regarding claims 1-22 of U.S. Patent No. 6,306,141 (Ex. 1001, “the ’141 Patent”), including background relating to the ’141 Patent, on behalf of Petitioners, Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC (collectively “Petitioners”).

2. This declaration is based on information currently available to me. To the extent that additional information becomes available, I reserve the right to revise, amend, or supplement this declaration.

3. In forming my opinions, I have reviewed and relied on the ’141 Patent (Ex. 1001) and its prosecution history (Ex. 1002), the materials listed in Exhibit A and cited in this declaration, and my own experience and expertise.

### **A. Qualifications and Engagement**

#### **1. Education and Work Experience**

4. I am the Howell N. Tyson, Sr., Professor of Mechanics and Professor of Materials Science, as well as Vice Provost at the California Institute of Technology. I have been on the faculty there since 1993.

5. I received my Bachelor of Technology degree from the Indian Institute of Technology, Madras, India in 1986. I received my Ph.D. degree in Mechanics from the University of Minnesota in 1991, and I did my post-doctoral

training at the New York University Courant Institute for Mathematical Sciences during 1991-1993. I have held visiting positions at Cornell University (1988), Heriot-Watt University in Scotland (1992), Max-Planck-Institute at Leipzig (1997-98), Isaac Newton Institute for Mathematical Sciences at the University of Cambridge (1999), Indian Institute of Science at Bangalore (2001), the National Aeronautics and Space Administration Jet Propulsion Laboratory (2006), and the University of Cambridge (2008-09).

6. My research broadly concerns various aspects of the behavior of materials, including mechanical/thermal behavior. I have authored over 150 publications in peer-reviewed publications in the fields of mechanics of materials, continuum mechanics, active materials, shape-memory alloys, heterogeneous materials, and density functional theory. I have delivered numerous plenary, keynote, and named lectures on these subjects around the world. I have extensive experience with the mechanical/thermal behavior of materials, including shape memory alloys.

7. Among other awards, I received the Warner T. Koiter Medal for distinguished contributions to the field of solid mechanics from the American Society of Mechanical Engineers (2015), and the Special Achievements Award for Young Investigators in Applied Mechanics from the American Society of Mechanical Engineers (2004).

8. I served as Editor of the Journal of the Mechanics and Physics of Solids, a leading scientific publication, for twelve years (2004-15). I also served on visiting committees of a number of departments and universities around the world. My research has been supported, at least in part, by the National Science Foundation, Air Force Office of Scientific Research, and the United States Army Research Laboratory.

9. I have conducted research in the area of shape-memory alloys, including nitinol, for three decades. Among my publications relating to shape-memory alloys, I have written a book entitled, "*Microstructure of martensite: why it forms and how it gives rise to the shape-memory effect*," that was published by Oxford University Press in 2004 and is used worldwide as a graduate textbook on the subject. I also co-authored the publication entitled, "*Stress-induced phase transformations in shape-memory polycrystals*," that was published in 2009 in the Archive for Rational Mechanics and Analysis, which is a scientific journal devoted to research in mechanics.

10. I have also given plenary lectures at the major international conferences on shape-memory alloys, including at the International Conference on Shape Memory and Superelastic Technologies (SMST), International Conference on Martensitic Transformations (ICOMAT), and the Conference on Smart Materials, Adaptive Structures and Intelligent Systems (SMASIS).

11. I have been engaged as a consultant by a number of medical device companies to advise them on technological aspects of shape memory alloys, such as nitinol, and use of such alloys in medical devices. I also have experience designing medical devices, including building models of medical devices.

12. I am named as an inventor on at least five U.S. patents.

13. My Curriculum Vitae, including publications and patents, is submitted herewith as Exhibit B, and it further highlights my experience and expertise. My Curriculum Vitae reflects my publications in the last ten years.

14. In view of my education and experience, I believe I am qualified to offer the testimony provided in this declaration.

## **2. Engagement**

15. I am being compensated at a rate of \$500 per hour for my study and time in this matter. I am also being reimbursed for reasonable and customary expenses associated with my work and time in this investigation. My compensation is not contingent on the outcome of this matter or the specifics of my testimony.

### **B. Statement of Legal Principles**

16. I am a technical expert and do not offer any legal opinions. I applied the legal framework outlined below in rendering the opinions reflected in this declaration.

**1. Level Of Ordinary Skill in the Art**

17. I understand that a person having ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art. I have been advised that factors that guide the determination of the level of ordinary skill in the art may include: (1) type of problems encountered in the art; (2) prior art solutions to those problems; (3) rapidity with which innovations are made; (4) sophistication of the technology; and (5) educational level of active workers in the field.

18. It is my opinion that the person having ordinary skill in the art (“PHOSITA”) at the time the first patent application leading to the ’141 Patent was filed on October 14, 1983, would have possessed the knowledge and skill known by an engineer, physician, or similar professional, having knowledge of, or experience with: (1) shape memory alloys exhibiting reversible stress-induced martensite behavior, and/or (2) designing medical devices using such shape memory alloys. The opinions and statements made in this declaration, unless otherwise noted, are made from the perspective of a PHOSITA as of October 14, 1983, although the same opinions and statements apply in the surrounding timeframe as well.

**2. Claim Construction**

19. I understand that, in a proceeding for *inter partes* review, a claim in an unexpired patent is to be given its broadest reasonable interpretation in light of

the specification in which it appears. I also understand that the words in the claims are to be evaluated from the perspective of a PHOSITA.

### **3. Legal Framework**

20. I understand that a patent claim may be unpatentable for a number of reasons, including, for example, if it recites subject matter that is not new or that would have been obvious to a PHOSITA.

21. I understand that a claim is not new if all of the elements of the claim are present in a single printed publication or patent. In these cases, I understand that the claim is said to be “anticipated.” I understand that to anticipate a claim, the prior art does not have to use the same words as the claim, but all of the requirements of the claim must have been disclosed, either inherently or expressly, to a PHOSITA.

22. I also understand that, even though every element of a claim is not disclosed in a single printed publication or patent, the claim may still be unpatentable if it would have been obvious to a PHOSITA at the time of the invention. In determining whether a claimed invention is obvious, I understand that a number of factors must be considered including the level of ordinary skill in the art at the time the invention was made, the scope and content of the prior art, and any differences between the prior art and the claimed invention.

23. I also understand that obviousness is not necessarily proved simply by showing the existence of each and every element of the claimed invention in the prior art. I understand that I should also consider whether there were reasons that would have prompted a PHOSITA to combine the known elements in a way the claimed invention does, including:

- common sense;
- whether the claimed invention was merely the predictable result of using prior art elements according to their known function(s);
- whether the claimed invention provides an obvious solution to a known problem in the relevant field;
- whether the prior art teaches or suggests the desirability of combining elements in the manner claimed in the invention;
- whether the prior art teaches away from combining elements in the manner claimed in the invention;
- whether it would have been obvious to try the combination of elements, such as when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions; and,
- whether the modification or combination would have resulted from design incentives or other market forces.



24. Moreover, I am advised that the prior art must provide a reasonable expectation of success. In addition, I understand that the use of hindsight is improper, and that only what was known at the time of the invention can be considered.

25. In addition, I also understand that objective evidence, or “secondary considerations,” that existed at the time of the invention and afterwards may shed light on the non-obviousness or obviousness of the claimed invention, and should be taken into account. These considerations include, for example:

- whether products incorporating the claimed invention have been commercially successful and, if so, whether the commercial success can be attributed to the claimed invention;
- whether the invention satisfied a long-felt, unmet need;
- whether others had tried and failed to make the invention;
- whether others copied the invention;
- whether the invention achieved unexpected results;
- whether others in the field praised the invention;
- whether persons having ordinary skill in the art in the technology of the invention expressed surprise or disbelief regarding the invention;

- whether the inventor proceeded contrary to the accepted wisdom in the field; and,
- whether there were independently made, simultaneous inventions made within a comparatively short space of time.

26. I also understand that, in order to be relevant to the issue of obviousness, any such secondary consideration must have some connection (or nexus) to the claimed invention.

## **II. OVERVIEW OF SHAPE MEMORY ALLOY TECHNOLOGY AND THE '141 PATENT**

### **A. Shape Memory Alloys**

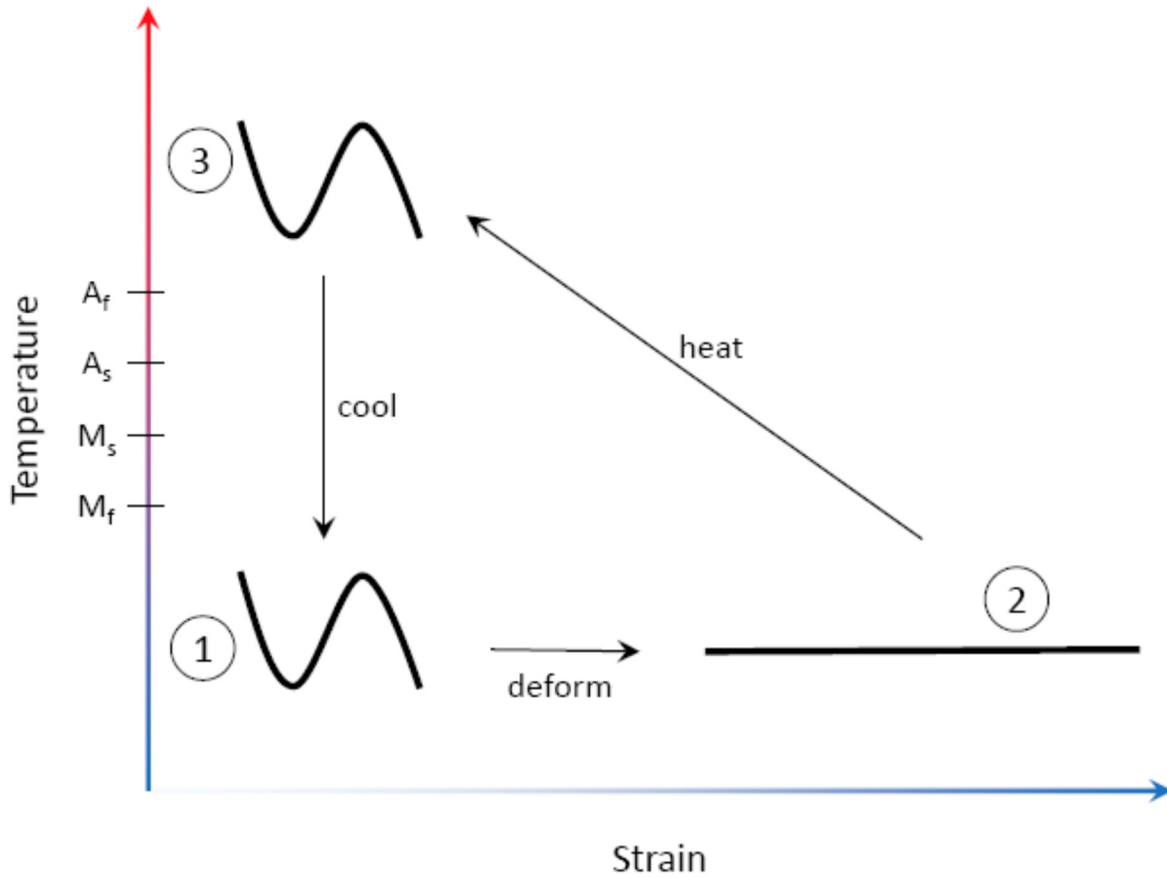
#### **1. Ordinary Elasticity**

27. When a force is applied to a solid body, the body deforms by some amount. The amount of deformation is proportional to the amount of applied force. When the deforming force is released, the body may return back to its original state. This is known as *elasticity*. However, the amount of elasticity that any material has is limited: if we apply too much force, i.e., cause too much deformation, then the material undergoes permanent deformation. In engineering practice, deformation is quantified by:

$$\textit{Strain} = \textit{Change in length of a segment} / \textit{Original length of the segment}$$

## 2. Shape-Memory Effect

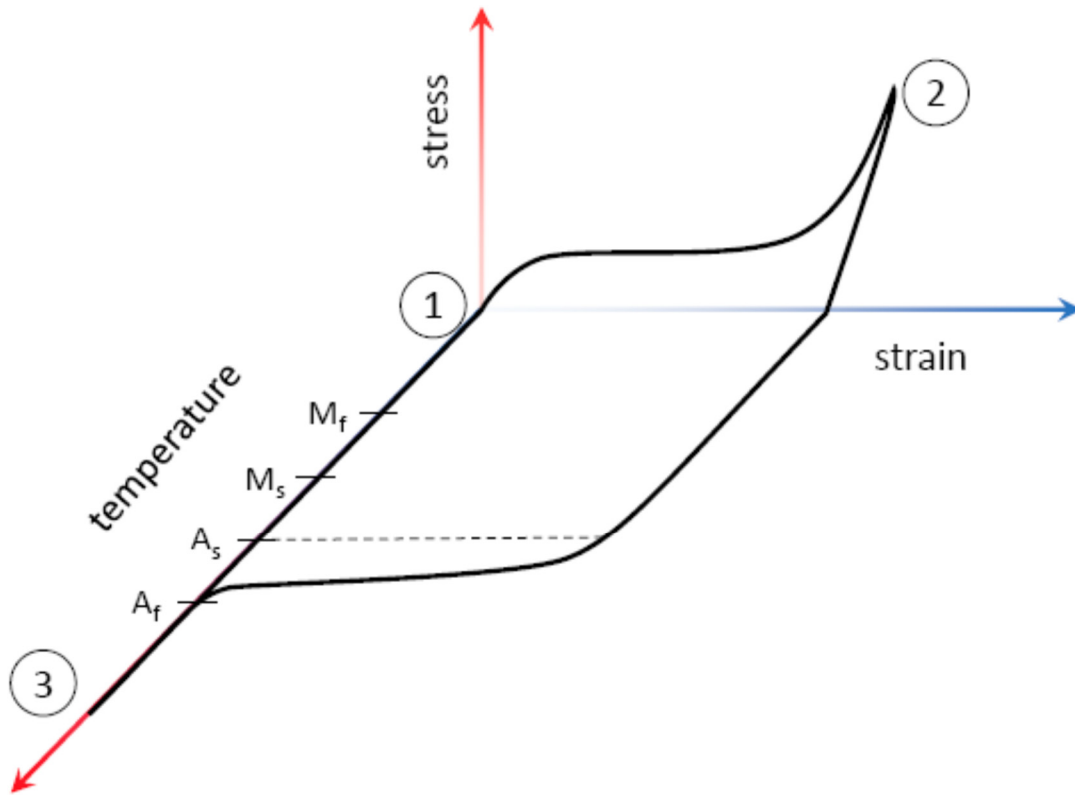
28. The shape-memory effect is the ability of shape memory alloys (SMAs) to recover or “remember” a shape after deformation. For example, the following figure illustrates shape memory effect based on temperature transitions.



**Fig. 1: Schematic of shape-memory effect based on temperature transitions**

29. The basic phenomenon of shape-memory effect is illustrated in Figure 1 above. The temperature values on the y-axis are defined as follows (and are further discussed below):  $M_s$  is the *martensite start* temperature at which austenite starts to transform to martensite;  $M_f$  is the *martensite finish* temperature

at which the specimen becomes fully martensitic;  $A_s$  is the *austenite start* temperature at which martensite starts to transform to austenite;  $A_f$  is the *austenite finish* temperature at which the specimen becomes fully austenitic. Now, consider a wire made of a SMA that displays a shape-memory effect at room temperature (where room temperature is below the  $M_f$  temperature, for illustrative purposes). In this example, the wire is preformed into a wavy shape (bottom left in Figure 1) and may look and feel quite unremarkable. It may be deformed at room temperature, for example into the straight shape shown at the bottom right of Figure 1. The wire may be described as ductile, as it deforms with little recoil. But if we dip the straightened wire into a cup of hot water thereby heating it (for example, to a temperature higher than the  $A_f$  temperature), it reforms back to its original wavy shape (top left in Figure 1). Now, if we take the wire out of the hot water and hold it in ambient air, it cools down with no change in shape and returns to the starting state and temperature (bottom left in Figure 1). This cycle illustrates shape-memory effect, and the cycle can be repeated.



**Fig. 2: Stress-strain-temperature behavior during the shape-memory effect**

30. The cycle shown schematically in Figure 2 illustrates stress-strain-temperature behavior during the shape-memory effect. We begin at low temperature at zero strain at the point marked “1” in Figure 2. (Note that along the temperature axis in Figure 2, “1” refers to a colder temperature and “3” refers to a warmer temperature). We now deform the material by an application of force, maintaining the low temperature. It is common practice to characterize the force by:

$$\textit{Stress} = \textit{Force applied to a body} / \textit{Cross-sectional area of the body}$$

We see in Figure 2 that there is an initial elastic response where the strain (deformation) is proportional to the stress (force) until the strain reaches a point where increases in the strain are no longer proportional to the stress. The material now suffers significant strain with little increase of stress giving rise to a plateau which may have a slope (rather than being parallel to the x-axis). At the end of the plateau, the stress begins to rapidly increase until it reaches the peak value, corresponding to a point marked “2” in Figure 2. If the force is released at this point (i.e., the stress is reduced to zero), the figure illustrates that the strain does not fully recover to zero. Instead, it goes to the value corresponding to a point on the “strain” axis below the point marked “2” in the figure. In other words, deformation at this temperature appears permanent (corresponding to going from the bottom left to bottom right in Figure 1).

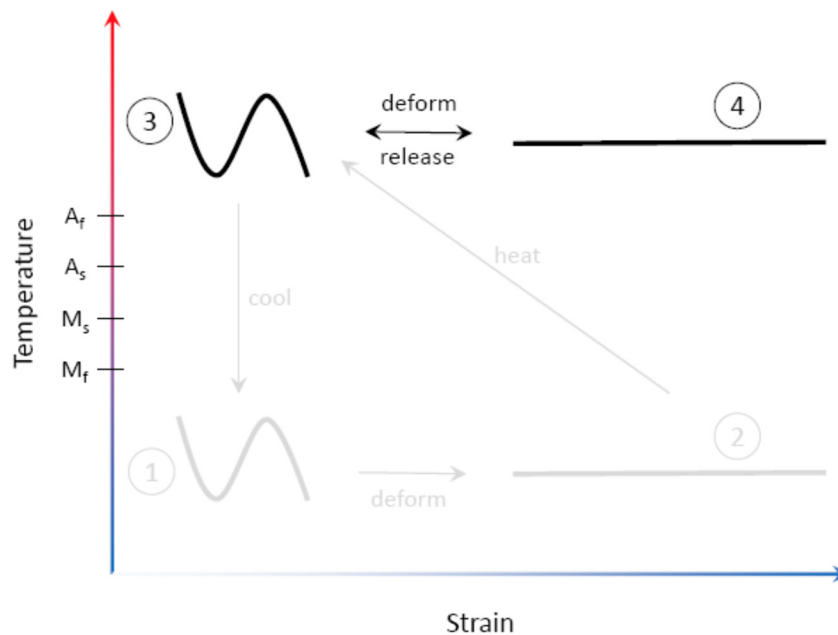
31. Continuing our description of Figure 2, if we now start heating the material with no applied stress (force), the following occurs. The temperature rises, but there is no physical change until we reach the temperature marked  $A_s$ . Beyond this temperature, the strain gradually decreases and goes to zero at the temperature marked  $A_f$ . Further heating does not lead to significant physical change in the material, and we reach the point marked “3”. The material has now fully recovered its apparently permanent deformation (corresponding to the step from bottom right to top left in Figure 1).

