UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,306,141

Case No. IPR2019-00123

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REGULATIONS

Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC (collectively, "Petitioners") respectfully request *inter partes* review of claims 1-22 of U.S. Patent No. 6,306,141 (Ex. 1001). USPTO assignment records indicate that the Patent Owner is Medtronic, Inc.

I. COMPLIANCE WITH *INTER PARTES* REVIEW REQUIREMENTS

A. Mandatory Notices (37 C.F.R. § 42.8)

1. Real Parties-in-Interest

Petitioners are the real parties-in-interest.

2. Related Matters

Petitioners are not aware of any judicial or administrative matters that would affect, or be affected by, a decision in this proceeding. Claims 1-22 of the '141 Patent were challenged in IPR2013-00269 and/or IPR2014-00362. Both proceedings were settled and terminated before any institution decision.

3. Lead And Back-up Counsel

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4. Service Information

Service on Petitioners may be made by mail or hand-delivery to the lead and back-up counsel at the addresses specified above. Petitioners also consent to service by e-mail at the addresses specified above.

B. Fee For *Inter Partes* Review (37 C.F.R. § 42.103)

The Office is authorized to charge any required fees, including those specified in 37 C.F.R. § 42.15(a), to Deposit Account No. 23-1925.

C. Timing Requirements (37 C.F.R. §§ 42.101 and 42.102)

The ’141 Patent issued on October 23, 2001. Neither Petitioners, nor their privies: own the patent, were served with a complaint alleging infringement of the

patent, filed a civil action challenging the validity of the patent, or are barred or estopped from challenging the claims of the patent.

D. Standing Certification (37 C.F.R. § 42.104(a))

Petitioners certify that the '141 Patent is available for *inter partes* review and that Petitioners are not barred or estopped from requesting an *inter partes* review challenging the claims of the '141 Patent as set forth below.

E. Claims, Grounds, And Relief (37 C.F.R. § 42.104(b))

Petitioners request that the Board cancel claims 1-22 of the '141 Patent, because each claim is obvious under 35 U.S.C. § 103 based on the following grounds:

Ground 1: Cragg, Pops, and Tanaka. (Exs. 1009, 1010, 1011).

Ground 2: Cragg, Tanaka, and Suzuki. (Exs. 1009, 1011, 1012).

Cragg published by March 25, 1983, (*see* Ex. 1023, ¶¶7, 9), and qualifies as prior art under pre-AIA 35 U.S.C. § 102(a). Pops published by November 23, 1971, (*see* Ex. 1023, ¶¶8, 9), and qualifies as prior art under pre-AIA 35 U.S.C. §§ 102(a) and (b). Tanaka published on December 25, 1984, (*see* Ex. 1011), and qualifies as prior art under pre-AIA 35 U.S.C. § 102(e). Suzuki published by December 3, 1982, (*see* Ex. 1022, ¶¶6-8), and qualifies as prior art under pre-AIA 35 U.S.C. § 102(a). (*See* Ex. 1025 (declaration regarding translation of Suzuki)).

Sections IV. and V. below identify where each element of claims 1-22 is found in the prior art, and provide a detailed description of the pertinence and manner of applying the prior art to the challenged claims.

F. Level Of Ordinary Skill In The Art

A person having ordinary skill in the art ("PHOSITA") at the time the first patent application leading to the '141 Patent was filed 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. (Ex. 1021, ¶¶17-18).

Petitioners submit with this Petition the Declaration of Kaushik Bhattacharya, Ph.D. (Ex. 1021). Dr. Bhattacharya is a Professor of Mechanics and Materials Science at the California Institute of Technology. He has extensive experience with the mechanical/thermal behavior of materials, including shape memory alloys. (*Id.*, ¶¶4-13).

Dr. Bhattacharya has authored over 150 publications, including numerous publications concerning shape memory alloys and stress-induced martensite behavior. (*Id.*, ¶6). He also is named as an inventor on at least five patents. (*Id.*, ¶12). In 2015, the American Society of Mechanical Engineering awarded Dr. Bhattacharya the Warner T. Koiter Medal for distinguished contributions to the

field of solid mechanics. (*Id.*, ¶7). The medical device industry relies on his expertise, as reflected by the list of medical device companies that seek his consulting advice. (*Id.*, ¶11, p. (stating that Dr. Bhattacharya was a consultant for Boston Scientific Corp., AGA Medical Corp., and St. Jude Medical, among others)). Indeed, Dr. Bhattacharya has experience designing medical devices, including building models of medical devices. (Ex. 1021, ¶11). Dr. Bhattacharya's Declaration further highlights his qualifications, and addresses the asserted prior art from the view of a PHOSITA at the relevant timeframe.

G. Claim Construction

A claim subject to *inter partes* review receives the "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b).

II. BACKGROUND

A. Background Relating To The '141 Patent

Patent Owner's Preliminary Response in IPR2014-00362 provides a background relating to the '141 Patent. (Ex. 1006; *see also* Ex. 1021, ¶¶27-61 (Petitioners' expert providing background relating to the '141 patent)). According to Patent Owner, "[t]he '141 patent is directed to medical devices made of shape

memory alloys ('SMAs')." (Ex. 1006, p. 7).[1] "SMAs can 'remember' their original shape and revert back to it after they have been deformed." (*Id*.). "This property has the advantage of enabling medical devices made with SMAs…to adopt a smaller configuration for insertion into a placement device, *e.g.*, a catheter, and in turn, deployment into the body." (*Id*.). "Once deployed, an SMA device can remember, and thereby return to, its original, larger configuration." (*Id*.).

Patent Owner explained that "[t]he ability of an SMA to remember its original shape is a consequence of its ability to exist in two different states (or crystal structures) that occur at the atomic level, namely 'austenite' and 'martensite.'" (Ex. 1006, p. 7). "The transformation between austenitic and martensitic states can be effected one of two ways: by [1] temperature or [2] mechanical stress." (*Id*.). "In the case of temperature, martensite forms at relatively lower temperatures, and austenite forms at relatively higher temperatures." (*Id*., pp. 7-8). "In the case of stress, martensite forms through the application of stress, and austenite forms when that stress is relieved." (*Id*., p. 8).

