

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARTHREX, INC.
Petitioner

v.

MEDSHAPE, INC.
Patent Owner

Case No. IPR2025-00053
Patent No. 7,985,222

**PETITION FOR INTER PARTES REVIEW
OF U.S. PATENT NO. 7,985,222**

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PETITIONER’S EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No 7,985,222 (“the ’222 Patent”)
1002	Declaration of Mike Sherman
1003	<i>Curriculum Vitae</i> of Mike Sherman
1004	Prosecution History of U.S. Patent Application 11/112,865
1005	U.S. Patent No. 6,685,708 (“Monassevitch”)
1006	U.S. Patent No. 4,275,717 (“Bolesky”)
1007	U.S. Patent No. 5,035,712 (“Hoffman”)
1008	Poncet, <i>Nitinol Medical Device Considerations</i> . SMST-2000: Proceedings Int’l. Conference Shape Memory and Superelastic Tech., 441-455 (2000)
1009	Duerig et al., <i>The Use of Superelasticity in Medicine</i> . Metall. 50, 569-74 (1996)
1010	Duerig et al., <i>An overview of superelastic stent design</i> . Minimally invasive therapy & allied technologies: MITAT: Official J. of the Society for Minimally Invasive Therapy vol. 9, 3-4. 235-46 (2000)
1011	Ryhanen, <i>Biocompatibility Evaluation of Nickel-Titanium Shape Memory Metal Alloy</i> , Diss., Oulu: University of Oulu (1999)

1012	Stoeckel, <i>The Shape Memory Effect – Phenomenon, Alloys and Applications</i> . Proceedings of Shape Memory Alloys for Power Systems, EPRI, 1-13 (1995)
1013	Kauffman et al., <i>The Story of Nitinol: The Serendipitous Discovery of the Memory Metal and Its Applications</i> , The Chemical Educator. 2. 1-21 (1996)
1014	Kirk-Othmer, <i>Encyclopedia of Chemical Technology</i> , 3 rd Ed., Vol. 20 (1982)
1015	van der Wijst, <i>Shape Memory Alloys featuring Nitinol</i> , TU Eindhoven, 62 (1992)
1016	Duerig, <i>The Use of Superelasticity in Modern Medicine</i> , MRS Bulletin 27, 101–104 (2002)
1017	U.S. Patent No. 5,190,546 (“Jervis”)

CLAIM LISTING

- [1.P] 1. A method, comprising:
- [1.1] inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment, wherein the inserting causes a first portion of the bone device to contact the first bone fragment and causes a second portion of the bone device to contact the second bone fragment, the second portion different from the first portion;
- [1.2] wherein the bone device comprises a shape memory alloy having an austenite finish temperature;
- [1.3] creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis;
- [1.4] after performing the stretching, fixing the second portion of the bone device to the second bone fragment; and
- [1.5] wherein the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy.
2. The method of claim 1, wherein stretching the bone device is performed with the bone device substantially in an austenitic phase.
3. The method of claim 1, further comprising: before performing the stretching, fixing the bone device to the first bone fragment

4. The method of claim 3, further comprising: holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the bone device to the first bone fragment is performed.
5. The method of claim 1, further comprising: holding the shape memory alloy at a temperature greater than the austenite finish temperature of the shape memory alloy while the stretching is performed.
6. The method of claim 1, further comprising: holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the second portion is performed.
7. The method of claim 1, wherein inserting the bone device into the second bone fragment is performed while the responsive portion is substantially in an austenitic phase.
8. The method of claim 1, wherein inserting the bone device into the first bone fragment is performed while the responsive portion is substantially in an austenitic phase.
9. The method of claim 1, wherein the first portion comprises the shape memory alloy.
10. The method of claim 1, wherein the second portion comprises the shape memory alloy.

MANDATORY NOTICES

A. Real Party-In-Interest (37 C.F.R. § 42.8 (b)(1))

Petitioner certifies that Arthrex, Inc. is the real party-in-interest.

Although Petitioner does not believe that Arthrex Manufacturing, Inc. is a real party-in-interest because Arthrex Manufacturing, Inc. does not exercise control over petitioner and has not funded or otherwise influenced this IPR, Petitioner identifies Arthrex Manufacturing, Inc. for purposes of the Board's consideration because Arthrex Manufacturing, Inc. was originally named in the Complaint filed in the below-identified related matter.

B. Related Matters (37 C.F.R. § (b)(2))

The '222 Patent is involved in: *Medshape, Inc. et al. v. Arthrex, Inc.*, Case No. 6-24-cv-00151 (W.D. Tex.).

C. Counsel and Service Information (37 C.F.R. § 42.8(b)(3) and (4))

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Service information for lead and backup counsel is provided in the designation above. Petitioner consents to electronic service by email at the email addresses provided above.

D. Payment of Fees Under 37 C.F.R. §§ 42.15(a) & 42.103

The required fees are submitted herewith in accordance with 37 C.F.R. §§ 42.103(a) and 42.15(a). If any additional fees are due during this proceeding, the Office is authorized to charge such fees to Deposit Account No. 22-0261. Any overpayment or refund of fees may also be deposited in this Deposit Account.

Arthrex, Inc. (“Arthrex”) requests *inter partes* review (“IPR”) of claims 1-10 of U.S. Patent No 7,985,222 (“the ’222 Patent”) (Ex. 1001) pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 *et seq.* The ’222 Patent is subject to pre-AIA 35 U.S.C. §§ 102 and 103.

I. INTRODUCTION

The ’222 Patent relates to methods for bone fracture fixation using devices that comprise a shape memory alloy (“SMA”), such as Nitinol, to apply compressive pressure across a fracture site. The only independent claim of the ’222 Patent (claim 1) recites a method with three basic steps: (i) inserting a bone device comprising an SMA into first and second bone fragments, (ii) creating (in a responsive portion of the bone device) at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the bone device’s longitudinal axis, and (iii) fixing a second portion of the bone device to the second bone fragment after the stretching. Each of these elements, individually and collectively, was well known in the art before the filing of the ’222 Patent.

As shown below, U.S. Patent No. 6,685,708 (“Monassevitch”) teaches (or renders obvious) all of the elements recited in the challenged independent claim. Monassevitch discloses a staple (bone device) made of SMA that is designed for fracture fixation. Monassevitch teaches stretching the staple along a longitudinal

axis to create stress-induced martensite in the SMA, which allows for compression across a fracture site when the staple is inserted.

The challenged claims would have also been obvious over U.S. Patent No. 4,275,717 (“Bolesky”) in view of U.S. Patent No. 5,035,712 (“Hoffman”). Bolesky teaches an intramedullary fixation device to provide compression across bone fragments. Although Bolesky does not expressly teach using SMA, it would have been obvious to modify Bolesky to use SMA based on the teachings of Hoffman (which describes the advantages of using SMA to provide compression in a similarly designed bone device). None of Monassevitch, Bolesky or Hoffman were considered by the Patent Office in deciding to allow the claims.

II. STANDING

Petitioner certifies that the ’222 Patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR. This petition is being filed within one year of Petitioner being served with a complaint alleging infringement of the ’222 Patent.

III. IDENTIFICATION OF CHALLENGES UNDER 37 C.F.R. § 42.104(b) AND RELIEF REQUESTED

Petitioner requests (i) review of claims 1-10 of the ’222 Patent on the grounds set forth below and (ii) that those claims be found unpatentable.

Ground	Claim(s)	Basis for Unpatentability
1	1-2, 5-10	Obvious over Monassevitch
2	1-10	Obvious over Bolesky and Hoffman

The grounds for unpatentability presented in this petition are neither cumulative nor redundant to prosecution of the '222 Patent. In support, Arthrex presents the Declaration of Mike Sherman, an expert with an advanced degree in Biomechanical Engineering and thirty-five years of experience in the medical device industry. Ex. 1002, 1003.

IV. BACKGROUND

A. Technical Background

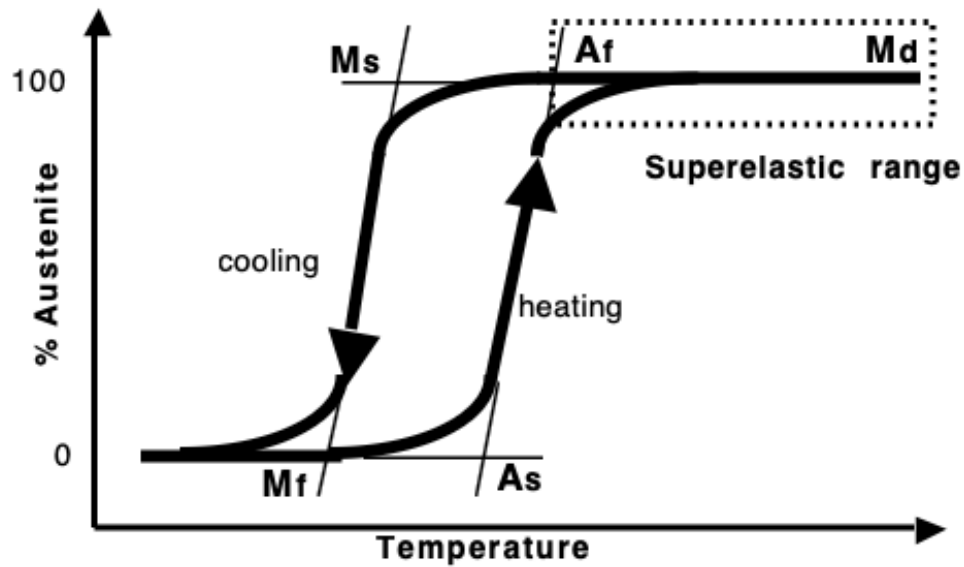
The '222 Patent relates to bone fracture fixation devices that utilize a shape memory alloy (“SMA”). Ex. 1001, Abstract, 1:15-17. SMAs possess an ability to “remember” their physical shape such that they can revert back to their original shape after the material has been deformed. Ex. 1002, ¶25. This ability stems from an SMA’s ability to exist, and transform between, two different phases of crystalline structures: austenite (which exists at higher temperatures) and martensite (which exists at lower temperatures). *Id.*

The transformation between the austenite and martensite can be affected in two ways: (1) temperature or (2) mechanical stress. *Id.*, ¶26. When cooled to low

temperatures, an SMA will transform from a generally rigid austenite state to a soft martensite state. *Id.* The SMA can be deformed while in the softer martensitic state and, upon application of heat, transform back into its original shape in the more rigid austenite state. *Id.* This transformation through temperature change is referred to as the “thermal shape memory effect.” *Id.*

Alternatively, when an SMA in an austenitic state is mechanically stressed (for example, by stretching) above a certain temperature referred to as the “austenite finish temperature,” the SMA will transform from an austenite state to a martensitic state. *Id.*, ¶¶27, 29. When the stress is relieved, the SMA reverts to the austenite state and recovers its original shape. *Id.* This property is called “super-elasticity” (or pseudo-elasticity), and the martensite formed due to the applied stress is referred to as “stress-induced martensite” (“SIM”). *Id.*

SMA’s exhibit a hysteresis characterized by five (5) specific temperatures; M_s , M_f , A_s , A_f and M_d .



Id., ¶28. Ex. 1008, p. 7. These five temperatures are defined as follows:

- **M_s** - the temperature at which transformation from austenite to martensite begins to form on cooling;
- **M_f** - the temperature at which transformation from austenite to martensite is complete on cooling;
- **A_s** - the temperature at which transformation from martensite to austenite begins to form on heating;
- **A_f** -- the temperature at which transformation of martensite to austenite is complete upon heating; and
- **M_d** -- the maximum temperature at which martensite formation can occur even under stress.

Ex. 1002, ¶28. Pertinent to the issues here, superelasticity (and the formation of SIM) occurs when the SMA is stressed at a temperature above A_f and in the range between A_f and M_d . Ex. 1002, ¶29; Ex. 1009, p.2; Ex. 1011, Section 2.3.6; Ex. 1012, p.2.

One well-known SMA is Nitinol, which is a composition of nickel and titanium. Ex. 1002, ¶30. Nitinol was developed in 1959. *Id.*; Ex. 1013, p.1. By the time the application that led to the '222 Patent was filed, it was well-known that Nitinol's properties made it particularly advantageous for use in medical devices. It was known that Nitinol is biocompatible in humans. Ex. 1002, ¶30; Ex. 1008, p.1; Ex. 1010; Ex. 1011, Abstract. It was also known that the range of temperatures within which Nitinol exhibits superelasticity can be engineered to include room temperature and/or body temperature. Ex. 1002, ¶31; Ex. 1010, p.235. Indeed, one typical Nitinol alloy composition being used for medical applications was known to have superelastic properties both at room and body temperature. Ex. 1002, ¶31; Ex. 1008, p. 12.

Accordingly, for medical device designers and researchers, Nitinol had “become one of the materials of choice” and a “staple of their design toolbox” for certain applications, like self-compressing devices for fracture fixation such as bone plates, marrow nails, splints, staples, and the like. Ex. 1002, ¶32; Ex. 1014, p. 733 (“In the area of orthopedic surgery, Nitinol applications have been highly successful.

Their range is as diverse as bone-fracture fixation, hip implants, and the reduction of spinal deformities and structural abnormalities such as scoliosis”); Ex. 1013, p. 12 (“Physicians...are using Nitinol splints, with which simple fractures can be mended several times faster than with conventional splints. The Nitinol splints not only hold the fractured bones in place more securely, but they also push the bones together so that the break heals more rapidly.”); Ex. 1015, Section 5.4 (“One of various applications is the NiTi bone plate, used for healing fractures in bone shafts”); Ex. 1017, 7:26-8:42; 9:58-10:34 (disclosing bone plates, marrow nails, staples, clips, etc. using the superelastic property of Nitinol).

B. The '222 Patent

The '222 Patent describes fracture fixation devices that use SMAs to “help maintain compressive load across the fracture site.” Ex. 1001, 2:6-10. The patent acknowledged that the use of “stainless steel or titanium in osteosynthetic devices,” such as “screws and plates,” were well known and had a “long history and reasonable record of success.” *Id.*, 1:48-52. The inventors believed, however, that “stainless steel and titanium fixation constructs” did not sufficiently “maintain compression across the fracture fragment.” *Id.*, 1:50-60. To address this issue, the '222 Patent describes using a fracture fixation device made of an SMA, such as nickel titanium (Nitinol) to “help maintain compressive load across the fracture site” for longer periods of time compared to prior devices. *Id.*, 2:6-13, 4:52-56.

The '222 Patent states that Nitinol “exhibit[s] the capacity to recover relatively large strains (e.g., about 6%) by the application of heat (shape memory) or by gradual unloading (pseudo-elasticity).” *Id.*, 4:57-60. The purported invention thus aims to “exploit the large strain capacity and recovery behavior of shape memory alloys such as Nitinol for bone repair.” *Id.*, 4:60-63. The patent depicts several examples of bones devices using an SMA, including a “bone screw” (*see* Figs 1-3), a “plate,” (*see* Figs. 4-7) and a “bone nail,” (*see* Fig. 8), each of which “can provide sustained compression... across a bone fracture over time.” *See, e.g., Id.*, 4:36-40.

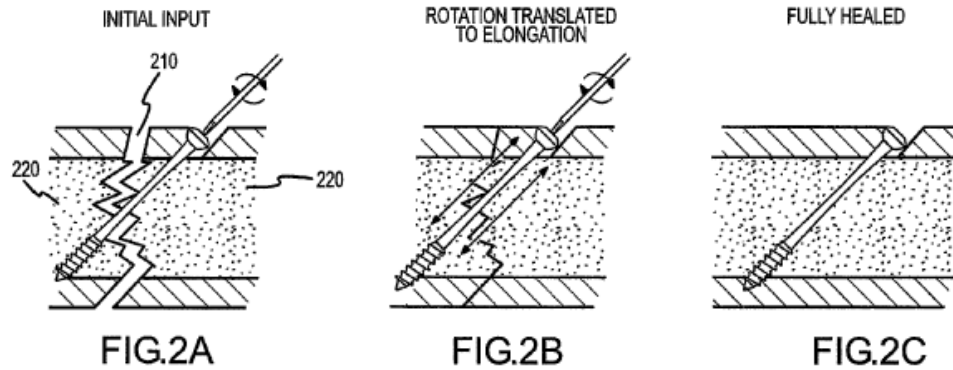
Claim 1 of the '222 Patent, which is the only independent claim, recites a method that comprises, *inter alia*, “inserting a bone device [comprising a shape memory alloy] ... into a first bone fragment and a second bone fragment,” “creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis,” and “after performing the stretching, fixing the second portion of the bone device to the second bone fragment.” The claim also recites that “the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy.” Dependent claims 2-10 depend directly or indirectly from claim 1 and provide further details on certain steps of the claimed method, such

as the sequence or temperatures at which steps may occur, or details about the structure of the bone device.