32. Finally, we cool the material to return to the starting point marked “1” (correspondingly top left to bottom left in Figure 1). During this cooling phase, there is no significant physical change in the shape of the material.

33. This process is sometimes referred to as shape memory effect, and alloys exhibiting this effect are referred to as SMAs.

### 3. Pseudoelasticity

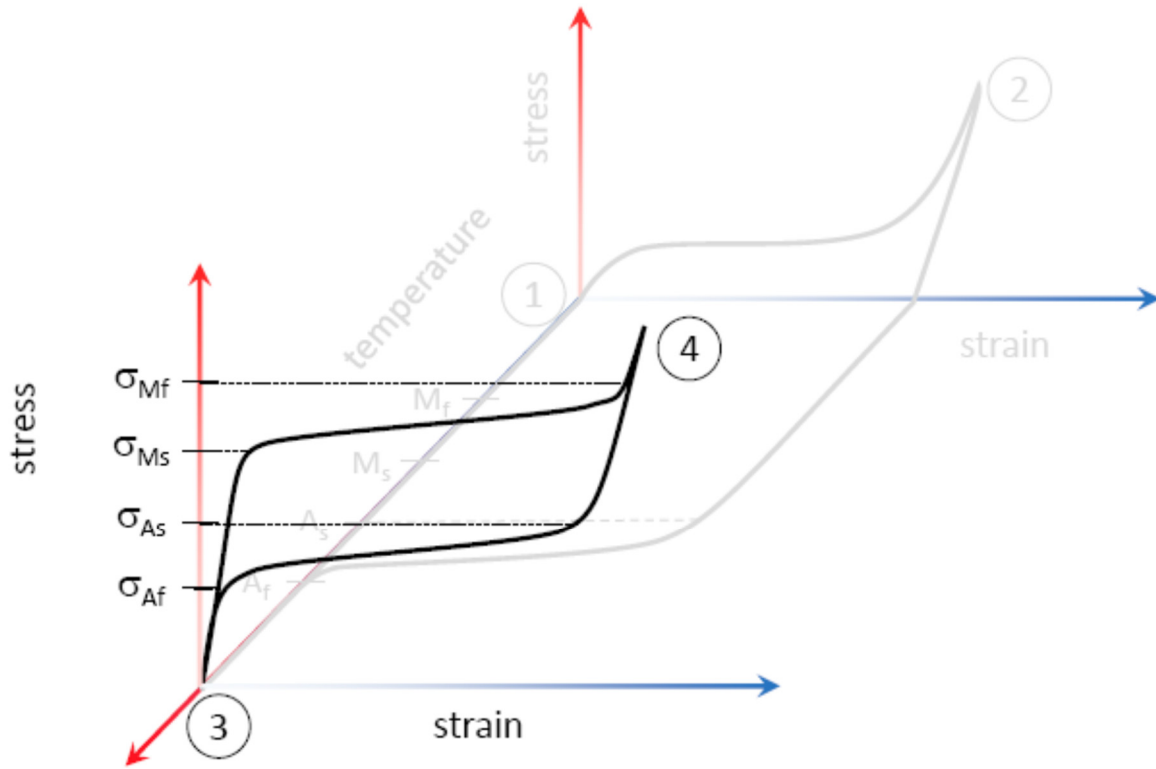
34. Pseudoelasticity is the ability of SMAs to recover strains beyond those possible by ordinary elasticity when the applied force is released. Pseudoelasticity is also widely referred to as superelasticity or reversible stress-induced martensite (SIM) behavior. Less common, pseudoelasticity is also referred to as ultraelasticity. Pseudoelasticity is further described below.



**Fig. 3: Schematic of pseudoelasticity**

35. Consider again the same wire shown in Figure 1 made of a SMA that displays a shape-memory effect at room temperature. We add the pseudoelasticity behavior to Figure 1, as shown in Figure 3. If we try to deform the wire while in the cup of warm water (top left in Figure 3) after it has resumed its original shape, it feels stiffer than when the wire is cold. However, if we apply a sufficient deforming force while keeping the wire in the cup of hot water, we can once again deform the wire into a straight shape (top right in Figure 3), without changing the temperature of the alloy as described above regarding Figure 1. However, once the deforming force (stress) is released, the wire returns to its original wavy shape (top right to top left in Figure 3). This phenomenon is pseudoelasticity (a.k.a. superelasticity or ultraelasticity), and it can be repeated.



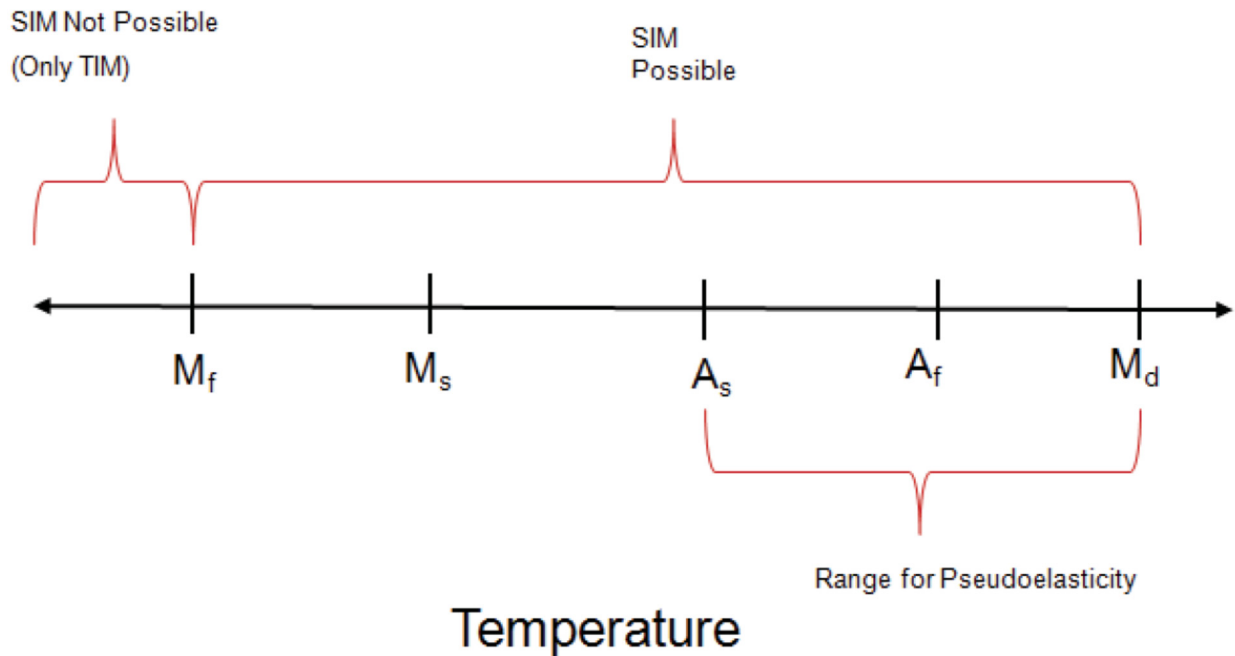


**Fig. 4: Stress-strain-temperature behavior associated with pseudoelasticity**

36. Pseudoelasticity is also shown schematically in Figure 4 (which adds to Figure 2), and illustrates stress-strain-temperature behavior associated with pseudoelasticity. We start at the state marked “3” in Figure 4 and apply stress (force). We see an initial elastic region followed by a plateau region though the value of the stress at the plateau is higher than the value of the stress at the plateau discussed previously with respect to Figure 1. At the end of the plateau region, the stress begins to rise as we reach the point marked “4” in Figure 4 (corresponding to the top right in Figure 3). When we release the force (stress), the strain fully

recovers returning us to the starting point of “3” in Figure 4 (corresponding to the top left in Figure 3).

37. A SMA exhibits pseudoelasticity by phase changing from austenite to martensite at the atomic level upon the application of stress, and changing back from martensite to austenite upon the removal of the stress, as further discussed below. The temperature ranges for formation of stress-induced martensite, including pseudoelasticity, are illustrated in Figure 5 below:



**Fig. 5: Temperature Ranges For SIM And Pseudoelasticity**

As shown, pseudoelasticity occurs over a temperature range between  $A_s$  and  $M_d$ , although stress-induced martensite behavior may occur over a temperature range between  $M_f$  and  $M_d$ . However, *reversible* stress-induced martensite behavior

occurs only over the pseudoelasticity range, because stress-induced martensite cannot be reversed (to austenite) at a temperature below the  $A_s$  temperature.

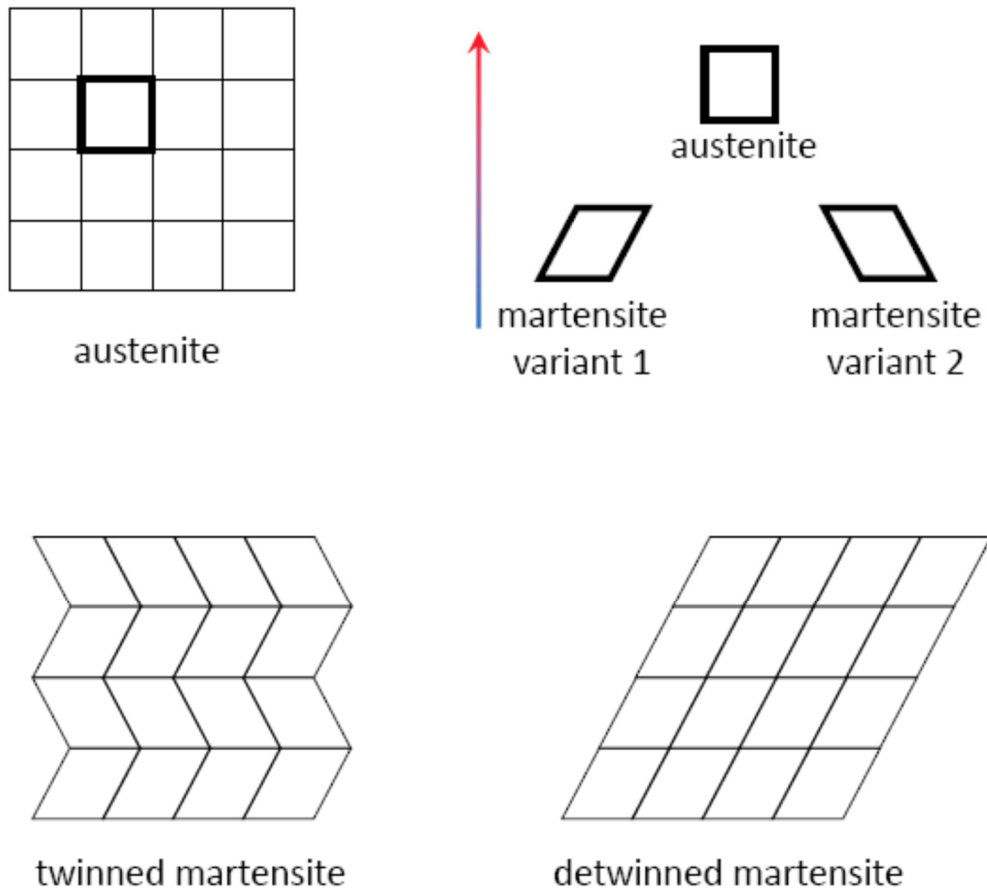
#### **4. Martensitic Phase Transformation**

38. Shape-memory, including pseudoelasticity, observed in SMAs is a manifestation of a phase transformation known as the martensitic phase transformation.

39. Phase transformations are common in nature – all matter can exist in different forms or phases depending on temperature, pressure, etc. Just as water can reversibly transform between different states (*e.g.*, water, steam, ice), SMAs can reversibly transform between their austenitic and martensitic states. At atmospheric pressure at sea level, water transforms to the steam phase (boiling/condensation) at 212°F and water transforms to the ice phase (freezing/melting) at 32°F. However, these phase transformation temperatures are not fixed, but depend on pressure. The water-steam phase transformation increases with increasing pressure (*e.g.*, water boils at higher temperature inside a pressure cooker), and decreases with decreasing pressure (*e.g.*, water boils at lower temperature at a higher elevation). Thus, for example, water existing as a steam at one temperature may be turned to liquid by the application of pressure *or* the reduction of temperature. Similarly, a SMA existing as austenite at one temperature may be turned into martensite by the application of stress (stress-

induced martensite or SIM) *or* the reduction of temperature (temperature-induced martensite or TIM). Austenite is not turned into martensite by increasing the temperature of the SMA.

40. Most solids, including shape-memory alloys like nitinol (a common SMA), are crystalline; i.e., their atoms are arranged in regular patterns or crystal structures. The martensitic phase transformation is a reversible solid to solid phase transformation where the crystal structure changes. The high-temperature phase is known as the *austenite* phase whereas the low-temperature phase is known as the *martensite* phase.



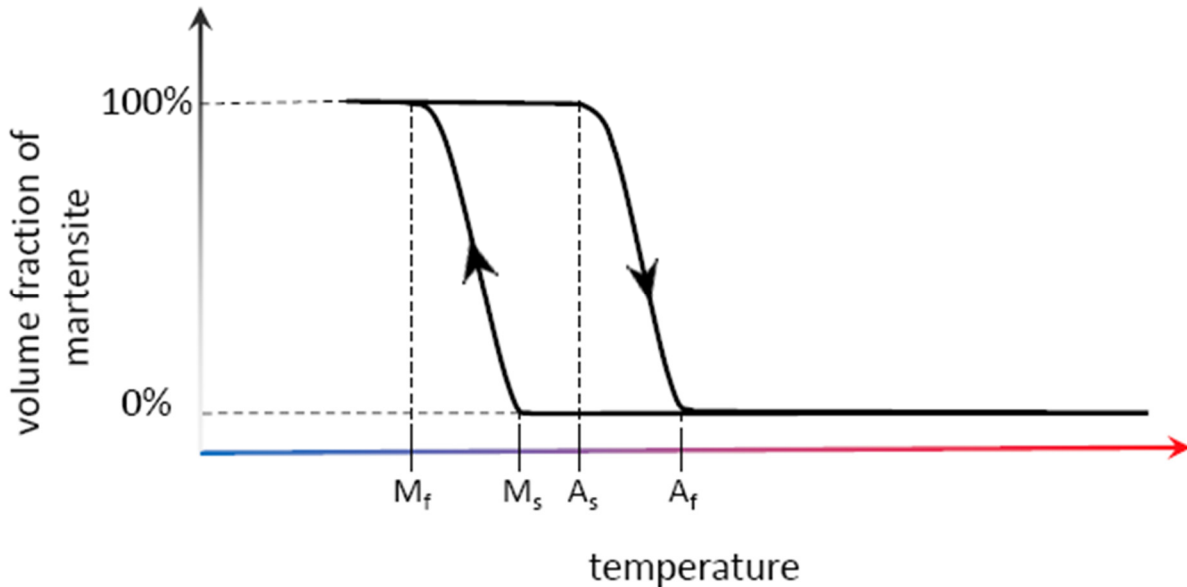
**Fig. 6: Martensitic phase transformation**

41. The martensitic phase transformation is shown schematically in Figure 6 above where the high temperature austenite phase is depicted as a square and the low temperature martensite phase is depicted as a slanted square. In the austenite phase, the SMA assumes a simple cubic crystalline structure referred to as austenite. At low enough temperatures, the SMA transforms to a crystal structure with lower symmetry known as martensite. There are two variants of martensite – one slanted to the right (labeled “martensite variant 1” above), and

one slanted to the left (labeled “martensite variant 2” above). The martensite in a SMA sample can consist of either (i) a mixture of both variants of martensite known as *twinned martensite* (labeled “twinned martensite” above) or (ii) as a single variant known as *detwinned martensite* (labeled “detwinned martensite” above).