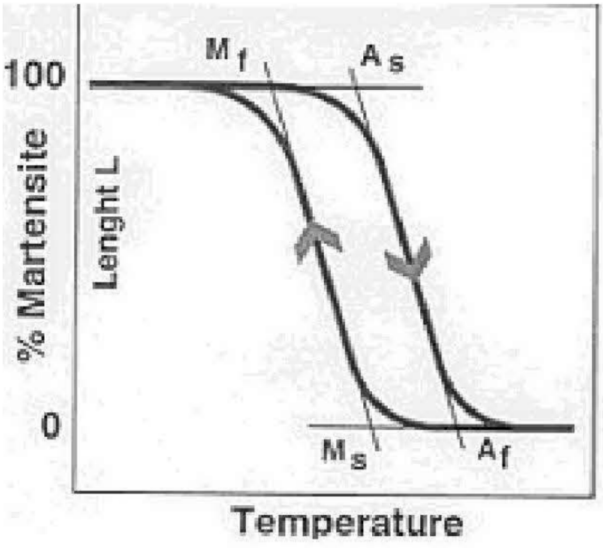
Dr. Bhattacharya explains that, just as water can reversibly transform between different states (*e.g.*, water, steam, ice), SMAs can reversibly transform

[1] Page number citations herein reference the exhibit numbering branded on the lower right corner of the exhibit, unless the context makes clear otherwise.

between their austenitic and martensitic states. (Ex. 1021, ¶39). For water, the state is dependent on the temperature and pressure of the water. (*Id.*). 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. (*Id.*). Similarly, a SMA existing as austenite at one temperature may be turned into martensite by the application of stress ***or*** the reduction of temperature. (*Id.*).

According to Patent Owner, "the medical community initially employed temperature to control SMA transformations between austenite and martensite, thereby exploiting the property known as temperature-induced martensite ('TIM')." (Ex. 1006, p. 8 (emphasis omitted)). "As pertinent here, the temperature at which austenite begins transforming to martensite is the martensite start temperature (M_s); the temperature at which the transformation is complete is the martensite finish temperature (M_f)." (*Id.*, pp. 8-9). "Corresponding temperatures for the martensite to austenite conversion are austenite start (A_s) and austenite finish (A_f)." (*Id.*, p. 9). "These transition temperatures may be graphically depicted as follows:"[2]

[2] The graph illustrates that the curve reflecting the transition from martensite to austenite (which includes the arrow pointing down) is different from the curve reflecting the transition from austenite to martensite (which includes the arrow



(Ex. 1006, p. 9 (citing Stoeckel (Ex. 1007))). According to Patent Owner, "these transition temperatures are highly dependent on the chemical composition of the SMA." (Ex. 1006, p. 9). TIM is created by decreasing the SMA's temperature below M_s, and TIM can be reversed to austenite by increasing the SMA's temperature above A_s. (Ex. 1021, ¶44).

Patent Owner stated that "the TIM approach had at least three problems." (Ex. 1006, p. 9). "First, the TIM approach required very precise temperature control for deploying an SMA device." (*Id.*). "This process included using low temperatures for converting the device to its martensitic state for insertion into a

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pointing up). This phenomenon is referred to as a hysteresis loop. (Ex. 1007, p. 3; Ex. 1021, ¶43). Thus, the temperature necessary to achieve a specific percentage of martensite may differ depending on whether the alloy is transitioning from martensite to austenite or vice-versa. (*Id.*).

placement device, followed by using higher temperatures to transform the device into its austenitic state for deployment." (Ex. 1006, p. 10). "Because such temperature manipulation would partly occur in the patient's body, tissue damage could result." (*Id*.). "Second, transition temperatures could vary greatly due to the variability of the chemical composition and heat treatment processing of the SMA." (*Id*.). "Lastly, the need for temperature manipulation was a source of substantial inconvenience for physicians." (*Id*.). "[T]emperature manipulation would involve such cumbersome techniques as the use of ice baths, cooling elements, and heating elements during surgical procedures." (*Id*.).

B. The '141 Patent

1. The Alleged Distinguishing Features Of The '141 Patent

According to Patent Owner, "[t]he invention of the '141 patent overcame these problems by controlling SMA transformations between austenite and martensite by applying or removing *stress* to an SMA device, thereby exploiting the property known as stress-induced martensite ('SIM')." (Ex. 1006, p. 10 (emphasis omitted)). "The application of stress to an SMA device at a temperature above its A_s transforms austenite to martensite, and removal of the stress transforms the SMA device back to its original austenitic state." (*Id*.).

The '141 Patent acknowledges that SMAs were already known and used in

medical devices. (Ex. 1001, 2:15-16 ("Various proposals have also been made to employ [SMAs] in the medical field"); *see also* Ex. 1002, p. 119). Further, the '141 Patent acknowledges that SMAs exhibiting SIM behavior were known. (Ex. 1001, 1:52-53 ("Many [SMAs] are known to display [SIM]."")). 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]"); 3:27-32; 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.")).[3]

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 those of ordinary skill in the [] art, having regard to this disclosure by testing for

[3] All emphasis is added herein unless otherwise noted.

the existence of the SIM effect at the desired temperature." (Ex. 1001, 4:22-27).

2. Prosecution File History

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). Finally, the Examiner relied upon Foster for the claimed "guide wire," because "Balko lacks a guide wire." (*Id.*, pp. 110-111).

Applicant appealed the rejection to the Board. 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).

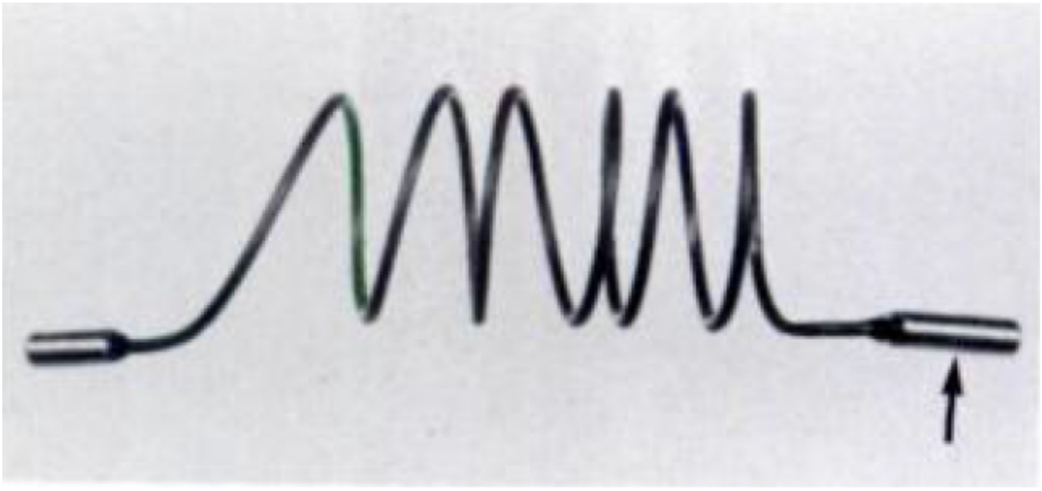
The Board credited Applicant's arguments, concluding "the examiner has not made out a *prima facie* case that the SMAs disclosed by Balko would inherently display SIM properties," because Seader did not establish that Balko's

nitinol alloy, in particular, inherently had SIM properties. (*Id.*, pp. 344-346).[4] As a result, the Board reversed the Examiner's rejections and the '141 claims issued.

III. ASSERTED PRIOR ART

A. Cragg

Cragg discloses a medical device including a coiled stent. (Ex. 1009). The stent is depicted below:



(Ex. 1009, Figure 1). The stent is made with a SMA relying on TIM behavior. (Ex. 1009, p. 1; Ex. 1021, ¶69). Cragg discloses implanting the stent in a mammal using a catheter and guide wire. (*Id.*).