C. Prosecution History

Claim 1 of the '222 Patent was originally presented as claim 47 of U.S. Patent Application No. 11/112,865 (“the ‘865 application”). During prosecution of the ‘865 application, the Examiner initially rejected claim 47 as being anticipated by U.S. Pat. 5,415,660 (“Campbell”). Ex. 1004, pp. 107-108. In response, Applicant amended the claim to recite that the step of “fixing the second portion of the bone device to the second bone fragment” is performed “after performing the stretching,” and argued that Campbell did not teach this limitation. *Id.*, pp. 88-89.

The Examiner also rejected the claim that would issue as claim 1 (and its dependents) under 35 U.S.C. § 112 for lack of written description. *Id.*, pp. 107-108. In response, Applicant argued that the claims were supported by the screw embodiment described in relation to Figs. 2A-2C (shown below). *Id.*, pp. 88-98. Applicant asserted that “Fig. 2A shows a bone device with a first portion contacting a first bone fragment and a second portion contacting a second bone fragment,” and stated that the formation of a stress-induced martensite phase occurs when the screw is elongated “during the insertion process into the fractured bone”, as “indicated by the arrows parallel to the longitudinal axis in Fig. 2B.” *Id.*, p. 94.



Applicant also asserted that this embodiment disclosed the claimed “fixing” and “stretching” limitations . With regard to issued claim 1 (requiring fixing the second portion after performing the stretching), Applicant argued that “Fig. 2C shows the second portion of the bone device (e.g., the threaded end) *in the fixed position after the stretching/elongation of the shank is completed.*” *Id.* at p. 95.¹ Then, with regard to issued claim 3 (requiring fixing the first portion before performing the stretching), Applicant asserted that “in FIGS 2A and 2B, the depicted stretching/elongation of the shank ... occurs *after the screw head is fixed in the first portion of bone while the screw threads of the bone device are driven into the second portion of the bone.*” *Id.* at p. 96.

The Examiner allowed claim 1, and its dependent claims, in view of the above-described arguments. *Id.*, pp. 72-73; *see also* p. 35. The Examiner maintained

¹ Emphasis is added throughout unless otherwise noted.

a written description rejection to pending claims 27-35, 37 and 38. *Id.* The Applicant ultimately cancelled those other claims. *Id.*, pp. 60-65. As such, the only independent claim that issued was claim 1.

V. THE PRIOR ART

A. Monassevitch

Filed on February 28, 2001 and issued on February 2, 2004, Monassevitch is prior art under pre-AIA 35 U.S.C. §102(a) and (e).

B. Bolesky

Filed on July 27, 1979 and issued on June 30, 1981, Bolesky is prior art under pre-AIA 35 U.S.C. §102(a), (b) and (e).

C. Hoffman

Filed on June 12, 1990 and issued on July 30, 1991, Hoffman is prior art under pre-AIA 35 U.S.C. §102(a), (b) and (e).

VI. LEVEL OF ORDINARY SKILL IN THE ART

Although the claims are unpatentable under any reasonable definition of a person of ordinary skill in the art (“POSITA”) at the time of the alleged invention of the ’222 Patent (April 2004), Arthrex believes the POSITA would have would have possessed the education, skill and experience of either:

- (1) an orthopedic or podiatric surgeon, having an M.D. or a Doctorate of Podiatric Medicine (DPM), having at least two years of experience in

practice using and/or designing implantable medical devices, and having knowledge of, or experience with, medical devices utilizing shape memory alloys; or

- (2) an engineer, or similar professional, having a B.S. or equivalent degree in one of biomedical engineering, biomechanical engineering, mechanical engineering, materials science, or a similar discipline and at least three to five years of experience researching, designing, developing, or testing (i) implantable medical devices and/or (ii) products using shape memory alloys; and having knowledge of, or experience with shape memory alloys in the context of medical devices.

For both categories above, graduate education or specific technical training may substitute for some years of experience, and vice-versa. Ex. 1002, ¶45-49.

VII. CLAIM CONSTRUCTION

For the purposes of this petition, Petitioner states that under any reasonable interpretation of the claims, including the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1327 (Fed. Cir. 2005) (“ordinary and customary meaning”), all limitations of the challenged claims are met in the prior art as discussed below.

A. “Bone Fragment”

In the district court litigation, Arthrex contends that the term “bone fragment” should be given its plain and ordinary meaning, which is “a piece of bone broken

from a larger bone.” Patent Owner also contends that “bone fragment” should be given its plain and ordinary meaning. However, Patent Owner has asserted that the ’222 Patent claims cover procedures that include inserting a bone device through multiple intact bones, such as the calcaneus, talus, and tibia, and so appears to interpret “bone fragment” more broadly to include intact bones as well as pieces of broken bone. Because the prior art in both grounds 1 and 2 below disclose fixation between two parts of a broken bone, and therefore render the claims obvious to a POSITA under either construction of “bone fragment” (Ex. 1002, ¶51), the Board need not resolve this dispute.

B. “Substantially in an Austenitic Phase”

Dependent claims 2, 7 and 8 each recite that a certain step (stretching or inserting) is performed while a certain structure (bone device or responsive portion) is “substantially in an austenitic phase.” In the district court litigation, Arthrex contends that these terms are indefinite. Patent Owner contends that the claims should be given their plain and ordinary meaning, but Patent Owner has not provided what it believes to be the plain and ordinary meaning. To the best that Petitioner can understand Patent Owner’s infringement contentions, Patent Owner appears to be arguing that an SMA is substantially in an austenitic phase if only part of the austenitic SMA is transformed to martensite due to the recited step or if the SMA is above the austenite finish temperature (in which case it would be fully austenitic)

prior to the recited step. Without conceding its positions, and because indefiniteness is not an issue in this petition,² Arthrex will apply Patent Owner’s apparent interpretation.

VIII. EXPLANATION OF GROUNDS FOR UNPATENTABILITY

A. Statement of the Law

Each of the grounds of unpatentability rely on obviousness under 35 U.S.C. § 103. A claim is obvious when “the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C. § 103(a); *see KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

B. Ground 1 – Claims 1-2 and 5-10 are Obvious over Monassevitch

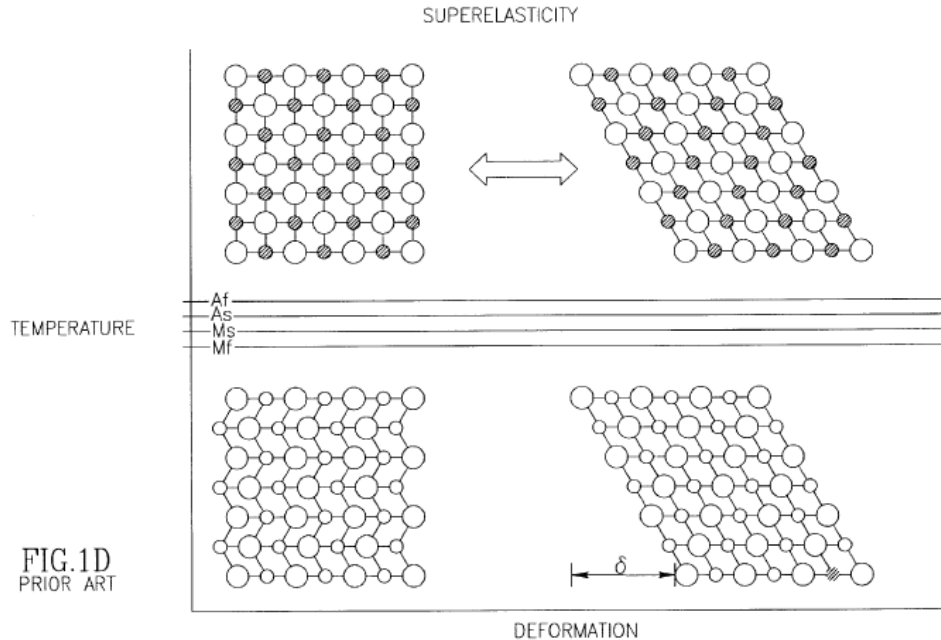
The limitations in claims 1-2 and 5-10 are rendered obvious by Monassevitch. As explained below, Monassevitch describes several embodiments that independently teach each limitation of claims 1-2 and 5-10. Ex. 1002, ¶53. However, to the extent that the Patent Owner may argue that any limitation is

² *Samsung Electronics America, Inc. v. Prisia Engineering Corp.*, 948 F.3d 1342, 1350 (Fed. Cir. 2020) (“[T]he Board may not cancel claims for indefiniteness in an IPR proceeding.”).

missing from any one embodiment, it would also be obvious to a POSITA to combine or modify aspects of the described embodiments to apply the teachings of Monassevitch and/or the knowledge of a skilled artisan in the way required by these claims. *Id.*

i. Overview of Monassevitch

Monassevitch discloses “a bone staple formed of a shape-memory alloy and an apparatus” that “deforms the staple by increasing its span length and facilitating its insertion into bone tissue.” Ex. 1005, Abstract; *see also Id.*, 1:6-9; 3:54-56; Ex. 1002, ¶¶54-56. Monassevitch explains that, as illustrated in Fig. 1D, SMAs possess super-elastic properties such that when deformed at temperatures above the austenite finish temperature (A_f), the SMA will form stress-induced martensite when under stress, and will then tend to revert to its original shape when the stress is removed. Ex. 1005, 2:13-27; Ex. 1002, ¶57.



Monassevitch describes numerous embodiments of SMA staples and methods for using them for fracture fixation. Pertinent here are three embodiments using staple 10 (Fig. 3A), staple 150 (Fig. 8) and staple 200 (Fig. 10A). *See* Ex. 1005, 12:5-29; 12:59-13:38; 13:62-14:43; Ex. 1002, ¶58-68. Each staple is inserted into two bone fragments to provide bone fracture fixation and stabilization. *Id.* Each embodiment utilizes the superelastic property of the SMA by stretching the staple, along its longitudinal axis, to create stress-induced martensite. *Id.*; *see also* Ex. 1005, 3:54-56; 5:31-35.

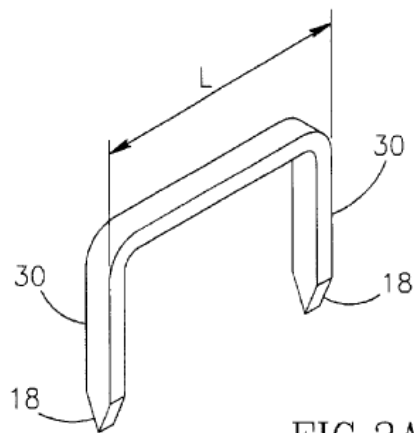


FIG. 3A

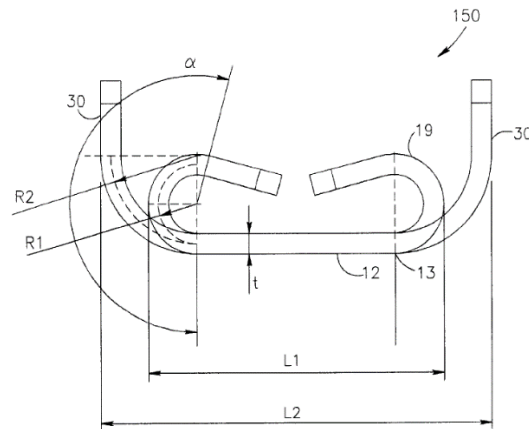


FIG. 8

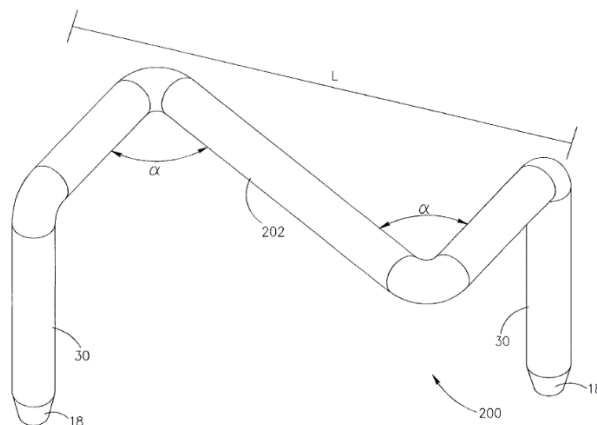


FIG. 10A

ii. [1.p] A method, comprising:

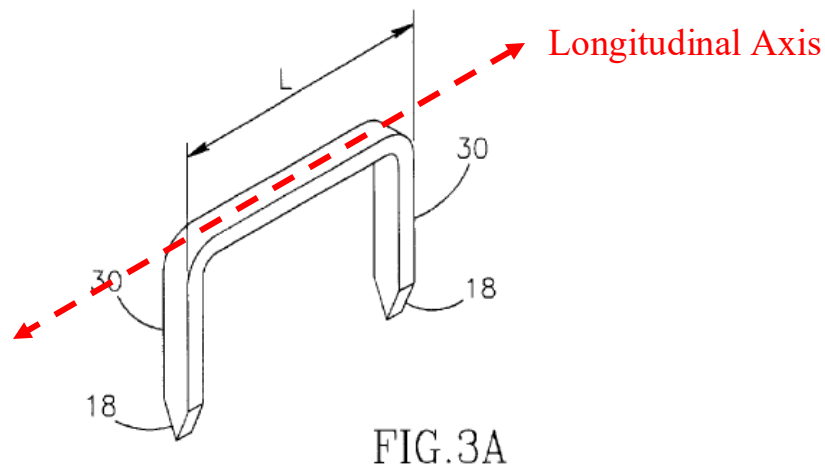
The preamble is not limiting. Nonetheless, Monassevitch teaches a method of bone fixation. Ex. 1002, ¶69; Ex. 1005, 3:54-56 (“It is an aim of the present invention to provide apparatus and method for adjusting the length spans of SMA staples for bone fixations, prior to their insertion into the bone.”); 12:5-23 (describing method of using staple 10); 12:59-13:34 (describing method of using staple 150); 13:62-14:35 (describing method of using staple 200).

- iii. [1.1] inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment, wherein the inserting causes a first portion of the bone device to contact the first bone fragment and causes a second portion of the bone device to contact the second bone fragment, the second portion different from the first portion

Monassevitch teaches three embodiments, which each discloses, or renders obvious, this limitation. Ex. 1002, ¶70-83.

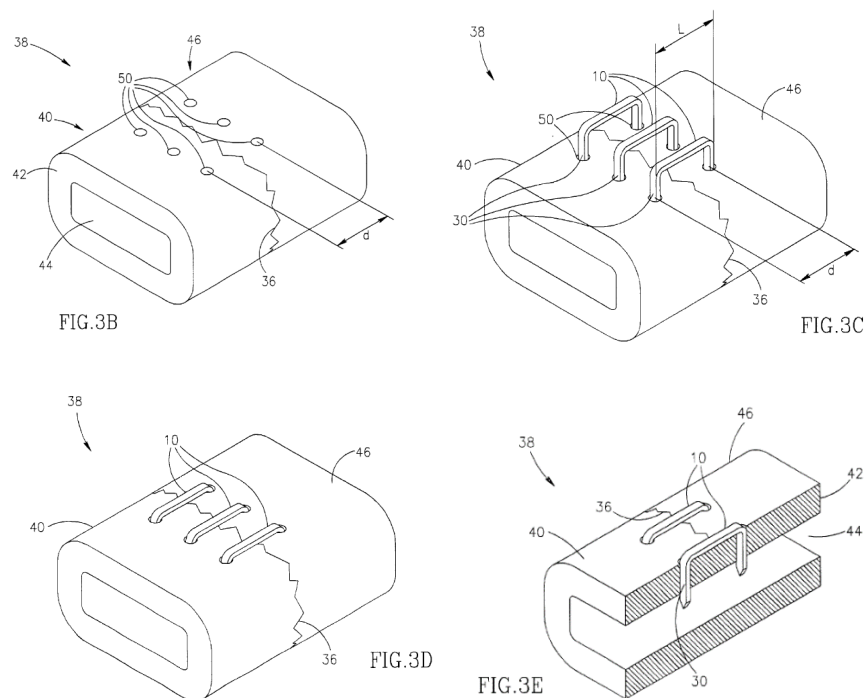
a) **Embodiment #1 – Staple 10**

Monassevitch discloses a **bone device** in the form of staple 10 (Fig. 3A). Ex. 1002, ¶71; Ex. 1005, 12:5-12:12. The staple 10 has a **longitudinal axis**, which a POSITA would understand as extending along the long end of the staple, as depicted with the dashed red line below. Ex. 1002, ¶¶71-72.