### 5. TIM Phase Transformations vs. SIM Phase Transformations

42. The following figure illustrates the martensite-austenite and austenite-martensite transitions for a typical SMA.

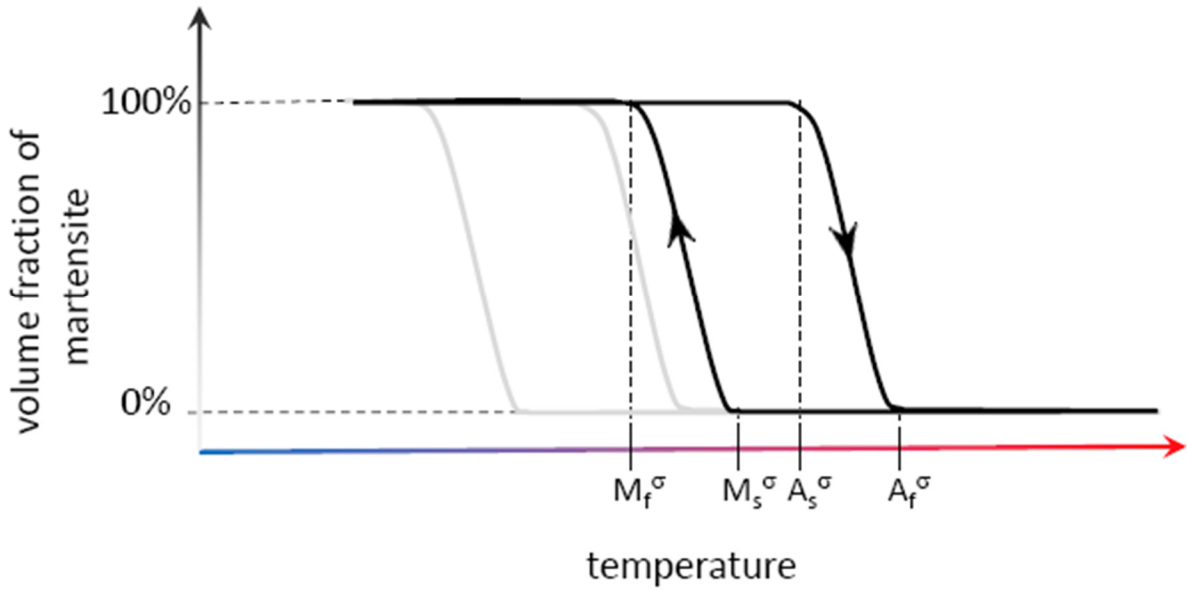


**Fig. 7: Temperature vs. volume fraction of martensite with no applied force**

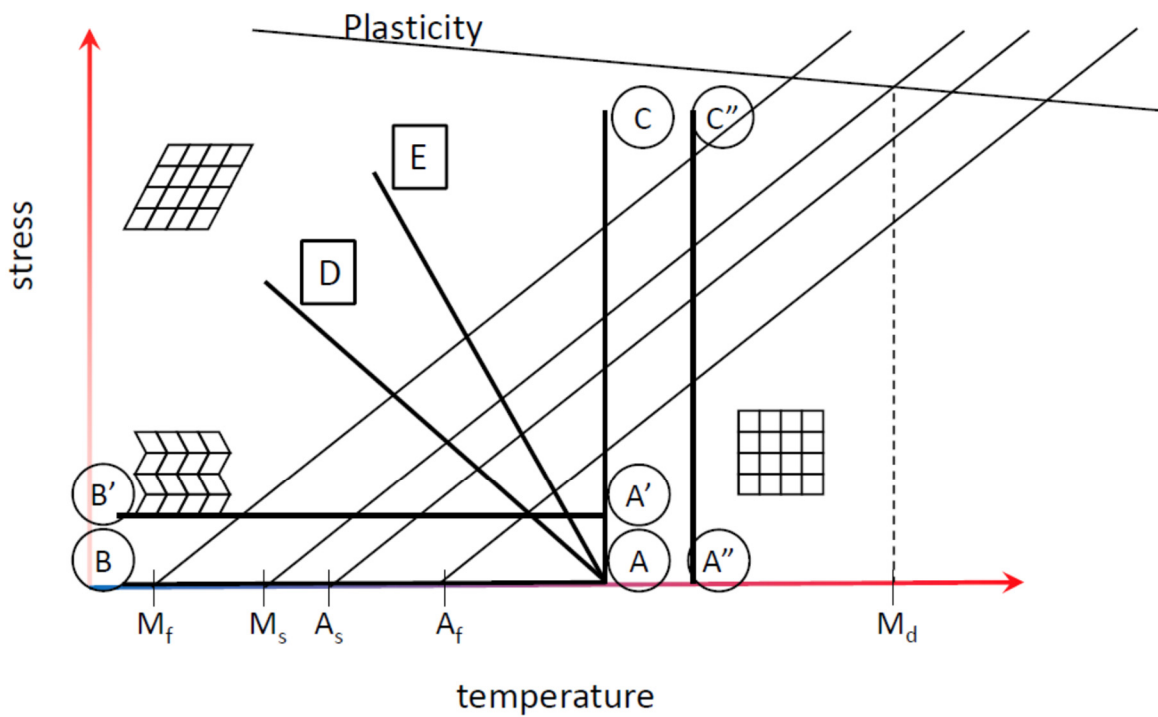
43. The temperature necessary to achieve a specific percentage of martensite may be different for a SMA depending on whether the alloy is transitioning from martensite to austenite or vice-versa. Indeed, Figure 7 illustrates

that the curve reflecting the transition from martensite to austenite (where the percentage of martensite decreases when the operating temperature rises above  $A_s$ , which is referenced by the arrow on the curve pointing down in the figure above) is different from the curve reflecting the transition from austenite to martensite (where the percentage of martensite increases when the operating temperature drops below  $M_s$ , which is referenced by the arrow on the curve pointing up in the figure above). This phenomenon is referred to as a hysteresis loop.

44. As mentioned above,  $M_s$  is the *martensite start* temperature at which austenite starts to transform to martensite;  $M_f$  is the *martensite finish* temperature at which the SMA becomes fully martensitic;  $A_s$  is the *austenite start* temperature at which martensite starts to transform to austenite;  $A_f$  is the *austenite finish* temperature at which the SMA becomes fully austenitic. Figure 7 reflects that decreasing temperature below  $M_s$  transforms austenite to martensite and increasing temperature above  $A_s$  transforms martensite to austenite. SMAs that rely upon such behavior during their use are said to rely upon TIM behavior. Further details are provided below.



**Fig. 8: Temperature vs. volume fraction of martensite with applied stress**



**Fig. 9: Transformation temperatures change with stress**



45. Consider a SMA specimen at a sufficiently high temperature with no applied forces, corresponding to the state marked “3” in Figure 1 above. It is completely in the austenite phase. Now start cooling the specimen. It remains in the austenite phase until cooled to the  $M_s$  temperature where some of the austenite transforms to martensite. As we continue to cool the specimen, the amount of martensite continues to increase as shown schematically in Figure 7. The transformation is complete and the specimen becomes fully martensitic at the  $M_f$  temperature.

46. Now start to heat the specimen that is in the martensite phase. The material remains in the martensite phase until we reach the  $A_s$  temperature where some of the martensite transforms to austenite. This is also called the reverse transformation. As we continue to heat the specimen, the amount of austenite continues to increase as shown in Figure 7 until the specimen is fully austenitic at the  $A_f$  temperature. The four transition temperatures are typically ordered as shown in Figure 7 for SMAs, including nitinol. Between  $A_f$  and  $M_f$  temperatures, both austenite and martensite phases can exist or co-exist depending on the temperature and mechanical history of the SMA.

47. In the discussion above, the martensite that forms on cooling the austenite phase specimen is referred to as *temperature-induced martensite* or TIM. It is twinned martensite (also known as self-accommodated martensite), and the

austenite to martensite transformation is not accompanied by any change of shape. This corresponds to the change from the state marked “3” to the state marked “1” in Figure 1 above. However, if we apply stress to the specimen while it is in the martensite phase, the twinned martensite changes to detwinned or deformed martensite. This is accompanied with a deformation (change of shape) that remains even when we remove the stress (assuming the specimen remains below the austenite start or  $A_s$  temperature). This corresponds to the change from the state marked “1” to the state marked “2” in Figure 1 above. This deformation is possible because both twinned and detwinned martensite are different forms of the same phase.

48. In addition, just like water boils at a higher temperature when pressure is applied, so do the martensitic phase transformation temperatures increase when force (stress) is applied to a martensitic material. This is shown in Figure 8. We start at a sufficiently high temperature and apply a mechanical force (stress) to the specimen. As discussed above, it is common to characterize the applied force as:

$$\text{Stress} = \text{Force applied to a body} / \text{Cross-sectional area of the body.}$$

While holding the stress fixed, we start to cool the specimen. Nothing happens until we reach the temperature marked  $M_s^\sigma$  (martensite start at stress  $\sigma$ ) when the austenite begins to transform to martensite. I note that the temperature  $M_s^\sigma$  is *greater* than the temperature  $M_s$  at which the martensite began to form when no

force was applied. Further cooling leads to further transformation and an increase in the volume fraction of martensite as shown in Figure 8. The transformation is complete at the temperature  $M_f^\sigma$  (martensite finish at stress  $\sigma$ ), and the temperature  $M_f^\sigma$  is *greater* than the martensite finish temperature with no applied force  $M_f$ . When we now heat the specimen, it begins the reverse transformation at  $A_s^\sigma$  (austenite start at stress  $\sigma$ ) and finishes it at  $A_f^\sigma$  (austenite finish at stress  $\sigma$ ). Similarly,  $A_s^\sigma$  and  $A_f^\sigma$  are higher than the corresponding temperatures  $A_s$  and  $A_f$  at zero applied stress.

49. The martensite that is formed in the specimen depicted in Figure 8 can be either twinned (or self-accomodated) martensite, or it can be the detwinned (or deformed) martensite depending on the level of applied stress.

50. We have seen above that the transformation temperatures increase when we apply a stress. The change of any particular temperature is proportional to the amount of applied stress; this is the well-known Clausius-Clapeyron relation. This is shown schematically in Figure 9. The two previous discussions of cooling with no applied stress (Figure 7) and cooling with applied stress (Figure 8) are denoted as the paths AB and A'B' respectively in Figure 9.

51. One can also induce the martensitic phase transformation through the application of stress, as mentioned above. For example, consider a situation where we are at a temperature above the austenite start ( $A_s$ ) temperature at zero stress

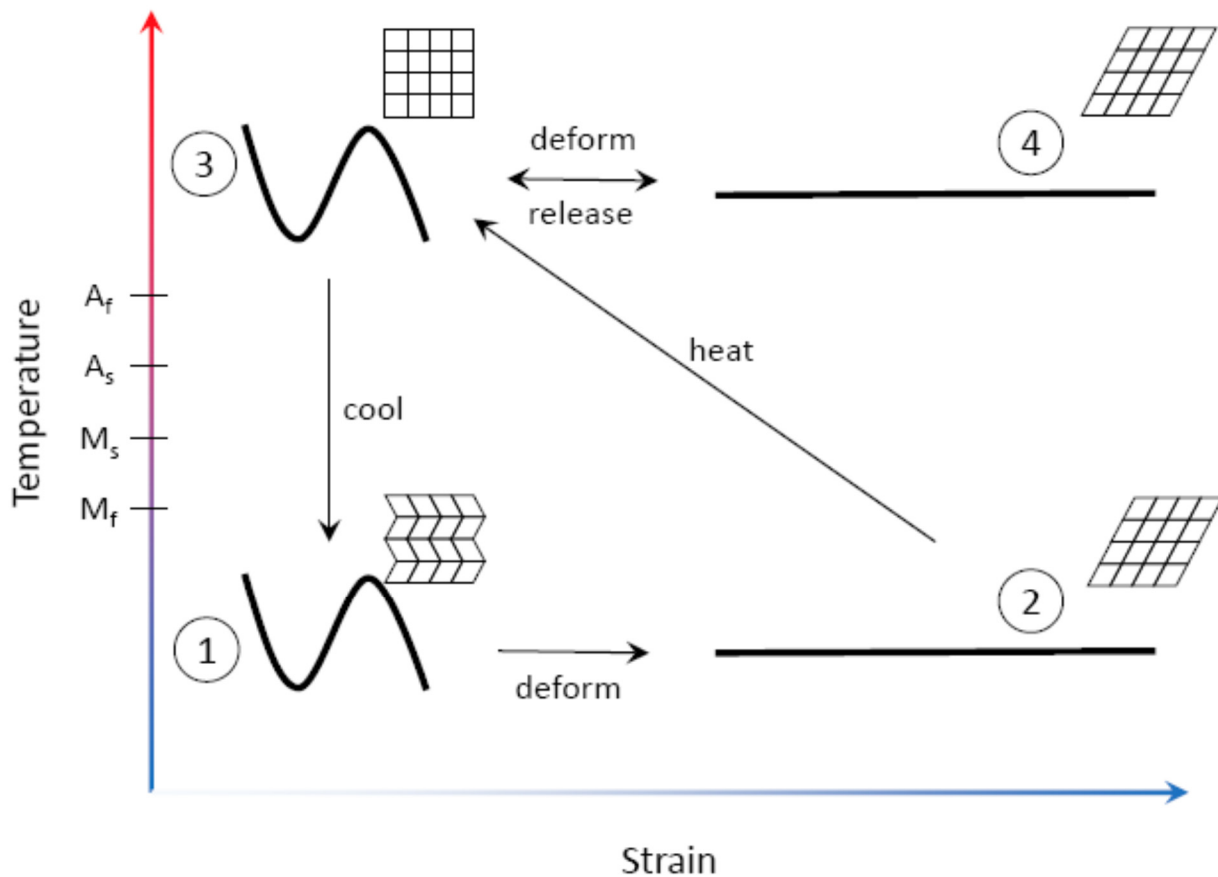
(point marked A in Figure 9) and fully in the austenite state. Now, holding the temperature constant, we apply sufficient stress until we reach the point marked C in Figure 9. This also corresponds to the change from the state marked “3” to the state marked “4” in Figure 4. The martensite we obtain in this manner is referred to as *stress-induced martensite* (SIM) and is accompanied by a change of shape.  $M_d$  (not labeled in Figures 7 and 8 above) refers to the maximum temperature at which martensite can be induced by stress. Stress-induced martensite occurs whenever stress is applied to a SMA above its  $M_f$  temperature and below its  $M_d$  temperature.

52. Just like the temperature at which the transformation-induced-martensite forms changes with the application of stress, the converse is also true; i.e., the stress at which the stress-induced-martensite forms increases with temperature. This is a consequence of the Clausius-Clapeyron relation. This is shown schematically in Figure 9 through the line A”-C”. We start at the point A” which is at a higher temperature than A and apply stress till we reach the point C”. Note that this line A”-C” crosses the diagonal lines (which indicate the various transformations) at a higher level of stress.

53. It is also possible to induce martensitic transformation using any number of combinations of temperature and stress. Some example pathways are indicated by the two angled lines labeled “D” and “E” in Figure 9.

### 6. How Martensitic Transformation Gives Rise To The Shape-Memory Effect And Pseudoelasticity

54. I now look back at the shape-memory effect and pseudoelasticity in light of this background on martensitic phase transformation. In this example, the SMA wire has a martensite finish ( $M_f$ ) temperature above room temperature and an austenite finish ( $A_f$ ) temperature below the temperature of the hot water in the cup.



**Fig. 10: Schematic of the shape-memory effect and pseudoelasticity along with crystallography**

55. Starting with the high temperature state in the top left of Figure 1, which is reproduced as Figure 10 along with a view of the crystallographic details,

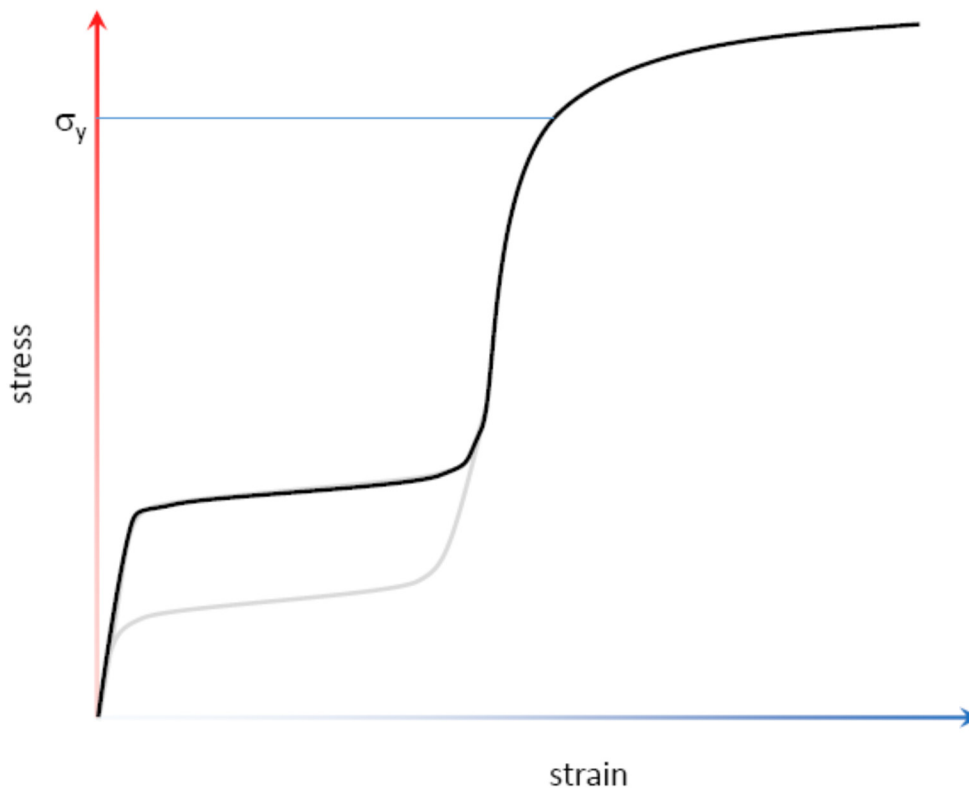
we are above the austenite finish ( $A_f$ ) temperature. Thus, the specimen is all in the austenite phase (top left in Figure 10). We gradually cool it to room temperature which is below martensite finish ( $M_f$ ), and so the austenite transforms to twinned (or self-accommodated) martensite (bottom left in Figure 10). This is TIM. Since the martensite is twinned, the regions that are slanted to the right and the regions that are slanted to the left compensate for each other and we have no net change in shape. Now, we deform the specimen holding the temperature constant. This deformation is accommodated not by distorting the lattice or tearing it apart, but by the left slanted cells snapping to the right slanted cells. As a result, we end up with deformed (or detwinned) martensite (bottom right in Figure 10). Since the specimen is still in the martensite phase and this phase is stable at this temperature, the specimen remains deformed even when the load is released. In other words, the deformation appears permanent. However, if we now heat the specimen by putting it in the hot water which is above the austenite finish ( $A_f$ ) temperature, all the martensite transforms back to the austenite (top left in Figure 10). Now all the cells are square, and the deformation is completely recovered. The specimen, therefore, reverts back to its original wavy shape. This is an example of the shape-memory effect.

56. Now focusing on pseudoelasticity, consider the wire in hot water that is above the austenite finish ( $A_f$ ) temperature, such that the wire is in the austenite

phase (top left in Figure 10). Holding the temperature constant, we deform the specimen. The material resists until we reach the stress necessary to induce the transformation. Beyond the stress necessary to induce transformation, the material transforms to the deformed martensite (top right in Figure 10). However, this martensite is unstable at this temperature without the stress. Therefore, the moment we release the stress, the martensite transforms back to the austenite returning the wire to its original shape (top left in Figure 10). This is reversible SIM behavior.

## 7. Ordinary Plasticity

57. There is one final phenomenon that one has to consider regarding SMA technology. All metals also deform by a mechanism known as *plasticity* when sufficient forces are applied to it. However, this deformation is permanent – in other words, releasing the applied force or heating the specimen does not restore the material to its original shape. Here, the atoms slide past one another, and therefore all “memory” of its original shape is lost. The stress at which plasticity begins is sometimes called the plastic *yield stress* of the material and denoted as  $\sigma_y$ . This value can be manipulated in typical metals, and in particular in shape-memory alloys, by heat-treatment and varying the composition.



