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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COOK INCORPORATED, COOK GROUP INCORPORATED, AND COOK MEDICAL LLC,
Petitioner,

v.

MEDTRONIC, INC.,
Patent Owner.

Case IPR2019-00123
Patent 6,306,141 B1

Before JAMESON LEE, KEN B. BARRETT, and JAMES A. TARTAL, *Administrative Patent Judges*.

BARRETT, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background and Summary

Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC (collectively, "Petitioner")[1] filed a Petition requesting *inter partes* review of U.S. Patent No. 6,306,141 B1 ("the '141 patent," Ex. 1001). Paper 1 ("Pet."). The Petition challenges the patentability of claims 1–22 of the '141 patent. Medtronic, Inc., ("Patent Owner")[2] filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). Petitioner, pursuant to our authorization, Paper 9, filed a Reply to Patent Owner's Preliminary Response, Paper 10 ("Pet. Reply to Prelim. Resp.").

An *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Having considered the arguments and evidence presented by Petitioner and Patent Owner, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the '141 patent is unpatentable. Accordingly, we institute an *inter partes* review as to all the challenged claims of the '141 patent on all the grounds of unpatentability set forth in the Petition.

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[1] Petitioner identifies Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC as real parties-in-interest. Pet. 1.

[2] Patent Owner, under the heading "Real Party-In-Interest," states that Medtronic, Inc. is the owner of the '141 patent and that "Medtronic plc is the ultimate parent of Medtronic, Inc." Paper 3, 1–2.

B. Related Proceedings

One or both parties identify, as matters involving or related to the '141 patent, *Medtronic, Inc. v. W.L. Gore & Assocs., Inc.*, No. 06-cv-04455 (N.D. Cal.), and *Medtronic, Inc. v. AGA Med. Corp.*, No. 07-cv-00567 (N.D. Cal.) and Patent Trial and Appeal Board cases IPR2013-00269 and IPR2014-00362. Pet. 1; Paper 3.

C. The '141 Patent

The '141 patent pertains to medical devices incorporating shape memory alloys (SMAs) and, specifically, to medical devices incorporating stress-induced martensite (SIM) alloys. Ex. 1001, Abstract, 1:21–23. According to the Abstract of the '141 patent:

> Medical devices which are currently proposed to use elements made from shape memory alloys may be improved by the use of stress-induced martensite alloy elements instead. The use of stress-induced martensite decreases the temperature sensitivity of the devices, thereby making them easier to install and/or remove.

Ex. 1001, Abstract.

The Specification explains that shape memory alloys were well known. *Id.* at 1:26–27. An article made from a shape memory alloy can be deformed from its original, heat stable configuration to a second, heat unstable configuration, and, upon application of heat alone, can be caused to revert to its original configuration. *Id.* at 1:27–34.

> Among metallic alloys, the ability to possess shape memory is a result of the fact that the alloy undergoes a reversible transformation from an austenitic state to a martensitic state with a change in temperature. This transformation is sometimes referred to as a thermoelastic martensitic transformation. An article made from such an alloy, for example a hollow sleeve, is easily deformed from its original configuration to a new

> configuration when cooled below the temperature at which the alloy is transformed from the austenitic state to the martensitic state. The temperature at which this transformation begins is usually referred to as M_s and the temperature at which it finishes M_f. When an article thus deformed is warmed to the temperature at which the alloy starts to revert back to austenite, referred to as A_s (A_f being the temperature at which the reversion is complete) the deformed object will begin to return to its original configuration.

Id. at 1:35–51. The parties refer to the property or behavior associated with an austenitic-to-martensitic transformation related to a temperature change as "temperature-induced martensite" or "TIM." See, *e.g.*, Prelim. Resp. 6; Pet. 7, 10.

The Specification further explains that a martensite state also may be induced by stress:

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

Ex. 1001, 1:52–2:3. "The recoverable deformation associated with the formation and reversion of stress-induced martensite has been referred to as pseudoelasticity." *Id.* at 4:12–15.

"Various proposals have also been made to employ shape memory alloys in the medical field . . . [and t]hese medical SMA devices . . . rely on the fact that when an SMA element is cooled to its martensitic state and is subsequently deformed, it will retain its new shape; but when it is warmed to its austenitic state, the original shape will be recovered." *Id.* at 2:15–28. According to the Specification, there were two principal disadvantages with this use of SMAs—it was difficult to control the transformation temperatures of SMAs with accuracy and many SMAs had a large hysteresis associated with the state transformation thus requiring a significant temperature excursion to reverse the state. *Id.* at 2:29–41. Additionally, it was "inconvenient to have to engage in any temperature manipulation" and human tissue could be damaged by temperatures outside of narrow limits. *Id.* at 2:41–48.

The '141 patent purports to disclose the discovery "that if, in a medical device containing a shape memory alloy element which uses the shape memory property of that alloy, an element which shows the property of stress-induced martensite is used instead, an improved device results." *Id.* at 2:59–63. The Specification characterizes the improvement due to the claimed invention as "compris[ing] the substitution of an alloy element which displays stress induced martensite at said body temperature for the shape memory alloy element [in a medical device intended for use in a mammalian body or a device that is substantially at body temperature]." *Id.* at 2:64–3:4.

"Suitable alloy for this invention i.e. those displaying stress-induced martensite at temperatures near mammalian body temperature (35°–40° C.), may be selected from known SMAs by those of ordinary skill in theart [sic], having regard to this disclosure by testing for the existence of the SIM effect at the desired temperature." *Id.* at 4:22–27.

In the Specification, the Cragg reference[3] is discussed as an example of how a SIM element could be implemented in a medical device using a shape memory alloy. *Id.* at 9:10–10:7. In Cragg, an SMA wire, of the alloy nitinol, was used to form a tubular coiled wire stent[4] that was straightened and introduced into the aorta via a catheter and precisely placed by use of guide wire upon extrusion from the catheter. *Id.* at 9:14–49. "Because of the difficulty of controlling the transformation temperature accurately, it has proved necessary to cool the straightened wire during insertion and/or to heat the wire to form the coil after insertion." *Id.* at 9:53–56. "These procedures add to the complexity of the operation." *Id.* at 9:56–57.

To address these issues, the Specification explains that:

> If an SIM pseudoelastic wire is used to form the coil, which is then isothermally deformed by loading into a catheter, then the need for temperature control is avoided. The wire remains straight when in the catheter, but re-forms the coil spontaneously when it is extruded from the catheter. Accurate

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[3] Cragg is in the record as Exhibit 1009 and is identified and discussed further below.

[4] The described stent is "a compacted nitinol coil [that] is readily positioned in a narrowed arterial segment and then expanded to its original form with a luminal diameter approximately equal to that of the adjacent, relatively normal, blood vessel. Expansion of the coil anchors it against the slightly stretched, but otherwise intact, surrounding blood vessel." Ex. 1001, 9:25–32.

> placement is thus readily obtainable, since there is no urgency as might be required with a conventional shape memory effect element.

Id. at 9:57–65.