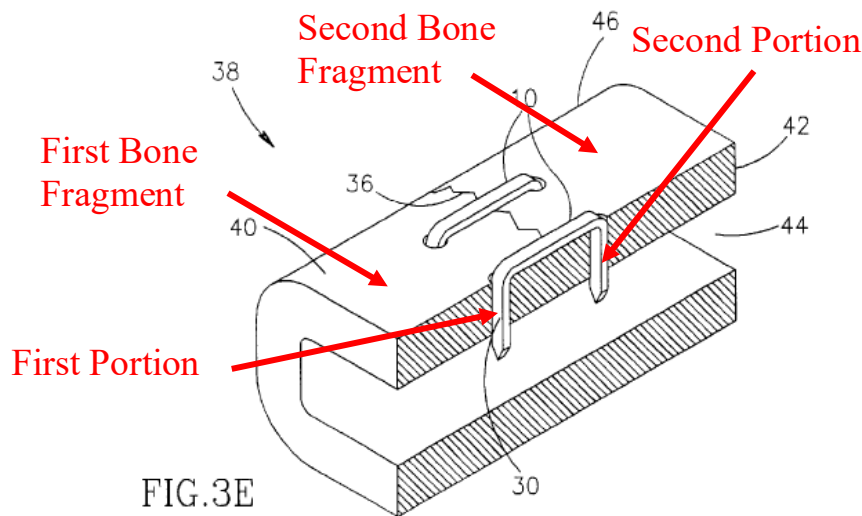
Monassevitch teaches that staple 10 is **inserted into a first bone fragment and a second bone fragment**. Ex. 1002, ¶73. To facilitate the insertion, “bore pairs 50 are drilled into fractured bone 38, across fracture interface 36, wherein each bore

pair 50 is associated with distance d between the bores of the pair, and wherein d is equal to or greater than length span L of staple 10.”). Ex. 1005, 12:13-17. As Monassevitch explains, “[e]ach pair of bores 50 includes one bore in **bone fragment 40**, and another bore in **bone fragment 46**, across interface 36.” *Id.*, 9:24-33. Then, “[w]here $d > L$, the surgeon (not shown) will adjust the length span L of staple 10 by increasing it.” *Id.*, 12:18-20. Once the length is increased, the staple 10 “**is inserted into bone 38**,” as shown in the Figures 3B-3E below. *Id.*, 12:21-22; *see also* 16:43-46.



The insertion of the **staple causes a first portion of the bone device to contact the first bone fragment and a second portion of the bone device to contact the second bone fragment**. Ex. 1002, ¶74. Staple 10 has two straightedges

30, and inserting the staple 10 into bore pairs 50 places each of the straightedges in contact with the respective bone fragments 40 and 46. Ex. 1005, 12:5-23; 9:52-57. Thus, one straightedge 30 represents the first portion (which contacts first bone fragment 40) and another straightedge 30 represents the second portion (which contacts a second bone fragment 46). Ex. 1002, ¶74. The **second portion is different from the first portion.** *Id.*



b) Embodiment #2 – Staple 150

In a second embodiment, Monassevitch discloses a **bone device** in the form of staple 150. Ex. 1002, ¶76; Ex. 1005, 12:61-63. Like staple 10, staple 150 has a **longitudinal axis**, which a POSITA would understand to be as depicted with the dashed red line in the image below. Ex. 1002, ¶76.

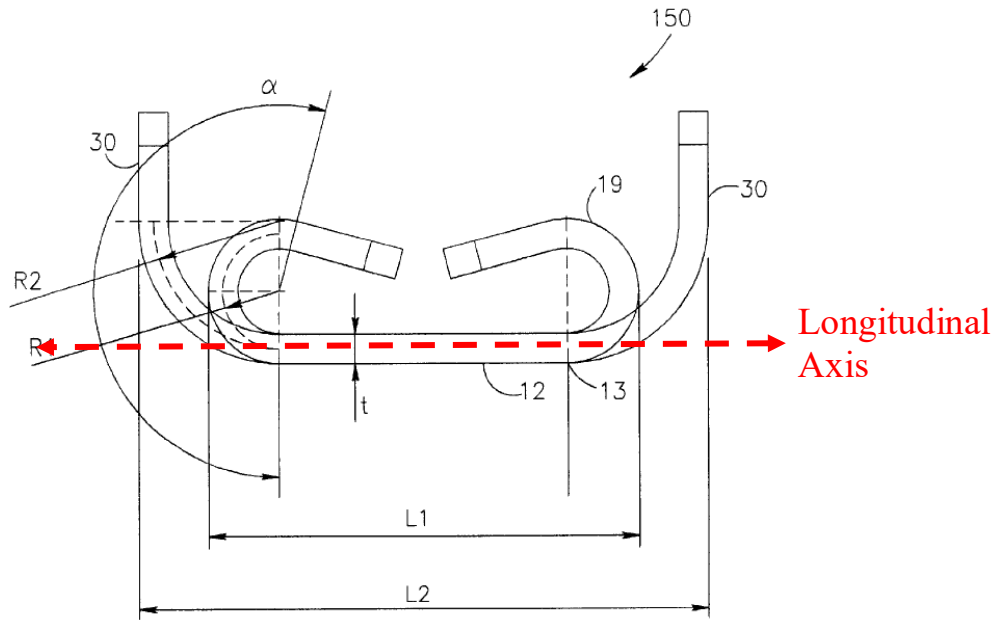


FIG. 8

Similar to staple 10, staple 150 includes two straightedges 30 that are **inserted into a first bone fragment 40 and a second bone fragment 46**. Ex. 1002, ¶77. As Monassevitch teaches: “staple 150 is plastically deformed to simultaneously achieve the following: 1. form straightedges 30, to **facilitate insertion into the bone**; and 2. Increase length span L1 to a length span L2.” *Id.*, 13:3-11; *see also* 13:32-33 (“staple 150 may be employed **to provide bone fixation**”).

Thus, as with staple 10, a first straightedge 30 represents the **first portion** and a second straightedge 30 represents the **second portion**. Ex. 1002, ¶78. And for the same reasons discussed above for staple 10, staple 150 is inserted into first and second bone fragments such that the first straightedge 30 (first portion) is **in contact with the first bone fragment 40** and the second straightedge 30 (second portion,

which is **different from the first portion**) is in contact with the second bone fragment 46. *Id.*

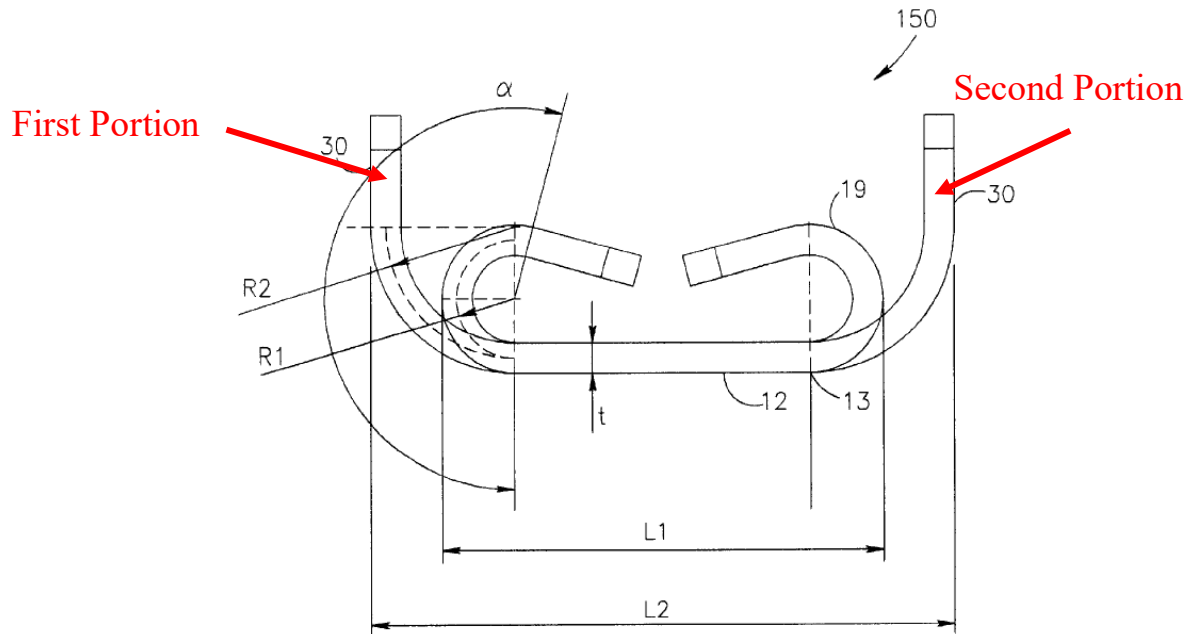


FIG. 8

c) Embodiment #3 – Staple 200

Monassevitch also teaches a third embodiment that discloses a **bone device** in the form of staple 200, as shown in Figures 10A and 10B Ex. 1002, ¶80. As Monassevitch explains, staple 200 has two straightedges 30 designed “in a manner similar to staple 10 of FIG. 3A.” *Id.*, 13:65-66. “In its austenitic shape, staple 200 includes a web 202, which has a length span L, at least one curvature 220, having a radius R1 and an angle C, and an effective web width V.” *Id.*, 13:62-14:2. “Additionally, staple 200 may have an additional curvature 230, also having radius R1 and angle C.” *Id.*, 14:2-3.

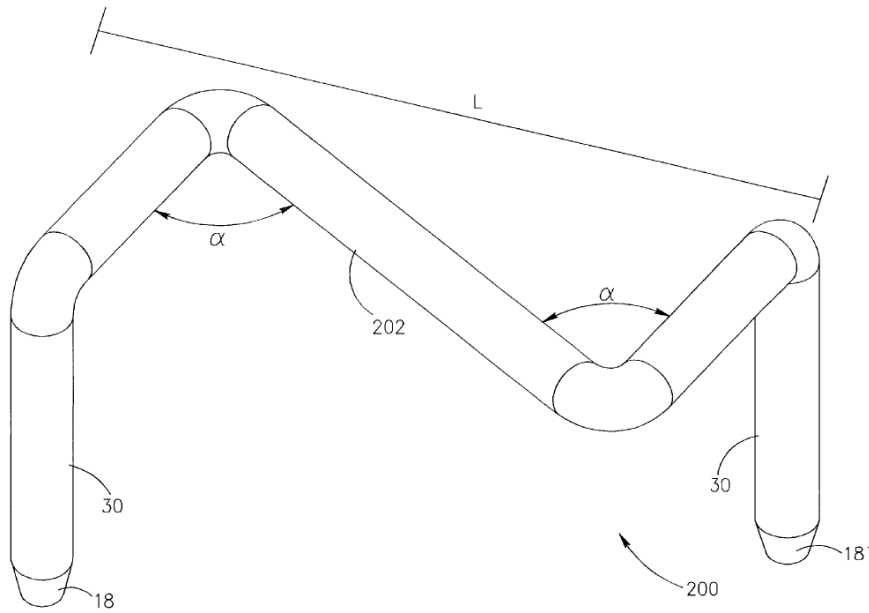


FIG. 10A

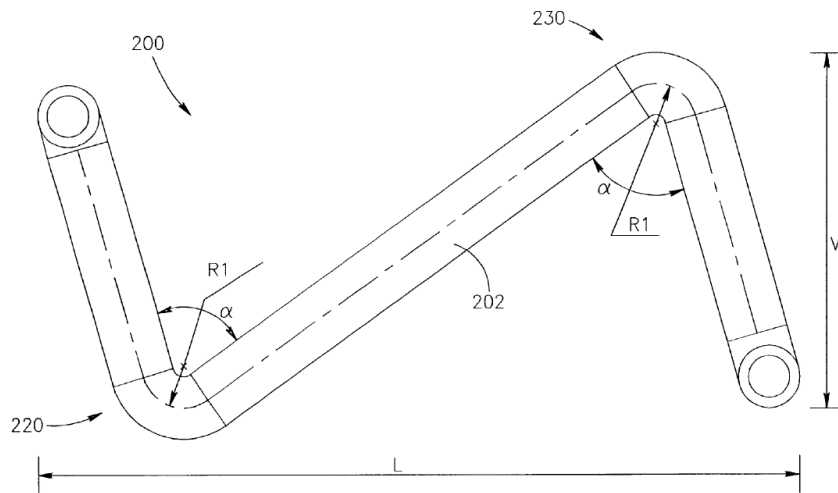


FIG. 10B

A POSITA would understand that, for staple 200, **the longitudinal axis** would be defined by the central line of the staple in the lengthwise direction, as depicted below. Ex. 1002, ¶81.

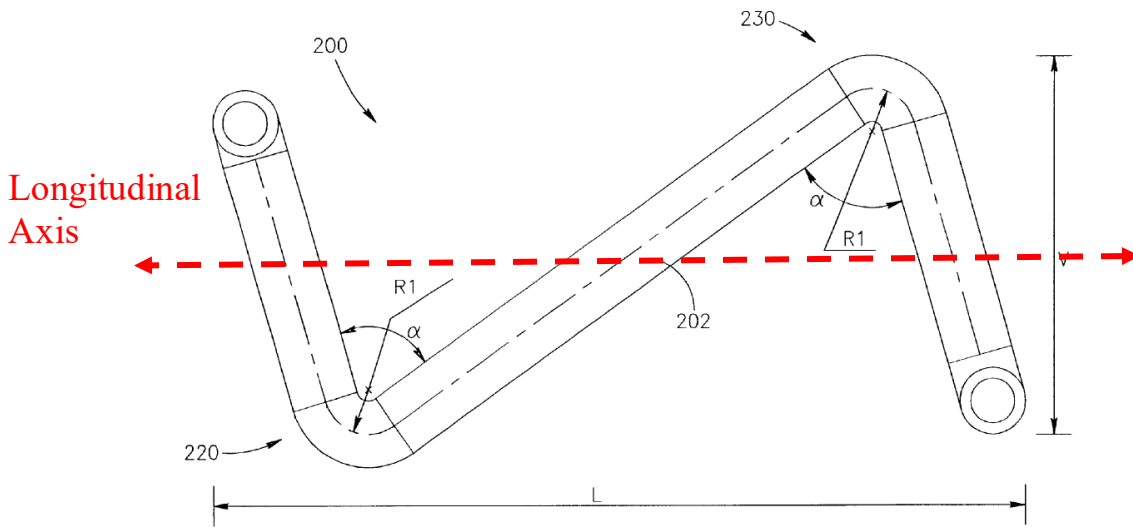
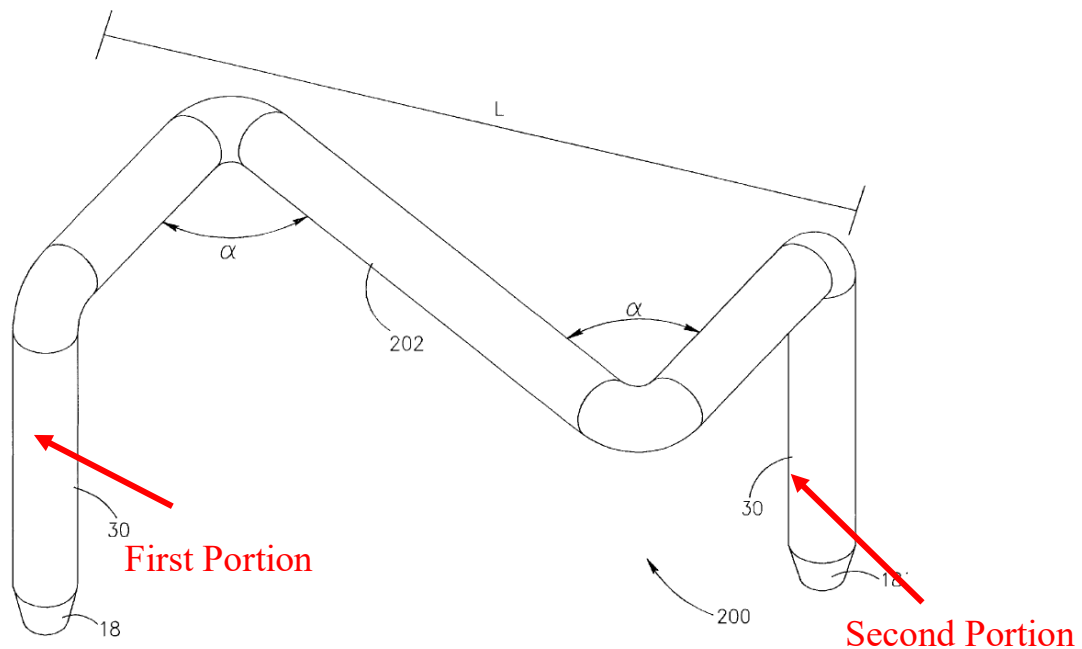


FIG.10B

Like staples 10 and 150, staple 200 is **inserted into a first bone fragment 40 and a second bone fragment 46**. Ex. 1002, ¶82; Ex. 1005, 14:23-28 (“staple 200 may be employed to provide bone fixation, while it is in a stress-induced martensite state”). A first straightedge 30 is the **first portion** and a second straightedge 30 is the claimed **second portion**. Ex. 1002, ¶82. And for the same reasons as discussed above for staples 10 and 150, the staple 200 is inserted into bone fragments such that the first straightedge 30 (first portion) is **in contact with the first bone fragment 40** and the second straightedge 30 (second portion, which is **different from the first portion**) is **in contact with the second fragment 46**. *Id.*

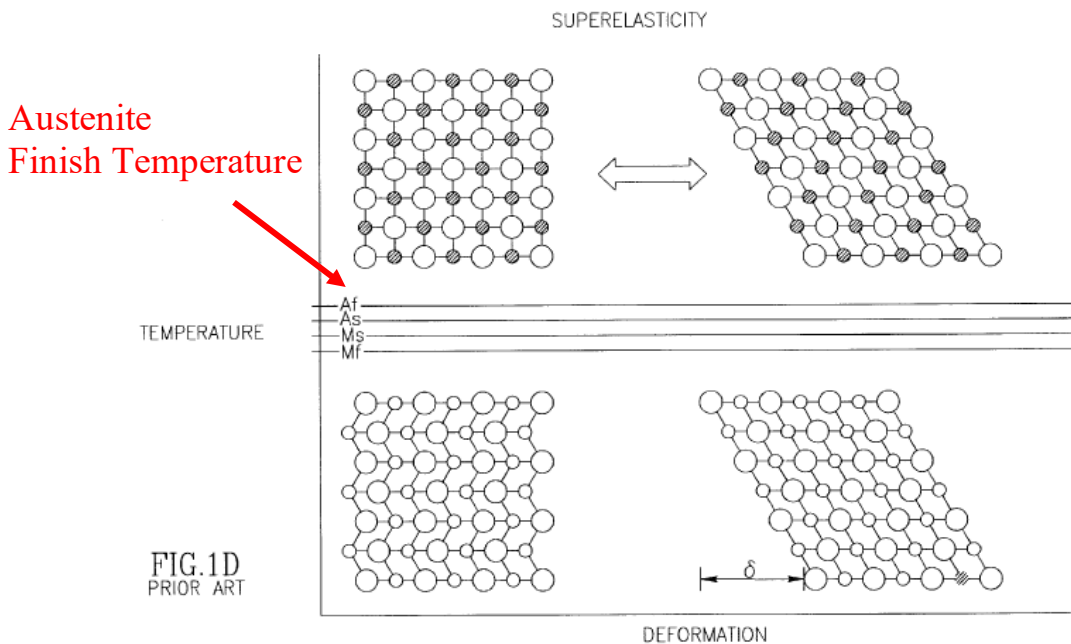


iv. [1.2] wherein the bone device comprises a shape memory alloy having an austenite finish temperature

For each embodiment described above, Monassevitch teaches that the staple (10, 150, and 200) is made of **a shape-memory alloy**. Ex. 1005, 14:36-38 (“In accordance with a preferred embodiment of the present invention, **staples 10, 150 and 200 are formed of a shape memory alloy...**”); *see also* 3:54-56; 4:35-36; 8:18-19; 12:28-29; 14:7; Ex. 1002, ¶84.