**Fig. 11: Plasticity in shape-memory alloys**

58. Shape-memory alloys also display plastic deformation if sufficient force is applied. As shown in Figure 11, in the case of pseudoelasticity, if the specimen is subjected to a stress that is extremely high, plastic deformation occurs.

### **8. Shape-Memory Effect And Pseudoelasticity In Nitinol**

59. Nickel-Titanium SMAs are often referred to as “nitinol” (even though the particular composition and properties of one nitinol alloy may differ from one to the next). The word *nitinol* refers to nickel-titanium and the U.S. Naval Ordnance Laboratory where its shape-memory property was discovered by



William J. Buehler and Frederick E. Wang in 1962.<sup>1</sup> Nitinol is a commonly used shape-memory alloy in medical devices.

60. It was accepted by 1974 that the shape-memory effect and pseudoelastic properties of nitinol correspond to the general principles described above for SMAs.<sup>2</sup> Indeed, in their widely cited review from 1974, Delaey *et al.*<sup>3</sup> state: “all essential features of present interest (in [nitinol]) correspond to those of the other alloys.” (Ex. 1016, p. 5). Further, “the essential equivalence of temperature and stress,” as well as the Clausius-Clapeyron relation, had been well established in nitinol wires, as described in Perkins *et al.*<sup>4</sup> in 1975.

61. Various applications of nitinol were explored well before 1983. In particular, potential medical application was widely publicized. Schetky in

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<sup>1</sup> George B. Kauffman & Isaac Mayo, *The Story of Nitinol: The Serendipitous Discovery of the Memory Metal and Its Applications*, 2 *Chemical Educator* 1, 4-6 (1996). Ex. 1019 is a true and correct copy of the Kauffman publication.

<sup>2</sup> See also Sections II.A.1. to II.A.7. above.

<sup>3</sup> L. Delaey et al., Thermoelasticity, Pseudoelasticity And The Memory Effects Associated With Martensitic Transformations, Part 1 Structural And Microstructural Changes Associated With The Transformations, *J. Materials Sci.* 1521, 1525 (1974). Ex. 1016 is a true and correct copy of the Delaey publication.

<sup>4</sup> Jeff Perkins *et al.*, *Shape Memory Effects In Alloys*, 273, 275-303 (Jeff Perkins ed. 1975). Ex. 1017 is a true and correct copy of the Perkins publication.

his 1979 article in *Scientific American* noted that “Nitinol does not react adversely with living tissue” and described using nitinol to fasten artificial joints, facilitate the alignment of fractured bones, and filtering blood clots out of the circulatory system.<sup>5</sup> (Ex. 1018, p. 6).

**B. The '141 Patent**

**1. The Specification**

62. The '141 Patent is entitled “Medical Devices Incorporating SIM Alloy Elements.” (Ex. 1001). The patent is directed to medical devices that use a SMA exhibiting reversible SIM behavior at body temperature. (Ex. 1001, 2:59-3:4, 3:27-32, 5:25-26, 7:6-7, 8:25-26, 10:26-27; *see also* Ex. 1002, p. 119).

63. The '141 Patent acknowledges that SMAs were already known and used in medical devices. The specification states that “[v]arious proposals have also been made to employ shape memory alloys in the medical field.” (Ex.1001, at 2:15-22 (citing U.S. Patent No. 3,620,212 (SMA intrauterine contraceptive device), U.S. Patent No. 3,786,806 (SMA bone plate), and U.S. Patent No. 3,890,977 (SMA catheter)); *see also* Ex. 1002, p. 119; Ex. 1003, p. 55). Further, the '141 Patent acknowledges that SMAs exhibiting SIM behavior were known. (Ex. 1001, 1:52-

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<sup>5</sup> *See* L. McDonald Schetky, *Shape-Memory Alloys*, 241 *Sci. Am.* 74 (1979). Ex. 1018 is a true and correct copy of the Schetky publication.

53 (“Many [SMAs] are known to display [SIM].”). Figure 2 of the ’141 Patent illustrates a SMA exhibiting reversible SIM behavior.

64. Thus, the ’141 Patent describes the alleged “invention” as a simple substitution of one prior art material (SMA exhibiting SIM behavior at body temperature) for another prior art material (SMA relying on TIM behavior at body temperature). (Ex. 1001, 2:59-63 (“I have discovered that if, in a medical device containing a [SMA] element which uses the shape memory property of that alloy, an element which shows the property of [SIM] is used instead, an improved device results.”); 2:64-3:4 (“this invention provides . . . the improvement in which comprises the substitution of an alloy element which displays [SIM] at . . . body temperature for the [SMA]”); 3:29-32; 5:25-26; 7:6-7; 8:25-26; 10:26-27; see also Ex. 1002, p. 119 (the invention “uses [SIM] material in place of conventional [SMA] material.”).<sup>6</sup>

65. The ’141 Patent describes the selection of a suitable alloy as routine. “Suitable alloy for this invention i.e. those displaying [SIM] at temperatures near mammalian body temperature (35°-40° C.), may be selected from known SMAs by

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<sup>6</sup> Page number citations herein reference the exhibit numbering branded on the lower right corner of the exhibit, unless the context makes clear otherwise.

those of ordinary skill in the [] art, having regard to this disclosure by testing for the existence of the SIM effect at the desired temperature.” (Ex. 1001, 4:22-27).

## 2. Prosecution File History

66. During prosecution, the claims were rejected as obvious based on Balko (Ex. 1027), Seader (Ex. 1028), and Foster (Ex. 1029). (Ex. 1002, p. 110). The Examiner stated that Balko discloses a SMA referred to as “nitinol” in a medical “graft structure,” but does not disclose that the SMA had SIM properties. (*Id.*). The examiner argued, however, that Seader discloses that nitinol has SIM properties and, thus, the nitinol alloy disclosed in Balko inherently had SIM properties. (*Id.*; *see also* pp. 218-219).

67. In response, Applicant appealed the rejection to the Board and submitted a declaration by Dr. Lee Middleman. (Ex. 1002, p. 171). Relying on the declaration, Applicant argued that “Balko does not teach [1] use of an SIM material or [2] use of a [SMA] that exhibits properties of an SIM material at about body temperature.” (*Id.*, pp. 168, 171-172). Applicant also argued that “Seader...says nothing about nitinol inherently having the characteristic of exhibiting SIM properties,” and not all “nitinol alloys can exhibit [SIM] behavior.” (*Id.*, p. 231).

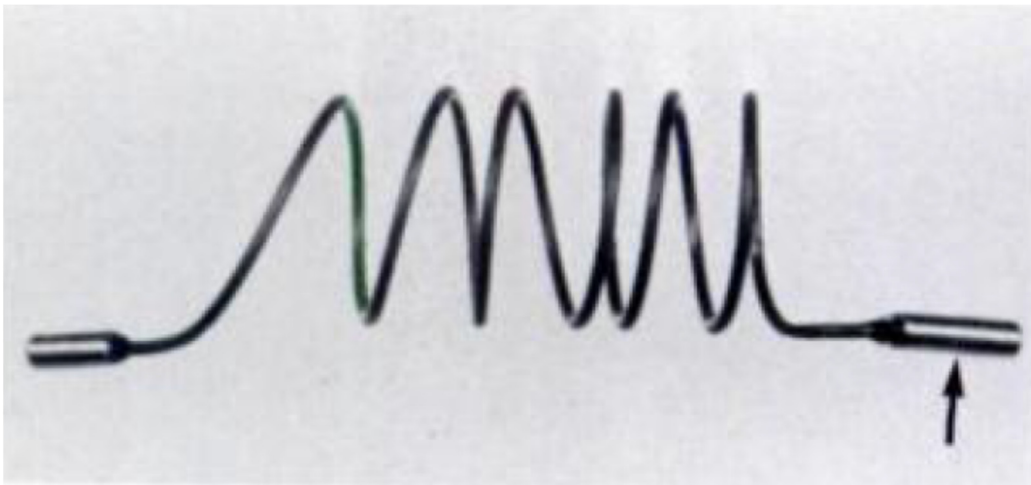
68. The Board credited Applicant’s arguments and Dr. Middleman’s declaration, concluding “the examiner has not made out a *prima facie* case that the

SMAAs disclosed by Balko would inherently display SIM properties,” because Seader did not establish that Balko’s nitinol alloy, in particular, inherently had SIM properties. (*Id.*, pp. 344, 346).<sup>7</sup> As a result, the Board reversed the Examiner’s rejections and the ’141 claims issued. (*Id.*, pp. 346-347, 361).

### III. PRIOR ART REFERENCES

#### A. Cragg (Ex. 1009)

69. I have been informed that the following publication is prior art to the ’141 Patent: Andrew Cragg *et al.*, *Nonsurgical Placement of Arterial Endoprostheses: A New Technique Using Nitinol Wire*, 147 *Radiology* 261, 261-263 (1983) (“Cragg”). Cragg discloses a medical device including a coiled stent. (Ex. 1009). The stent is depicted below:



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<sup>7</sup> The Board referred to Seader as the “Kirk-Othmer” reference. (Ex. 1002, p. 342).

(Ex. 1009, Figure 1). The stent is made with a SMA relying on TIM behavior.

(Ex. 1009, p. 1). Cragg discloses implanting the stent in a mammal using a catheter and guide wire. (*Id.*).

**B. Pops (Ex. 1010)**

70. I have been informed that the following publication is prior art to the '141 Patent: Horace Pops, *Stress-Induced Pseudoelasticity in Ternary Cu-Zn Based Beta Prime Phase Alloys*, 1 Metallurgical Transactions 251 (1970) (“Pops”). Pops discloses copper-zinc-silicon and copper-zinc-tin SMAs exhibiting reversible SIM behavior at various temperatures, including body temperature. (Ex. 1010, Table 1, Figures 4(a) and 5(a)).

**C. Tanaka (Ex. 1011)**

71. I have been informed that the following publication is prior art to the '141 Patent: U.S. Patent No. 4,490,112 (“Tanaka”). Tanaka discloses a nickel-titanium SMA exhibiting reversible SIM behavior at body temperature, and using the alloy to make an implantable medical device. (Ex. 1011, 3:67-4:8, 4:34-64). As discussed above, nickel-titanium alloys are often referred to as “nitinol” alloys, although one nitinol may differ from the next in the relative quantities of nickel and titanium and the manner in which the alloy is made.

**D. Suzuki (Ex. 1012)**

72. I have been informed that the following publication is prior art to the '141 Patent: Yuichi Suzuki, *Shape Memory and Super-elasticity Effects in NiTi Alloys*, Titanium & Zirconium, Vol. 30, No. 4 (1982) (“Suzuki”). Suzuki discloses a nitinol SMA exhibiting reversible SIM behavior, and that this alloy can be substituted for SMAs relying on TIM behavior in medical device applications. (Ex. 1012, pp. 10-12, 15).

**E. The Asserted Prior Art Discloses the Alleged Distinguishing Features That Applicant Convinced the USPTO Were Missing From the Prior Art**

73. As discussed above, the USPTO issued the '141 Patent after Applicant successfully argued to the Board that “Balko does not teach [1] use of an SIM material or [2] use of a [SMA] that exhibits properties of an SIM material at about body temperature.” (See Section II.B.2. above, pp. 44-45). These features, however, are disclosed in Pops, Tanaka, and Suzuki. As discussed in detail below, Pops and Tanaka each disclose SMAs exhibiting properties of an SIM material at about body temperature, and Tanaka and Suzuki each disclose the use of an SIM material in a medical device. (Exs. 1010, 1011, 1012). It would have been obvious in view of these references to make the stent disclosed by Cragg using one of these alloys, making each of claims 1-22 obvious, as further discussed below.

74. Pops was not cited during prosecution of the '141 Patent. Tanaka, Suzuki, and Cragg were each cited during prosecution, but none of these references were substantively discussed by the Examiner or the Board, none are cumulative to any references (including Balko and Seader) addressed during prosecution, and the Applicant did not address the obviousness testimony below.

**IV. GROUND 1: CLAIMS 1-22 WOULD HAVE BEEN OBVIOUS IN VIEW OF CRAGG, POPS, AND TANAKA**

**A. Independent Claim 1**

**1. “A medical device for insertion into a mammalian body, the device comprising”**

75. I am informed that the preamble is not limiting. Nonetheless, Cragg discloses a medical device for insertion into a human (mammalian) body, the device in the form of a coiled stent and equipment to place the coiled stent. (Ex. 1009, p. 1 (describing a coiled stent); Sections IV.A.2.-IV.A.9. below, pp. 48-73).

**2. “(a) a hollow placement device;”**

76. Cragg discloses “a hollow placement device” in the form of a catheter. (Ex. 1009, p. 1 (stating that the “endoprosthesis...can be readily passed through a catheter”); *see* Section IV.A.3. below, pp. 49-70 (especially pp. 66-70) (describing catheter in modified device)). Dependent claim 5 confirms that a catheter constitutes a “hollow placement device.” (Ex. 1001, 11:29-30).



**3. “(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,”**

77. Cragg discloses the medical device includes a stent formed from a “memory alloy element” known as “nitinol,” which was a SMA relying on TIM behavior. (Ex. 1009, p. 1). Cragg states that the stent is made from a “metal alloy (nitinol) with a heat-sensitive memory.” (*Id.*).

78. Cragg does not state that the specific nitinol alloy he used was a “pseudoelastic shape-memory alloy” or that “the alloy display[ed] reversible [SIM] at about body temperature.” As discussed below, however, it would have been obvious to substitute a SMA exhibiting reversible SIM behavior at body temperature for the SMA used to make Cragg’s stent.

**a. The Use Of SMAs To Make Medical Devices, Including Stents, Was Known**

79. Applicant admitted during prosecution of a parent application to the ’141 Patent that “[i]t is of course well known that many medical devices...have in fact been made from [SMAs].” (Ex. 1003, p. 55). The specification similarly states that “[v]arious proposals have also been made to employ [SMAs] in the medical field,” including stents like Cragg’s stent. (Ex. 1001, 2:15-21, 9:14-57).

**b. SMAs Exhibiting Reversible SIM Behavior, Including At Body Temperature, Were Also Known**

80. Applicant admitted during prosecution of a parent application to the '141 Patent that “[i]t is also well known that many [SMAs] exhibit [SIM].” (Ex. 1003, p. 55; *see also* Ex. 1001, 1:52-53 (“[m]any shape memory alloys...are known to display stress-induced martensite (SIM).”). In addition, Applicant admitted that “the concept of pseudoelasticity is well known to those skilled in the art.” (Ex. 1003, p. 55). “Pseudoelasticity,” according to the '141 specification, is another name for reversible SIM behavior. (Ex. 1001, 4:12-16 (“The recoverable deformation associated with the formation and reversion of [SIM] has been referred to as pseudoelasticity.”). This is consistent with a PHOSITA’S understanding of pseudoelasticity.

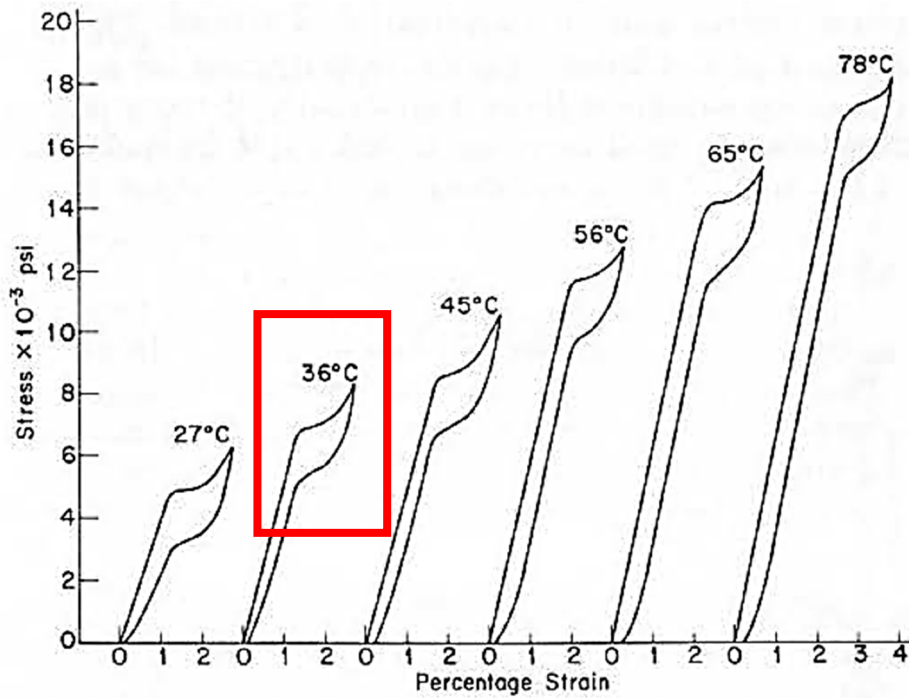
81. According to Patent Owner, the temperature range over which a SMA exhibits reversible SIM behavior “can vary” based on the composition of the alloy. (Ex. 1006, p. 9). Nevertheless, the prior art disclosed various SMAs exhibiting reversible SIM behavior at body temperature. Pops, for example, identifies six alloys (shown below) comprised of copper (Cu), zinc (Zn), silicon (Si), and/or tin (Sn):

**Table I. Compositions of Alloys in at. pct, Used for Deformation Studies**

Alloy	Cu	Zn	Si	Sn
A	62.5	36.5	1.0	—
B	63.3	35.3	1.4	—
C	64.1	34.1	1.8	—
D	62.9	35.9	—	1.2
E	63.8	34.55	—	1.65
F	64.9	32.9	—	2.2

(Ex. 1010, Table 1). According to Pops, each of these alloys exhibits “stress induced pseudoelasticity,” which Pops describes as being “produced as a result of a stress induced reversible martensitic transformation.” (Ex. 1010, pp. 10-11).