D. Illustrative Claim

Of the challenged claims of the '141 patent, claims 1, 6, 11, 15, 16, and 18 are independent claims. The remaining challenged claims depend directly or indirectly from one of these independent claims. Claim 1, reproduced below, is illustrative:

> 1. A medical device for insertion into a mammalian body, the device comprising
>
> (a) a hollow placement device;
>
> (b) a memory alloy element formed at least partly from pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about body temperature such that it has a stress-induced martensitic state and an austenitic state, the memory alloy element having (i) a deformed shape when the alloy is in its stress-induced martensitic state and (ii) a different unstressed shape when the alloy is in its austenitic state; and
>
> (c) a guide wire;
>
> the memory alloy element being within the hollow placement device, and the placement device being guidable by the guide wire, the hollow placement device stressing the memory alloy element at a temperature greater than the A_s of the alloy so that the memory alloy element is in its deformed shape,
>
> wherein the memory alloy element can be extruded from the hollow placement device by the guide wire at a temperature greater than the A_s of the alloy to transform at least a portion of the alloy from its stress-induced martensitic state so that the memory alloy element transforms from its deformed shape to its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the placement device or the memory alloy element.

Ex. 1001, 10:60–11:20.

E. Evidence

Petitioner relies on the following references:

Reference	**Exhibit No.**
Andrew Cragg et al., *Nonsurgical Placement of Arterial Endoprostheses: A New Technique Using Nitinol Wire*, 147 RADIOLOGY 261 (1983) ("Cragg")	Ex. 1009
Horace Pops, *Stress-Induced Pseudoelasticity in Ternary Cu-Zn Based Beta Prime Phase Alloys*, 1 METALLURGICAL TRANSACTIONS 251 (1970) ("Pops")	Ex. 1010
U.S. Patent No. 4,490,112; filed Sept. 2, 1982; issued Dec. 25, 1984 ("Tanaka")	Ex. 1011
Yuichi Suzuki, *Shape Memory and Super-elasticity Effects in NiTi Alloys*, TITANIUM & ZIRCONIUM, Vol. 30, No. 4 (1982) ("Suzuki")	Ex. 1012

Petitioner also relies on the Declaration of Kaushik Bhattacharya, Ph.D, dated September 28, 2018 (Ex. 1021), in support of its arguments. Patent Owner relies on the Declaration of Dr. Christopher K. Zarins, M.D., dated March 12, 2009 (Ex. 2003), filed in earlier litigation, and the declaration of Dr. Lee Middleman (Ex. 1002, 128–133), filed during the prosecution of the application that issued as the '141 patent, in support of its arguments. The parties rely on other exhibits as discussed below.

F. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

References	**Basis**	**Claims**
Cragg, Pops, and Tanaka	§ 103(a)	1–22
Cragg, Tanaka, and Suzuki	§ 103(a)	1–22

II. ANALYSIS

A. Principles of Law

Petitioner bears the burden of persuasion to prove unpatentability of the claims challenged in the Petition, and that burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) any objective evidence of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. The Level of Ordinary Skill in the Art

Petitioner's declarant, Dr. Bhattacharya, opines that:

> [T]he person having ordinary skill in the art ("PHOSITA") at the time the first patent application leading to the '141 Patent was filed on October 14, 1983, would have possessed the knowledge and skill known by an engineer, physician, or similar professional, having knowledge of, or experience with: (1) shape memory alloys exhibiting reversible stress-induced martensite behavior, and/or (2) designing medical devices using such shape memory alloys.

Ex. 1021 ¶ 18; *see* Pet. 4. At this stage of the proceeding, Patent Owner does not disagree. *See generally* Prelim. Resp. (not addressing explicitly the level of ordinary skill in the art). Based on the current record and for the

purposes of this Decision, we adopt Petitioner's declarant's proposed description of the person of ordinary skill in the art. Further, we determine that the prior art of record reflects the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). We will make a final determination as to the level of ordinary skill in the art, however, based on the full trial record.

C. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear.[5] 37 C.F.R. § 42.100(b) (2018)[6]; *see also Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). "Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history." *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016).

In this case, neither party's brief includes, under the "claim construction" heading, a proposed construction for any term. Pet. 5; Prelim. Resp. 14–15. Patent Owner, however, in arguing that Petitioner has failed to account for a limitation, sets forth a proposed construction as to what it

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[5] Patent Owner asserts that the '141 patent will expire in 2022 and that the broadest reasonable construction standard should be applied in this case. Prelim. Resp. 14–15; *see also* Pet. 5 (Petitioner also advocating the application of the broadest reasonable construction standard.).

[6] A recent amendment to this rule does not apply here because the Petition was filed before November 13, 2018. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,340 (Oct. 11, 2018).

characterizes as "a key aspect of all the challenged intendent claims." Prelim. Resp. 2. Patent Owner contends that "all independent claims require a device or a component stressing the SIM alloy to induce the martensitic state and disengaging the SIM alloy from the stress-inducing device or component to revert the SIM alloy to its austenitic, non-deformed state, without having to change the temperature." *Id.* at 2 n.1; *see also id.* at 12, 21.

We find it helpful to address Patent Owner's proposed construction. The following discussion pertains to the language of independent claim 1, and applies similarly to the other challenged independent claims. Our claim construction analysis here is preliminary, and we encourage the parties to address the matters further in future briefing.

1. Patent Owner's "Disengaging" Position

Independent claim 1 is an apparatus claim and recites "[a] medical device" comprising three components. Ex. 1001, 10:60–11:20. Generally speaking, those three components are: a hollow placement device, a memory alloy formed from a shape-memory alloy, and a guide wire. *Id.* The alloy displays "reversible stress-induced martensite at about body temperature such that it has a stress-induced martensitic state and an austenitic state." *Id.* at 10:63–67. The claim further recites that the memory alloy element is within the hollow placement device, and "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." *Id.* at 11:6–11; *see also id.* at 1:47–48 ("A_s" is the temperature at which the alloy starts to revert back to austenite).

The last recitation of claim 1, and that which pertains to Patent Owner's arguments, *see, e.g.*, Prelim. Resp. 21–22, states:

> wherein the memory alloy element *can be extruded* from the hollow placement device by the guide wire at a temperature greater than the A_s of the alloy to transform at least a portion of the alloy from its stress-induced martensitic state so that the memory alloy element transforms from its deformed shape to its unstressed shape, and wherein the alloy is selected so that the *transformation can occur* without any change in temperature of the placement device or the memory alloy element.

Ex. 1001, 11:12–21 (emphasis added).

Patent Owner, pointing to this language, argues that "[e]ach independent claim requires . . . ***disengaging*** the SIM alloy from the same device/restraint (i.e. removing stress) in order to revert the SIM alloy to its austenitic/unstressed state, without having to change the temperature." Prelim. Resp. 21–22 (emphasis in original).

At this initial stage and on the limited record, we do not agree with Patent Owner's argument. First, "disengaging" is an act or step, whereas claim 1 (as well as each of the other challenged claims) is an apparatus claim that should be defined by structure, not by acts or steps that may be performed with or to an apparatus. Second, the claim language quoted above refers to the structure of the memory alloy element and of the alloy itself in functional terms—the element "*can* be extruded" and the alloy "is selected so that the transformation *can* occur without any change in temperature." The claim does not require the completion of the act of extruding or the act of transformation, but rather requires structure capable of performing the recited functions.