A POSITA would also understand that the SMA, for any of staples 10, 150, or 200, would have **an austenite finish temperature**. Ex. 1002, ¶85. As explained in Section IV.A, SMAs are characterized by various transformation temperatures. One of these is the austenite finish temperature (A_f), which is the temperature at

which the transformation of martensite to austenite is complete. *Id.* Indeed, as Monassevitch teaches, a “fully austenitic SMA element, **at a temperature above A_f** , will become martensitic and plastic under high stress, and deform under the stress.” Ex. 1005, 2:16-18; *see also Id.*, 5:20-24; 9:58-10:5. And Monassevitch depicts the austenite finish temperature A_f in Fig 1D, which illustrates the superelastic property of SMAs. *Id.*, 2:28-30. Accordingly, a POSITA would understand—based both on the teachings of Monassevitch and/or the knowledge of a POSITA—that the SMA used for staples 10, 150, and 200, as described above, has an austenite finish temperature. Ex. 1002, ¶¶85-86.



- v. **[1.3] creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis**

Monassevitch teaches this limitation for each of the three relevant embodiments. Ex. 1002, ¶¶87-101.

a) Embodiment #1 – Staple 10

Monassevitch discloses **stretching** the length span L of staple 10 such that the deformation results in the SMA staple being inserted in a **stress-induced martensite state** to provide bone fixation.

3. Where $d > L$, the surgeon (not shown) **will adjust the length span L of staple 10 by increasing it**, using any of the aforementioned apparatus; and

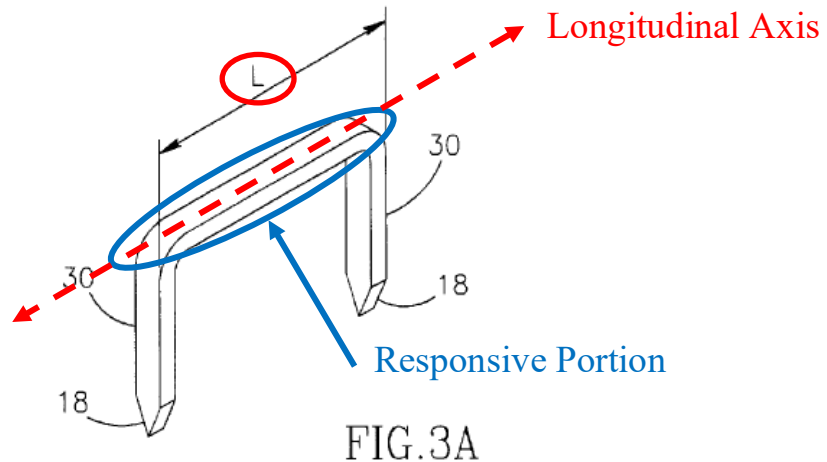
4. As seen in FIGS. 3C-3E, staple 10 of adjusted length span L, so that L is equal to d, is inserted into bone 38.

In accordance with a preferred embodiment of the present invention, staple 10 may be employed in a plastically deformed state that results from the length-span increase. In other words, **the deformed shape that results from the length-span increase** is the final shape, and staple 10 may be used to provide bone fixation, while **in a stress-induced martensite state**.

Ex. 1005, 12:18-29, 2:16-18 (“a fully austenitic SMA element, at a temperature above A_f , will become martensitic and plastic under high stress, and deform under the stress.”), 15:35-16:3 (claiming a method that includes “plastically deforming the staple, to **increase its length span**” where “plastically deforming the staple includes **plastically deforming the staple in a stress-induced martensitic phase at a**

temperature range of the fully austenitic phase.”). A POSITA would thus understand, or at least find it obvious, that **stretching** the length span L (which is made of SMA) results in the creation of **at least a partial transformation into a stress-induced martensitic phase** within the length span L of the staple. Ex. 1002, ¶88.

Because length span L of staple 10 is made of SMA and designed to be lengthened to create stress-induced martensite (so as to provide compression to the bone when the staple is inserted), a POSITA would also recognize that the length span L represents a “**responsive portion**” of staple 10. Ex. 1002, ¶89-90. And, as illustrated below, the lengthening of span L (and thus the creation of a partial transformation into a stress-induced martensitic phase) is caused by the responsive portion being **stretched along the longitudinal axis of the bone device**. *Id.*, ¶89; Ex. 1005, 12:5-8 (explaining that the stretching can be performed using “any of apparatus 60 (Fig. 4A), apparatus 90 (Fig. 5A), apparatus 100 (Fig. 6A), or apparatus 140 (Fig. 7)”).



b) Embodiment #2 – Staple 150

Similar to staple 10, Monassevitch teaches a method in which **at least a partial transformation into a stress-induced martensitic phase** is created in staple 150:

“[S]taple 150 posses [sic] **superelasticity** and the plastic deformation is performed while staple 150 is fully austenitic, **to form stress-induced martensite.**”

In accordance with a preferred embodiment of the present invention, staple 150 may be employed in its plastically deformed state, which resulted from **the length-span increase**. In other words, staple 150 may be employed **to provide bone fixation, while it is in a stress-induced martensite state.**”

Ex. 1005, 13:25-34; Ex. 1002, ¶¶91-92.

To create the stress-induced martensite, Monassevitch teaches that staple 150 is deformed by **stretching** the staple to simultaneously “1. form straightedges 30, to facilitate insertion into the bone; and 2. **increase the length spank L1 to a length span L2.**” Ex 1005, 13:4-9; 13:25-34 (staple 150 may be employed in its plastically

deformed state, which **resulted from the length-span increase....**to provide bone fixation, while it is in a stress-induced martensite state.”), 15:35-50, 15:60-61, 15:67-16:3, 16:43-65, 17:3-7; Ex. 1002, ¶93. A POSITA would understand, or at least find it obvious, that the stretching would create at least a partial transformation into a stress-induced martensite phase in **a responsive portion** of staple 200, as depicted below. Ex. 1002, ¶94, 96-97.

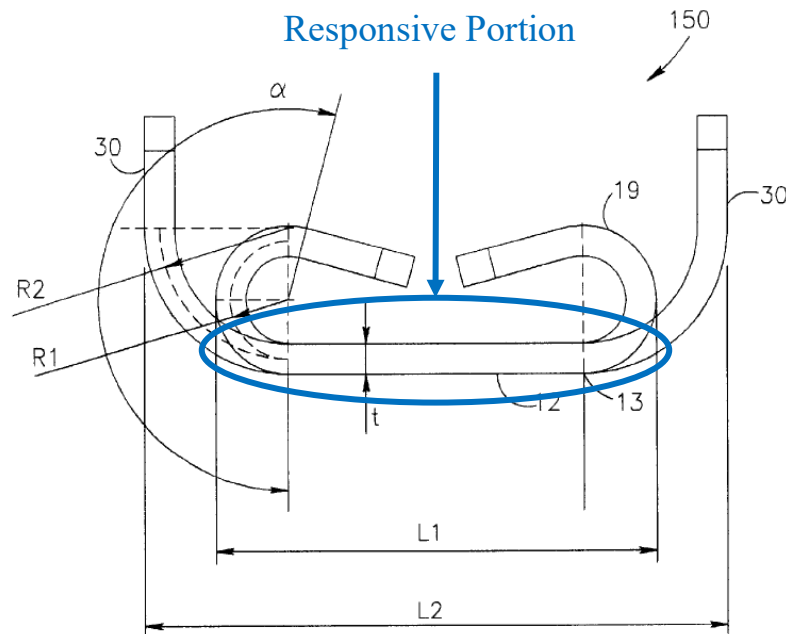


FIG. 8

Notably, depending on how much staple 150 is stressed, a POSITA would recognize that stress-induced martensite may be created along the entire responsive portion depicted above (for example, if the surgeon continues to stretch the staple after straightedges 30 are straightened, such that web 12 is also stretched) or only at

the ends of the responsive portion (for example, if the surgeon stops stretching once straightedges 30 are straightened). Ex. 1002, ¶96. In either instance, **at least a partial transformation into a stress-induced martensitic phase is created in the responsive portion.** *Id.*

Furthermore, as illustrated below, the stretching that results in the creation of stress-induced martensite in the responsive portion occurs “**along the longitudinal axis**” of the device. Ex. 1002, ¶95. As Monassevitch explains, the deformation of staple 150 “can be achieved, for example, by apparatus 90,” which is depicted in Fig. 5B. *Id.*; Ex. 1005, 13:10-11. Monassevitch teaches that this device is used to increase the length span of staple 150 from length L1 to length L2. Ex. 1005, 13:3-9. And the length span being increased, as shown in annotated Figure 8 below, extends along the longitudinal axis of the staple 150. Ex. 1002, ¶95. Thus, a POSITA would recognize that the direction of the stretching of staple 150 is along the longitudinal axis of the staple. *Id.*

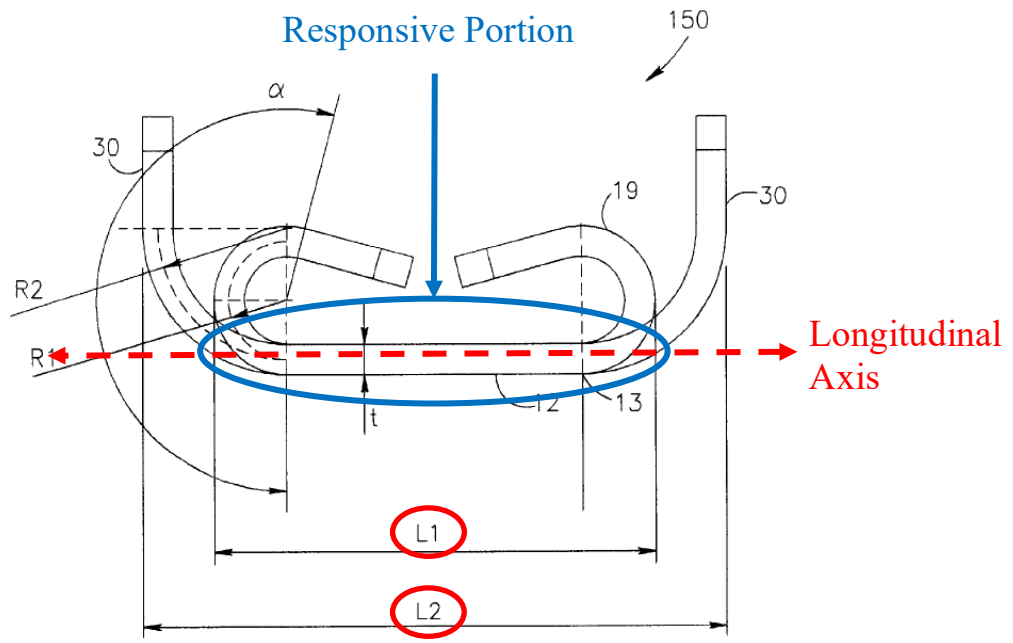


FIG. 8

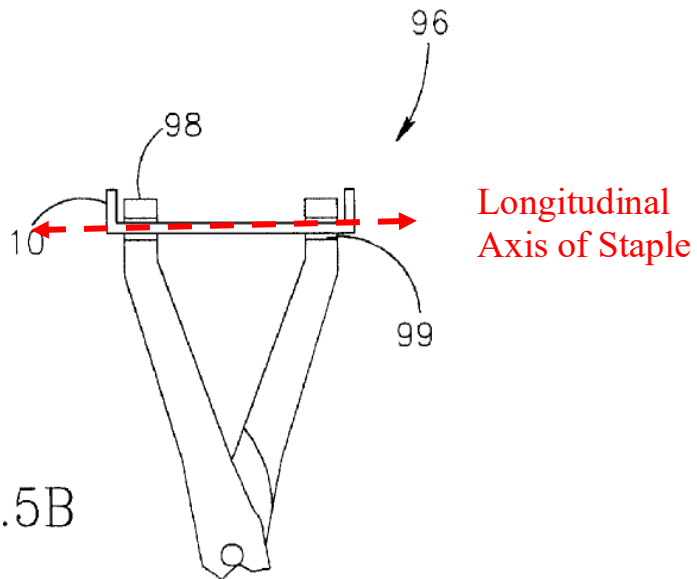


FIG. 5B

c) Embodiment #3 – Staple 200

Monassevitch also teaches a method that involves **creating at least a partial transformation into a stress induced martensitic phase** in staple 200:

“Staple 200 posses [sic] **superelasticity** and the plastic deformation is performed while staple 200 is fully austenitic, **to form stress-induced martensite**.

In **accordance** with a preferred embodiment of the present invention, staple 200 may be employed in its plastically deformed state, which resulted from **the length-span increase**. In other words, staple 200 may be **employed to provide bone fixation, while it is in a stress-induced martensite state.**”

Ex. 1005, 14:20-28; Ex. 1002, ¶98.

Monassevitch teaches that the stress-induced martensite is created by **stretching** the staple 200 to lengthen span L. Ex. 1002, ¶99. As Monassevitch explains, “length span L of staple 200 may be increased by straightening, or partially straightening at least one curvature 220, or curvatures 220 and 230.” Ex. 1005, 14:5-12. In other words, stretching staple 200 causes one or both of curvatures 220 and 230 to be straightened, which lengthens span L of the staple. *Id.*, Ex. 1002, ¶99. A POSITA would thus understand (or at least find it obvious) that stress-induced martensite would be created in one or both of curvatures 220 and 230. Ex. 1002, ¶99.