82. Pops tested the reversible SIM behavior of these alloys at various temperatures. Figure 4(a) (reproduced below) shows the “[s]tress-strain curves” of the copper-zinc-silicon alloy designated as “Alloy C” in Table 1 above “at different test temperatures”:



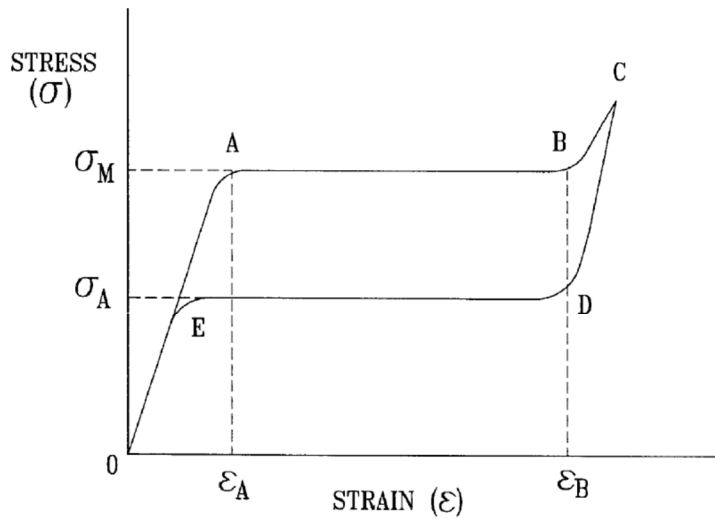
(Ex. 1010, pp. 6-7, Figure 4(a)). Pops states that “[s]imilar behavior was observed for all ternary alloys containing silicon,” including the alloys designated as “Alloy A” and “Alloy B” in Table 1 above. (*Id.*, p. 7, Figure 4(a)). The stress-strain curve at 36°C (annotated with the red box above) corresponds to body temperature,<sup>8</sup> and

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<sup>8</sup> Human body temperatures differ from one person to the next depending on factors like the person’s level of activity, the time of day, age, sex, food/drink consumed, menstrual cycle, health (such as sickness), and the like. For a typical adult, body temperature can range from about 33.2°C to 38.2°C (or about 91.8°F to 100.8°F), although the actual temperature for a given person may be higher or lower. (Martha Sund-Levander *et al.*, *Normal oral, rectal, tympanic and axillary body temperature in adult men and women: a systematic literature review*, 16 *Scandinavian J. Caring Sci.* 122 (2002) (Ex. 1020). Exhibit 1020 is a true and

illustrates that Pops' copper-zinc-silicon alloys exhibit reversible SIM behavior at body temperature.

83. Indeed, the stress-strain curve is consistent with the stress-strain curve depicted in Figure 2 of the '141 Patent (reproduced below), which illustrates "stress-induced martensite" behavior according to the '141 Patent. (Ex. 1001, 3:6-9, 4:3-16).

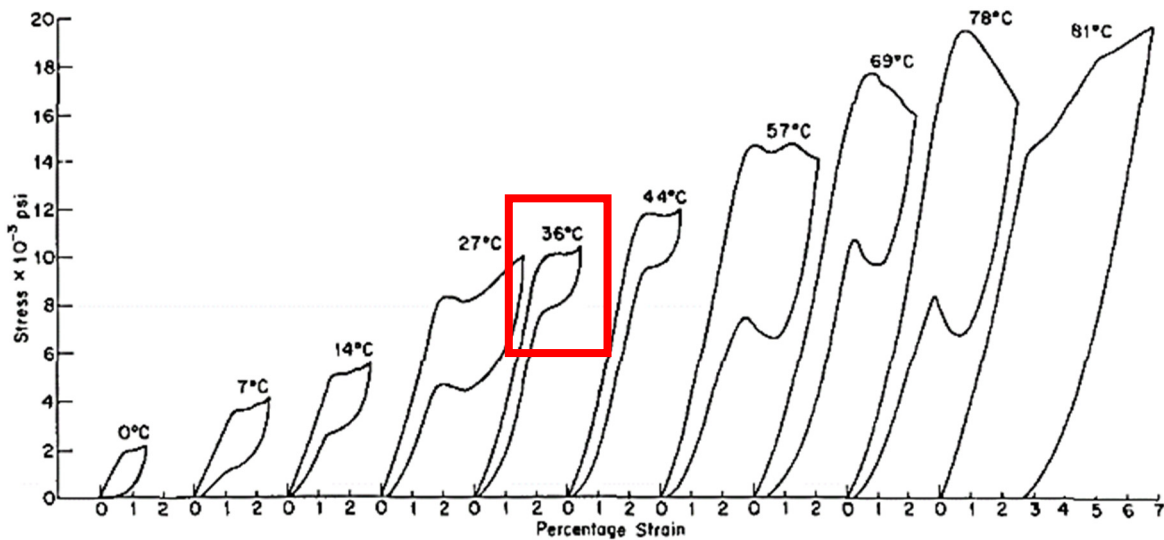


*Fig. 2*

84. According to Pops, "[t]ensile stress-strain curves for the [copper-zinc-tin] alloys," which includes the alloys designated as "Alloy D," "Alloy E," and "Alloy F" in Table 1 above, "were similar to those described for the [copper-zinc-silicon] alloys, as shown in Fig. 5(a)" reproduced below.

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correct copy of the Sund-Levander publication. The '141 Patent refers to body temperature as about "35°-40°C." (Ex. 1001, 4:25).



(Ex. 1010, pp. 6-7, Figure 5(a)). The stress-strain curve at 36°C (annotated with the red box above) corresponds to body temperature, and illustrates that Pops’ copper-zinc-tin alloys also exhibit reversible SIM behavior at body temperature (consistent with Figure 2 of the ’141 Patent above). Indeed, Pops states that “pseudoelasticity occurs in the temperature range between -6°C...and less than 81°C” for the copper-zinc-tin alloys, which includes body temperature. (Ex. 1010, p. 7, Figure 5(a)).

85. Furthermore, determining whether a prior art SMA exhibits reversible SIM behavior at body temperature would have been routine. For example, a PHOSITA would simply test the alloy to determine the temperature range over which the alloy exhibits reversible SIM behavior. Such testing techniques were well known by 1983, as exemplified by Pops, which illustrates the testing of SMAs

for reversible SIM behavior at various temperatures. This is consistent with the '141 Patent specification, which states that a “[s]uitable alloy for this invention...may be *selected from known SMAs* by [a PHOSITA], having regard to this disclosure *by testing* for the existence of the SIM effect at the desired temperature.” (Ex. 1001, 4:22-27). Thus, it would have been a routine matter to test known SMAs to identify additional alloys that exhibited reversible SIM behavior at body temperature. (*Id.*).

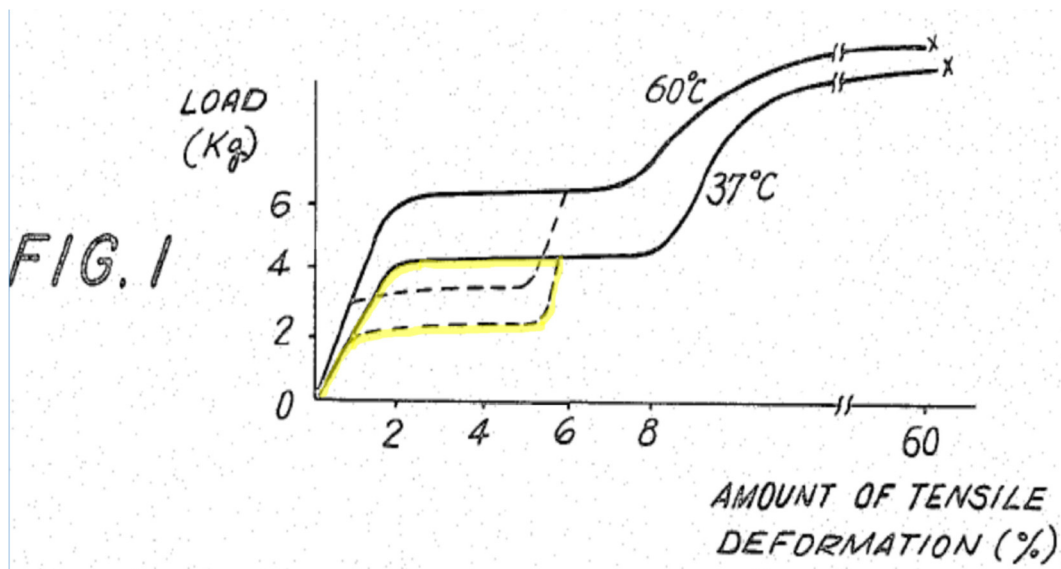
**c. Use in Medical Devices of SMAs Exhibiting Reversible SIM Behavior, Including At Body Temperature, Was Also Known**

86. Using a SMA with reversible SIM behavior in a medical device was not new. Tanaka, for example, discloses an implantable medical device in the form of an “orthodontic system” for correcting “malaligned teeth.” (Ex. 1011, 1:5-9). “The orthodontic system...is formed utilizing a material exhibiting ultra-elasticity,” which “returns to its original shape upon removal of the deforming load.” (*Id.*, 3:67-4:8). The term “ultraelastic” is used by Tanaka to refer to reversible SIM behavior. (*See also* Ex. 1005, p. 108 (Applicant acknowledging that “an ultraelastic alloy...is ‘often called [a] pseudoelasticity alloy.’”)).

87. Tanaka states that “ultraelastic metallic materials which can be utilized” include nickel-titanium (a.k.a. “nitinol”), as well as copper-zinc-silicon and copper-zinc-tin alloys. (Ex. 1011, 4:35-44). Tanaka explains that the

“ultraelasticity [of these alloys] is derived from the martensitic transformation *caused by stress* at a temperature range above the martensitic transformation temperature and *the inverse transformation thereof.*” (*Id.*, 4:44-54). This is reversible SIM behavior.

88. The nitinol alloy described by Tanaka “exhibits ultraelasticity [at] 37°C, which corresponds to...body temperature.” (Ex. 1011, 4:65-68). Figure 1 depicts the stress-strain curve of the alloy at body temperature (with the “solid line curves” reflecting application of stress and the “broken lines” reflecting removal of the stress):



(*Id.*, 5:34-40). “Load” on the y-axis refers to stress, and “amount of tensile deformation” on the x-axis refers to strain. This stress-strain curve (see the portion highlighted yellow) shows reversible SIM behavior consistent with Figure 2 of the ’141 Patent (reproduced above).



89. During use, Tanaka's SMA "is placed under bending and tensile stresses...which urges [the SMA] to recover its original shape" and causes the formation of SIM. (Ex. 1011, 6:58-61). As the temperature in a patient's mouth is increased (such as by drinking "hot tea"), the temperature of the SMA "is raised temporarily," which "produces a higher stress" on the SMA. (Ex. 1011, 6:63-7:4). This process is reflected in Figure 1 reproduced above, which shows that as the temperature is increased (from 37°C to 60°C), the stress increases, but the strain remains the same. This process reflects the so-called Clausius-Clapeyron relation between temperature and stress in SMAs (i.e., as the temperature of a SMA increases, its stress increases at a constant strain).

90. This temperature change in Tanaka's SMA does not result in TIM, or reflect TIM behavior, like the SMAs that I described in the background above (Section II.A., pp. 18-42), because the SMA is above the  $A_f$  temperature (5°C according to Tanaka) and the temperature is *increased*, not decreased. (Ex. 1011, 5:25-27, 5:64-6:2; 6:62-7:4). As discussed above in Section II.A. (pp. 18-42), TIM relies on a *decrease* in temperature. Rather, Tanaka believed that periodically increasing the stress of the SMA by *raising* its temperature "enable[d] more effective simultaneous correction of a plurality of malaligned teeth." (Ex. 1011, 7:11-24).

91. Applicant's actions during prosecution of a parent application to the '141 Patent highlight the significance of Tanaka to a PHOSITA. Claim 1 of Applicant's original patent application recited a medical device with a SMA element, "the improvement...compris[ing] the substitution of an alloy element which displays [SIM] at...body temperature." (Ex. 1004, p. 24). Applicant later filed an amendment cancelling this claim and stated: "Claim 1 was cancelled in view of Tanaka." (*Id.*, p. 40). A PHOSITA would consider this cancellation an admission by Applicant that Tanaka discloses the subject matter of this claim.

92. Similar to Tanaka, Suzuki also discloses the use of SMAs with reversible SIM behavior in implantable medical devices, including orthodontics (braces) and wires for "clamping bones in plastic surgery." (Ex. 1012, p. 15). According to Suzuki, the previous wires used to make braces "have a poor range of elasticity," and "use of a [SMA with reversible SIM behavior, which Suzuki called a super-elastic alloy] can overcome these problems." (Ex. 1012, p. 15).

**d. It Would Have Been Obvious To Substitute A SMA Exhibiting Reversible SIM Behavior At Body Temperature For The SMA Used To Make Cragg's Stent**

93. As explained above in Section II.B.1. (pp. 42-45), the '141 Patent describes the alleged "invention" as a simple substitution of one type of prior art

SMA for another type of prior art SMA, both of which were previously used in medical devices. Here, the substitution yielded an obvious, predictable result.

94. Cragg expressly recommends that another SMA should be substituted for the SMA used to make his stent:

By regulating the composition of the alloy, the transition temperature of nitinol wire can be adjusted to provide transformation over a narrow temperature range (*e.g.*, 36-38° C). The wire we used in this study transformed over a broad temperature range (25-38° C), which required flushing the introducing catheter with cold saline to minimize transformation of the wire in the catheter....These difficulties can be overcome by *the development of a wire with a more precise transition temperature.*

(Ex. 1009, p. 2). Cragg encountered “difficulties” with the SMA used to make his stent, because it started transforming (from martensite to austenite and, thus, reforming its original shape) too early, before the coiled stent was positioned for deployment. (*Id.*). Indeed, Cragg describes “the *partially transformed coil in the catheter,*” and “flushing the introducing catheter with cold saline *to minimize transformation of the wire in the catheter.*” (Ex. 1009, p. 2).

95. Cragg suggests that one way these “difficulties” may be overcome is by using “a wire with a more precise transition temperature,” but Cragg does not state that the *only* way to overcome the difficulties is to use another SMA relying

on TIM behavior. (Ex. 1009, p. 2). Nor does Cragg criticize, discredit, or discourage using a SMA exhibiting reversible SIM behavior. Rather, Cragg specifically encourages using “a suitable alloy with optimal transformation characteristics” to make his stent. (*Id.*).

96. A PHOSITA would have recognized that a “suitable alloy with optimal transformation characteristics” includes prior art SMAs exhibiting reversible SIM behavior at body temperature. A PHOSITA would have been motivated to make Cragg’s stent using such an alloy, because this substitution would have been expected to overcome the “difficulties” described by Cragg.

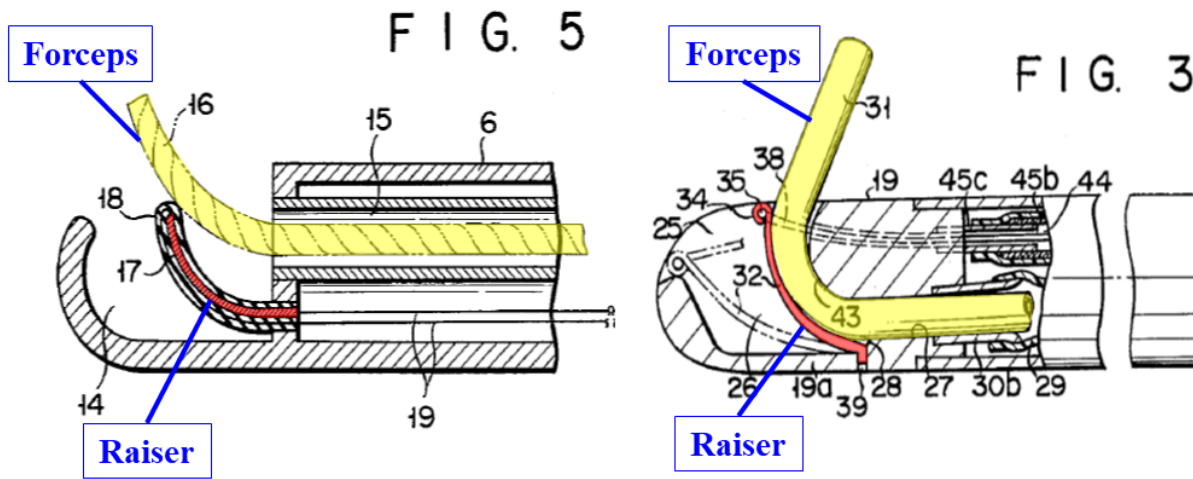
97. If a SMA exhibiting reversible SIM behavior at body temperature were used to make Cragg’s stent, the transition from the deformed, low-profile shape of the stent while in the catheter, on the one hand, to the original, larger shape of the stent when the stent is extruded from the catheter, on the other hand, would have been accomplished by simply removing the restraint (catheter) maintaining the stent in its deformed, low-profile shape. No change in temperature would have been necessary.

98. Thus, using such an alloy to make Cragg’s stent would have addressed the “difficulties” encountered by Cragg, because the transformation would not have been dependent on a change in temperature. As a result, the modification would have obviated Cragg’s concerns regarding the transitional “temperature

range” and premature transformation of the stent (which inconveniently required flushing the introducing catheter with cold saline).

99. Indeed, Patent Owner acknowledged that “the need for temperature manipulation was a source of substantial inconvenience for physicians.” (Ex. 1006, p. 10; *see also* Ex. 1001, 2:42-43; Ex. 1002, pp. 119, 123). This confirms my opinion that a PHOSITA would have been motivated to substitute a SMA exhibiting reversible SIM behavior at body temperature (which does not rely on TIM behavior during placement) for Cragg’s SMA (which relied on TIM behavior during placement). This simple substitution would have addressed the “source of substantial inconvenience for physicians.” (*Id.*).

100. A PHOSITA would have had additional motivations to substitute a SMA exhibiting reversible SIM behavior at body temperature for Cragg’s SMA. For example, the prior art illustrated in the context of medical devices that SMAs relying on reversible SIM behavior can be substituted for SMAs relying on TIM behavior. Ueda and Utsugi, for example, each disclose an endoscope with a “raiser” component made of a SMA for raising the end of a treatment tool, such as forceps, inserted into the endoscope. (Exs. 1014, 1015 (I am informed that both references are prior art)).



Ueda Fig. 5 (annotated excerpt)

Utsugi Fig. 3 (annotated excerpt)

101. These patents were both filed in 1981 by the same company, Olympus Optical Co. (Exs. 1014, 1015). Ueda discloses using a SMA relying on TIM behavior to make the raiser (referred to as the “forceps raiser 17”). (Ex. 1015, 1:49-57, 2:44-62, 3:5-36). Utsugi, on the other hand, discloses using a SMA relying on SIM behavior to make the raiser (referred to as the “raising member 32”). (Ex. 1014, 3:34-4:25). Together, Ueda and Utsugi teach that a medical device component can be made of a SMA with TIM behavior *or* SIM behavior, and that a SMA with SIM behavior can be substituted for a SMA with TIM behavior.