We preliminarily determine that the last recitation of claim 1 requires, using functional language, a structural relationship defined by, at least, the

alloy properties, the size and configuration of the memory alloy element (*e.g.*, the stent), and the size and configuration of the hollow placement device (*e.g.*, a catheter).

2. Patent Owner's Arguments Concerning Transformation Without the Use of Temperature

Patent Owner also argues that the claims of the'141 patent "require stressing and releasing the SIM alloy to effect changes between states without the use of temperature." Prelim. Resp. 26; *see also id.* at 12 ("Importantly, the claims require that the application and removal of stress induce the transition between austenitic and martensitic states, without any change in temperature."). In addition to the questionable assertions that the claimed apparatus is defined by acts or steps, Patent Owner appears to argue that the claims preclude an act involving the use of temperature.

The complete pertinent phrase of claim 1 recites: "the alloy is selected so that the *transformation can occur* without any change in temperature of the placement device or the memory alloy element." Ex. 1001, 11:17–20 (emphasis added). Thus, the drafter defined the alloy functionally as one that is capable of transformation without a temperature change. On the record before us, it is not clear that the capability to transform via temperature and the capability to transform via stress are mutually exclusive. In other words, we cannot determine at this time that a given alloy could not display both temperature-induced martensite and stress-induced martensite in appropriate conditions. The Specification suggests that some shape-memory alloys exhibit both characteristics. *See* Ex. 1001, 1:35–2:3 (explaining, *inter alia*, that "the ability to possess shape memory is a result of the fact that the alloy undergoes a reversible transformation from an austenitic state to a martensitic state with a change in

temperature [and m]any shape memory alloys (SHAs [sic, SMAs]) are known to display stress-induced martensite (SIM)."); *id.* at 22–25 ("Suitable alloy for this invention i.e. those displaying stress-induced martensite at temperatures near mammalian body temperature (35°—40° C.), may be selected from known SMAs."). Thus, it may be that Patent Owner implicitly is advocating for a limitation based on the intended use of the device. We decline to construe the challenged apparatus claims as being limited based on how the apparatus is used.

In light of the above, we preliminarily determine that claim 1 requires an alloy having the capability of transformation without a change in temperature, and that claim 1 does not preclude that same alloy from also having the capability of transformation due to a temperature change.

In sum, Petitioner, to meet its burden at this initial stage, must demonstrate a likelihood of prevailing on its assertion of obviousness of a device having, *inter alia*, a memory alloy element that "can be extruded" from the hollow placement device to transform the device and an alloy selected such that "the transformation can occur without any change in temperature." Ex. 1001, 11:11–20. In other words, the proposed combination needs to render obvious a device having a structure such that certain actions *can* occur, but the prior art need not disclose the actual occurrence of the act of extruding or the act of transformation without a change in temperature.

D. The Alleged Obviousness of Claims 1–22 Over Cragg, Pops, and Tanaka

Petitioner alleges that all of the challenged claims of the '141 patent, claims 1–22, would have been obvious over Cragg, Pops, and Tanaka. *See*

Pet. 17–41 (addressing claim 1). Petitioner relies on Cragg for disclosure of much of the claimed device and proposes a modification where the alloy of Pops is substituted for the material used to make Cragg's stent. *See* Pet. 14, 31. Petitioner argues that Tanaka discloses the use of such alloys in a medical device. *See id.* at 14.

Patent Owner argues that Petitioner has failed to demonstrate that the prior art disclosed a "key aspect" of the challenged claims, has failed to demonstrate "any sufficient motivation to combine" the references, and has failed "to address known secondary considerations of obviousness." Prelim. Resp. 2–4.

For the reasons that follow, we determine that Petitioner has made an adequate showing at this stage that at least claim 1 would have been obvious over Cragg, Pops, and Tanaka.

1. Cragg (Ex. 1009)

Cragg discloses the use of a coil shaped stent made from a "thermal shape memory alloy (nitinol)." Ex. 1009, 1. "Nitinol is a specially formulated alloy of nickel and titanium . . . [with t]he striking property . . . that it undergoes a phase change at a certain temperature." *Id.* "The 'transition temperature' is determined by the composition of the alloy." *Id.* The nitinol alloy was drawn into a wire, which was annealed while being constrained in the desired coil shape. *Id.*

> After cooling, the wire can be straightened and introduced *via* catheter into the body. At or near body temperature the wire transforms into its original shape. This property of the wire allows one to introduce into the body various complex, preformed shapes *via* catheter.

Id.

The coils of Cragg's stent, after straightening in ice water, were fastened to a guide wire to allow accurate placement and were passed through a catheter to the abdominal aorta. *Id.* "To minimize transformation of the wire to its original shape in the catheter, a cold saline solution (10° C) was flushed continuously through the catheter during introduction of the wire." *Id.* "[T]he wire was extruded from the catheter." *Id.*

Cragg explains:

> At room temperature, the nitinol coil is a straight, pliable wire that can be passed through a catheter. As the coil is extruded from the catheter and warmed to body temperature, it reverts to its "memorized" shape, (*i.e.*, a coil). 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. We also used a 10-F Teflon introducing catheter to reduce friction of the partially transformed coil in the catheter. These difficulties can be overcome by the development of a wire with a more precise transition temperature.

Id. at 2.

Cragg concludes that, "[w]ith the development of a suitable alloy with optimal transformation characteristics, nitinol coil grafts may offer a simple, inexpensive alternative to surgery in numerous forms of cardiovascular disease." *Id.*

2. Pops (Ex. 1010)

Pops discloses the composition and testing at various temperatures of copper-zirconium based shape memory alloys[7] with "stress induced pseudoelastic" (STRIPE) properties. Ex. 1010, 5, 10. Pops states that "[v]ery large 'pseudo' elastic strains are produced as a result of a stress induced reversible martensitic transformation; the phenomenon may be called stress induced pseudoelasticity (STRIPE)," and that "[t]he stress induced martensite phase is elastically balanced within the matrix, so that it disappears upon unloading." *Id.* at 11.

3. Tanaka (Ex. 1011)

Tanaka discloses "[a]n orthodontic system including an ultraelastic arch wire [of a nickel-titanium alloy] having a transformation temperature of normal body temperature of about 37° C." Ex. 1011, Abstract, 3:67–4:1. "An ultraelastic material returns to its original shape upon removal of the deforming load even if deformation of about 8% is imposed during a tensile test." *Id.* at 4:4–7. "This high elastic deformability permits bending or pulling required for any orthodontic purposes." *Id.* at 4:7–8.

> In order to provide an orthodontic device having these desired properties, it is not sufficient merely to utilize an ultraelastic Ni-Ti alloy, but it is necessary to select an appropriate alloy composition. Additionally, it is necessary to select appropriate conditions for the preparation of the orthodontic device by appropriate heat treatment. The utlimate [sic] properties of the orthodontic device can also vary with the shape of the device, for example the diameter of the wire or the cross-section. When these factors are appropriately considered with

[7] The parties agree that Pops discloses shape memory alloys. *See* Pet. 13; Prelim. Resp. 16; *see also* Ex. 1021 ¶ 70.