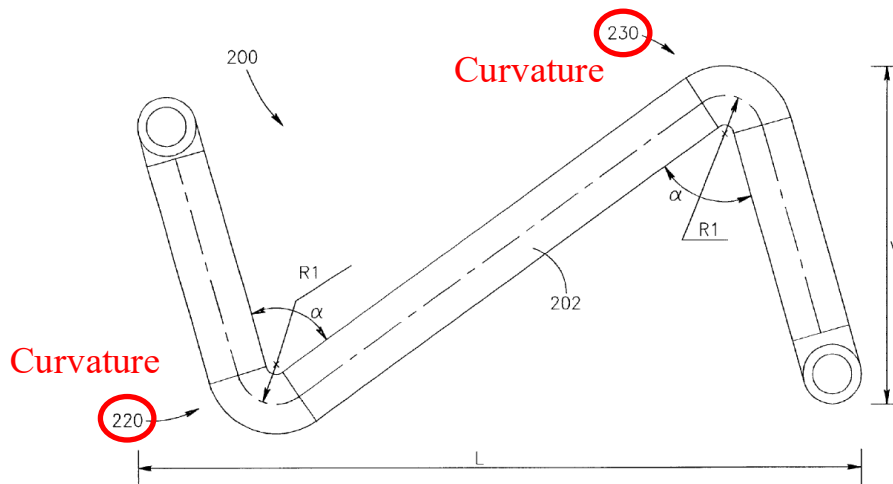


FIG. 10B

Accordingly, a POSITA would understand that this embodiment (staple 200) also discloses or suggests **stretching a responsive portion along the longitudinal axis** of the staple, such that **at least a partial transformation into a stress-induced martensitic phase is created in the responsive portion**. Ex. 1002, ¶100. A POSITA would recognize that the portion of staple 200 highlighted in blue below is **a responsive portion** of the staple because this portion includes a region or regions of the staple (i.e., one or more of the curvatures in the top portion of the staple) that are being deformed and exhibit stress-induced martensite (to provide compression to the bone when the staple is inserted). *Id.* In addition, Monassevitch teaches that the stretching is performed using apparatus 210, which is “similar in construction and operation to apparatus 60,” for “increasing length span L of web 202 of staple 200.” Ex. 1005, 14:29-35; *see also* 10:6-41 (describing operation of apparatus 60). And as illustrated below, the stretching created by apparatus 210 that causes this

deformation and lengthening to occur is performed **along the longitudinal axis** of the staple 200. Ex. 1002, ¶¶100-101.

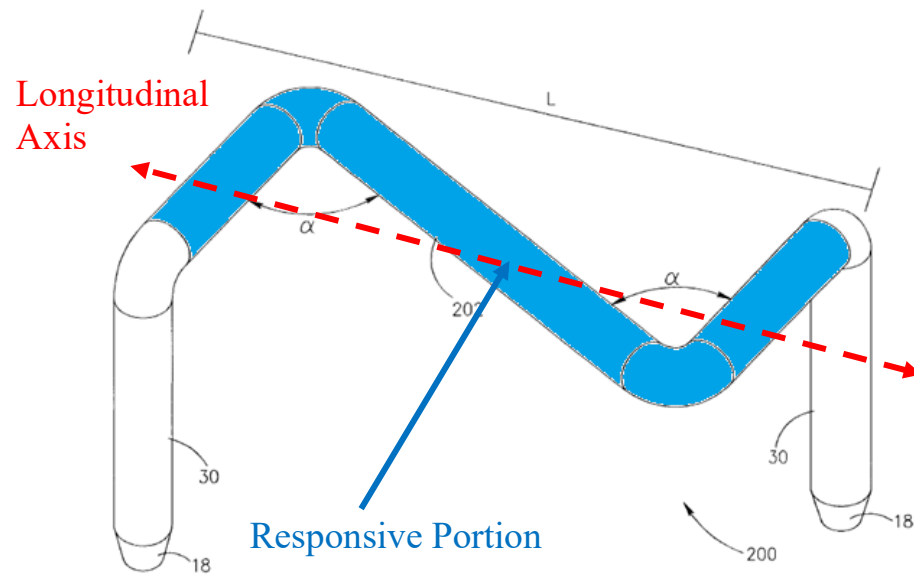


FIG. 10A

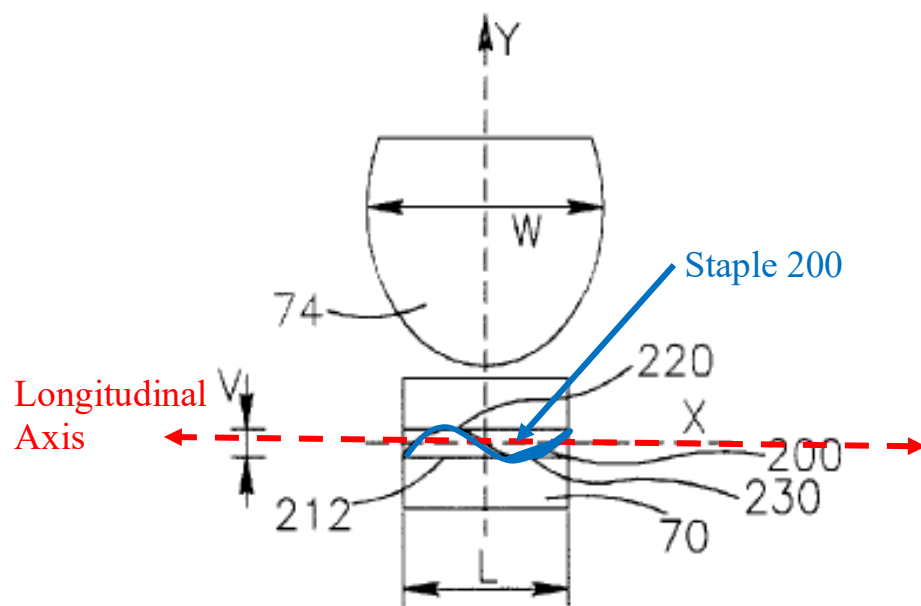
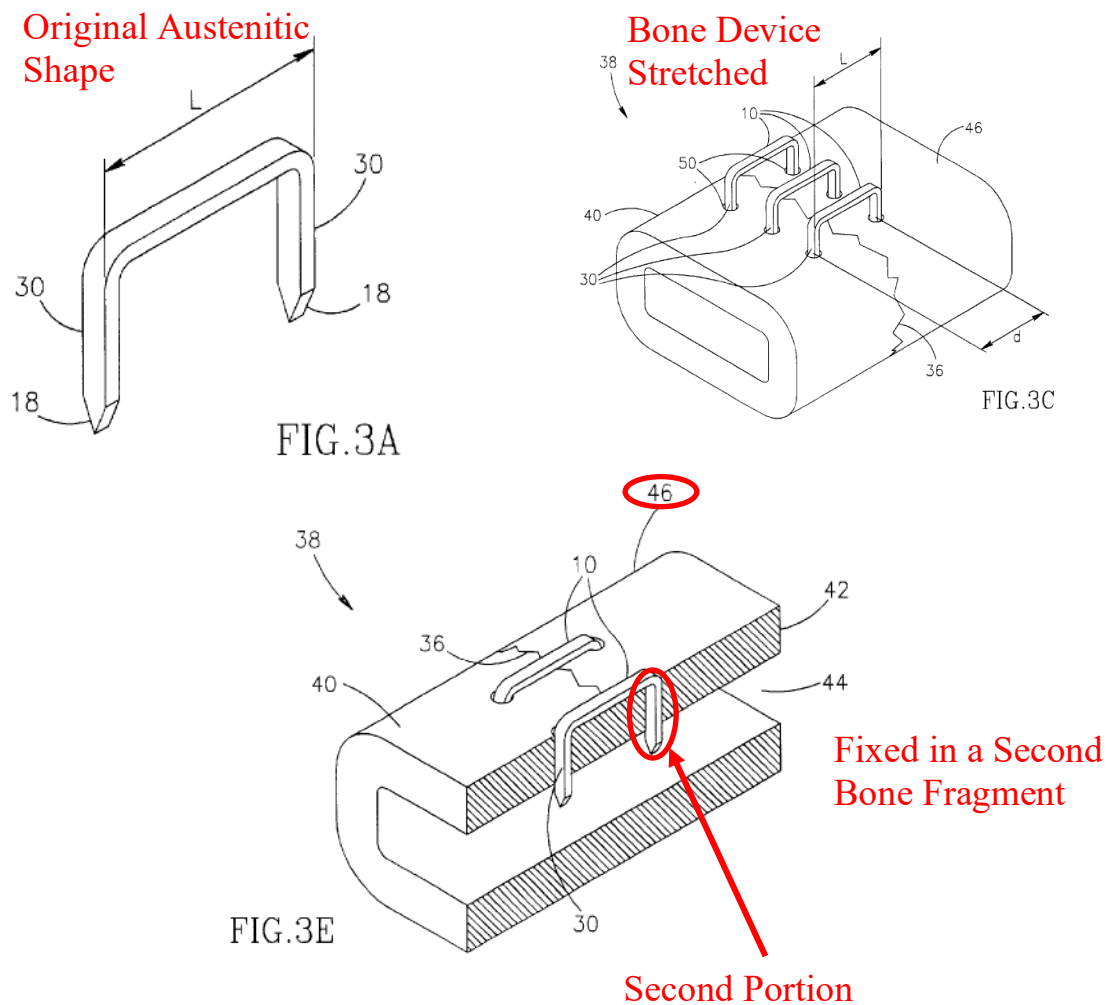


FIG. 11C

vi. **[1.4] after performing the stretching, fixing the second portion of the bone device to the second bone fragment; and**

For each of the three embodiments discussed above (staple 10, 150, and 200), Monassevitch teaches and/or suggests this limitation. Ex. 1002, ¶¶102-105.

With regard to staple 10, Monassevitch describes that the second portion of staple 10 is **fixed to the second bone fragment after the staple 10 has been stretched**. Ex. 1002, ¶103. As explained in element [1.1], Monassevitch teaches elongating length span L of the staple prior to inserting the staple into the second bone fragment 46. *Id.*; Ex. 1005, 12:21-29 (“As seen in FIGS 3C-3E, staple 10 of adjusted length span L, so that L is equal to d, is inserted into bone 38 ... staple 10 may be employed in a plastically deformed state that results from the length-span increase. In other words, the deformed shape that results from the length-span increase is the final shape, and staple 10 provides bone fixation, while in a stress-induced martensite state.”). As depicted below, once inserted, the staple 10 attempts to return to its original austenitic shape. Ex. 1002, ¶103. A POSITA would understand, or at least find it obvious, that the completion of insertion of the staple 10 into the bone fixes it to the bone fragment and the force caused by the staple 10 attempting to return to its pre-stretched austenitic shape results in the staple 10, including the second portion of staple 10, being further fixed in the second bone fragment 46. *Id.*



Likewise, for staple 150, Monassevitch teaches that the second portion of staple 150 is inserted into and **fixed to the second bone fragment 46 after stretching**. Ex. 1002, ¶104; Ex. 1005, 13:30-34 (“[S]taple 150 may be employed in its plastically deformed state, which resulted from the length-span increase. In other words, staple 150 may be employed to provide bone fixation, while it is in a stress-induced martensite state.”). A POSITA would understand, or at least find it obvious,

that the second portion of the staple would be fixed in the second bone fragment for the same reasons as discussed above for the first embodiment (i.e., the completion of insertion of the staple 150 into the bone fixes it to the bone fragment and the force caused by staple 150 attempting to return to its austenitic shape results in the staple, including the second portion, being further fixed in the second bone fragment). Ex. 1002, ¶104.

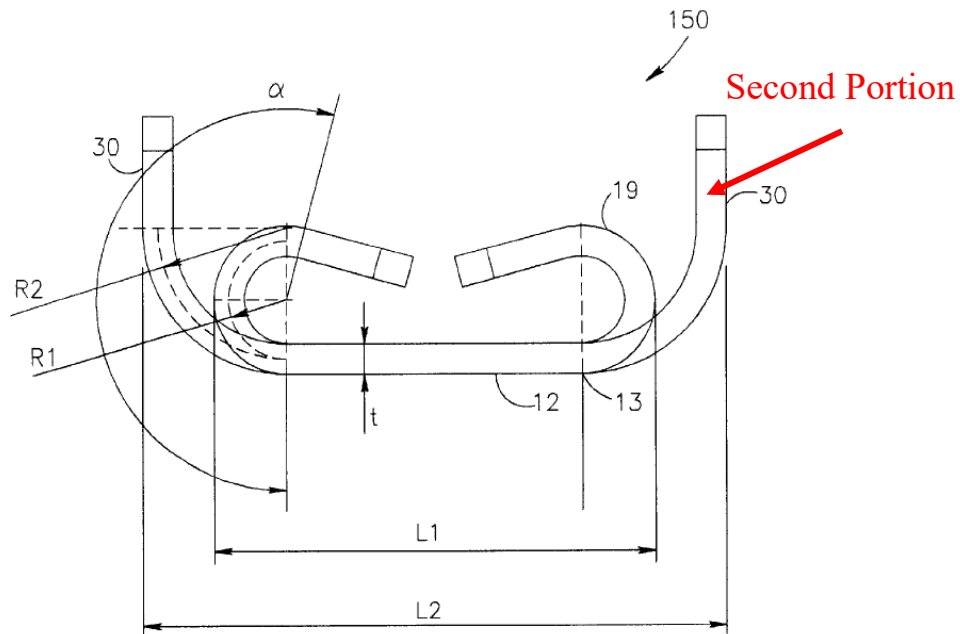
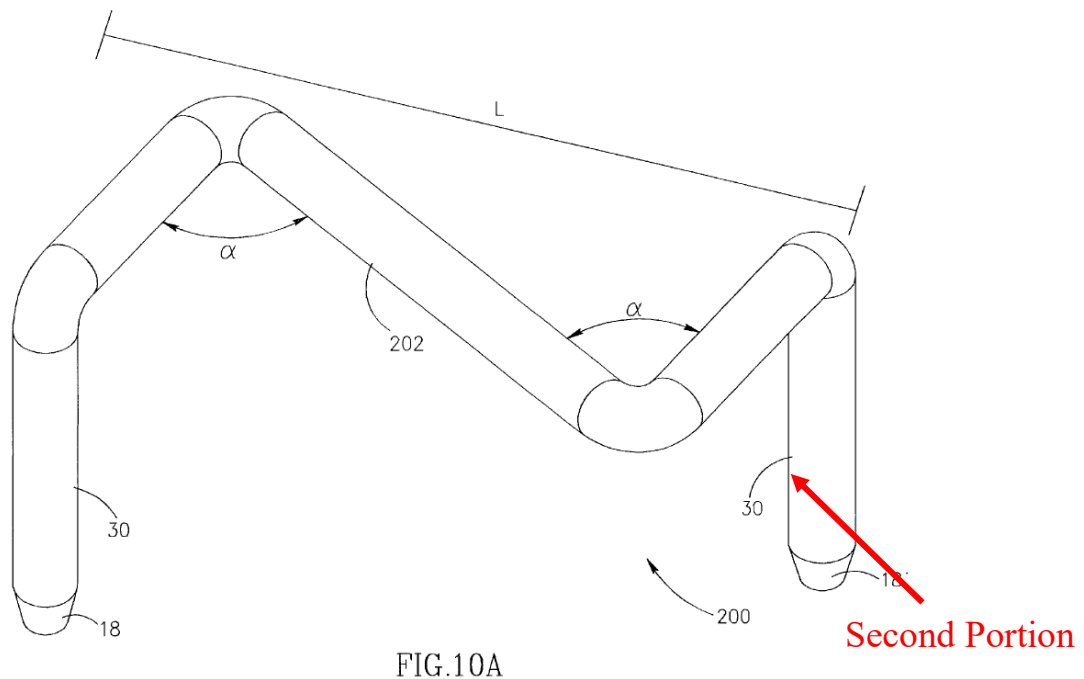


FIG. 8

The same is also true for staple 200, as Monassevitch teaches that staple 200 is inserted into and **fixed to the second bone fragment 46 after stretching** length span L of the staple. Ex. 1002, ¶105; Ex. 1005, 14:24-28 (“[S]taple 200 may be employed in its plastically deformed state, which resulted from the length-span increase. In other words, staple 200 may be employed to provide bone fixation,

while it is in a stress-induced martensite state.”). As with staples 10 and 150, a POSITA would understand, or at least find it obvious, that after insertion the second portion will be fixed in the second bone fragment (i.e., the completion of insertion of staple 200 into the bone fixes it to the bone fragment and the force caused by staple 200 attempting to return to its austenitic shape results in the staple, including the second portion, being further fixed in the second bone fragment). Ex. 1002, ¶105.



- vii. [1.5] wherein the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy.