102. Suzuki confirms this teaching and motivation. Suzuki states that SMAs with reversible SIM behavior (called “super-elastic alloys” by Suzuki) are “used in medical fields, in the same way as” SMAs relying on TIM behavior (called “shape memory alloys” by Suzuki). (Ex. 1012, p. 15). Suzuki also states

that SMAs with reversible SIM behavior are “of major interest for functional materials.” (Ex. 1012, p. 11). A PHOSITA would have been encouraged by these statements to make Cragg’s stent using a SMA with reversible SIM behavior (which is a functional material in that application).

103. In view of the motivations and state of the art highlighted above, it would have been obvious to make Cragg’s stent using one of Pops’ copper-zinc SMAs exhibiting reversible SIM behavior at body temperature. (*See* Ex. 1010, Table 1 (identifying copper-zinc alloys)). Indeed, Tanaka discloses using such alloys in an implantable medical device, and the substitution would lead to the predictable result of obviating the “difficulties” raised by Cragg regarding his SMA, as discussed above. (Ex. 1011).

104. The prior art illustrates that copper-based alloys were used in implantable medical devices. Tanaka, for example, recommends using copper-zinc-silicon and copper-zinc-tin alloys like those disclosed by Pops in an implantable medical device (orthodontic braces). (Ex. 1011, 4:35-44). Similarly, Krumme discloses the use of a copper-zinc alloy (brass) in an implantable medical device (surgical staples). (Ex. 1013, 7:1-3 (I am informed that Krumme is prior art)). Krumme describes using the staples to staple together two ends of a colon,” as well as “many [other] surgical procedures.” (Ex. 1013, 1:14-17, 7:58-8:7). Indeed, surgical staples were used in the vascular system (where Cragg’s stent may

be used), as Applicant acknowledged during prosecution. (Ex. 1005, p. 116 (referring to “staple for attaching blood vessels together”)).

105. Further, if biocompatibility were a concern, a PHOSITA would have recognized that the surface finish of any alloy selected to make Cragg’s stent would be optimized, as necessary, to limit potential corrosion or leaching of undesirable materials into the body after implantation. This would be accomplished, for example, simply by applying a coating to the stent, such as a hydrophilic coating. Such processing would have been selected so that it would not have impacted the desired SIM behavior of the alloy. These processing techniques would have been well known to a PHOSITA for optimization of the stent at the relevant time.

106. Alternatively, instead of using Pops’ SMAs, it would have been obvious simply to test known SMAs to identify one with reversible SIM behavior at body temperature, and to use that alloy to make Cragg’s stent. Such testing would have involved, at most, routine skill.

107. A PHOSITA would have had a reasonable expectation of success with substituting Cragg’s SMA with a SMA exhibiting reversible SMA behavior at body temperature identified through such testing, or substituting the SMAs disclosed by Pops. Each such alternative modification is a simple substitution of one known element for another to obtain predictable results.



**e. The SMA Exhibiting Reversible SIM Behavior Used To Make Cragg's Stent In The Modified Device Would Have A  $M_s$  And  $A_s$  Temperature Lower Than Body Temperature, And A  $M_d$  Temperature Higher Than Body Temperature**

108. The SMA used to make Cragg's stent would have been selected so that the  $A_s$  temperature of the alloy (the temperature at which martensite starts to transition to austenite (*see* Section II.A. above, p. 31)), is lower than the desired temperature range at which SIM behavior is desired, such as body temperature. The  $A_s$  temperature of the alloy must be lower than body temperature, for example, if the alloy is expected to transition from martensite to austenite at body temperature through reversible SIM behavior.

109. For most SMAs, the  $A_s$  temperature is higher than the  $M_s$  temperature (the temperature at which austenite starts to transition to martensite (*see* Section II.A. above, p. 31)). Given that the SMA must have an  $A_s$  temperature lower than the desired temperature range at which SIM behavior is desired (as discussed in the preceding paragraph), and the  $A_s$  temperature is higher than the  $M_s$  temperature for most alloys, the  $M_s$  temperature is also lower than such desired temperature range for such alloys.

110. For those few alloys where the  $M_s$  temperature is actually higher than the  $A_s$  temperature, the alloy would still have been selected so that the  $M_s$  temperature of the alloy is lower than the desired temperature range at which

reversible SIM behavior is desired, such as body temperature. In this circumstance, the  $M_s$  temperature of the alloy must be lower than body temperature, for example, if the alloy is expected to transition from martensite to austenite at body temperature through reversible SIM behavior.

111. The temperature range over which a SMA exhibits SIM behavior, furthermore, is always less than the  $M_d$  temperature (which the '141 Patent explains is “the maximum temperature at which martensite formation can occur even under stress”). (Ex. 1001, 1:56-57). Thus, in summary, reversible SIM behavior only occurs when an alloy’s temperature is below its  $M_d$  temperature, and above its  $M_s$  and  $A_s$  temperatures.

112. With respect to Pops, the copper-zinc SMAs tested by Pops exhibited reversible SIM behavior at, and below, body temperature. (Ex. 1010 at Figures 4(a) and 5(a) (27°C and 36°C)). Each of these temperatures was below the  $M_d$  temperature, and above the  $M_s$  and  $A_s$  temperatures, for each respective copper-zinc SMA. (Ex. 1010, Figures 4(b) and 5(b) (identifying  $M_s$  and  $A_s$  temperatures as being less than 15°C for each alloy)). These fundamental principles of SIM were well-known to a PHOSITA by 1983.

**f. The Modified Device Meets The Claim Requirements**

113. The modified device includes “a memory alloy element” in the form of a SMA. (See Sections IV.A.3.a.-d. above, pp. 49-64 (especially pp. 63-64)).

The “memory alloy element” in the modified device is a “pseudoelastic shape-memory alloy,” because it exhibits reversible SIM behavior. (*See id.*). As discussed above, the alloy in the modified device exhibits reversible SIM behavior at body temperature. (*Id.*).

114. It would have been obvious to make and use the modified device at least in the following manner. Cragg’s stent would be formed using a SMA exhibiting reversible SIM behavior at body temperature, such as Pops’ SMAs (or another suitable SMA identified through routine testing). Thus, the stent would be “a memory alloy stent,” “coil stent,” or “wire stent” “formed at least partly from a pseudoelastic shape-memory alloy.”

115. The wire used to make the stent would be annealed while constrained in the coiled shape disclosed by Cragg. After cooling to at least body temperature, the wire would be stressed into a lower profile shape, such as a partially or fully straightened wire (to make the stent easier to insert into a patient through endoluminal techniques for endarterial positioning) by using a hollow catheter to engage and restrain (and, thus, stress and hold) the stent at the lower, deformed profile within the catheter.

116. The deformation of the stent in this manner results in at least a portion of the stent transforming from austenite to martensite through the application of stress by the catheter. This is SIM. In particular, the catheter would stress “the

memory alloy element” (stent) “at a temperature greater than the  $A_s$  of the alloy” so that “the memory alloy element” (stent) “is in its deformed shape.” As discussed above, the  $A_s$  temperature of the alloy would be lower than body temperature when relying on reversible SIM behavior to transform martensite to austenite at body temperature.

117. The stent/catheter combination would be at a temperature less than body temperature (and above the  $A_s$  temperature) before introduction of the stent/catheter into a patient, such as when the physician prepared (e.g., at room temperature) to insert the stent/catheter combination into the patient (or at any temperature between the  $A_s$  temperature and body temperature).

118. The deformed stent would be connected to a guide wire, as disclosed in Cragg. The catheter would be guided with a guide wire for endarterial placement of the stent in a human patient’s body at body temperature such that the stent is at, or substantially at, body temperature. The restraint then would be removed from the stent, for example by extruding the stent from the catheter using the guide wire, or otherwise removing the restraint (the catheter and the stent are movable relative to one another).

119. Upon removal of the restraint (which was applying stress to the stent), at least a portion of the stent would be unstressed and would transition from martensite to austenite, resulting in the stent forming or attempting to form its

original, unstressed coiled stent shape. The stent, thus, would be disengaged from the catheter and spontaneously transformed from its deformed, relatively straightened shape towards its unstressed relatively coiled shape upon removal of the restraint (catheter). Furthermore, the extrusion of the stent, and transition from martensite to austenite, would occur at, and/or at about, body temperature (a temperature greater than the  $A_s$  temperature of the SMA, as discussed above), and demonstrates that the SMA exhibits “reversible stress-induced martensite at about body temperature such that it has a stress-induced martensitic state and an austenitic state.”

120. In the modified device, the reversible “stress-induced martensitic state” is the state of the SMA when deformed (and stressed) by the catheter to cause SIM (*e.g.*, in the deformed, relatively straightened shape). The “austenitic state” is the state of the SMA when the restraint (and stress) applied to the SMA is at least partially or fully removed to cause at least a portion, or all, of the martensite to be unstressed and transition to austenite (thereby resulting in the SMA moving to a different shape, *e.g.*, the unstressed relatively coiled shape). The SMA, thus, 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.”

121. The transition of the SMA from SIM to austenite as the stress to the SMA is removed (thereby transforming the SMA from its deformed, relatively straightened shape towards its unstressed, relatively coiled shape) occurs at body temperature, as discussed above. This transition, in particular, would occur without any change in the state of the “placement device,” “restraint,” or “restraining means” (catheter). Likewise, the transition would occur without any change in the temperature of the “placement device,” “restraint,” “restraining means,” or “restraining member” (catheter), SMA (stent), or medical device. (*See* Ex. 1009, p. 1). This is because the SMA exhibits reversible SIM behavior at body temperature, which means that the transition from martensite to austenite as the stress is removed occurs without any change in the state or temperature of the catheter, and without any change in the temperature of the SMA (stent) or medical device.

4. **“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”**

122. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

**5. “(c) a guide wire;”**

123. The modified device includes a “guide wire.” (Ex. 1009, p. 1 (“The nitinol coils were fastened to a threaded *guiding wire* to allow accurate placement after being deposited in the aorta. ...[P]recise placement...was accomplished by advancing or withdrawing the *guide wire* in the aorta.”); *see also* Section IV.A.3. above, pp. 49-70 (especially pp. 66-70)).

**6. “the memory alloy element being within the hollow placement device, and the placement device being guidable by the guide wire,”**

124. In the modified device, “the memory alloy element” (the coiled stent) is “within the hollow placement device” (the catheter). (Ex. 1009, p. 1 (stating that the coiled stent “can be readily passed *through* a catheter,” that the stent is “introduced *via* catheter into the body,” that the stent is “passed *through* a 10-F Teflon catheter in the abdominal aorta,” and that the stent “was extruded *from* the catheter”); *see also* Section IV.A.3. above, pp. 49-70 (especially pp. 66-70)).

125. In addition, in the modified device, the “placement device” (catheter) is “guidable by the guide wire.” (Ex. 1009, p. 1 (“The nitinol coils were fastened to a threaded *guiding wire* to allow accurate placement after being deposited in the aorta....[P]recise placement...was accomplished by advancing or withdrawing the *guide wire* in the aorta. ...After coil placement, the catheter and guide wire were withdrawn”); *see also* Section IV.A.3. above, pp. 49-70 (especially pp. 66-70)). In

addition, a PHOSITA would have understood that the standard procedure for endoluminal placement of a stent as of 1983 included inserting a guide wire into the patient, and then using the guide wire to guide a catheter to the desired site. (*See also* Ex. 1002, p. 111 (“[I]t is well known in the art that [a] guide wire is used for guiding a catheter into [a] body.”)).

7. **“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,”**

126. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 56-70).

8. **“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,”**

127. In the modified device, “the memory alloy element” (coiled stent) is “extruded” from the “hollow placement device” (catheter) “by the guidewire.” (Ex. 1009, p. 1 (“The nitinol coils were fastened to a threaded *guiding wire* to allow accurate placement after being deposited in the aorta. ...Once the [coiled stent] was *extruded from the catheter*, precise placement...was accomplished by



advancing or withdrawing the *guide wire* in the aorta.”), p. 2 (stating that “the coil is extruded from the catheter”)).

128. The modified device also includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

**9. “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.”**

129. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially p. 70).

**B. Claim 2**

130. Claim 2 depends from claim 1 and further requires “the memory alloy element is a stent.” The “memory alloy element” in the modified device is a stent, as discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-68). (*See also* Ex. 1009, p. 2 (“Loosely wound coils could be used as *stents* to maintain vessel patency.”)).

**C. Claim 3**

131. Claim 3 depends from claim 2 and further requires “a guide wire for endarterial placement of the stent graft.” The modified device includes the claimed “guide wire.” (Ex. 1009, p. 1 (“The nitinol coils were fastened to a threaded *guiding wire* to allow accurate placement after being deposited in the aorta.

...[P]recise placement...was accomplished by advancing or withdrawing the *guide wire* in the aorta.”); *see also* Section IV.A.3. above, pp. 49-70 (especially pp. 68-69)).

132. I note that Claim 3 refers to “the stent graft.” The antecedent basis for this limitation is the “stent” recited in claim 2. Thus, “the stent graft” in claim 3 is understood to refer to the “stent” in claim 2. Even if “stent graft” means something different than “stent,” Cragg discloses that the coiled stent may also be considered a stent graft. (Ex. 1009, p. 1 (referring to the coiled stent as “Nitinol wire coil grafts,” “Nitinol endovascular coil grafts,” “transcatheter arterial graft[s],” “grafts,” and “nitinol coil grafts.”)).

**D. Claim 4**

133. Claim 4 depends from claim 1 and further requires that “the transformation occurs without any change in the state of the placement device.” The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially p. 70).

**E. Claim 5**

134. Claim 5 depends from claim 1 and further requires that “the hollow placement device is a catheter.” In the modified device, the “hollow placement device” is a “catheter” for the reasons discussed above in Section IV.A.2. (p. 48).

**F. Independent Claim 6**

**1. “A medical device which comprises:”**

135. I am informed that the preamble is not limiting. Nonetheless, Cragg discloses a medical device for the reasons discussed above in Section IV.A.1. (p. 48).

**2. “(a) a stent for endarterial placement within a human body so that the stent is substantially at human body temperature,”**

136. Cragg discloses a “stent for endarterial placement within a human body.” (Ex. 1009, p. 2 (“Loosely wound coils could be used as stents to maintain vessel patency.”), p. 2 (“it indicates that long-term patency of nitinol coil grafts may be possible in humans.”). The stent is substantially at human body temperature when placed within the human body, as further discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

**3. “the stent comprising a shape memory alloy which displays stress-induced martensite behavior at body temperature; and”**

137. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 63-64, 66-70).

**4. “(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;”**

138. The modified device includes “a restraint” in the form of a catheter. (Ex. 1009, p. 1 (stating that the “endoprosthesis...can be readily passed through a catheter”)). Dependent claim 8 confirms that a catheter constitutes a “restraint.” (Ex. 1001, 11:51-52). As discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70), the catheter in the modified device holds the stent “for endarterial positioning of the stent within the human body in its deformed configuration, the deformation occurring through the formation of stress-induced martensite.”

139. This claim also requires that the restraint “hold[] the stent in a deformed configuration at a temperature less than the body temperature of the human.” Applicant explained during prosecution of a related patent application that this limitation means simply that the combination of the SMA and “the restraint must at some time be at a temperature less than body temperature.” (Ex. 1026, pp. 157, 168, 181-182, 195, 197-200). The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

140. Even if this claim language requires the SMA to exhibit reversible SIM behavior at a temperature less than body temperature, this limitation would still be met, because the alloy in the modified device also exhibits reversible SIM behavior at a temperature less than body temperature. (*See* Section IV.A.3. above, pp. 49-70). SMAs exhibit reversible SIM behavior over a temperature range, not just at a single temperature. Pops, for example, tested various copper-zinc SMAs for reversible SIM behavior at various temperatures, and the alloys exhibited reversible SIM behavior at every temperature, including body temperature and a temperature less than body temperature. (Ex. 1010, Figures 4(a) and 5(a) (curves labeled 36°C (body temperature) and 27°C (below body temperature))).

141. Thus, substituting the SMA used to make Cragg's stent with one of the copper-zinc SMAs identified by Pops, as discussed above in Section IV.A.3. (pp. 49-70), would result in a stent made from a SMA exhibiting SIM behavior at body temperature as well as below body temperature. During use, for example, the catheter would engage and stress such a stent at a temperature less than body temperature, and greater than the  $A_s$  temperature of the alloy, when the catheter/stent are maintained at a temperature between these temperatures, such as 27°C. (*See* Section IV.A.3., pp. 49-70 (especially at pp. 66-70) (describing positioning the stent in the modified device within the body while the stent is in its deformed, relatively straightened shape)).

142. It also would have been obvious to simply test known SMAs to identify one with reversible SIM behavior at body temperature and below body temperature, and to use that alloy to make Cragg's stent, for the additional reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 54-55, 64). Indeed, using such a SMA to make Cragg's stent would, for example, permit it to be deformed within the catheter at room temperature and deployed at body temperature, each relying on SIM behavior rather than TIM behavior (which would have been more convenient for physicians and/or device makers than attempting to both deform and deploy the stent at body temperature to avoid the problems with relying on TIM behavior discussed above). During use, for example, the catheter would engage and stress such a stent at a temperature less than body temperature, and greater than the  $A_s$  temperature of the alloy, when the catheter/stent are maintained at a temperature between these two temperatures, such as at room temperature.

143. A PHOSITA would have had a reasonable expectation of success with substituting Cragg's SMA with a SMA exhibiting reversible SIM at body temperature (and below body temperature) identified through such testing, or substituting it with Pops' SMAs. Each is a simple substitution of one known element for another to obtain predictable results.

**5. “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 portion of the stent from its deformed configuration.”**

144. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70). Cragg discloses that the “stent” is extruded from the “restraint” (catheter) with the guide wire. (Ex. 1009, p. 1 (“The nitinol coils were fastened to a threaded guiding wire to allow accurate placement after being deposited in the aorta. ...Once the [coiled stent] was extruded from the catheter, precise placement...was accomplished by advancing or withdrawing the *guide wire* in the aorta.”), p. 2 (stating that “the coil is extruded from the catheter”)). Extrusion of the “stent” from the “restraint” (catheter) constitutes the “removal of the restraint from the stent.”