[4] The Board referred to Seader as the "Kirk-Othmer" reference. (Ex. 1002, p. 342).

B. 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); Ex. 1021, ¶70).

C. 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; Ex. 1021, ¶71). 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 it is made. (Ex. 1021, ¶71).

D. Suzuki

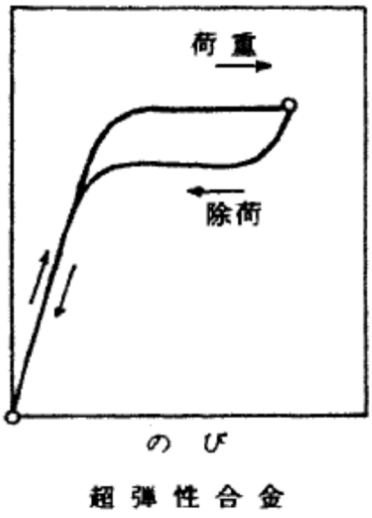
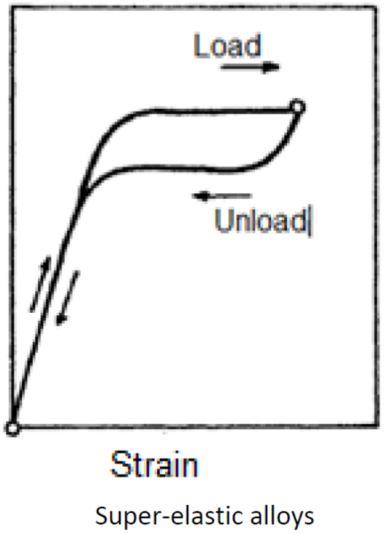
Suzuki discloses a nitinol SMA exhibiting reversible SIM behavior, and that this alloy can be substituted for SMAs relying on TIM behavior in medical device applications. (Ex. 1012, pp. 10-12, 15; Ex. 1021, ¶72).

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

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). These features, however, are disclosed in Pops, Tanaka, and Suzuki. (Ex. 1021, ¶73). 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 to make the stent disclosed by Cragg using one of these alloys, making claims 1-22 of the '141 Patent obvious, as further discussed below.

Pops was not cited during prosecution of the '141 Patent. Tanaka, Suzuki, and Cragg were each cited in an IDS, but they were not substantively discussed or relied upon by the USPTO in any rejection. (Ex. 1002, pp. 78-89 (IDS); Ex. 1021, ¶74). Suzuki, furthermore, is written in Japanese, but Applicant submitted an incomplete, non-certified translation and told the USPTO that "[t]here is no translation provided to [Applicant] that bears a date." (Ex. 1005, p. 225). For example, Applicant's translation of Suzuki is missing a translation of Suzuki's figures, such as the figure reproduced below. (*Compare* Ex. 1005, pp. 8-30 (Applicant's Suzuki translation) *with* Ex. 1012, pp. 9-16 (Petitioner's Suzuki translation)). The missing translation of this figure is important, because it illustrates that Suzuki's "super-elastic alloys" are SMAs with SIM behavior (as further discussed below at pp. 26, 30-31, 62-63).

SUZUKI (ORIGINAL)	SUZUKI (APPLICANT'S TRANSLATION)	SUZUKI (PETITIONERS' TRANSLATION)
 (Ex. 1012, p. 3).	No translation of figure submitted to USPTO.	 (Ex. 1012, p. 11).

Pops, Tanaka, Suzuki, and Cragg also are not cumulative to any references substantively addressed during prosecution. (Ex. 1021, ¶¶73-74). To the extent Medtronic argues that Tanaka is cumulative to Wayman (Ex. 1008) addressed during prosecution of a parent to the '141 Patent, because both references disclose an SMA wire used for dental braces applications, Medtronic is wrong. Unlike Wayman, Tanaka expressly discloses dental braces made with an SMA with SIM behavior at body temperature along with the precise composition of the SMA and how to make it. (*See* pp. 23-26, 31, 61-62, below). Likewise, to the extent Medtronic argues that Suzuki is cumulative to Seader, because both references disclose SMAs with SIM behavior, Medtronic is wrong. Unlike Seader, Suzuki discloses the use of SMAs with reversible SIM behavior at body temperature in

implantable medical devices, and states that SMAs with TIM behavior in medical devices may be substituted with SMAs with SIM behavior. (*See* pp. 26, 30-31, 62-63, below). And to the extent Medtronic argues that Cragg is cumulative to Balko, because both references disclose a coiled stent made of a SMA, Medtronic is wrong again. Unlike Balko, Cragg expressly discloses a guide wire and catheter used to introduce Cragg's stent, both of which are claimed features. (*See* pp. 17, 39, 41-42, below).

Moreover, the obviousness arguments and combinations below were not addressed during prosecution. (Ex. 1021, ¶¶73-74). As discussed above, the primary issue during prosecution of the '141 Patent was whether Balko inherently disclosed an SMA with SIM behavior at body temperature. The obviousness arguments and combinations below, however, identify prior art SMAs with SIM behavior at body temperature, and substitute these SMAs for the SMA used to make Cragg's stent (an entirely different combination and analysis).

In short, the Examiner erred in not appreciating the relevance and applicability of Tanaka, Suzuki, and Cragg during prosecution, but in any event, she did not have the benefit of Pops during prosecution. Consideration of these references anew is appropriate here. *See Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (identifying discretionary factors to consider concerning petition based on cited references).

IV. GROUND 1: THERE IS A REASONABLE LIKELIHOOD THAT 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"

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); Ex. 1021, ¶75; Sections IV.A.2.-IV.A.9. below).

2. "(a) a hollow placement device;"

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"); Ex. 1021, ¶76; *see* Section IV.A.3. below (especially pp. 33-38) (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,"

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; Ex. 1021, ¶77). Cragg states that the stent is made from a "metal alloy (nitinol) with a heat-sensitive memory." (*Id*.).

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

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

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). 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."); Ex. 1021, ¶80).