> respect to one another, it is possible to provide the properties required for varying orthodontic purposes.

Id. at 4:21–33.

Alloys that may be utilized in Tanaka's device:

> are of the "thermoelastic" type having a superlattice and which undergo a martensitic transformation. Their ultraelasticity is derived from the martensitic transformation caused by stress at a temperature range above the martensitic transformation temperature and the inverse transformation thereof. There is only a small degree of hysteresis in the normal and reverse transformation between the austenite and the martensite; therefore, these alloys undergo crystallographically reversible transformation.

Id. at 4:42–51.

An ultraeleastic wire is prepared in a straight form and fastened to tooth 2 to be moved and to normal teeth 3, 4 on either side. *Id.* at 6:39–40, 48–51, Fig. 3. "Archwire 1 is placed under bending and tensile stresses along an array of teeth 3, 2 and 4 and a force (or load) which urges wire 1 to recover its original shape bears on tooth 2 in the direction of the arrow [shown in Figure 3]." *Id.* at 6:58–61. The "orthodontic member . . . applies variable orthodontic load in response to a difference between normal body temperature and the temperature prevailing upon placement of a temperature affecting material in the mouth is provided." *Id.* at 1:61–66. Tanaka explains:

> Tooth 2 is moved gradually by the load applied thereto and aligned correctly. Under normal circumstances, the temperature in the mouth is equal to the normal body temperature of 37° C., and therefore, ultraelastic wire 1 in accordance with the invention produces only a slight stress or load. However, once hot tea or coffee is taken into the mouth, or during a meal, the temperature of the wire is raised temporarily to a higher temperature in the range of, for example, 50° C. to 60° C. This elevated temperature

> produces a higher stress or load which serves to move tooth 2 orthdontically. If on the other hand, cold water, ice or any other substance having a lower temperature than the normal mouth temperature is taken in, wire 1 produces a smaller stress or load which at times may be zero. Intermittent application of the load as hereinabove described is quite effective orthodontically.

Id. at 6:63–7:10.

4. The Alleged Obviousness of Claim 1 in View of Cragg, Pops, and Tanaka

For reasons discussed below, Petitioner has shown a reasonable likelihood that it would prevail in establishing unpatentability of independent claim 1 as obvious over Cragg, Pops, and Tanaka.

a. "A medical device for insertion into a mammalian body, the device comprising (a) a hollow placement device; (b) a memory alloy element . . . ; and (c) a guide wire"

As mentioned, independent claim 1 recites a device that, generally speaking, comprises three components—a hollow placement device, a memory alloy element, and a guide wire. Examples of the first two components include, respectively, a catheter and a stent formed from a shape memory alloy. *See, e.g.*, Ex. 1001, 11:21–22, 29–30 (dependent claims 2 and 5). Petitioner contends that Cragg discloses a medical device for insertion into a mammalian body with the device having a catheter, a stent made from the shape memory alloy known as nitinol, and a guide wire. Pet. 17–18, 39 (citing Ex. 1009, 1; Ex. 1021 ¶¶ 75–77, 123). Patent Owner does not appear to dispute these assertions. *See* Prelim. Resp. 15–16 (Patent Owner characterizing Cragg as disclosing the use of a stent formed from a shape memory alloy having *temperature*-induced martensite properties.).

b. "a memory alloy element formed at least partly from pseudoelastic shape-memory alloy, the alloy displaying reversible stress-induced martensite at about body temperature such that it has a stress-induced martensitic state and an austenitic state, the memory alloy element having (i) a deformed shape when the alloy is in its stress-induced martensitic state and (ii) a different unstressed shape when the alloy is in its austenitic state"

Petitioner agrees that "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.'" Pet. 18 (quoting claim 1). Petitioner contends that "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." *Id.* Petitioner further contends that Pops discloses such a shape memory alloy exhibiting reversible SIM behavior at body temperature. *Id.* at 19–23; *cf.* Prelim. Resp. 16 (Patent Owner stating "Pops' alloys comprise Copper, Zinc, Silicon, and Tin with 'STRIPE' or 'stress induced pseudoelastic' properties."). For the claimed aspects of a deformed shape and a different unstressed shape, Petitioner, relying on the testimony of Dr. Bhattacharya, argues that the proposed modification—Cragg's stent made using a shape memory alloy exhibiting reversible SIM behavior at body temperature—would result in a stent having the two shapes. Pet. 28 (citing Ex. 1021 ¶ 97), 35–38 (citing Ex. 1021 ¶¶ 113–121), 38 (citing Ex. 1021 ¶ 122); *see also id.* at 38 (referring to "transforming the SMA from its deformed, relatively straightened shape towards its unstressed, relatively coiled shape.").

c. "the memory alloy element being within the hollow placement device, and the placement device being guidable by the guide wire, the hollow placement device stressing the memory alloy element at a temperature greater than the A_s of the alloy so that the memory alloy element is in its deformed shape"

For this aspect of the claim, Petitioner asserts that Cragg discloses a coiled stent introduced in a body via a catheter and extruded therefrom. Pet. 39 (citing Ex. 1009, 1; Ex. 1021 ¶ 124). Petitioner also asserts that Cragg's catheter is guidable by a guide wire, and contends that the standard procedure for endoluminal placement of a stent in 1983 included the use of a guide wire to guide a catheter to the desired site. *Id.* at 39–40 (citing Ex. 1009, 1; Ex. 1021 ¶ 125; Ex. 1002, 111 (the Examiner stating, during prosecution, that "it is well known in the art that the guide wire is used for guiding a catheter into the body.")). Petitioner, relying on Dr. Bhattacharya's testimony, also argues that it would be obvious to use the device of the proposed modification in a manner where

> the wire [used to make the stent] 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. [Ex. 1021 ¶ 115]. 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.*).

Id. at 35–36 (citing Ex. 1021 ¶¶ 114–116); *see id.* at 40 (citing Ex. 1021 ¶ 126).

> *d. "wherein the memory alloy element can be extruded from the hollow placement device by the guide wire at a temperature greater than the A_s of the alloy to transform at least a portion of the alloy from its stress-induced martensitic state so that the memory alloy element transforms from its deformed shape to its unstressed shape, and wherein the alloy is selected so that the transformation can occur without any change in temperature of the placement device or the memory alloy element"*

Petitioner, quoting from Cragg's description of extruding the stent from the catheter, maintains that the modified device similarly would have a memory alloy element extruded from a hollow placement device by a guidewire. Pet. 40 (quoting Ex. 1009, 1–2; Ex. 1021 ¶ 127). Petitioner relies on its earlier arguments, discussed above, in asserting that, in the modified device, the stent can be extruded from the catheter at a temperature and in a manner such that recited transformations would occur. *Id.* at 40 (citing Pet. 35–38; Ex. 1021 ¶ 128).