As explained above in claim element [1.3], for each of the embodiments discussed (i.e., staples 10, 150, and 200), Monassevitch teaches and/or suggests that

the step of stretching the responsive portion along the longitudinal axis is performed in order to create stress-induced martensite:

[S]taple 10 may be employed in a plastically deformed state that results from the length-span increase. In other words, the deformed shape that results from the length-span increase is the final shape, and staple 10 may be used to provide bone fixation, **while in a stress-induced martensite state.**

* * *

Staple 150 posses [sic] Superelasticity and the plastic deformation is **performed while staple 150 is fully austenitic, to form stress-induced martensite...**In other words, staple 150 may be employed to provide bone fixation, while it is **in a stress-induced martensite state.**

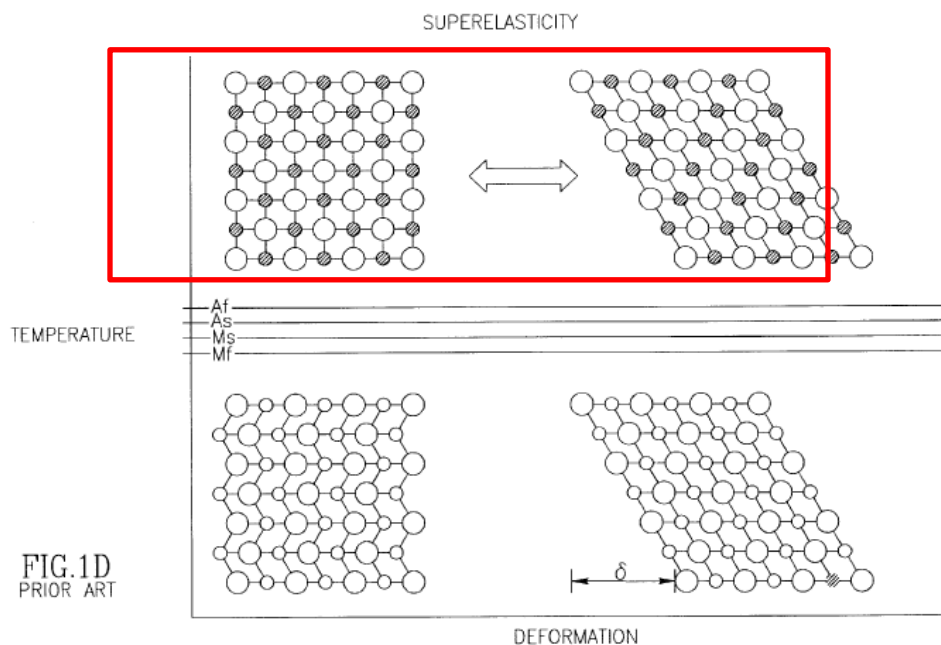
* * *

Staple 200 posses [sic] superelasticity and the plastic deformation is **performed while staple 200 is fully austenitic, to form stress-induced martensite...**In other words, staple 200 may be employed to provide bone fixation, while it is **in a stress-induced martensite state.**

Ex. 1005, 12:24-29, 13:25-34, 14:20-28; Ex. 1002, ¶107.

Monassevitch further teaches that the superelastic property of SMAs is exhibited at temperatures above A_f because that is the temperature range at which the SMA is austenitic and will form stress-induced martensite under stress. Ex. 1002, ¶108; Ex. 1005, 2:13-18 (“Another property that can be imparted to SMA elements ... is super-elasticity, or Stress-Induced Martensite (SIM). With this property, **a fully austenitic SMA element, at a temperature above A_f , will become martensitic and plastic under high stress, and deform under the stress.**”). As Monassevitch explains, “**a fully austenitic SMA element, at a temperature above**

A_f , will become martensitic and plastic under high stress, and deform under the stress.... **this property is present only above the temperature A_f ...** Ex. 1005, 2:16-25. Monassevitch further illustrates in Fig. 1D “a typical cyclic transformation of a superelastic alloy, at a constant temperature **above the temperature A_f ,**” which depicts “the transformation between the austenitic phase and a stress-induced martensitic phase” at a temperature above the austenite finish temperature A_f . *Id.*, 2:28-33; 15:35-16:3 (claiming a method that includes **plastically deforming the staple in a stress-induced martensitic phase at a temperature range of the fully austenitic phase;**” and 16:43-65 17:3-7 (same).



Accordingly, a POSITA would understand Monassevitch as describing that creating stress-induced martensite in staple 10, 150, and 200 involves stretching the

staple at a temperature greater than the austenite finish temperature. Ex. 1002, ¶106-108.

Moreover, as explained in Section IV.A, it was well known in the art that SMAs exhibit superelasticity (in which stress-induced martensite is formed upon the application of stress) at temperatures above the austenite finish temperature (A_f). Ex. 1002, ¶109. Indeed, Applicant acknowledged this fact during prosecution of the '222 patent. Ex. 1004, pp. 96-97 (8/19/10 Response) (explaining that “**Skilled artisans recognize the austenite finish temperature as the transition temperature (T1) of shape memory alloys** for the purposes of creating pseudo-elastic behavior. Namely, **the austenite finish temperature is the temperature at/above which the alloy "finishes" its transformation to the austenite phase and at/above which the only existing martensitic phase must be a stress-induced martensitic phase.**”).

A POSITA would thus have understood that, to create stress-induced martensite in staples 10, 150, and 200, as taught by Monassevitch, the stretching would be performed at a temperature greater than the austenite finish temperature of the SMA. Ex. 1002, ¶109. At a minimum, it would have been obvious to a POSITA to select an SMA for staples 10, 150, and 200 that has an austenite finish temperature lower than the temperature at which the staple would be stretched (operating room temperature), as doing so would ensure that that SMA staple would be austenitic—

and so capable of forming stress-induced martensite—when being stretched. *Id.*, ¶110.

viii. Claim 2

Claim 2 depends from claim 1 and further requires “**wherein stretching the bone device is performed with the bone device substantially in an austenitic phase.**” Monassevitch discloses and/or renders obvious to a POSITA, this limitation with respect to each of the staple 10, 150, and 200 embodiments, for the reasons described above in elements [1.2], [1.3] and [1.5]. Ex. 1002, ¶¶111-115.

With regard to staple 10, Monassevitch teaches that “the deformed shape that results from the length-span increase is the final shape, and staple 10 may be used to provide bone fixation, **while in a stress-induced martensite state.**” Ex. 1005, 12:26-29. Because the staple is lengthened to create a stress-induced martensite state, a POSITA would understand that the staple is being stretched while it is austenitic.³ Ex. 1002, ¶112-113; Ex. 1005, 2:13-18 (“Another property that can be imparted to SMA elements ... is super-elasticity, or Stress-Induced Martensite

³ During prosecution, in addressing a 112 rejection, Applicant argued that this claim was supported by disclosure in the specification that taught stretching when the shape memory alloy was fully austenitic. Ex. 1004, pp. 94-95 (8/19/10 Response); Ex. 1002, ¶112.

(SIM). With this property, **a fully austenitic SMA element**, at a temperature above A_f , will become martensitic and plastic under high stress, and deform under the stress.”); 15:66-16:3 (“plastically deforming the staple by reversible martensitic deformation includes **plastically deforming the staple in a stress-induced martensitic phase at a temperature range of the fully austenitic phase.**”).

Monassevitch likewise teaches that staples 150 and 200 are stretched while fully austenitic. Ex. 1002, ¶114-115; Ex. 1005, 13:25-34 (“[S]taple 150 possesses [sic] super elasticity and **the plastic deformation is performed while staple 150 is fully austenitic**, to form stress-induced martensite.”); 14:20-22 (“[S]taple 200 possesses [sic] superelasticity and **the plastic deformation is performed while staple 200 is fully austenitic**, to form stress-induced martensite.”).

ix. Claim 5

Claim 5 depends from claim 1 and further requires “**holding the shape memory alloy at a temperature greater than the austenite finish temperature of the shape memory alloy while the stretching is performed.**” For each of the three embodiments described above, Monassevitch discloses and/or renders obvious this limitation for the reasons described above with respect to claim limitation [1.5] and claim 2. Ex. 1002, ¶116.

x. Claim 6

Claim 6 depends from claim 1 and further requires “**holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the second portion is performed.**” Monassevitch discloses and/or renders obvious this limitation with respect to each of the three embodiments described above. Ex. 1002, ¶117.

For each of staples 10, 150, and 200, Monassevitch teaches that the staple is not only stretched to create a stress-induced martensitic state, but that it is used to “provide bone fixation” in the stress-induced martensitic state. Ex. 1005, 12:24-29 (“staple 10 may be employed in a plastically deformed state that results from the length-span increase. In other words, the deformed shape that results from the length-span increase is the final shape, and staple 10 may be used **to provide bone fixation, while in a stress-induced martensite state**”); 13:25-34. (“staple 150 may be employed **to provide bone fixation, while it is in a stress-induced martensite state**”; 14:20-28 (“staple 200 may be employed **to provide bone fixation, while it is in a stress-induced martensite state.**”). For the reasons discussed above with regard to element [1.5], a POSITA would have understood that, in order to create stress-induced martensite, and thus be in a stress-induced martensite state, the shape memory would be at a temperature greater than the austenite finish temperature of the SMA. Ex. 1002, ¶118.

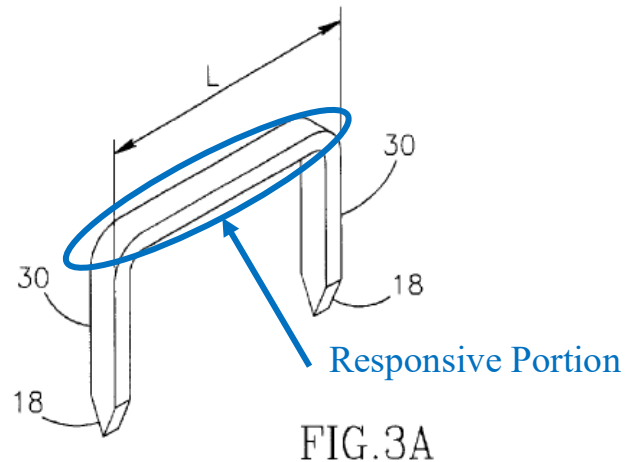
Accordingly, because Monassevitch teaches that the staple (10, 150, and/or 200) is lengthened to create a stress-induced martensite state and is inserted into the bone while in the stress-induced martensite state, a POSITA would understand that **the responsive portion is being held above the austenite finish temperature of the shape memory alloy while the staple (which includes the second portion) is being fixed.** Ex. 1002, ¶119. Indeed, as Monassevitch explains, the “super-elasticity, or Stress-Induced Martensite” property of a SMA is “**present only above the temperature A_f .**” Ex. 1005, 2:13-27.

xi. Claim 7

Claim 7 depends from claim 1 and further requires “**wherein inserting the bone device into the second bone fragment is performed while the responsive portion is substantially in an austenitic phase.**” Monassevitch discloses and/or renders obvious this limitation with respect to each of the three embodiments described above (staple 10, 150, and 200). Ex. 1002, ¶¶120-131.

a) Embodiment #1 – Staple 10

As described above, Monassevitch discloses that staple 10 is stretched to create stress-induced martensite in a responsive portion of the staple. *See* claim element [1.3].



Monassevitch further teaches that staple 10 can be provided in varying lengths (ranging from “as low as 4mm to as high as 80 or 100mm”), which are then capable of being stretched to varying lengths for insertion into the bone fragments. Ex. 1002, ¶123; Ex. 1005, 8:22-23; 12:30-58; 18:23-38. A POSITA would understand that the amount of stress-induced martensite that is created in the responsive portion would depend on the amount of stress that is applied and thus the resulting strain (i.e., the amount of stretching that is performed), and would recognize that reducing the overall stress on a device would be advantageous in certain applications as it may have a positive impact on the device’s fatigue performance. Ex. 1002, ¶124. Taking for instance the example of Monassevitch where a staple of 25mm length span L is arranged for use with length spans between 25 and 30mm (Ex. 1005, 12:52-53)—if the staple is stretched to 30 mm, there may be more stress-induced martensite formed than if the staple were stretched to 26mm. *Id.* Accordingly, if the staple is only stretched to only a little above 25mm, such as 26mm, then during insertion there

may only be a small amount of stress-induced martensite present in the responsive portion. *Id.* In this instance, a POSITA would understand that, even though some stress-induced martensite was created, the responsive portion of staple 10 would still be substantially in an austenitic phase. *Id.*, ¶124-125.

b) Embodiment #2– Staple 150

As described above, Monassevitch also discloses that staple 150 is stretched to induce stress-induced martensite in the responsive portion of the staple. *See* claim element [1.3].

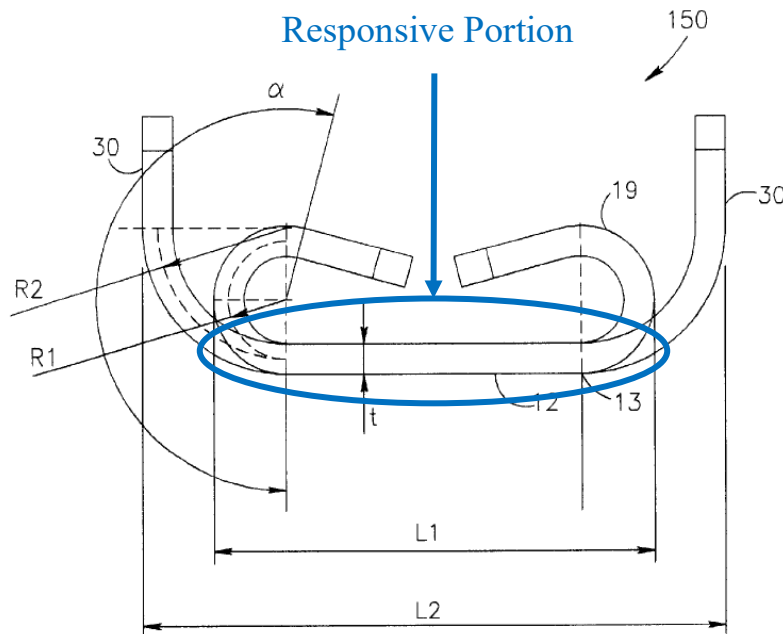


FIG. 8

As also described above in element [1.3], it would be obvious to a POSITA that, depending on how much staple 150 is stressed along the longitudinal axis, the stress-induced martensite may be created along the entire responsive portion (if the

surgeon continues to stretch the staple after straightedges 30 are straightened, such that web 12 is also stretched) or only at the ends of the responsive portion (if the surgeon stops stretching once straightedges 30 are straightened). Ex. 1002, ¶127. In either instance, at least a partial transformation into a stress-induced martensitic phase is created in the responsive portion. *Id.* However, in the latter instance (where stress-induced martensite is formed only at the ends of the responsive portion), a large part of the responsive portion, as highlighted in red below, will still be entirely austenitic when the staple is inserted into the bone. *Id.* Monassevitch thus discloses, or at least renders obvious to a POSITA, staple 150 being inserted into the bone fragments while the responsive portion is still substantially in an austenitic phase. *Id.*, ¶128.

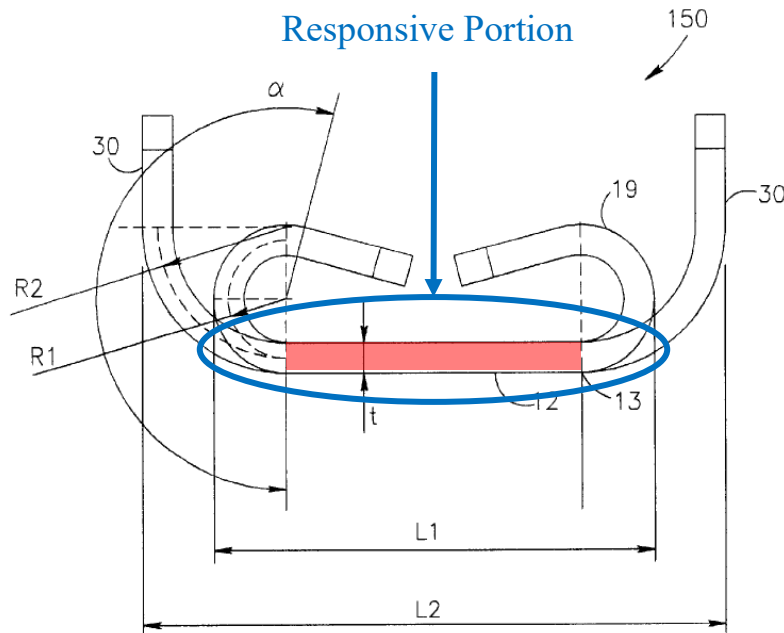


FIG.8

c) Embodiment #3– Staple 200

Likewise, Monassevitch teaches that staple 200 is also stretched to create stress induced martensite in a responsive portion of the staple 200: *See* claim element [1.3].