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 identifies six alloys (shown below) comprised of copper (Cu), zinc (Zn), silicon (Si), and/or tin (Sn):

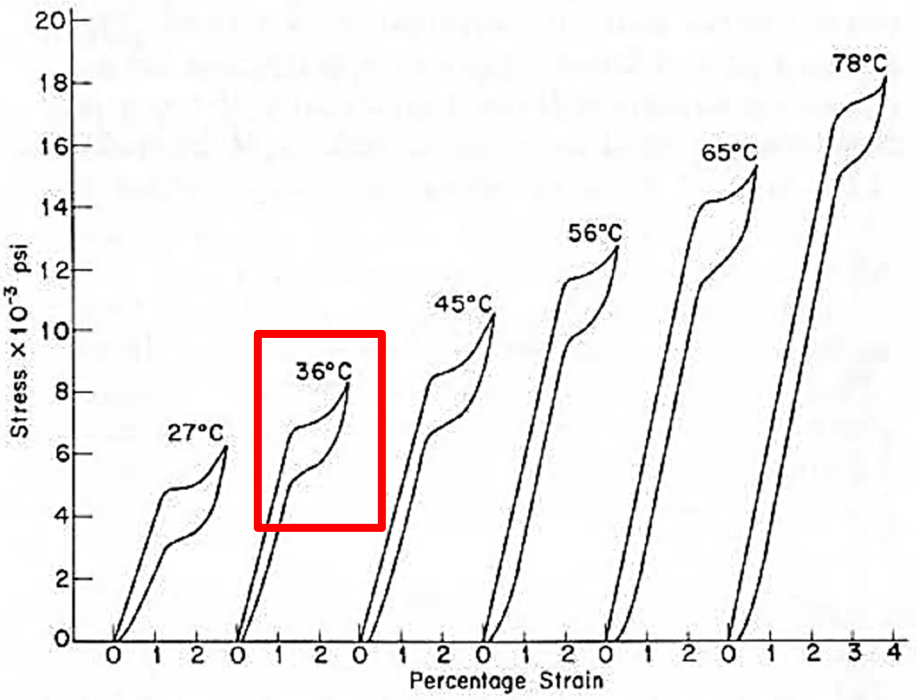
Table I. Compositions of Alloys in at. pct, Used for Deformation Studies

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; Ex. 1021, ¶81). 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).

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,[5] and illustrates that Pops' copper-zinc-silicon alloys exhibit reversible SIM behavior at body temperature. (Ex. 1021, ¶82). Indeed, the stress-strain

[5] Human body temperatures differ from one person to the next and can range from about 33.2°C to 38.2°C for adults. (Ex. 1021, ¶82, n.8). The '141 Patent refers to body temperature as about "35°–40° C." (Ex. 1001, 4:25).

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. (*Id.*, ¶83; Ex. 1001, 3:6-9, 4:3-16).

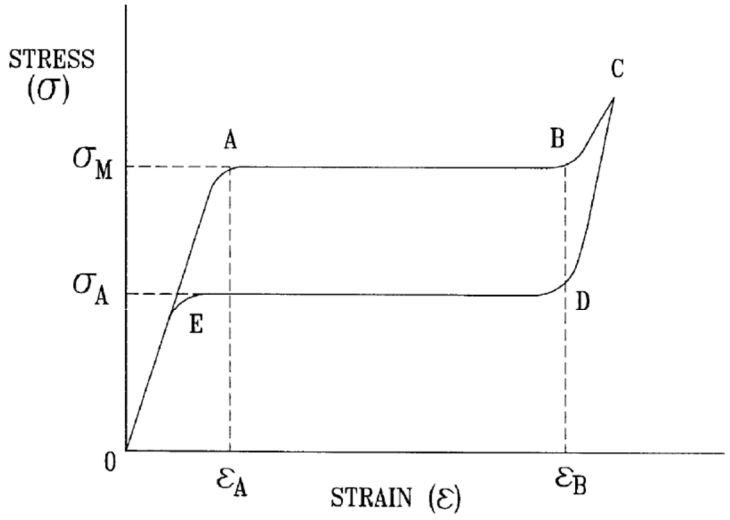
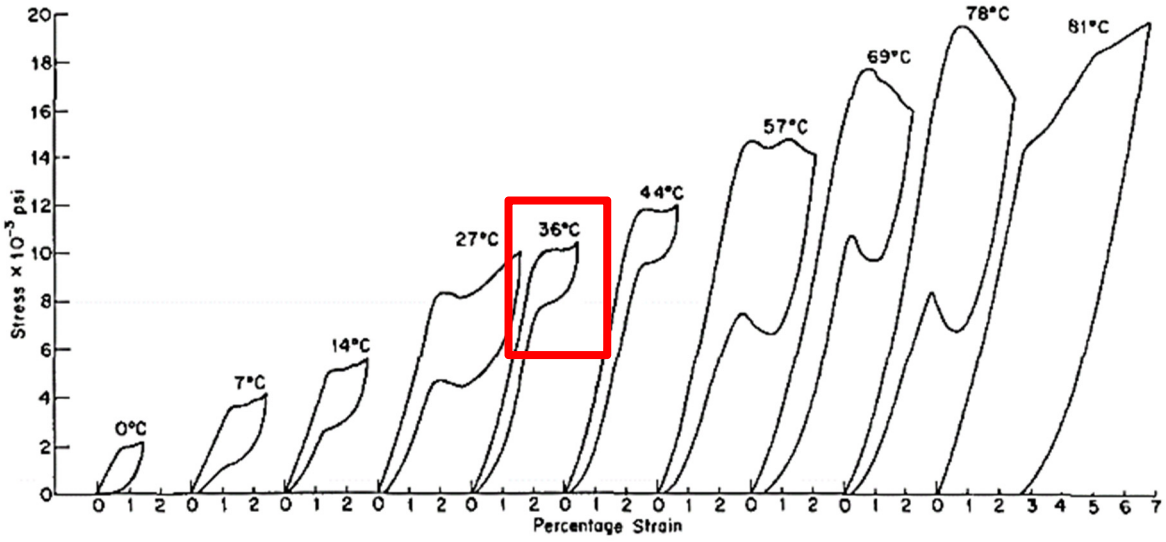


FIG. 2

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.



(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). (Ex. 1021, ¶84). Indeed, Pops states that "pseudoelasticity occurs in the temperature range between -6ºC…and less than 81ºC" for the copper-zinc-tin alloys, which includes body temperature. (Ex. 1010, p. 7, Figure 5(a)).

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. (Ex. 1021, ¶85). 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. (*Id.*). 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).

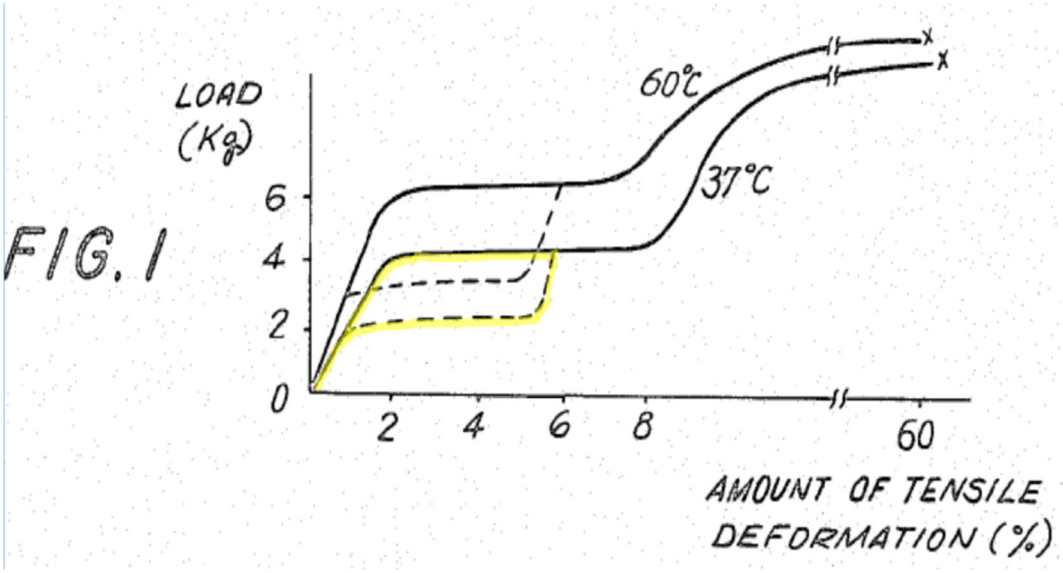
c. Use in Medical Devices of SMAs Exhibiting Reversible SIM Behavior, Including At Body Temperature, Was Also Known