Claim 1 also recites "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." Ex. 1001, 11:17–20. Regarding this aspect of the claim, Petitioner argues that Pops discloses such alloys and, specifically, alloys that exhibit reversible SIM behavior at body temperature. *See* Pet. 19–22. Petitioner further argues that, if—as in the proposed modification—a SMA exhibiting reversible SIM behavior at body temperature were used to make Cragg's stent, the transition would occur when the stent is extruded from the catheter and with no change in

temperature necessary. *Id.* at 28 (citing Ex. 1021 ¶ 97), 38 (citing Ex. 1021 ¶ 121; Ex. 1009, 1), 41. Petitioner further argues:

> [D]etermining 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).

Id. at 22–23.

e. Reason to Modify

Petitioner contends that it would have been obvious to substitute for the material of Cragg's stent a shape-memory alloy exhibiting reversible SIM behavior at body temperature. Pet. 18.

Petitioner asserts that the Applicant admitted during prosecution of a parent application and again in the Specification of the '141 patent that it was known to use shape-memory alloys in medical devices, including stents, and that shape-memory alloys exhibiting reversible SIM behavior at body temperature were well known. *Id.* at 18–19 (quoting Ex. 1003, 55 (prosecution history for Appl. No. 06/541,852); Ex. 1001, 1:52–53 ("Many shape memory alloys (SHAs [sic, SMAs]) are known to display stress-induced martensite (SIM)."), 2:15–21 ("Various proposals have also been made to employ shape memory alloys in the medical field.")).

During the prosecution of an application listed in the chain of related applications for the '141 patent, Applicant explained the level of knowledge in the art:

> It is of course well known that many medical devices pointed out by the Examiner and cited by Applicant have in fact been made from shape memory alloys. It is also well known that many shape memory alloys exhibit stress induced martensite. And further the concept of pseudoelasticity is well known to those skilled in the art. All of this Applicant is in full agreement with the Examiner.

Ex. 1003, 55 (prosecution history for Appl. No. 06/541,852, Response to Office Action dated January 23, 1986); *see* Ex. 1001, 1 (60) (the face of the '141 patent identifying Appl. No. 06/541,852). Further in this regard, the Specification of the '141 patent states that a "[s]uitable alloy for this invention i.e. those displaying stress-induced martensite at temperatures near mammalian body temperature (35°—40° C.), may be selected from known SMAs by those of ordinary skill in theart [sic], having regard to this disclosure by testing for the existence of the SIM effect at the desired temperature." Ex. 1001, 4:22–27.

Petitioner argues using a shape-memory alloy with reversible SIM behavior in a medical device was not new and, in support, maintains that Tanaka discloses an example of the use of such, and particularly an implantable medical device in the form of an orthodontic system.[8] Pet. 23 (quoting Ex. 1011, 1:5–9).

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[8] Patent Owner, regarding Tanaka, argues that Petitioner fails to explain "how braces which reside outside the teeth can be considered 'implantable.'" Prelim. Resp. 24–25. We note that Petitioner refers to Tanaka's "SMA wire used for dental braces applications," Pet. 15, in addition to "orthodontics (braces)," *id.* at 26. We do not decide at this time whether Tanaka discloses

Petitioner argues that the claimed invention would have been obvious "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," and that the substitution would have yielded predictable results. *Id.* at 26–27 (citing *KSR*, 550 U.S. at 415–16); *see also id.* at 31 ("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.").

Petitioner contends that Cragg expressly recommends the substitution of another shape-memory alloy in the stent. *Id.* at 27. Petitioner quotes from Cragg's discussion of a problem encountered in use, where the stent had to be cooled during insertion to minimize transformation in the catheter. *Id.* (quotient Ex. 1009, 2). According to Petitioner, "Cragg specifically encourages using 'a suitable alloy with optimal transformation characteristics' to make his stent." *Id.* at 28 (emphasis omitted, quoting Ex. 1009, 2; citing Ex. 1021 ¶ 95). Petitioner, relying on the testimony of Dr. Bhattacharya, argues that a person of ordinary skill in the art "would have recognized that a 'suitable alloy with optimal transformation characteristics' includes prior art SMAs exhibiting reversible SIM behavior at body temperature." *Id.* (citing Ex. 1021 ¶ 96). Petitioner maintains that a person of ordinary skill in the art "would have been motivated to make Cragg's stent using such an alloy, because this substitution would have been

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an implantable device, as characterized by Petitioner, or, if not, whether that ultimately is fatal to Petitioner's challenges.

expected to overcome the 'difficulties' described by Cragg." *Id.* (citing Ex. 1021 ¶ 96).

Petitioner also asserts that Ueda and Usugi provide additional motivations to substitute for the alloy of Cragg a shape-memory alloy exhibiting reversible SIM behavior at body temperature. *Id.* at 29–30 (citing Ex. 1014, Ex. 1015); *see id.* at 29 (Petitioner arguing that "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."). Petitioner further asserts that Suzuki teaches that shape-memory alloys with reversible SIM behavior may be used in the medical field in the same way as those with temperature-induced martensite behavior. *Id.* at 30–31 (citing Ex. 1002, 15, Ex. 1021 ¶ 102).

f. Patent Owner's Arguments

Patent Owner argues:

> Petitioners fail to identify ***any*** reference that uses a SIM alloy as part of an implantable medical device that does not rely on temperature to induce shape changes. As demonstrated below, both grounds rely primarily on the same deficient art—namely, Cragg and Tanaka—both of which rely on changes in temperature to operate the disclosed medical devices. As such, both grounds are missing the key limitations requiring manipulation of stress—and ***not*** temperature—to transition the medical device's alloy between its martensitic and austenitic state.

Prelim. Resp. 20. In so arguing, Patent Owner seemingly asserts that the claim requires that a certain act be performed while precluding another certain act, i.e. requiring the act of "manipulation of stress—and ***not*** temperature—to transition the medical device's alloy." *Id.* Patent Owner

does not explain adequately how this purported missing key aspect translates into a structural limitation of the claimed apparatus. It appears that Patent Owner is attempting to distinguish the claimed apparatus over the prior art based on how it is used rather than its structure. As discussed above in the claim construction section, we preliminary construe at least claim 1 as requiring a device capable of stress-induced transformation in the absence of a temperature change but as not excluding a device also capable of temperature-induced transformation. Thus, even assuming Patent Owner's characterizations are correct, we fail to see how it is fatal to Petitioner's case that certain relied-upon references disclose "changes in temperature to operate the disclosed medical devices." *Id.* The issues in this case are ones involving structure and pertain to an alloy element that *can be extruded* from a hollow placement device to transform states and where the alloy is selected so that transformation *can occur* with a change in temperature. *See* Claim 1 (the "wherein" clause). Petitioner, as discussed above, has presented argument and evidence to account for these structural limitations.

Similarly, we do not find persuasive, at this point in the proceeding, Patent Owner's argument that no single reference discloses disengaging an alloy element from a stress-inducing component to effect a change. Prelim. Resp. 21–27. Contrary to Patent Owner's position, we preliminarily determine that at least claim 1 does not require the acts of "***disengaging*** the SIM alloy from the . . . device/restraint (i.e. removing stress)" or "releasing stress using a component." *Id.* at 21, 25; *see also id.* at 24 ("[N]o reference discloses disengaging a stress-inducing component (i.e. the removal of stress) in a medical device."), 26 ("unlike the claims of the '141 patent, which require stressing and releasing the SIM alloy to effect changes").