**G. Claim 7**

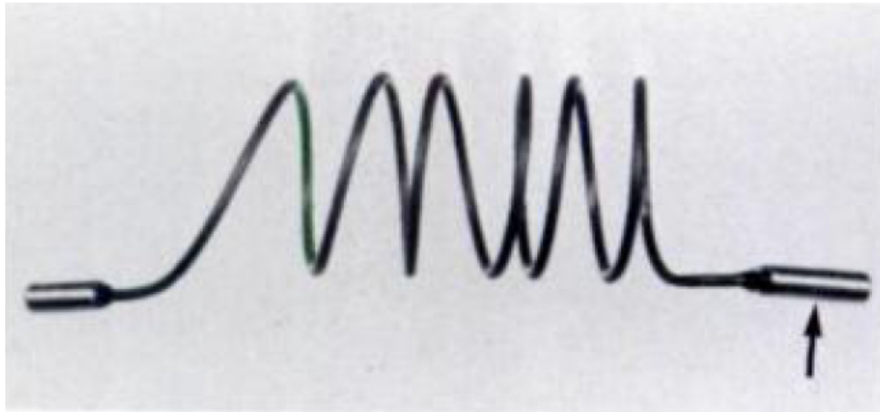
145. Claim 7 depends from claim 6 and further requires that “the restraint is hollow, and the stent is positioned at least partially within the restraint.” The modified device includes this limitation. (Ex. 1009, p. 1 (stating that the stent “can be readily passed *through* a catheter,” that the stent is “introduced *via* catheter into the body,” that the stent is “passed *through* a 10-F Teflon catheter in the abdominal aorta,” and that the stent “was extruded *from* the catheter”); *see also* Section IV.A.3., pp. 49-70 (especially pp. 66-70)).

**H. Claim 8**

146. Claim 8 depends from claims 6 or 7 and further requires “the restraint is a catheter.” The modified device includes this limitation for the reasons discussed above in Section IV.F.4. (pp. 76-78).

**I. Claim 9**

147. Claim 9 depends from claims 6 or 7 and further requires “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.” The modified device includes a coiled stent having a “transverse dimension,” which corresponds to the diameter of the coiled stent (in a direction perpendicular to the longitudinal axis of the stent) when the stent is in its relaxed configuration, as depicted in Cragg Figure 1:



(Ex. 1009, Figure 1).

148. The coiled stent also has a “longitudinal dimension,” which corresponds with the length of the coiled stent along its longitudinal axis. As



discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70), the stent is “deformed by its transverse dimension being reduced” (e.g., the diameter is reduced) when the stent is deformed within the “restraint” (catheter) for insertion into a body. In this configuration, the “restraint” (catheter) “prevents transverse expansion of the stent,” as further described in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

**J. Claim 10**

149. Claim 10 depends from claim 6 and further requires “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.” The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

**K. Independent Claim 11**

**1. “A medical device suitable for placement within a mammalian body for treatment of the mammalian body, the device comprising:”**

150. I am informed that the preamble is not limiting. Nonetheless, Cragg discloses a medical device suitable for placement within a mammalian body for treatment of the mammalian body for the reasons discussed above in Section IV.A.1. (p. 48).

2. **“(a) a stent formed at least partly from a pseudoelastic shape-memory alloy, the alloy having a reversible 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; and”**

151. The modified device includes this limitation for the reasons discussed above in Sections IV.A.3., pp. 49-70 (especially pp. 63-64, 66-70).

3. **“(b) restraining means engaging and stressing the stent at a temperature less than the body temperature of the mammal and greater than the  $A_s$  of the alloy for positioning the stent within the mammalian body while the stent is in its deformed shape;”**

152. Claim 11 recites a “restraining means engaging and stressing the stent...[and] for positioning the stent within the mammalian body.” The structure disclosed in the specification to perform the claimed functions (restraining, engaging, stressing, and positioning the stent) is a catheter. (Ex. 1001, 9:41-65). In any event, dependent claim 13 confirms that a catheter constitutes a “restraining means.” (Ex. 1001, 12:23-24).

153. The modified device includes the claimed “restraining means” in the form of a catheter. (Ex. 1009, p. 1 (stating that the “endoprosthesis...can be readily passed through a catheter”)). The modified device also includes this limitation for the reasons discussed above in Sections IV.A.3., pp. 49-70, and IV.F.4., pp. 76-78, (especially pp. 66-70, 76-78).

4. **“wherein the alloy is selected so that removal of the restraining means from the stent at a temperature greater than the  $A_s$  of the alloy when the device is placed within the mammalian body, transforms at least a portion of the alloy from its stressed-induced martensitic state so that the stent transforms from its deformed relatively straightened shape towards its unstressed relatively coiled shape, without any change in temperature of the restraining means or the stent being required for the transformation of the alloy.”**

154. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

**L. Claim 12**

155. Claim 12 depends from claim 11 and further requires that “the transformation of the alloy occurs without any change in state of the restraining means.” The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially p. 70).

**M. Claim 13**

156. Claim 13 depends from claim 11 and further requires that “the restraining means is a catheter.” The modified device includes this limitation for the reasons discussed above in Section IV.K.3. (p. 82).

**N. Claim 14**

157. Claim 14 depends from claim 13 and further requires that “the stent is within the catheter.” In the modified device, the “stent” is “within the catheter.”

(Ex. 1009, p. 1 (stating that the coiled stent “can be readily passed *through* a catheter,” that the stent is “introduced *via* catheter into the body,” that the stent is “passed *through* a 10-F Teflon catheter in the abdominal aorta,” and that the stent “was extruded *from* the catheter”); *see also* Section IV.A.3. above, pp. 49-70 (especially pp. 66-70)).

**O. Independent Claim 15**

**1. “A medical device for treatment of a mammalian body, the device comprising:”**

158. I am informed that the preamble is not limiting. Nonetheless, Cragg discloses a medical device for treatment of a mammalian body for the reasons discussed above in Section IV.A.1. (p. 48).

**2. “(a) a memory alloy stent formed at least partly from a pseudoelastic shape-memory alloy,”**

159. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 63-64, 66-70).

**3. “the alloy displaying reversible stress-induced martensite at about the mammalian body temperature such that it has a stress-induced martensitic state and an austenitic state,”**

160. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

4. **“the memory alloy stent having (i) a deformed relatively straightened shape when the alloy is in its stress-induced martensitic state and (ii) a different unstressed relatively coiled shape; and”**

161. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

5. **“(b) a hollow restraining member with the memory alloy stent being within the restraining member,”**

162. The modified device includes a “hollow restraining member” in the form of a catheter. (Ex. 1009, p. 1 (stating that the “endoprosthesis...can be readily passed through a catheter”)). Dependent claim 21 confirms that a catheter constitutes a “hollow restraining member” (referred to as the “restraint” in claim 21). (Ex. 1001, 14:19-20).

163. In the modified device, the “memory alloy stent” is “within the [hollow] restraining member.” (Ex. 1009, p. 1 (stating that the coiled stent “can be readily passed *through* a catheter,” that the stent is “introduced *via* catheter into the body,” that the stent is “passed *through* a 10-F Teflon catheter in the abdominal aorta,” and that the stent “was extruded *from* the catheter”); *see also* Section IV.A.3., pp. 49-70 (especially pp. 66-70)).

6. **“the restraining member engaging and stressing the memory alloy stent at a temperature less than the body temperature of the mammal and greater than the  $A_s$  of the alloy for positioning the memory alloy stent within the human body while the memory alloy coil stent is in its deformed relatively straightened shape;”**

164. The modified device includes this limitation for the reasons discussed above in Sections IV.A.3., pp. 49-70, and IV.F.4., pp. 76-78 (especially pp. 66-70, 76-78).

7. **“wherein the restraining member and the memory alloy stent are movable relative to each other to transform at least a portion of the alloy from its stress-induced martensitic state at a temperature greater than the  $A_s$  of the alloy so that the memory alloy element transforms from its deformed shape towards its unstressed relatively coiled shape,”**

165. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

8. **“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 coil stent.”**

166. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

**P. Independent Claim 16**

- 1. “A medical device suitable for placement within a mammalian body for treatment of the mammalian body, the device comprising”**

167. I am informed that the preamble is not limiting. Nonetheless, Cragg discloses a medical device suitable for placement within a mammalian body for treatment of the mammalian body for the reasons discussed above in Section IV.A.1. (p. 48).

- 2. “(i) a restraint”**

168. The modified device includes “a restraint” in the form of a catheter and for the reasons discussed above in Section IV.F.4. (pp. 76-78). Dependent claim 21 confirms that a catheter constitutes a “restraint.” (Ex. 1001, 14:19-20; *see also* Section IV.A.3., pp. 49-70 (especially pp. 66-70)).

- 3. “(ii) a coil stent formed at least partly from a pseudoelastic shape-memory alloy,”**

169. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 63-64, 66-70).

- 4. “the alloy displaying reversible stress-induced martensite by virtue of being above its  $A_s$  and above its  $M_s$  and below its  $M_d$  at about body temperature;”**

170. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 65-70).

**5. “such that it has a stress-induced martensitic state and an austenitic state,”**

171. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

**6. “the element having (i) a relatively straightened shape when the alloy is in its stress-induced martensitic state and (ii) a different relatively coiled shape;”**

172. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

**7. “wherein the restraint is (i) stressing the coil stent at a temperature less than the body temperature of the mammal for placement of the coil stent in its relatively straightened shape in the mammalian body”**

173. The modified device includes this limitation for the reasons discussed above in Sections IV.A.3., pp. 49-70, and IV.F.4., pp. 76-78 (especially pp. 66-70, 76-78).

**8. “wherein the restraint...(ii) is capable of being at least partially removed from the coil stent while the coil stent is within the body at the body temperature and the coil stent is therefore at an operating temperature greater than the  $A_s$  and  $M_s$  and below the  $M_d$  of the alloy,”**

174. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 65-70).



- 9. “such removal of the restraint causing at least a portion of the alloy to transform from its stress-induced martensitic state to its austenitic state so that the coil stent spontaneously transforms from its relatively straightened shape towards its relatively coiled shape,”**

175. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

- 10. “and such transformation can occur without a change in temperature of the restraint or of the coil stent from the operating temperature.”**

176. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

**Q. Claim 17**

177. Claim 17 depends from claims 1, 11, 15, or 16 and further requires “the mammalian body is a human body.” The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70). (*See also* Ex. 1009, p. 2 (“Loosely wound coils could be used as stents to maintain vessel patency....long-term patency of nitinol coil grafts may be possible *in humans.*”)).

**R. Independent Claim 18**

**1. “A medical device comprising:”**

178. I am informed that the preamble is not limiting. Nonetheless, Cragg discloses a medical device for the reasons discussed above in Section IV.A.1. (p. 48).

**2. “(a) a wire stent formed at least partly from a pseudoelastic shape memory alloy,”**

179. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 63-64, 66-70).

**3. “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”**

180. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

**4. “(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,”**

181. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 65-70). Furthermore, the modified device includes “a restraint” in the form of a catheter and for the reasons

discussed above in Section IV.F.4. (pp. 76-78). Dependent claim 21 confirms that a catheter constitutes a “restraint.” (Ex. 1001, 14:19-20).

**5. “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”**

182. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

**6. “wherein the alloy is selected so that the transformation can occur without any change in temperature of the restraint or the wire stent.”**

183. The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 63-64, 66-70).

**S. Claim 19**

184. Claim 19 depends from claims 6, 11, 15, 16 or 18 and further requires “a guide wire for endarterial placement of the stent.” The modified device includes this limitation for the reasons discussed above in Section IV.C. (pp. 73-74).

**T. Claim 20**

185. Claim 20 depends from claims 15, 16 or 18 and further requires “the transformation of the alloy occurs without any change in state of the restraint.”

The modified device includes this limitation for the reasons discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-70).

**U. Claim 21**

186. Claim 21 depends from claims 1, 15, 16 or 18 and further requires “the restraint is a catheter.” The modified device includes this limitation for the reasons discussed above in Section IV.P.2. (p. 87).

**V. Claim 22**

187. Claim 22 depends from claims 1, 11, 15, or 18 and further requires “the stent is a coil stent.” In the modified device, the stent “is a coil stent,” as discussed above in Section IV.A.3., pp. 49-70 (especially pp. 66-69).

**V. GROUND 2: CLAIMS 1-22 WOULD HAVE BEEN OBVIOUS IN VIEW OF CRAGG, TANAKA, AND SUZUKI**

188. Ground 2 mirrors Ground 1, except that instead of substituting Pops’ copper-zinc SMAs or another suitable SMA identified through routine testing (each a “Ground 1 SMA”) for Cragg’s SMA to make Cragg’s stent, Tanaka’s nitinol SMA is substituted for Cragg’s SMA to make the stent.

**A. Independent Claim 1**

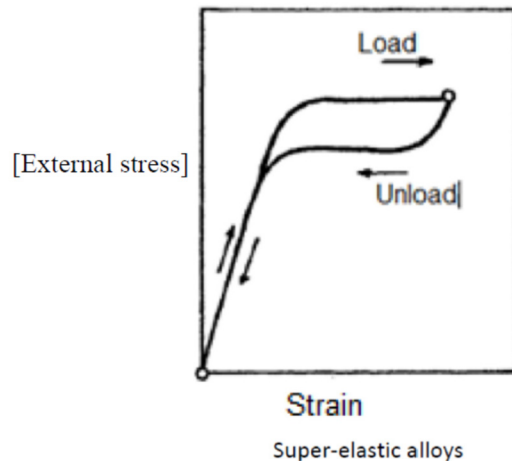
189. I rely on and repeat the same evidence and testimony regarding claim 1 recited above with respect to Ground 1 at Section IV.A. (pp. 48-73). However, instead of substituting Cragg’s nitinol SMA with a Ground 1 SMA to make

Cragg's stent, Cragg's nitinol SMA is substituted with Tanaka's nitinol SMA to make the stent.

190. Tanaka discloses a nitinol SMA made of 50.7% nickel and 49.3% titanium, along with a detailed description of how to make and use the alloy in an implantable medical device. (Ex. 1011, 4:65-7:24). Although Applicant successfully convinced the Board during prosecution of the '141 patent that the nitinol SMA disclosed by Balko did not inherently exhibit reversible SIM behavior, (*see* Section II.B.2. above, pp. 44-45), there is no doubt that Tanaka's nitinol SMA exhibits reversible SIM behavior.

191. Tanaka states that the nitinol SMA is "ultraelastic," which is a term that Tanaka used to refer to reversible SIM behavior. (Ex. 1011, 3:67-4:8, 4:42-54, 4:65-68, 5:34-41, Figure 1). Tanaka's SMA has an  $M_s$  temperature of  $-40^{\circ}\text{C}$  and an  $A_f$  temperature of  $5^{\circ}\text{C}$  (meaning that the  $A_s$  temperature is less than  $5^{\circ}\text{C}$ ). (Ex. 1011, 5:25-27, 5:65-6:2). The SMA exhibits reversible SIM behavior at body temperature, as discussed above in Section IV.A.3. (especially pp. 55-58), which is higher than the  $M_s$  and  $A_s$  temperatures (and lower than the  $M_d$  temperature) of the SMA. Thus, in the modified device, the catheter stresses (and deforms) the SMA at a temperature greater than the  $M_s$  and  $A_s$  temperatures, and lower than the  $M_d$  temperature) when the catheter/stent is at body temperature (or any temperature between the  $A_s$  temperature and body temperature, such as room temperature).

192. Suzuki also discloses the use of a nitinol SMA with reversible SIM behavior at body temperature in implantable medical devices, including orthodontics (braces) and wires for “clamping bones in plastic surgery.” (Ex. 1012, pp. 10-12, 15). Suzuki uses the term “super-elastic” to refer to reversible SIM behavior. According to Suzuki, “a super-elastic alloy does not require heating for recovering from strain. If the load [stress] is removed after the alloy has been deformed...the strain, as shown in Fig. 1, returns to zero.” (Ex. 1012, pp. 11-12 (describing mechanism of SIM behavior)). This is reversible SIM behavior. Figure 1 (reproduced in part below) shows reversible SIM behavior consistent with Figure 2 of the '141 Patent.



193. As discussed above, Suzuki states that nitinol SMAs with reversible SIM behavior are “used in medical fields, in the same way as” SMAs with TIM behavior (called “shape memory alloys” by Suzuki). (Ex. 1012, p. 15). By stating that nitinol SMAs with SIM behavior are “used...in the same way” as SMAs with

TIM behavior, Suzuki teaches and motivates a PHOSITA to substitute a SMA with SIM behavior for a SMA relying on TIM behavior. Indeed, Suzuki states that SMAs with reversible SIM behavior are “of major interest for functional materials,” as discussed above. (Ex. 1012, p. 11).

194. Nitinol also was known to be biocompatible. Suzuki, for example, states that nitinol alloys “do not react with organic substances” such as living tissue, and thus, “it is expected that they will be used in implants in living tissues.” (Ex. 1012, p. 13).

195. As discussed above, Cragg discloses a coiled stent made with a nitinol SMA. (Ex. 1009). Cragg’s nitinol SMA, however, relied on TIM behavior during use, which resulted in “difficulties” for the reasons discussed above in Section IV.A.3. (pp. 49-70). It would have been obvious to substitute Tanaka’s nitinol SMA (exhibiting reversible SIM behavior at body temperature) for the nitinol SMA used to make Cragg’s stent, for all of the reasons discussed here and above in Section IV.A.3. (pp. 49-70). This substitution merely involves substituting one nitinol alloy for another nitinol alloy, which provides yet another motivation to make this substitution.

196. A PHOSITA would have had a reasonable expectation of success with substituting Cragg’s nitinol SMA with Tanaka’s nitinol SMA to make Cragg’s

stent. This modification is a simple substitution of one known element for another to obtain predictable results.

**B. Claim 2**

197. I rely on and repeat the same evidence and testimony regarding claim 2 recited above with respect to Ground 1 at Section IV.B. (p. 73), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**C. Claim 3**

198. I rely on and repeat the same evidence and testimony regarding claim 3 recited above with respect to Ground 1 at Section IV.C. (pp. 73-74), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**D. Claim 4**

199. I rely on and repeat the same evidence and testimony regarding claim 4 recited above with respect to Ground 1 at Section IV.D. (p. 74), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**E. Claim 5**

200. I rely on and repeat the same evidence and testimony regarding claim 5 recited above with respect to Ground 1 at Section IV.E. (p. 74), except that



Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**F. Independent Claim 6**

201. I rely on and repeat the same evidence and testimony regarding claim 6 recited above with respect to Ground 1 at Section IV.F. (pp. 75-79), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent, as discussed above with respect to claim 1 (Section V.A., pp. 92-96).

202. If Patent Owner argues that the claim language reciting a restraint "holding the stent in a deformed configuration at a temperature less than the body temperature of the human," requires the SMA to exhibit reversible SIM behavior at a temperature less than body temperature, this limitation is still met, because Tanaka's SMA in the modified device also exhibits reversible SIM behavior at a temperature less than body temperature. (*See also* Section IV.A.3., pp. 49-70).