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. (Ex. 1021, ¶86; *see also* Ex. 1005, p. 108 (Applicant acknowledging that "an ultraelastic alloy…is 'often called [a] pseudoelasticity alloy.'")).

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; Ex. 1021, ¶87). 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. (Ex. 1021, ¶87).

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. (Ex. 1021, ¶88). This stress-strain curve (see the portion highlighted yellow) shows reversible SIM behavior consistent with Figure 2 of the '141 Patent (reproduced above). (*Id.*).

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; Ex. 1021, ¶89). 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. As Dr. Bhattacharya explains, 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). (Ex. 1021, ¶89).

This temperature change in Tanaka's SMA does not result in TIM, or reflect TIM behavior, like the SMAs described in the background above (Section II.A.), 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; Ex. 1021, ¶90). As discussed above in Section II.A., 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).

Applicant's actions during prosecution of a parent application to the '141 Patent highlight the significance of Tanaka. 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). This cancellation constitutes an admission by Applicant that Tanaka discloses the subject matter of this claim.

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; Ex. 1021, ¶92). 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] can overcome these problems." (Ex. 1012, p. 15; Ex. 1021, ¶92).

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

As explained above in Section II.B.1., 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. Under *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007) and its progeny, however, substitution of one element with another known in the field to obtain a predictable

result fails the threshold for patentability. *Id*., 415-16. Here, the substitution yielded an obvious, predictable result.

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*.; Ex. 1021, ¶94). 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).

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

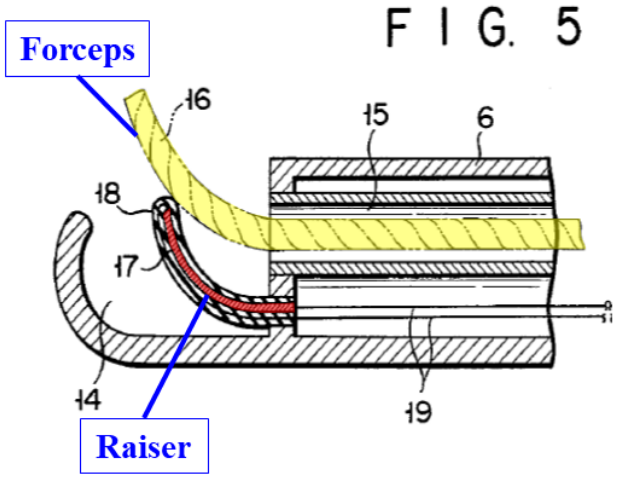
TIM behavior. (Ex. 1009, p. 2; Ex. 1021, ¶95). Nor does Cragg criticize, discredit, or discourage using a SMA exhibiting reversible SIM behavior. Rather, Cragg specifically encourages using "a ***suitable alloy with optimal transformation characteristics***" to make his stent. (*Id*.).

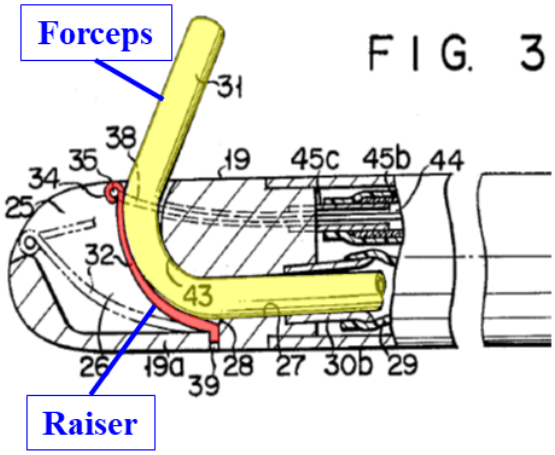
A PHOSITA would have recognized that a "suitable alloy with optimal transformation characteristics" includes prior art SMAs exhibiting reversible SIM behavior at body temperature. (Ex. 1021, ¶96). A PHOSITA would have been motivated to make Cragg's stent using such an alloy, because this substitution would have been expected to overcome the "difficulties" described by Cragg. (*Id*.). 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. (*Id*., ¶97). No change in temperature would have been necessary. (*Id*.). 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. (*Id*., ¶98). 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). (*Id*.).

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 Dr. Bhattacharya's 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). (Ex. 1021, ¶99). This simple substitution would have addressed the "source of substantial inconvenience for physicians." (*Id*.).

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. (Ex. 1021, ¶100). 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. (*Id.*; Exs. 1014, 1015 (both prior art under pre-AIA 35 U.S.C. § 102(e))).





Ueda Fig. 5 (annotated excerpt) **Utsugi Fig. 3 (annotated excerpt)**

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. (Ex. 1021, ¶101).

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; Ex. 1021, ¶102). 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). (Ex. 1021, ¶102).

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. (Ex. 1021, ¶103; *see also* 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; Ex. 1021, ¶103).

Medtronic may try to argue that copper-based alloys are not biocompatible and, thus, a PHOSITA would have not used Pops' copper-based alloys in an implantable medical device. This argument is shown to be wrong by the prior art. As discussed above, for example, Tanaka 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; Ex. 1021, ¶104). Similarly, Krumme discloses the use of a copper-zinc alloy (brass) in an implantable medical device (surgical staples). (Ex. 1013, 7:1-3; Ex. 1021, ¶104). 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. 1021, ¶104; Ex. 1005, p. 116 (referring to "staple for attaching blood vessels together")).

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. (Ex. 1021, ¶105). This would be accomplished, for example, simply by applying a coating to the stent, such as a hydrophilic coating. (*Id*.). Such processing would have been selected so that it would not have impacted the desired SIM behavior of the alloy. (*Id*.). These processing techniques would have been well known to a PHOSITA for optimization of the stent at the relevant time. (*Id*.).

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. (*Id*., ¶106). Such testing would have involved, at most, routine skill. (*Id*.).

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. (*Id*., ¶107). Each such alternative modification is a simple

substitution of one known element for another to obtain predictable results. (*Id*.). *See KSR*, 550 U.S. at 415-16.

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

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)), is lower than the desired temperature range at which SIM behavior is desired, such as body temperature. (Ex. 1021, ¶108). 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. (*Id*.).