Claim 1 requires a device structurally configured such that "the [recited] memory alloy element can be extruded" to transform the shape. Petitioner has addressed that requirement.

Patent Owner argues that no reference discloses a SIM-based stent and that Petitioner improperly is relying on "hindsight-driven" expert testimony to fill the gaps. Prelim. Resp. 27–31. Patent Owner appears to contend that those gaps are "limitations" directed to a stent stressed by a catheter and that, "[u]pon removal of the restraint[,] . . . at least a portion of the stent would be unstressed and would transition from martensite to austenite[.]" *Id.* (quoting Pet. 36, internal quotations omitted). According to Patent Owner, "Dr. Bhattacharya's declaration . . . fails to identify a reference disclosing these limitations or provide a basis for the 'modified device' to have this function." *Id.* (citing Ex. 1021 ¶¶ 115–116).

To the extent that Patent Owner contends that a challenge to an apparatus claim must include a single reference disclosing actions involving both stressing and unstressing of an alloy, we do not find that persuasive at this stage of the proceeding. As discussed above, we preliminary construe at least apparatus claim 1 as not requiring the performance of actions (method steps). And, in evaluating an obviousness ground, the focus is on the proposed combination of teachings as a whole, not whether any single reference discloses the claimed invention. *See In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) ([T]he test is whether the references, taken as a whole, would have suggested appellant's invention to one of ordinary skill in the medicinal chemical arts at the time the invention was made."); *id.* ("Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a

combination of references. . . . Thus, [a reference] must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole."). On the present record, we credit Dr. Bhattacharya's testimony (Ex. 1021 ¶¶ 115–116) directed to how the apparatus of the proposed combination would function and would be created and used in practice by a person of ordinary skill in the art at the time of the invention. We, however, make no final fact findings in that regard at this preliminary stage, and Patent Owner is welcome to pursue this line of opposition going forward.

Patent Owner argues that Petitioner has failed to articulate a reason why a person of ordinary skill in the art at the time of the invention would have been motivated to combine the references as proposed and to arrive at the claimed subject matter. Prelim. Resp. 31–40. Patent Owner asserts that only hindsight provides a reason why one would have used a SIM alloy in Cragg's stent because no asserted reference provides a motivation to combine the references. *Id.* at 32–33. At this preliminary stage and on the present record, we determine that Petitioner has articulated, as discussed above, an adequate reason to combine. *See also KSR*, 550 U.S. at 418–19 (the Court rejecting the rigid requirement of a teaching, suggestion or motivation to combine known elements, and noted that an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a [tribunal] can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.").

Lastly, Patent Owner argues that Petitioner has failed to address objective indicia of non-obviousness and that this is fatal to the Petition. Prelim. Resp. 40–47. Patent Owner contends that such evidence of

non-obviousness was referenced in a Patent Owner Preliminary Response filed in a prior *inter partes* review and during the prosecution of the application that led to the '141 patent. *Id.* at 41–43 (citing Ex. 1006, 8–9 (preliminary response in IPR2014-00362); Ex. 2002 (a technical article)).

Patent Owner's objective-indicia argument primarily is one of procedure rather than substance. Patent Owner, in effect, faults Petitioner for not predicting arguments that Patent Owner might make in this case regarding purported evidence of non-obviousness and for not preemptively addressing those arguments. We note that the cited portion of the prior preliminary response is to a section with the heading "FACTUAL BACKGROUND . . . The Technology of the '141 Patent," rather than an argument section clearly identifying and analyzing anything as purported evidence of objective indicia of non-obviousness. *See* Ex. 1006, 8–9. Patent Owner also refers to an expert declaration it filed in a district court action, which "is publicly available on PACER," and impliedly argues that Petitioner should have sought out this document, treated it as evidence of non-obviousness, and then argued why it is not evidence of non-obviousness. Prelim. Resp. 45; *see id.* at 46–47 (similarly arguing that Petitioner and its expert should have discerned objective-indicia testimony in a declaration filed during prosecution and then countered that testimony). On the specific facts of this case, we decline to place such a burden on this Petitioner at this preliminary stage. The parties may develop further the record concerning objective indicia during the trial.

g. Conclusions as to Ground 1—The Obviousness Challenge Based on Cragg, Pops, and Tanaka

Having considered the evidence and all of the parties' arguments, we are persuaded that Petitioner has articulated a sufficient reason, for purposes

of this Decision, why one of ordinary skill in the art would have combined the teachings of Cragg, Pops, and Tanaka. We determine that Petitioner has demonstrated sufficiently, for purposes of this Decision, that the proposed combination teaches or suggests each limitation of at least challenged independent claim 1. And we determine that the weight attributable to any evidence in the record of objective indicia of non-obviousness is not so large as to merit denial of institution. At this junction, Patent Owner does not present separate arguments concerning the remaining challenged independent claims 6, 11, 15, 16, and 18, or for the challenged dependent claims. Petitioner presents argument and evidence concerning those remaining challenged claims. Pet. 41–60. We determine that Petitioner has established that there is a reasonable likelihood of prevailing with respect to at least one claim challenged as being unpatentable under 35 .U.S.C. § 103 as obvious over Cragg, Pops, and Tanaka.

E. The Alleged Obviousness of Claims 1–22 Over Cragg, Tanaka, and Suzuki

Petitioner alleges that all of the challenged claims of the '141 patent, claims 1–22, would have been obvious over Cragg, Tanaka, and Suzuki. *See* Pet. 60–64 (addressing claim 1). According to Petitioner, "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." *Id.* at 60. Petitioner alleges that Suzuki provides a teaching and motivation to make the proposed substitution. *See id.* at 63.

We have discussed above Cragg and Tanaka. Petitioner asserts that Suzuki (Ex. 1012) "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." Pet. 13 (citing Ex. 1012, 10–12, 15; Ex. 1021 ¶ 72). In articulating a reason to modify the references, Petitioner argues that, "[b]y stating that nitinol SMAs with SIM behavior are 'used . . . in the same way' as SMAs with TIM behavior, Suzuki teaches and motivates a [person of ordinary skill in the art] to substitute a SMA with SIM behavior for a SMA relying on TIM behavior." *Id.* at 63 (quoting Ex. 1012, 15) (citing Ex. 1021 ¶ 193).

Patent Owner directs most of its arguments to both of Petitioner's grounds. *See, e.g.*, Prelim. Resp. 19 (Patent Owner arguing that "Petitioners assert two grounds of invalidity under 35 U.S.C. §103, but the same fundamental flaws run through both grounds and warrant denial of institution."). Specific to the second ground, Patent Owner argues "Suzuki did not claim the wholesale ability of SIM devices to replace TIM devices—instead, this was merely an introduction to ***identify*** two SIM devices that 'are used in medical fields, in the same way' as TIM devices at the time of the invention: braces and bone clamping." *Id.* at 39 (citing Ex. 1012, 15). Patent Owner further argues that Petitioner fails to explain why the use of SIM in braces and bone clamping would motivate a person of ordinary skill in the art to replace a TIM alloy with a SIM alloy in a stent. *Id.* at 39–40.