203. Tanaka states that "it is necessary that the [medical] device in accordance with the invention be formed from a material capable of undergoing inverse martensitic transformation *at a temperature below normal mouth temperature of 37°C.*" (Ex. 1011, 5:3-12, 6:3-12, 8:12-15). The "inverse martensitic transformation" temperature refers to the  $A_f$  temperature of the alloy, (Ex. 1011, 5:23-28, 5:64-6:2), and "normal mouth temperature of 37°C" refers to

body temperature. (Ex. 1011, 4:66-68). Given that the  $A_s$  temperature of the alloy is lower than the  $A_f$  temperature ( $5^\circ\text{C}$ ), Tanaka thus discloses that the  $A_s$  temperature is lower than  $5^\circ\text{C}$  and, thus, lower than body temperature. As a result, the alloy exhibits reversible SIM behavior not only at body temperature, but at a temperature less than body temperature (any temperature between the  $A_s$  temperature and body temperature, including room temperature).

204. Thus, substituting the SMA used to make Cragg's stent with Tanaka's nitinol SMA, as discussed above, would result in a stent made from a SMA exhibiting SIM behavior at body temperature as well as below body temperature. During use, for example, the catheter would engage and stress such a stent at a temperature less than body temperature, and greater than the  $A_s$  temperature of the alloy, when the catheter/stent are maintained at a temperature between these temperatures, such as room temperature. (*See also* Section IV.A.3., pp. 49-70 (especially pp. 66-70) (describing positioning the stent in the modified device within the body while the stent is in its deformed, relatively straightened shape)).

**G. Claim 7**

205. I rely on and repeat the same evidence and testimony regarding claim 7 recited above with respect to Ground 1 at Section IV.G. (p. 79), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**H. Claim 8**

206. I rely on and repeat the same evidence and testimony regarding claim 8 recited above with respect to Ground 1 at Section IV.H. (p. 80), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**I. Claim 9**

207. I rely on and repeat the same evidence and testimony regarding claim 9 recited above with respect to Ground 1 at Section IV.I. (pp. 80-81), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**J. Claim 10**

208. I rely on and repeat the same evidence and testimony regarding claim 10 recited above with respect to Ground 1 at Section IV.J. (p. 81), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**K. Independent Claim 11**

209. I rely on and repeat the same evidence and testimony regarding claim 11 recited above with respect to Ground 1 at Section IV.K. (pp. 81-83), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's

nitinol SMA to make Cragg's stent, as discussed above with respect to claims 1 and 6 (Sections V.A., pp. 92-96, and V.F., pp. 97-98).

**L. Claim 12**

210. I rely on and repeat the same evidence and testimony regarding claim 12 recited above with respect to Ground 1 at Section IV.L. (p. 83), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**M. Claim 13**

211. I rely on and repeat the same evidence and testimony regarding claim 13 recited above with respect to Ground 1 at Section IV.M. (p. 83), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**N. Claim 14**

212. I rely on and repeat the same evidence and testimony regarding claim 14 recited above with respect to Ground 1 at Section IV.N. (pp. 83-84), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**O. Independent Claim 15**

213. I rely on and repeat the same evidence and testimony regarding claim 15 recited above with respect to Ground 1 at Section IV.O. (pp. 84-86), except that

Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent, as discussed above with respect to claims 1 and 6 (Sections V.A., pp. 92-96, and V.F., pp. 97-98).

**P. Independent Claim 16**

214. I rely on and repeat the same evidence and testimony regarding claim 16 recited above with respect to Ground 1 at Section IV.P. (pp. 87-89), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent, as discussed above with respect to claims 1 and 6 (Sections V.A., pp. 92-96, and V.F., pp. 97-98).

**Q. Claim 17**

215. I rely on and repeat the same evidence and testimony regarding claim 17 recited above with respect to Ground 1 at Section IV.Q. (p. 89), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**R. Independent Claim 18**

216. I rely on and repeat the same evidence and testimony regarding claim 18 recited above with respect to Ground 1 at Section IV.R. (p. 90-91), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent, as discussed above with respect to claims 1 and 6 (Sections V.A., pp. 92-96, and V.F., pp. 97-98).

**S. Claim 19**

217. I rely on and repeat the same evidence and testimony regarding claim 19 recited above with respect to Ground 1 at Section IV.S. (p. 91), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**T. Claim 20**

218. I rely on and repeat the same evidence and testimony regarding claim 20 recited above with respect to Ground 1 at Section IV.T. (pp. 91-92), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**U. Claim 21**

219. I rely on and repeat the same evidence and testimony regarding claim 21 recited above with respect to Ground 1 at Section IV.U. (p. 92), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**V. Claim 22**

220. I rely on and repeat the same evidence and testimony regarding claim 22 recited above with respect to Ground 1 at Section IV.V. (p. 92), except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent.

**VI. SECONDARY CONSIDERATIONS**

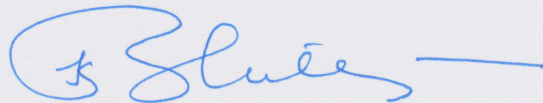
221. I am not aware of any applicable secondary considerations.

**VII. CONCLUSION**

222. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both.

223. I further declare under penalty of perjury that the foregoing is true and correct.

Executed September 28, 2018 at Pasadena, California.



Kaushik Bhattacharya, Ph.D.

# EXHIBIT A



**MATERIALS REVIEWED**

<b>Exhibit No.</b>	<b>Description</b>
Ex. 1001	U.S. Patent No. 6,306,141 (“the ’141 Patent”)
Ex. 1002	Prosecution file history of the ’141 Patent
Ex. 1003	Prosecution file history of U.S. Application No. 06/541,852 filed October 14, 1983
Ex. 1004	Prosecution file history of U.S. Application No. 06/865,703 (now U.S. Patent No. 4,665,906) filed May 21, 1986
Ex. 1005	Prosecution file history of U.S. Application No. 07/252,019 (now U.S. Patent No. 5,067,957) filed September 27, 1988
Ex. 1006	Medtronic’s Preliminary Response to Inter Partes Review Petition in IPR2014-00362 for the ’141 Patent
Ex. 1007	Dieter Stoeckel, The Shape Memory Effect - Phenomenon, Alloys and Applications, Proceedings: Shape Memory Alloys for Power Sys. EPRI (1995)
Ex. 1008	C.M. Wayman, <i>Some Applications of Shape-Memory Alloys</i> , Journal of Metals (June 1980), pp. 129-137 (“Wayman”)
Ex. 1009	Andrew Cragg et al., Nonsurgical Placement of Arterial Endoprostheses: A New Technique Using Nitinol Wire, 147 Radiology 261 (1983) (“Cragg”)
Ex. 1010	Horace Pops, Stress-Induced Pseudoelasticity in Ternary Cu-Zn Based Beta Prime Phase Alloys, 1 Metallurgical Transactions 251 (1970) (“Pops”)
Ex. 1011	U.S. Patent No. 4,490,112 (“Tanaka”)
Ex. 1012	Yuichi Suzuki, Shape Memory and Super-elasticity Effects in NiTi Alloys, Titanium & Zirconium, Vol. 30, No. 4 (1982) (“Suzuki”)
Ex. 1013	U.S. Patent No. 4,550,870 (“Krumme”)
Ex. 1014	U.S. Patent No. 4,452,236 (“Utsugi”)

Exhibit No.	Description
Ex. 1015	U.S. Patent No. 4,427,000 (“Ueda”)
Ex. 1016	L. Delaey et al., Thermoelasticity, Pseudoelasticity And The Memory Effects Associated With Martensitic Transformations, Part 1 Structural And Microstructural Changes Associated With The Transformations, 9 J. Materials Sci. 1521 (1974)
Ex. 1017	Jeff Perkins et al., Shape Memory Effects in Alloys 273-302 (Jeff Perkins ed. 1975)
Ex. 1018	L. McDonald Schetky, Shape-Memory Alloys, 241 Sci. Am. 74 (1979)
Ex. 1019	George B. Kauffman & Isaac Mayo, The Story of Nitinol: The Serendipitous Discovery of the Memory Metal and Its Applications, 2 Chem. Educator 1 (1996)
Ex. 1020	Martha Sund-Levander et al., Normal Oral, Rectal, Tympanic and Axillary Body Temperature in Adult Men and Women: A Systematic Literature Review, 16 Scandinavian J. Caring Sci. 122 (2002)
Ex. 1022	Declaration of Shigeru Itoh (regarding Suzuki)
Ex. 1023	Declaration of Brian Durrance (regarding Cragg and Pops)
Ex. 1024	Declaration of Edwin Mann (regarding exhibits)
Ex. 1025	Declaration of Michael O’Keeffe (regarding translation of Suzuki)
Ex. 1026	Prosecution file history of U.S. Application No. 07/956,653 (now U.S. Patent No. 5,597,378) filed October 2, 1992
Ex. 1027	U.S. Patent No. 4,512,338 (“Balko”)
Ex. 1028	Schetky, Shape-Memory Alloys, 20 Kirk-Othmer Encyclopedia of Chemical Technology 726-736 (3d Ed. 1982) (“Seader”)
Ex. 1029	U.S. Patent No. 4,485,805 (“Foster”)
	Any other materials referenced in the declaration above.

# EXHIBIT B

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### Education

Ph.D. 1991 University of Minnesota  
B.Tech. 1986 Indian Institute of Technology, Madras

### Professional Experience

2010–Current Howell N. Tyson Sr. Professor of Mechanics and Professor of Materials Science,  
California Institute of Technology  
2000–Current Professor, California Institute of Technology  
1999 Associate Professor, California Institute of Technology  
1993–99 Assistant Professor, California Institute of Technology  
1991–93 Associate Research Scientist, Courant Institute of Mathematical Sciences  
1986–91 Graduate Assistant, University of Minnesota

### Visiting Positions

2008-09 Cavendish Laboratory and Clare Hall, University of Cambridge  
2006 Jet Propulsion Laboratories  
2001 Indian Institute of Science, Bangalore  
1999 Isaac Newton Institute, University of Cambridge  
1997–98 Max-Planck-Institute for Mathematics in the Sciences, Leipzig  
1992 International Center for Mathematical Sciences, Edinburgh  
1988 Mathematical Sciences Institute, Cornell University

### Professional Recognition and Awards

Outstanding Achievement Award, University of Minnesota, 2018.  
Warner T. Koiter Medal for distinguished contributions to the field of Solid Mechanics, American Society of Mechanical Engineering, 2015.  
Fellow, Society for Industrial and Applied Mathematics, 2013.  
Graduate Student Council Teaching and Mentoring Award, California Institute of Tech., 2013.  
Spanish Mechanics Lecturer, 2013.  
EPSRC Visiting Fellowship, 2008-2009.  
Southwest Mechanics Lecturer, 2007-2008.  
Midwest Mechanics Lecturer, 2006-2007.  
Special Achievement Award in Applied Mechanics, Applied Mechanics Division, American Society of Mechanical Engineering, 2004.  
Society of Engineering Sciences Young Investigator Award, 2004.

2004 Best Paper Award in the area of active materials (with E. Burcsu and G. Ravichandran), American Society of Mechanical Engineering, 2005.

NSF Young Investigator, 1994

### **Professional and Administrative Activities**

Vice-Provost, California Institute of Technology, 2016-Current.

Executive Officer (Department Chair) for Mechanical and Civil Engineering, California Institute of Technology, 2007-2016.

Member of the Faculty Board, California Institute of Technology, 2014-15.

Editor (2004-2015) and Senior Editorial Advisor (2016-Current), Journal of the Mechanics and Physics of Solids.

Member of the Editorial Board, Archive for Rational Mechanics and Analysis from 1999, Applied Mathematics Research Express from 2003 - 2014, Communications on Mathematical Sciences for Applications from 2001-2004.

Member of Visiting Committee/Expert Panel: Department of Engineering Mechanics, Tsinghua University (2010); Department of Education, Government of Singapore (2011-2016); Department of Mechanical Science and Engineering, University of Illinois at Urbana Champaign (2014); Department of Mechanical and Aerospace Engineering, Hong Kong University of Science and Technology (from 2015), Department of Aerospace Engineering and Mechanics, University of Minnesota (2017).

Expert Consultant, 2017-2018, Brinks, Gilson and Lione on behalf of Cook Medical LLC.

Technical Consultant, 2011-2013, Leading medical device company.

Expert Consultant, 2015, Pillsbury Winthrop Shaw Pittman LLP on behalf of Fluidmaster.

Technical Consultant, 2010, Ormco Corporation.

Expert Consultant, 2010-2013, Carlson, Caspers, Vandenburg, Lindquist & Shuman, P.A on behalf of AGA Medical Corporation/ St. Jude Medical Inc.

Expert Consultant, 2009-2013, AGA Medical Corporation.

Expert Consultant, 2008-2009, Alston and Bird, L.L.P on behalf of AGA Medical Corporation.

Technical Consultant, 2002-05 Boston Scientific Corporation

Expert Consultant, 2000-2002, Fulbright and Jaworski L.L.P on behalf of Boston Scientific Corporation.

### **Publications: Books and Book Chapters**

- [1] K. Bhattacharya. *Microstructure of martensite. Why it forms and how it gives rise to the shape-memory effect*, Oxford University Press, 2003.
- [2] R. Abeyaratne, K. Bhattacharya, and J.K. Knowles. Strain-energy functions with local minima: Modeling phase transformations using finite thermoelasticity. In *Nonlinear elasticity: Theory and applications* (ed. Y. Fu and R.W. Ogeden), Cambridge University Press, 433-490, 2001.
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- [4] K. Bhattacharya. The microstructure of martensite and its implications on the shape-memory effect. In *Microstructure and phase transition* (ed. D. Kinderlehrer, R.D. James and M. Luskin) IMA volumes in mathematics and its applications, Springer Verlag, 1-25, 1993.

## Publications: Journal Articles

- [1] C-J. Hsueh and K. Bhattacharya Optimizing microstructure for toughness: The model problem of peeling. *Struc. Mult. Opt.*, 58:1067-1080, 2018.
- [2] D. Sun, M. Ponga, K. Bhattacharya and M. Ortiz. Proliferation of twinning in HCP metals: Application to magnesium. *J. Mech. Phys. Solids* 112: 368-384.
- [3] P. Plucinsky, B. A. Kowalski, T. J. White and K. Bhattacharya. Patterning nonisometric origami in nematic elastomer sheets. *Soft Matter* 14: 3127-3134, 2018.
- [4] V. Agrawal and K. Bhattacharya. Impact induced depolarization of ferroelectric materials. *J. Mech. Phys. Solids* 115: 142-166, 2018.
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- [9] L. Avellar, T. Reese, K. Bhattacharya and G. Ravichandran. Effect of cohesive zone size on peeling of heterogeneous adhesive tape. *J. Appl. Mech.*, to appear 2018.
- [10] L. Collins and K. Bhattacharya. Optimal design of a model energy conversion device. *Struc. Mult. Opt.*, to appear, 2018.
- [11] J. Yang and K. Bhattacharya. Augmented Lagrangian digital image correlation. Submitted, 2018.
- [12] J. Yang and K. Bhattacharya. Combining image compression with digital image correlation. Submitted, 2018.
- [13] A. Tutcuoglu, K. Bhattacharya and D. Kochmann. Stochastic modeling of discontinuous dynamic recrystallization at finite strains in hcp metals. Submitted, 2018.
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## Patents

P. Mazur, K. Bhattacharya and B. McKeon, Flow control technique by dielectric materials US Patent Application. Submitted.

M.Z. Hossain, C-J Hsueh, K. Bhattacharya, G. Ravichandran, B.A. Bourdin. Systems and methods for determining the effective toughness of a material and for implementing materials possessing improved effective toughness characteristics. US Patent Application. Submitted.

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## Selected Presentations in the Past Five Years

Mechanics of Multifunctional Materials, Bad Honnef, June 2018 (Plenary)

Polycrystals: Microstructure and Effective Properties, Oxford, March 2018

International Liquid Crystal Elastomers Conference, Houston, October 2017

International Conference on Martensitic Transformations, Chicago, July 2017 (Plenary)

Magnesium Workshop: Alloys and Lightweight Structural Systems, Baltimore, April 2017

SIAM Conference on Materials Science, Philadelphia, May 2016 (Plenary)

Koiter Lecture, International Congress and Exhibition in Mechanical Engineering, Houston, November 2015

Gordon Research Conference on Physical Metallurgy, Biddeford, July 2015

Pan-American Conference on Applied Mechanics XV, Urbana, May 2015 (Plenary)

Institute for Advanced Studies Focused Program on Multiscale Modeling and Simulation, Hong Kong, December 2014

CISM Summer School on Ferroic Functional Materials: Experiment, Modeling and Simulation, Udine, September 2014 (6 lectures)

IUTAM Symposium on Thermomechanical-Electromagnetic Coupling in Solids, Paris, June 2014

IUTAM Symposium on Micromechanics of Defects in Solids, Seville, June 2014

International Conference on Microscale Morphology of Component Surfaces, Kaiserslautern, Feb. 2014

Conference on Smart Materials, Adaptive Structures and Intelligent Systems, Salt Lake City, Sept. 2013 (Keynote).

Eringen Medal Symposium and Prager Medal Symposium, Society of Engineering Sciences Conference, Providence, June 2013.

ERC Workshop on Variational Views in Mechanics and Materials, Pavia, June 2013

ICMS Workshop on Differential Geometry and Continuum Mechanics, Edinburgh, June 2013.

Seminars in various universities including College du France, Indian Institute of Science, Indian Institute of Technology, Madras, Max-Planck-Institute Leipzig, McGill University, Oxford University, Technical-University Berlin, Technical-University Darmstadt, Technion, University of Bath, University of Bonn, University of Cambridge University of Metz, University of Oxford Arizona State University, Carnegie Mellon University, Cornell University, Courant Institute of Mathematical Sciences, Georgia Institute of Technology, Harvard University, Illinois Institute of Technology, Massachusetts Institute of Technology, Northwestern University, Notre Dame University, Pennsylvania State University, Purdue University, Stanford University, Texas A&M University, University of Arizona, University of California Los Angeles, University of California San Diego, University of California Riverside, University of California Santa Barbara, University of Illinois, University of Houston University of Maryland, University of Massachusetts, University of Minnesota, University of Oklahoma, University of Pennsylvania, University of Pittsburgh, University of Southern California, University of Texas, University of Utah, Yale University.

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