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)). 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. (Ex. 1021, ¶109).

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. (*Id*., ¶110). 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. (*Id*.).

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; Ex. 1021, ¶111). 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. (Ex. 1021, ¶111).

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) (27ºC and 36ºC); Ex. 1021, ¶112). 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. 1021, ¶112; Ex. 1010, Figures 4(b) and 5(b) (identifying M_s and A_s temperatures as being less than 15ºC for each alloy)).

These fundamental principles of SIM were well-known to a PHOSITA by the alleged priority date in 1983. (*Id.*).

f. The Modified Device Meets The Claim Requirements

The modified device includes "a memory alloy element" in the form of a SMA. (*See* Sections IV.A.3.a.-e. above (especially pp. 31-33)). The "memory alloy element" in the modified device is a "pseudoelastic shape-memory alloy," because it exhibits reversible SIM behavior. (*See id.*; Ex. 1021, ¶113). As discussed above, the alloy in the modified device exhibits reversible SIM behavior at body temperature. (*Id.*).

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." (Ex. 1021, ¶114) The wire used to make the stent would be annealed while constrained in the coiled shape disclosed by Cragg. (*Id.*, ¶115). 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. (*Id*.). The deformation of the stent in this manner results in at least a portion of the stent transitioning from austenite to martensite through the application of stress by the catheter. (*Id*., ¶116). This is SIM. (*Id*.). 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." (*Id*.). As discussed above, the A_s temperature of the alloy would be lower than body temperature when relying on reversible SIM behavior to transition martensite to austenite at body temperature. (*Id*.).

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). (*Id.*, ¶117). The deformed stent would be connected to a guide wire, as disclosed in Cragg. (*Id.*, ¶118). 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. (*Id*.). 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). (*Id*.). 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. (*Id*., ¶119). 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." (*Id*.).

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). (*Id.*, ¶120). 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). (*Id*.). 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." (*Id*.).

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. (*Id.*, ¶121). This transition, in particular, would occur without any change in the state of the "placement device," "restraint," or "restraining means" (catheter). (*Id*.). 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 id*.; 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. (*Id*.).

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"

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶122).

5. "(c) a guide wire;"

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."); Ex. 1021, ¶123; *see also* Section IV.A.3. above (especially pp. 35-38)).

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

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"); Ex. 1021, ¶124; *see also* Section IV.A.3. above (especially pp. 35-38)).

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"); Ex. 1021, ¶125; *see also* Section IV.A.3. above (especially pp. 35-

38)). 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 and using the guide wire to guide a catheter to the desired site. (Ex. 1021, ¶125; Ex. 1002, p. 111).

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,"

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶126).

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,"

In the modified device, "the memory alloy element" (coiled stent) is "extruded" from the "hollow placement device" (catheter) "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. …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"); Ex. 1021, ¶127).

The modified device also includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶128).

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."

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially p. 38). (Ex. 1021, ¶129).

B. Claim 2

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. (especially pp. 35-38). (*See also* Ex. 1009, p. 2 ("Loosely wound coils could be used as *stents* to maintain vessel patency."); Ex. 1021, ¶130).

C. Claim 3

Claim 3 depends from claim 2 and further requires "a guide wire for endarterial placement of the stent graft."[6] The modified device includes the

[6] Claim 3 refers to "the stent graft." The antecedent basis for this limitation is the "stent" recited in claim 2. (Ex. 1021, ¶132). Thus, "the stent graft" in claim 3 is understood to refer to the "stent" in claim 2. (*Id*.). Even if "stent graft" means something different than "stent," Cragg discloses that the coiled stent may also be

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."); Ex. 1021, ¶131; *see also* Section IV.A.3. above (especially pp. 35-38)).

D. Claim 4

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. (especially p. 38). (Ex. 1021, ¶133).

E. Claim 5

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. 17).

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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."); Ex. 1021, ¶132).

F. Independent Claim 6

1. "A medical device which comprises:"

The preamble is not limiting. Nonetheless, Cragg discloses a medical device for the reasons discussed above in Section IV.A.1. (p. 17). (Ex. 1021, ¶135).

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

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."); Ex. 1021, ¶136). The stent is substantially at human body temperature when placed within the human body, as further discussed above in Section IV.A.3. (especially pp. 35-38).

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

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 31-38). (Ex. 1021, ¶137).

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;"

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"); Ex. 1021, ¶138). Dependent claim 8 confirms that a catheter constitutes a "restraint." (Ex. 1001, 11:51-52). As discussed above in Section IV.A.3. (especially pp. 35-38), 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."

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. (especially pp. 35-38). (Ex. 1021, ¶139).

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. (Ex. 1021, ¶140; Section IV.A.3. above). SMAs exhibit reversible SIM behavior over a temperature range, not just at a single temperature. (Ex. 1021, ¶140). 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 36ºC (body temperature) and 27ºC (below body temperature)); Ex. 1021, ¶140). 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., would result in a stent made from a SMA exhibiting SIM behavior at body temperature as well as below body temperature. (Ex. 1021, ¶141). 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 27ºC. (*Id.*; Section IV.A.3. (especially at pp. 35-38) (describing positioning the stent in the modified device within the body while the stent is in its deformed, relatively straightened shape)).

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. (especially pp. 22-23, 32-33). (Ex. 1021, ¶142). 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). (*Id.*). 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. (*Id*.).

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. (Ex. 1021, ¶143). Each is a simple substitution of one known element for another to obtain predictable results. (*Id*.). *See KSR*, 550 U.S. at 415-16.

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."

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). 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." (Ex. 1021, ¶144).

G. Claim 7

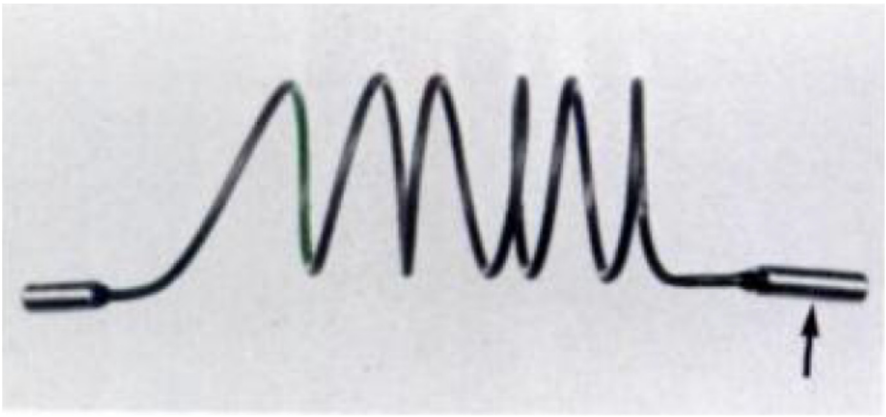
Claim 7 depends from claim 6 and further requires that "the restraint is hollow, and the stent is positioned at least partially within the restraint." The modified device includes this limitation. (Ex. 1009, p. 1 (stating that the stent "can be readily passed *through* a catheter," that the stent is "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"); Ex. 1021, ¶145; *see also* Section IV.A.3. above (especially pp. 35-38)).