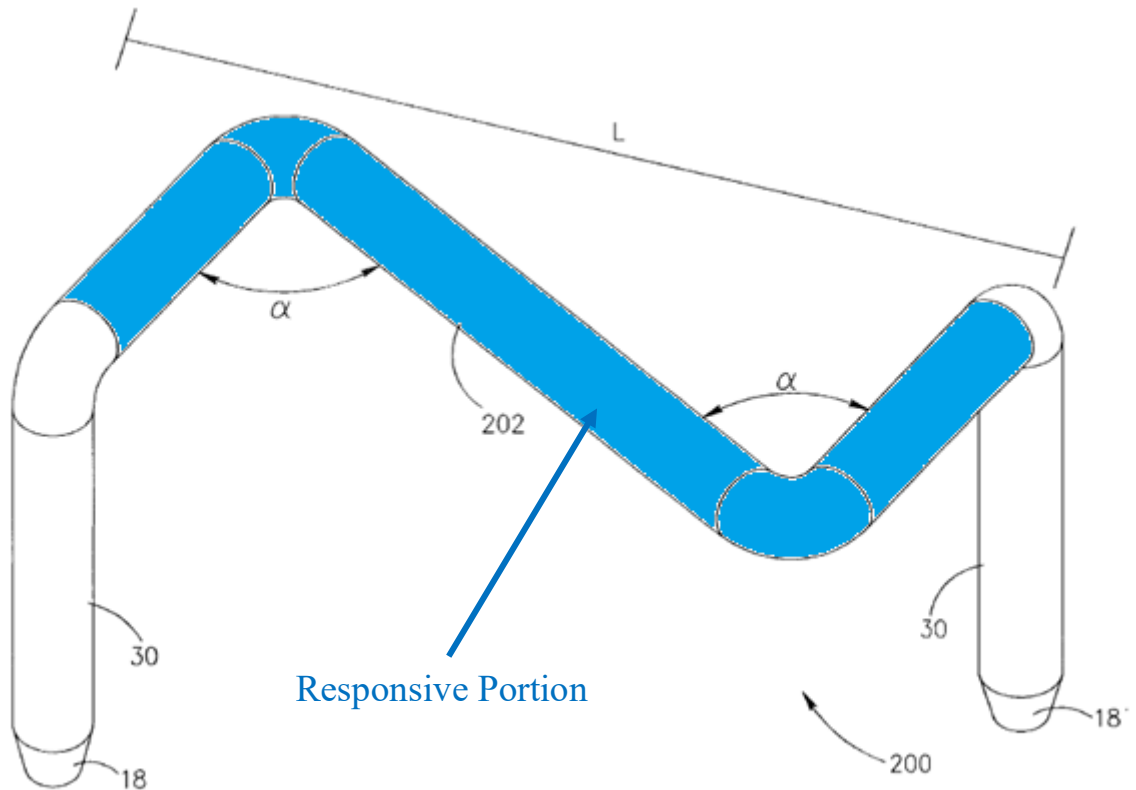


FIG.10A

As explained above, Monassevitch teaches that increasing the length span L (i.e., stretching the length span in the longitudinal direction) of staple 200 would result in the deformation of one or both of curvatures 220 and 230 (thus increasing the one or both angles α shown in figure 10A). *See* claim element [1.3]; Ex. 1005, 14:5-10 (“[L]length span L of staple 200 may be increased by straightening, or

partially straightening at least one curvature 220, or curvatures 220 and 230.’’). Thus, a POSITA would understand, or at least find it obvious, that the stress-induced martensite would be concentrated in one or both of curvatures 220 and 230. Ex. 1002, ¶130. As a result, a POSITA would also understand that most of the responsive portion, as depicted in red below, would remain austenitic when the staple is being inserted into the bone. *Id.* Accordingly, Monassevitch discloses, or at least renders obvious to a POSITA, staple 200 being inserted into the bone fragments while the responsive portion is still substantially in an austenitic phase. *Id.*, ¶131.

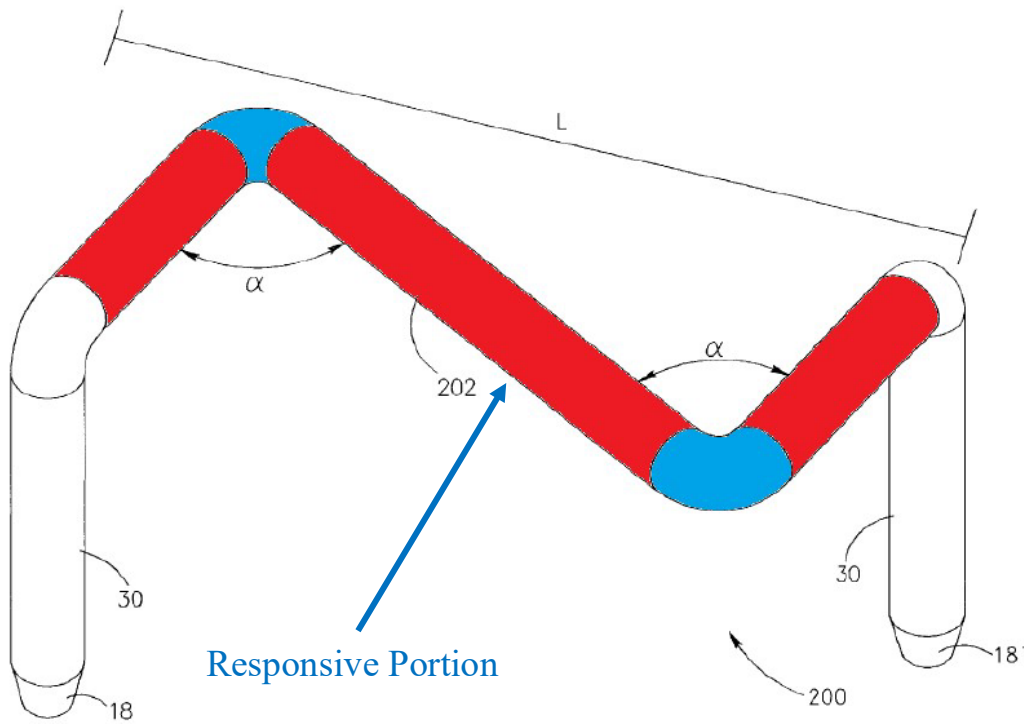


FIG.10A

xii. Claim 8

Claim 8 depends from claim 1 and further requires “**wherein inserting the bone device into the first bone fragment is performed while the responsive portion is substantially in an austenitic phase.**” Each of staples 10, 150, and 200 are inserted into the first bone fragment at the same time that they are inserted into the second bone fragment. Ex. 1002, ¶132; *see also* Ex. 1005, Fig. 3C. As such, for each of the three relevant embodiments, Monassevitch discloses and/or renders obvious this limitation for the same reasons as discussed for claim 7. Ex. 1002, ¶132.

xiii. Claim 9

Claim 9 depends from claim 1 and further requires “**wherein the first portion comprises the shape memory alloy.**” Monassevitch teaches that each of staples 10, 150, and 200 is made entirely of SMA. Ex. 1005, 14:36-38 (“**staples 10, 150 and 200 are formed of a shape memory alloy...**”); 3:54-56; 4:35-36; 8:18-19; 12:28-29; 14:7. Accordingly, the first portion of each of staples 10, 150, and 200 “comprises the shape memory alloy.” Ex. 1002, ¶¶133-134.

xiv. Claim 10

Claim 10 depends from claim 1 and further requires “**wherein the second portion comprises the shape memory alloy.**” Monassevitch teaches that the entirety of each of staples 10, 150, and 200 is made of SMA. Ex. 1005, 14:36-38 (“In accordance with a preferred embodiment of the present invention, **staples 10,**

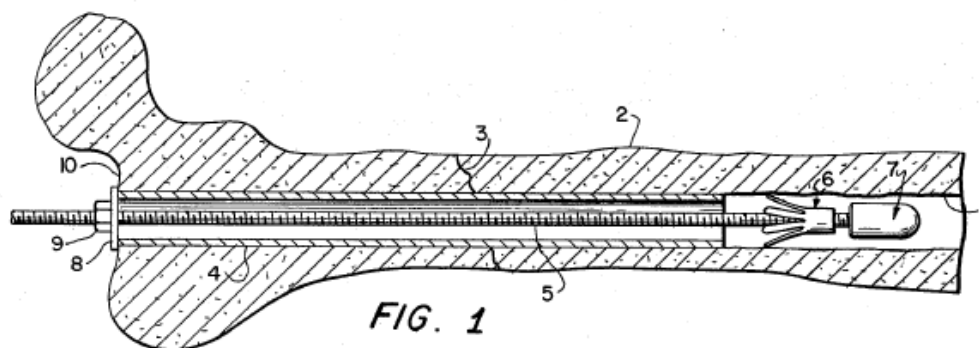
150 and 200 are formed of a shape memory alloy...”); 3:54-56; 4:35-36; 8:18-19; 12:28-29; 14:7. Accordingly, the second portion of each of staples 10, 150, and 200 “comprises the shape memory alloy.” Ex. 1002, ¶¶135-136.

C. Ground 2 – Claims 1-10 are Obvious Over Bolesky and Hoffman

All of the limitations recited by claims 1-10 would have been obvious to a POSITA in view of the teachings of Bolesky and Hoffman.

i. Overview of Bolesky

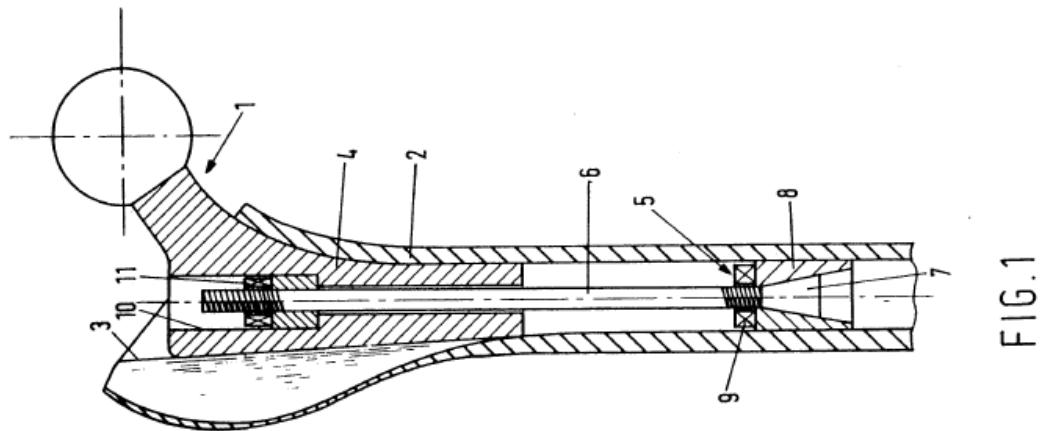
Bolesky is directed to “a fracture fixation device for use within the medullary canal of a fractured tubular bone.” Ex. 1006, Abstract. Bolesky explains that “[a]s a result of prior art work in the treatment of bone fractures, it has been learned that a stable osteosynthesis at the fracture is obtained if the bone portions of the fracture can be secured and supported in a completely stable condition in compression or in distraction.” *Id.*, 1:6-10. An object of Bolesky is to provide a device “for supporting the fracture in compression.” *Id.*, 1:45-48. To that end, Bolesky discloses a fracture fixation device, as illustrated below. *See also Id.*, 2:61-3:20.



Once the device has been inserted into the bone, “nut 9 is turned until washer 8 is snug against the end face of the bone.” *Id.*, 3:56-61. Bolesky teaches that as the nut is tightened, the gripper unit 6 is moved towards the bone canal entrance (i.e. to the left in Fig. 1 above), which causes the tips of the fingers in the gripper unit 6 to “penetrate the wall of canal 1” and resist further movement *Id.*, 3:63-4:2. Then, with the further tightening of the nut, a “force is developed which tensions rod 5.” *Id.* This “effects a positive compressive force at the fracture site, which “secures the bone in a stable condition which promotes osteosynthesis.” *Id.*, 4:9-12.

ii. Overview of Hoffman

Hoffman discloses a bone device to secure a prosthesis to a section of bone. Ex. 1007, Abstract. The Hoffman device has a generally similar design to that of Bolesky. Ex. 1002, ¶142. It includes a “tip 5” that is designed to be fixed in a canal in the bone, a “tie member 6” (also referred to in Hoffman as a “rod 6”) that is designed to be tensioned, and a “nut 11” that is turned to tension the rod Ex. 1007, 4:51-5:11.



Hoffman teaches that “the tie element is a rod of shape memory metal (NITINOL)” that, when in tension, places the two ends of the device in a state of compression. *Id.*, Abstract, 1:60-61, 2:18-21. Hoffman explains that, by providing a rod made of SMA, the superelastic property of the material can be utilized to create compression (i.e., the SMA tie member/rod will undergo a “martensitic structural change in the solid state, induced by stress, which is reversible and in the martensitic range has a shape recovery stress of constant value. This effect is called superelasticity.”). *Id.*, 5:4-17.

Similar to the Bolesky device, tip 5 of Hoffman is first inserted in the marrow cavity of a long bone, such as a femur, with “a number of segments 8” extending therefrom that, like the gripper unit 6 of Bolesky, grip the inner surface of the bone cavity. *Id.*, 4:57-66; Ex. 1002, ¶144. When the tip 5 has been fixed in the bone, the tie member/rod 6 “is stretched by tightening nut 11....” *Id.*, 5:18-22. At this point,

the tie member “becomes stress-induced martensite” and “[w]hen the elongation is consumed, the material automatically returns into the austenitic phase.” *Id.*, 5:12-17. This will cause “the proximal part 4 [to be] pulled in the direction of tip 5 with a constant force.” *Id.*, 5:24-28.

iii. Overview of The Combination

The combination of Bolesky and Hoffman renders the challenged claims obvious. Ex. 1002, ¶145. Bolesky discloses a fracture fixation device for a long bone that operates by tensioning a rod to create compression between two bone fragments. Bolesky does not expressly teach the rod is made of SMA. However, using shape memory materials such as Nitinol to enhance and maintain compression in medical devices was well-known by 2004, and Hoffman expressly teaches a device for use in a long bone that tensions a Nitinol rod to create compression through the superelastic property of SMA. *Id.* Thus, it would have been obvious to modify the device of Bolesky to use a rod made out of SMA and, more specifically, to utilize the superelastic property of the SMA rod taught by Hoffmann (i.e., by tensioning the rod to create stress-induced martensite) to provide continuous compression across the fracture site. *Id.*

iv. Rationale (Motivation) Supporting Obviousness

A POSITA would also have been motivated to apply the teachings of Hoffman to Bolesky for the reasons described in the claim mapping below. For example, both

references are directed to fixation of implantable orthopedic devices in a long bone (such as a femur) and for providing compression between the distal and proximal ends of the device. Ex. 1002, ¶146. Both devices are designed to be inserted into the marrow canal of the long bone. *Id.* Both devices provide the compression by tensioning a rod. *Id.* And both devices tension the rod by turning a nut. *Id.* Thus, a POSITA looking for ways to improve or enhance the compression in the fracture fixation device of Bolesky would naturally look to Hoffmann. *Id.* As a POSITA would understand, Hoffmann's superelastic rod provides for continuous compression over time that improves upon traditional non-SMA devices inasmuch as such traditional designs can lose compression over time due to stress relaxation and/or bone resorption. *Id.*

v. Graham Factors

The **level of ordinary skill** is as proposed in Section VI.

The **scope and content of the prior art** are discussed throughout the Ground.

The **differences between the prior art and the claims** are discussed in the "Overview of the Combination" and below.

Petitioner is not aware of any **secondary considerations** that would make an interference of non-obviousness more likely.

vi. Analogous Art

Bolesky and Hoffman are analogous art. They are in the same field of endeavor as the '222 Patent. Ex. 1002, ¶147. Although Bolesky and the '222 Patent address a slightly different issue (fracture fixation) than Hoffman (securing a prosthesis to a bone), all three relate to implantable orthopedic devices utilizing compression. *Id.*; Ex. 1006, Abstract; Ex. 1007, Abstract, Ex. 1001, Abstract. Bolesky and Hoffman are also both pertinent to the problem that the '222 Patent purports to be addressing; namely maintaining compression across fracture fragments. Ex. 1002, ¶147; Ex. 1001, 1:48-62; Ex. 1006, 1:45-48; Ex. 1007, 1:4-5, 2:25-30. Thus, all three patents relate to maintaining compression on bone via an orthopedic implant. Ex. 1002, ¶147.

vii. Reasonable Expectation of Success

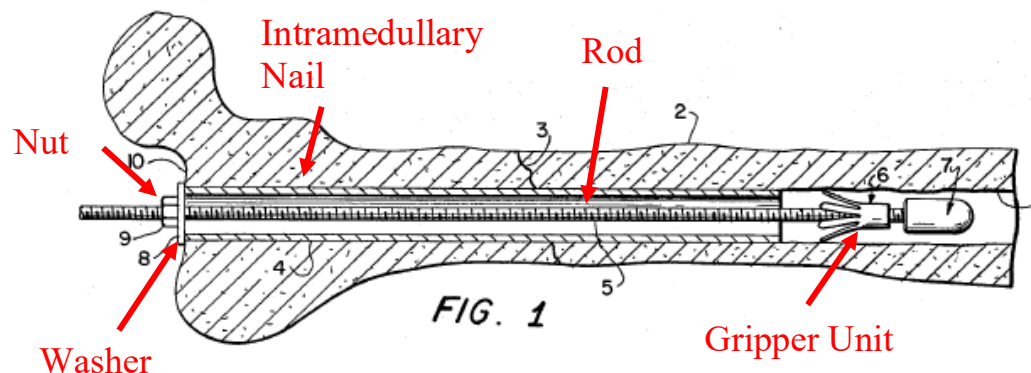
A POSITA would have a reasonable expectation of success in using a Nitinol rod, as taught in Hoffman, as a substitute for the threaded rod of Bolesky. Ex. 1002, ¶148. A POSITA would have known that Nitinol was biocompatible and a suitable alternative to the stainless steel used in Bolesky. *Id.* Additionally, the superelastic properties of Nitinol were well known in the art and routinely used by skilled artisans in the design of orthopedic fracture fixation devices. *Id.* Thus, a POSITA in the relevant timeframe would have had a reasonable expectation of success in combining Bolesky and Hoffman in the manner discussed herein. *Id.*

viii. [1.p] A method, comprising:

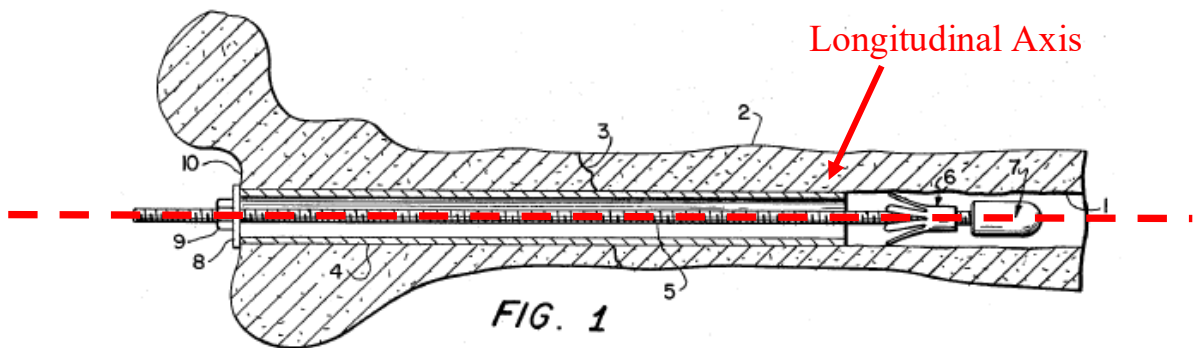
The preamble is not limiting. Nonetheless, Bolesky discloses a method for using a “fixation device adapted for use within the medullary canal of a fractured tubular bone.” Ex. 1006, Abstract; 1:45-48; Ex. 1002, ¶150. Hoffman likewise discloses a method, namely for using a device that is “received in... a marrow cavity” to “secur[e] a prosthesis to a bone.” Ex. 1007, Abstract; Ex. 1002, ¶150.