At this threshold stage and on the limited record before us, we determine that Petitioner has articulated adequately a reason why a person of ordinary skill in the art would have found the claimed subject matter to be obvious. As we have determined, for the reasons discussed in the context of

the first ground, that Petitioner has demonstrated a likelihood of prevailing in its challenge as to at least one claim, we also institute a review on the second ground—the obviousness challenge to claims 1–22 based on Cragg, Tanaka, and Suzuki.

F. Discretionary Denial Arguments

1. Overview

Patent Owner asserts that we should exercise our discretion to deny the Petition under 35 U.S.C. § 314(a) because the factors enumerated in *General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, Case IPR2016-01357, slip op. at 9–10 (PTAB Sept. 6, 2017) (Paper 19) ("*General Plastic*") (precedential as to § II.B.4.i) should be applied to two prior *inter partes* reviews filed by other petitioners and to two prior and concluded district court actions involving defendants other than Petitioner. Prelim. Resp. 48–54. Patent Owner argues that there are three applicable *General Plastic* factors in this case, and two of those factors weigh strongly in favor exercising discretion to deny the Petition and the third factor is neutral. *Id.* at 54. Patent Owner additionally contends that we should deny the Petition under 35 U.S.C. § 325(d), arguing that "the same or substantially the same prior art has been previously presented to the Office." *Id.* (internal quotations omitted). We address these arguments in turn.

2. 35 U.S.C. § 314(a)

We turn to Patent Owner's assertion that we should exercise our discretion to deny the Petition under 35 U.S.C. § 314(a) because the factors enumerated in *General Plastic* should be applied to prior petitions and district court actions. We note that Patent Owner does not allege that

Petitioner was a party to those prior proceedings or has any relevant and substantial relationship to the other parties or proceedings.

In *General Plastic*, the Board outlined several non-exhaustive factors that will be considered in exercising our discretion to institute under § 314(a):

> 1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
> 2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known it;
> 3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition;
> 4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
> 5. whether petition provides adequate explanation for the time elapsed between the filing of multiple petitions directed to the same claims of the same patent;
> 6. the finite resources of the Board; and
> 7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Directed notices institution of review.

General Plastic, slip. op. at 9–10. "The *General Plastic* factors, alone or in combination, are not dispositive, but part of a balanced assessment of all relevant circumstances in the case, including the merits." Trial Practice Guide Update, available at https://go.usa.gov/xU7GP (referenced at 83 Fed. Reg. 39,989 (Aug. 13, 2018)), at 10. Additionally, "our application of the *General Plastic* factors is not limited solely to instances when multiple petitions are filed by the same petitioner." *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00062, slip op. at 2 (PTAB April 2, 2019) (Paper 11)

(precedential). "Rather, when different petitioners challenge the same patent, we consider any relationship between those petitioners when weighing the *General Plastic* factors." *Id.* In *Valve Corp.*, the Board found the later petitioner, Valve, was similarly situated to the earlier petitioner, HTC, because "both were co-defendants . . . accused of infringing the '934 patent based on the same product," "Valve represented that 'HTC's VIVE devices incorporate certain Valve Technologies,'" and "Valve employees did provide HTC with technical assistance during development of the accused VIVE devices." *Id.* at 9–10.

Patent Owner argues that *General Plastic* factors 3 and 5 strongly favor denial of the Petition and that factor 1 is neutral. Prelim. Resp. 50–54. Patent Owner appears to contend that the remaining factors either are not applicable or are neutral because this Petitioner is not the same as in the prior cases. *See id.* at 50, 53–54.

Factor 3 pertains to the time of the filing of the present petition relative to when a petitioner received the patent owner's preliminary response to the earlier petition or received the Board's decision on whether to institute a review on that earlier petition. Patent Owner implies that Petitioner engaged in an undue delay after Petitioner "had access to Patent Owner's prior preliminary responses in IPR2013-00269 and IPR2014-00362" and after Petitioner "had access to the Northern District of California's orders denying a motion for summary judgment of obviousness relying on Cragg." Prelim. Resp. 50–51. Patent Owner argues that Petitioner crafted a petition "to make up the deficiencies in earlier proceedings." *Id.* at 51. Patent Owner, however, fails to identify with any

specificity such deficiencies for which Petitioner could gain an advantage due to the knowledge thereof.

As for the prior petitions before this Board, we note that both prior *inter partes* reviews were settled prior to the issuance of a decision on institution. Thus, Petitioner did not gain the benefit of the Board's analysis of the petitions filed by others. Patent Owner does not elaborate adequately on the allegation that Petitioner gained a benefit from seeing prior Patent Owner Preliminary Responses. Prelim. Resp. 50–52. We note, for example, that Patent Owner's Preliminary Response in IPR2013-00269 did not include substantive arguments directed to the art-based challenges. IPR2013-00269, Paper 9, 2 ("[A]lthough none of the references or combinations of references that Petitioner relies upon is reasonably likely to result in the invalidation of any one of claims 1-10 and 18-22 of U.S. Patent No. 6,306,141 ('the '141 patent') [Grounds 1-5], Patent Owner has not addressed those substantive issues in this Preliminary Response."). We fail to see, and Patent Owner does not explain adequately, what tactical advantage could be gained by Petitioner seeing Patent Owner's Preliminary Response in that *inter partes* review.

As for the District Court's orders, we note that both of the summary judgment motions were denied due to flaws in the defendants' cases at the pre-trial stage of the proceedings, and that the cases were not terminated at that point but were to proceed to trial. *See* Ex. 2004, 4–5; Ex. 2006, 9–10 ("Again, this ruling is based upon the record currently before the Court and is not intended to preclude [defendant] Gore from presenting additional evidence on the issue at trial."). For example, one reason for denial of summary judgment was because "[defendant] Gore's comparison of the

asserted claims to these prior art references is supported only by attorney argument." Ex. 2006, 9. Somewhat similarly, summary judgment was denied because "[defendant] AGA has failed to present any evidence in support of this assertion [of a motivation to combine references' teachings]." Ex. 2004, 4. We fail to see how Petitioner would gain much of a tactical advantage from being informed of the need for evidence to support a motion for summary judgment.

Patent Owner mentions, in various places in the Preliminary Response, a jury verdict in one of these district court cases. For example, Patent Owner impliedly argues that the denial of summary judgment and "jury verdict of validity" constitute objective indicia of non-obviousness. *See* Prelim. Resp. 44–45. Although Patent Owner makes a passing reference to the verdict in summarizing its discretionary denial arguments, *id.* at 5 (under the heading "Introduction"), Patent Owner does not elaborate on how that verdict fits into our discretionary denial analysis, *see id.* at 48–57. Petitioner, however, asserts that the "jury verdict of no obviousness" was only directed to 6 of the 22 claims challenged here and that "the jury never considered the combinations raised here or their equivalents." Pet. Reply to Prelim. Resp. 1 (citing Ex. 2005, 5 (jury form indicating that defendant AGA had not proven by a clear and convincing evidence that claims 1, 2, 5, 17, 18, and 21 would have been obvious); Ex. 1030, 13–15). Petitioner asserts, "according to Patent Owner, none of the references addressed by the jury disclosed an SMA exhibiting SIM behavior, in contrast to the references raised in the Petition here." *Id.* at 1–2 (citing Ex. 1030, 13–15).