H. Claim 8

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. (p. 44). (Ex. 1021, ¶146).

I. Claim 9

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; Ex. 1021, ¶147). The coiled stent also has a "longitudinal dimension," which corresponds with the length of the coiled stent along its longitudinal axis. (Ex. 1021, ¶148). As discussed above in Section IV.A.3.

(especially pp. 35-38), 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. (Ex. 1021, ¶148). In this configuration, the "restraint" (catheter) "prevents transverse expansion of the stent," as further described in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶148).

J. Claim 10

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. (especially pp. 35-38). (Ex. 1021, ¶149).

K. Independent Claim 11

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

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. 17). (Ex. 1021, ¶150).

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"

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 31-38). (Ex. 1021, ¶151).

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;"

Claim 11 recites a "restraining means engaging and stressing the stent…[and] for positioning the stent within the mammalian body." If "restraining means" is considered a means-plus-function limitation, the corresponding 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; Ex. 1021, ¶152). In any event, dependent claim 13 confirms that a catheter constitutes a "restraining means." (Ex. 1001, 12:23-24).

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"); Ex. 1021, ¶153). The modified device also includes this

limitation for the reasons discussed above in Sections IV.A.3. and IV.F.4. (especially pp. 35-38, 44-46).

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."

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶154).

L. Claim 12

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. (especially p. 38). (Ex. 1021, ¶155).

M. Claim 13

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. (pp. 50-51). (Ex. 1021, ¶156).

N. Claim 14

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"); Ex. 1021, ¶157; *see also* Section IV.A.3. (especially pp. 35-38)).

O. Independent Claim 15

1. "A medical device for treatment of a mammalian body, the device comprising:"

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. 17). (Ex. 1021, ¶158).

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

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 31-38). (Ex. 1021, ¶159).

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,"

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶160).

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"

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶161).

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

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"); Ex. 1021, ¶162). 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).

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"); Ex. 1021, ¶163; *see also* Section IV.A.3. (especially pp. 35-38)).

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;"

The modified device includes this limitation for the reasons discussed above in Sections IV.A.3. and IV.F.4. (especially pp. 35-38, 44-46). (Ex. 1021, ¶164).

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,"

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶165).

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."

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶166).

P. Independent Claim 16

1. "A medical device suitable for placement within a mammalian body for treatment of the mammalian body, the device comprising"

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. 17). (Ex. 1021, ¶167).

2. "(i) a restraint"

The modified device includes "a restraint" in the form of a catheter for the reasons discussed above in Section IV.F.4. (p. 44). Dependent claim 21 confirms that a catheter constitutes a "restraint." (Ex. 1001, 14:19-20; Ex. 1021, ¶168; *see also* Section IV.A.3. (especially pp. 35-38)).

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

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 31-38). (Ex. 1021, ¶169).

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;"

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 33-38). (Ex. 1021, ¶170).

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

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶171).

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;"

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶172).

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"

The modified device includes this limitation for the reasons discussed above in Sections IV.A.3. and IV.F.4. (especially pp. 35-38, 44-46). (Ex. 1021, ¶173).

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,"

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 33-38). (Ex. 1021, ¶174).

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,"

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶175).

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

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶176).

Q. Claim 17

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. (especially pp. 35-38). (*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*."); Ex. 1021, ¶177).

R. Independent Claim 18

1. "A medical device comprising:"

The preamble is not limiting. Nonetheless, Cragg discloses a medical device for the reasons discussed above in Section IV.A.1. (p. 17). (Ex. 1021, ¶178).

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

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 31-38). (Ex. 1021, ¶179).

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"

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶180).

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,"

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 33-38). Furthermore, the modified device includes "a restraint" in the form of a catheter for the reasons discussed above in Section IV.F.4. (p. 44). Dependent claim 21 confirms that a catheter constitutes a "restraint." (Ex. 1001, 14:19-20; Ex. 1021, ¶181).

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"

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 35-38). (Ex. 1021, ¶182).

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

The modified device includes this limitation for the reasons discussed above in Section IV.A.3. (especially pp. 31-38). (Ex. 1021, ¶183).

S. Claim 19

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. 41-42). (Ex. 1021, ¶184).

T. Claim 20

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. (especially pp. 35-38). (Ex. 1021, ¶185).

U. Claim 21

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. 55). (Ex. 1021, ¶186).

V. Claim 22

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. (especially pp. 35-38). (Ex. 1021, ¶187).

V. GROUND 2: THERE IS A REASONABLE LIKELIHOOD THAT CLAIMS 1-22 WOULD HAVE BEEN OBVIOUS IN VIEW OF CRAGG, TANAKA, AND SUZUKI

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. Further details are provided below.

A. Independent Claim 1

Petitioners rely on and repeat the same evidence and arguments regarding claim 1 recited above with respect to Ground 1 at Section IV.A. However, instead of substituting Cragg's nitinol SMA with a Ground 1 SMA to make Cragg's stent,

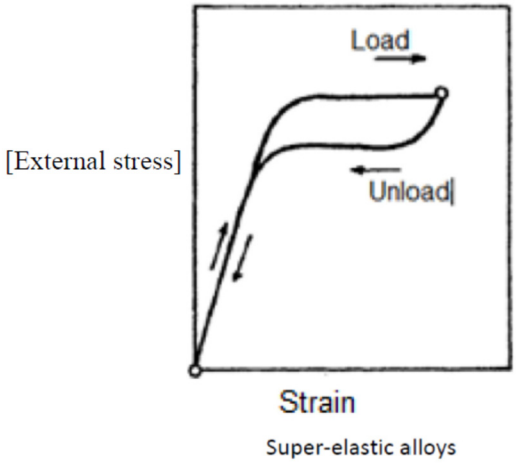
Cragg's nitinol SMA is substituted with Tanaka's nitinol SMA to make the stent. Further details regarding this alternative substitution are provided below.

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), there is no doubt that Tanaka's nitinol SMA exhibits reversible SIM behavior. (Ex. 1021, ¶190).

Tanaka states that the nitinol SMA is "ultraelastic," which is a term that Tanaka used to refer to reversible SIM behavior. (*Id.*, ¶191; 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°C and an A_f temperature of 5°C (meaning that the A_s temperature is less than 5°C). (Ex. 1011, 5:25-27, 5:65-6:2; Ex. 1021, ¶191). The SMA exhibits reversible SIM behavior at body temperature, as discussed above in Section IV.A.3. (especially pp. 23-26), which is higher than the M_s and A_s temperatures (and lower than the M_d temperature). (Ex. 1021, ¶191). 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). (*Id.*).

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; Ex. 1021, ¶192). Suzuki uses the term "super-elastic" to refer to reversible SIM behavior. (*Id.*). 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. (Ex. 1021, ¶192). Figure 1 (reproduced in part below) shows reversible SIM behavior consistent with Figure 2 of the '141 Patent. (*Id.*).



As discussed above, Suzuki states that nitinol SMAs with reversible SIM behavior are "***used in medical fields, <u>in the same way as</u>***" SMAs with TIM

behavior (called "shape memory alloys" by Suzuki). (Ex. 1012, p. 15; Ex. 1021, ¶193). 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. (*Id.*). Indeed, Suzuki states that SMAs with reversible SIM behavior are "***of major interest*** for functional materials," as discussed above. (Ex. 1012, pp. 11, 13).

Nitinol also was known to be biocompatible. (Ex. 1021, ¶194). 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." (*Id.*; Ex. 1012, pp. 13, 15).

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. 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. (Ex. 1021, ¶195). This substitution merely involves substituting one nitinol alloy for another nitinol alloy, which provides yet another motivation to make this substitution. (*Id.*).

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. (Ex. 1021, ¶196). This modification is a simple substitution of one known element for another to obtain predictable results. (*Id*.). *See KSR*, 550 U.S. at 415-16.

B. Claim 2

Petitioners rely on and repeat the same evidence and arguments regarding claim 2 recited above with respect to Ground 1 at Section IV.B., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶197).

C. Claim 3

Petitioners rely on and repeat the same evidence and arguments regarding claim 3 recited above with respect to Ground 1 at Section IV.C., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶198).

D. Claim 4

Petitioners rely on and repeat the same evidence and arguments regarding claim 4 recited above with respect to Ground 1 at Section IV.D., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶199).

E. Claim 5

Petitioners rely on and repeat the same evidence and arguments regarding claim 5 recited above with respect to Ground 1 at Section IV.E., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶200).

F. Independent Claim 6

Petitioners rely on and repeat the same evidence and arguments regarding claim 6 recited above with respect to Ground 1 at Section IV.F., 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.). (Ex. 1021, ¶201).

If Medtronic 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. (Ex. 1021, ¶202; *see also* Section IV.A.3.).

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, 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; Ex. 1021, ¶203), and "normal mouth temperature of 37° C" refers to body temperature. (Ex. 1011, 4:66-68; Ex. 1021, ¶203). Given that the A_s temperature of the alloy is lower than the A_f temperature (5°C), Tanaka thus discloses that the A_s temperature is lower than 5°C and, thus, lower than body temperature. (Ex. 1021, ¶203). 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). (*Id.*).

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. (*Id.*, ¶204). 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. (*Id.*; *see also* Section IV.A.3. (especially pp. 35-38) (describing positioning the stent in the modified

device within the body while the stent is in its deformed, relatively straightened shape)).

G. Claim 7

Petitioners rely on and repeat the same evidence and arguments regarding claim 7 recited above with respect to Ground 1 at Section IV.G., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶205).

H. Claim 8

Petitioners rely on and repeat the same evidence and arguments regarding claim 8 recited above with respect to Ground 1 at Section IV.H., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶206).

I. Claim 9

Petitioners rely on and repeat the same evidence and arguments regarding claim 9 recited above with respect to Ground 1 at Section IV.I., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶207).

J. Claim 10

Petitioners rely on and repeat the same evidence and arguments regarding claim 10 recited above with respect to Ground 1 at Section IV.J., except that

Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶208).

K. Independent Claim 11

Petitioners rely on and repeat the same evidence and arguments regarding claim 11 recited above with respect to Ground 1 at Section IV.K., 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. and V.F.). (Ex. 1021, ¶209).

L. Claim 12

Petitioners rely on and repeat the same evidence and arguments regarding claim 12 recited above with respect to Ground 1 at Section IV.L., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶210).

M. Claim 13

Petitioners rely on and repeat the same evidence and arguments regarding claim 13 recited above with respect to Ground 1 at Section IV.M., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶211).

N. Claim 14

Petitioners rely on and repeat the same evidence and arguments regarding claim 14 recited above with respect to Ground 1 at Section IV.N., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶212).

O. Independent Claim 15

Petitioners rely on and repeat the same evidence and arguments regarding claim 15 recited above with respect to Ground 1 at Section IV.O., 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. and V.F.). (Ex. 1021, ¶213).

P. Independent Claim 16

Petitioners rely on and repeat the same evidence and arguments regarding claim 16 recited above with respect to Ground 1 at Section IV.P., 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. and V.F.). (Ex. 1021, ¶214).

Q. Claim 17

Petitioners rely on and repeat the same evidence and arguments regarding claim 17 recited above with respect to Ground 1 at Section IV.Q., except that

Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶215).

R. Independent Claim 18

Petitioners rely on and repeat the same evidence and arguments regarding claim 18 recited above with respect to Ground 1 at Section IV.R., 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. and V.F.). (Ex. 1021, ¶216).

S. Claim 19

Petitioners rely on and repeat the same evidence and arguments regarding claim 19 recited above with respect to Ground 1 at Section IV.S., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶217).

T. Claim 20

Petitioners rely on and repeat the same evidence and arguments regarding claim 20 recited above with respect to Ground 1 at Section IV.T., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶218).

U. Claim 21

Petitioners rely on and repeat the same evidence and arguments regarding claim 21 recited above with respect to Ground 1 at Section IV.U., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶219).

V. Claim 22

Petitioners rely on and repeat the same evidence and arguments regarding claim 22 recited above with respect to Ground 1 at Section IV.V., except that Tanaka's nitinol SMA (rather than a Ground 1 SMA) is substituted for Cragg's nitinol SMA to make Cragg's stent. (Ex. 1021, ¶220).

VI. SECONDARY CONSIDERATIONS

Petitioners are not aware of any applicable secondary considerations.

VII. CONCLUSION

Petitioners respectfully request the PTAB to grant this petition for *inter partes* review.

Date: November 9, 2018

Respectfully submitted,

By: /s/ Dominic P. Zanfardino
Dominic P. Zanfardino
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Lead Counsel for Petitioners

CERTIFICATE OF COMPLIANCE

The undersigned certifies that this petition complies with the type-volume limitations of 37 C.F.R. § 42.24(a)(1)(i). The word count of this petition as determined by Microsoft Word, excluding a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing, is 13,939 words.

The undersigned further certifies that this petition complies with the typeface requirements of 37 C.F.R. § 42.6(a)(2)(ii) and typestyle requirements of 37 C.F.R. § 42.6(a)(2)(iii). The Petition has been prepared using Microsoft Word 2016 in Times New Roman 14 point font.

Date: November 9, 2018

Respectfully submitted,

By: /s/ Dominic P. Zanfardino
Dominic P. Zanfardino
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Lead Counsel for Petitioners

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Petition For *Inter Partes* Review of U.S. Patent 6,306,141 and supporting materials (Exhibits 1001-1029 and Power of Attorney) have been served in their entirety on November 9, 2018, by Federal Express (Overnight Delivery) on:

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