In sum, Patent Owner's arguments regarding the district court actions amount to an implied request for us to impart onto Petitioner the flaws of

other parties' challenges made at the summary judgment phase of the litigation and before a jury.

Regarding *General Plastic* factor 5, Patent Owner argues that Petitioner has failed to provide an adequate explanation for the time elapsed between the earlier petitions filed by others and the filing of the present Petition. Prelim. Resp. 52–53. Patent Owner makes the conclusory argument that Petitioner's "silence" on timing "results in Factor 5 strongly favoring the Board's exercise of discretion to deny institution." *Id.* at 53 (citing *United Fire Protection Corp. v. Engineered Corrosion Solutions, LLC*, Case IPR2018-00991, slip op. at 16–17 (PTAB Nov. 15, 2018) (Paper 10)). However, Patent Owner does not identify a triggering event specific to this Petitioner from which to calculate the purportedly unreasonable delay. As mentioned, Patent Owner does not allege a relationship between Petitioner and any of the prior petitioners or district court defendants. Petitioner, in reply, argues that there was no delay as "Petitioners promptly filed the present Petition after determining that the '141 Patent should be challenged in an IPR proceeding." Pet. Reply to Prelim. Resp. 4. In the case cited by Patent Owner, *United Fire Protection Corp.*, the panel found that "the availability of Patent Owner's arguments and the Board's findings and conclusions of law in the [earlier] IPR provided substantial potential benefit to Petitioner to tailor its arguments," and that the later petitioner waited nearly a year after a final decision in the earlier IPR. *United Fire Protection Corp.*, IPR2018-00991, Paper 10 at 15–16. As the Board has not made determinations on the merits in the prior IPRs, such "substantial potential benefits" due to a purported delay are not present in this case.

Factor 1 asks whether the same petitioner previously filed a petition directed to the same claims of the same patent. Although Patent Owner states that factor 1 is neutral notwithstanding that Petitioner is not a prior petitioner, Patent Owner's arguments made in the context of factor 1—particularly those pertaining to "rehash[ing] similar arguments" and "a third bite at the apple"—imply that this factor should weigh in favor of denial. *See* Prelim. Resp. 53. However, unlike in *Valve Corp.*, there is no indication of a relationship between Petitioner and prior petitioners. Similarly, there is no indication that Petitioner was involved in the prior district court actions or had any relevant relationship with the defendants in those cases. We determine that *General Plastic* factor 1 does not weigh in favor of exercising our discretion to deny institution.

3. 35 U.S.C. § 325(d)

Patent Owner also asserts that we should exercise discretion under 35 U.S.C. § 325(d) and not institute an *inter* partes review. Prelim. Resp. 54. Pursuant to 35 U.S.C. § 325(d), the "Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." *See NHK Spring Co. v. Intri-Plex Techs., Inc.*, Case IPR2018-00752, slip op. at 11–18 (PTAB Sept. 12, 2018) (Paper 8) ("NHK") (precedential) (analyzing several factors and denying institution, in part, because the asserted prior art was "a subset of the same prior art that the Examiner applied in rejecting the claims during prosecution").

In this regard, Patent Owner argues that "the vast majority of the asserted references in the Petition already were considered by the Patent Office, justifying the Board exercising its discretion to deny institution under

these facts." Prelim. Resp. at 55 (citations omitted). Patent Owner's citations in support of its argument are to the '141 patent itself, a list of art cited by the applicant, and a statement by the Examiner that certain references, including Suzuki, were made of record and not relied upon. *See id.* (citing Ex. 1001, 9:19–57, Ex. 1002 (prosecution history), 76, 78, 84, 86, 87). Patent Owner does not direct our attention to any substantive discussion of any of these references by the Examiner.

In contrast, Petitioner argues that "the obviousness arguments and combinations [in the Petition] were not addressed during prosecution." Pet. 16. Petitioner further argues that "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." *Id.*

Patent Owner does not articulate adequately or explain persuasively whether or how the arguments made in the Petition were considered previously by the Office. Patent Owner, referring to an appeal of the Examiner's rejection during prosecution, argues that this Board has "refused to sustain the Examiner's obviousness rejection based, in part, on the prior art allegedly disclosing a SIM alloy, much like the Tanaka and Suzuki references." Prelim. Resp. 55–56 (citing Ex. 1002, 342–347). Patent Owner does not elaborate on this argument and does not explain adequately why that appeal decision justifies a denial of institution now. As indicated by Patent Owner's argument, the rejection then before the Board did not involve the same references before us now. Further, the Board's reversal in that appeal was not, as might be inferred from Patent Owner's argument, based on a conclusion that utilizing a SIM alloy was not obvious. Rather,

the Board determined that the Examiner had not made a prima facie showing that the nitinol alloy of the reference inherently possessed SIM properties at about body temperature. Ex. 1002, 343–346.

We do not find persuasive Patent Owner's additional arguments that we should disregard Petitioner's relied upon but previously non-considered references because they purportedly are cumulative disclosures of a SIM or irrelevant. Prelim. Resp. 56–57 (Patent Owner arguing that Pops is cumulative of Tanaka's disclosure of a SIM and that "Ueda discloses only a component showing TIM behavior with no relevance to the use of a SIM.").

We also are not persuaded to discretionarily deny institution based on Patent Owner's assertion that the primary reference here, Cragg, is discussed by the applicant in the specification of the '141 patent. *See id.* at 56 (citing Ex. 1001, 9:19–57).

4. Summary Regarding Discretionary Denial

We have considered all of Patent Owner's arguments, but are not persuaded that it is appropriate to exercise discretion to deny the petition in this case. Although Patent Owner argues that [a]llowing this fifth proceeding to go forward would be a waste of Patent Office resources," Prelim. Resp. 48, we note that institution in this case will be the first proceeding to go forward in the Office, and is the first proceeding to involve the Petitioner.

To deny institution based on Patent Owner's arguments, in effect, would require us to impart onto Petitioner the consequences of the actions of other, unrelated parties, and without regard to the merits of the case—which have not been evaluated in a prior *inter partes* review. Patent Owner does not adequately explain why it would be equitable to prevent Petitioner from

raising timely filed unpatentability arguments in a Petition because unrelated parties raised non-identical arguments in another forum or because unrelated petitioners settled with Patent Owner prior to the issuance of decisions on institution. Further, Petitioner has demonstrated a reasonable likelihood that the challenged claims would have been obvious over combinations of references that were not before the Examiner, and it is not evident that the Examiner ever considered the arguments set forth in the Petition.

In view of the foregoing, we decline to exercise our discretion to deny institution under § 314(a) or § 325(d).

III. CONCLUSION

Petitioner has demonstrated a reasonable likelihood of prevailing in showing the unpatentability of at least one of the challenged claims of the '141 patent. At this stage of the proceeding, we have not made a final determination with respect to the patentability of any of the challenged claims.

IV. ORDER

For the foregoing reasons, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–22 of the '141 patent is instituted with respect to all grounds of unpatentability set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '141 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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