- ix. [1.1] inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment, wherein the inserting causes a first portion of the bone device to contact the first bone fragment and causes a second portion of the bone device to contact the second bone fragment, the second portion different from the first portion;**

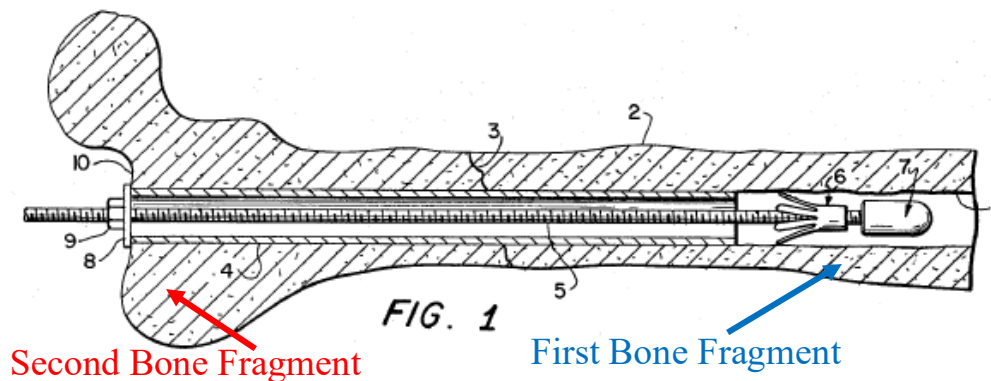
Bolesky discloses a **bone device** in the form of a “fracture fixation device.” Ex. 1002, ¶151; Ex. 1006, 2:61-3:4. The device comprises, *inter alia*, an “intramedullary nail 4,” a “threaded rod 5,” a “gripper unit 6,” “washer 8,” and a “nut 9.” *Id.*



The device has a **longitudinal axis**, which a POSITA would understand as being depicted by the dashed red line below. Ex. 1002, ¶152.

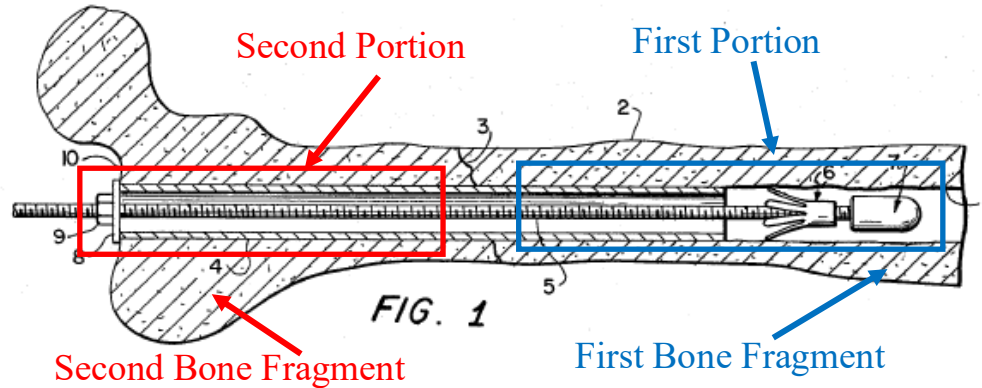


Bolesky teaches that the fixation device is **inserted into a first bone fragment and a second bone fragment**. Ex. 1002, ¶153. As Bolesky explains, the fixation device is installed “within the medullary canal of a fractured hollow bone, such as the femur and tibia.” Ex. 1006, 1:51-54. Fig. 1 illustrates the device “in place in the medullary canal 1 of a **femur 2 which has been fractured at 3.**” *Id.*, 2:61-63. Thus, in Fig. 1, there is a first bone fragment to the right of the fracture location 3 and a second bone fragment to the left of the fracture location 3. Ex. 1002, ¶153. Both are bone fragments because each is a piece of bone that was broken from the original intact femur. *Id.*



Bolesky teaches that, to insert the device, “canal 1 is reamed.” *Id.*, 2:63-65. The “subcombination of a threaded rod 5, a gripper unit 6 and a nose member 7 is then inserted through the bored entrance into the medullary canal.” *Id.*, 2:65-67. “An open ended intramedullary nail 4 is then inserted over the rod 5 so that the nail **extends from the entrance of the canal to a point well beyond the fracture 3** to facilitate stabilization.” *Id.*, 3:1-4.

Insertion of the fixation device causes **a first portion of the device to contact a first bone fragment and a second portion of the device to contact a second bone fragment**, where **the second portion is different from the first portion**. Ex. 1002, ¶¶154-156. As illustrated in annotated Fig. 1 below, the first portion of the device, which includes a portion of nail 4 and/or gripper unit 6, is positioned in contact with a first bone fragment. *Id.*, ¶155. The second portion of the device, which includes a different portion of nail 4, washer 8, and nut 9, is positioned in contact with a second bone fragment. *Id.*



- x. [1.2] wherein the bone device comprises a shape memory alloy having an austenite finish temperature;

Bolesky states that the device “is to be made out of a biocompatible material.”

Ex. 1006, 4:62-63. Bolesky expressly identifies only “316 Stainless Steel” as an example of such a biocompatible material. *Id.* As discussed below, however, it would have been obvious to a POSITA to substitute a different biocompatible material, such as a **shape memory alloy** like Nitinol, for the threaded rod 5 of Bolesky. Ex. 1002, ¶¶157-171.

- a) **The object of Bolesky is to provide compression across the fracture site**

Bolesky teaches that “stable osteosynthesis at [a] fracture is obtained if the bone portions of the fracture can be secured and supported in a completely stable condition in compression or in distraction.” Ex. 1006, 1:6-10. Thus, Bolesky explains that one object of the fixation device is to “support[] the fracture in compression.” *Id.*, 1:45-48.

The Bolesky device creates compression by tensioning a rod that spans both sides of a fracture site. Ex. 1002, ¶¶158-159. Bolesky teaches that “[a]fter the device has been installed in the bone, nut 9 is turned until washer 8 is snug against the end face of the bone ... to move rod 5 and gripper unit 6 a predetermined small distance toward the entrance of the canal.” Ex. 1006, 3:56-61. “As the nut is tightened, movement of gripper unit 6 ... causes the tips 13 of the fingers to penetrate the wall of canal 1.” *Id.*, 3:63-66. “As such penetration increases, the fingers 13 resist further movement of the gripper unit relative to the bone, and, with tightening of the nut still causing hub 11 to move, **a force is developed which tensions rod 5.**” *Id.*, 3:66-4:2. As Bolesky explains, “[t]he resilient force created by the tightening of the nut 9 against washer 8 and bone interface 10 ... **effects a positive compressive force at the fracture site.**” *Id.*, 4:5-9. “This force at the fracture site exerts uniform compression on the entire perimeter of the fracture line and secures the bone in a stable condition which promotes osteosynthesis.” *Id.*, 4:9-12.

b) SMAs Were Known To Improve Compression In Medical Devices

The use of SMAs, such as Nitinol, in medical devices was well known long before the filing of the '222 patent,. Ex. 1002, ¶160. By the 1990s, Nitinol was “becoming one of the materials of choice for many designers and engineers.” *Id.* (citing Ex. 1008). Engineers considered it a “staple of their design toolbox.” *Id.*

(citing Ex. 1016). And physicians were “routinely familiar with both Nitinol and superelasticity.” *Id.* (citing Ex. 1016).

As discussed in Section IV.A, Nitinol was known to be biocompatible in humans. *Id.*, ¶161 (citing Ex. 1008; Ex. 1010; Ex. 1011). And it was known that Nitinol could be tailored to exhibit superelasticity at room and/or body temperature (i.e., the austenite finish temperature below room and/or body temperature). *Id.* (citing Ex. 1010). In fact, one typical Nitinol composition being used in many medical devices was superelastic at both room and body temperature. *Id.* (citing Ex. 1008).

It was also known that Nitinol could provide the ability to make “self-locking, self-expanding, and self-compressing implants.” *Id.*, ¶162 (citing Ex. 1011). Indeed, long before the priority date of the ’222 patent, researchers had taught and disclosed using Nitinol, and specifically the superelastic property of Nitinol, to improve upon the compression capabilities of bone plates, marrow nails, staples, clips, and the like. *Id.* (citing Ex. 1017).

c) Hoffman Discloses A Bone Device Having An SMA Rod Tensioned to Provide Compression

Hoffman discloses a bone device similar to that of Bolesky albeit for securing a prosthesis to a section of bone using an SMA (nitinol) tie member that, when in tension, places the bone in a state of compression. Ex. 1002, ¶163. Ex. 1007, Abstract, 1:60-61, 2:18-21. As illustrated in Fig. 1 below, the Hoffman device

includes a “tip 5,” “tie member 6” (also referred to in Hoffman as a “rod 6”) and “nut 11.” *Id.*, 4:51-5:11. Hoffman teaches that the tie member/rod is preferably “made of a **shape memory metal (NITINOL).**” *Id.*, 1:60-61.

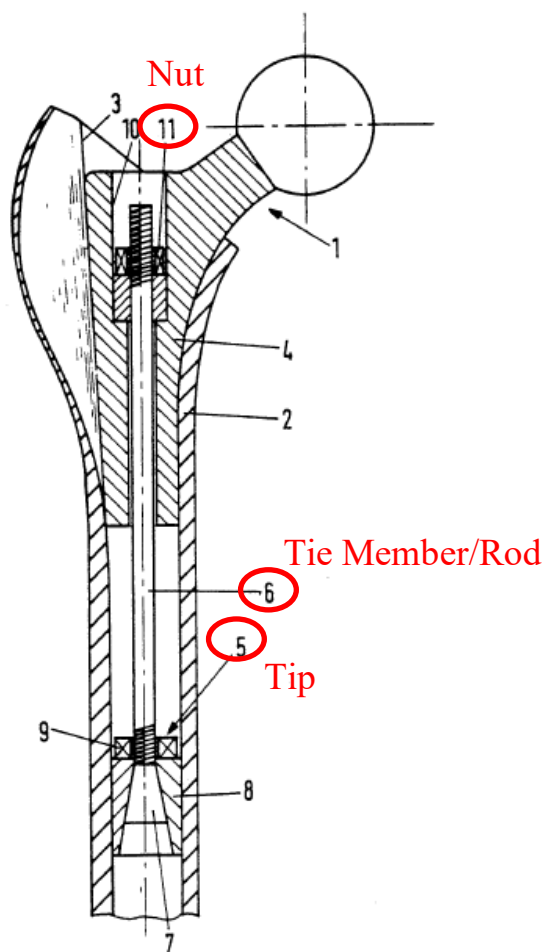


FIG. 1

Similar to Bolesky, tip 5 of Hoffman is inserted “in the marrow cavity” of a long bone, such as a femur, and “[w]hen the tip 5 has been fixed in bone 2, tie member 6 is stretched by tightening nut 11.” *Id.*, 5:18-22. The purpose of using SMA for the tie member/rod is to utilize the material’s superelastic properties to

create compression between the two ends of the device. *Id.*, 5:4-28. As Hoffman explains, the “tie member is a rod...made of shape memory metal...such as [Nitinol]...capable of undergoing a martensitic structural change induced by stress, which is reversible.” *Id.*, 5:4-10. Hoffman teaches that this property, “called superelasticity,” is utilized “by stretching the shape memory metal in the austenitic phase, as a result of which [the shape memory material] becomes stress-induced martensite.” *Id.*, 5:10-17. Then, as “long as the elongation has not been ‘consumed,’” the stress-induced martensite created in the tensile member/rod will cause “the proximal part 4 [to be] pulled in the direction of tip 5 with a constant force.” *Id.*, 5:24-28.

In summary, Hoffman discloses an implantable bone device that stretches an SMA rod in its austenitic phase (via tightening nut 11) to create stress-induced martensite, which in turn provides a tension force between the two ends of the rod and draws the two ends of the Hoffman implant toward each other. Ex. 1002, ¶¶164-165.

d) It Would Have Been Obvious To Modify Bolesky to Use A Rod Comprising SMA

A POSITA looking for improved or enhanced means of compressing opposite ends of the fracture fixation device of Bolesky would naturally look to the prior art and find Hoffmann, which shows the use of an SMA “tie-member,” placed in tension, for the purposes of compressing fixed, opposite ends of a bone. Ex. 1002,

¶166. Replacing the rod of Bolesky with the SMA rod of Hoffman to benefit from the superelastic properties of Nitinol would be an obvious design choice to a POSITA. *Id.* A POSITA would have a high expectation of success in combining these teaching to create compression across a fracture. *Id.* Both Bolesky and Hoffman teach structurally similar devices, and SMAs (like Nitinol) were well known as being capable of providing continuous compression within the body to promote healing. *Id.*

Additionally, a POSITA would have recognized that Nitinol is a suitable “biocompatible material” that can readily substitute for stainless steel in applications like the Bolesky rod. *Id.*, ¶167. The availability and use of Nitinol in medical devices was well known and addressed in the literature. *Id.* A POSITA would have been motivated to modify Bolesky’s rod to use Nitinol because this substitution would improve upon Bolesky’s goal of providing compression across the fracture site. *Id.*

The modified device would thus either be (i) a simple substitution of the Nitinol rod 6 in Hoffman for the stainless steel rod 5 in Bolesky, or (ii) the threaded rod 5 of Bolesky manufactured from Nitinol material. Ex. 1002, ¶168. In either approach, the device would operate using the fixation method of Bolesky, which would stretch the SMA rod, thus creating stress-induced martensite. *Id.* This will

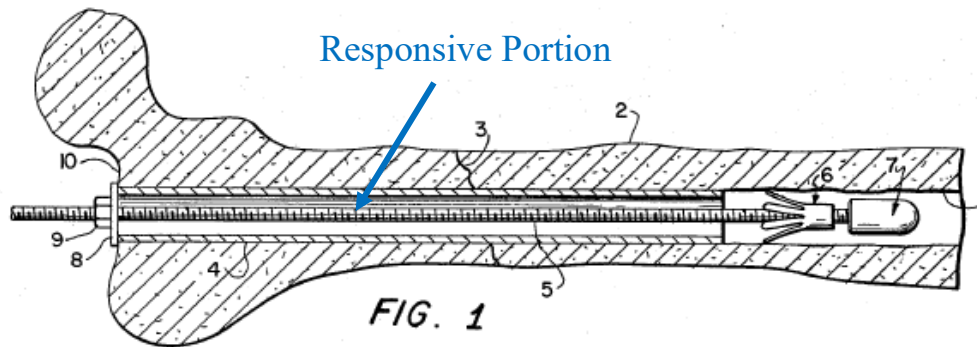
in turn create a superelastic effect resulting in a constant force providing compression across the fracture site. *Id.*

Alternatively, it would also have been obvious to a POSITA to further modify Bolesky to use both the rod and the fixation approach of Hoffman, which is expressly disclosed as being used to create stress-induced martensite in an SMA rod. Ex. 1002, ¶¶169-170. Specifically, it would have been obvious to substitute the gripper unit 6 and nose 7 elements of Bolesky with the distal attachment assembly of Hoffman (i.e., wedge-shaped part 7, segments 8 and nut 9). *Id.* In this case, the modified distal attachment assembly would be used to fix the distal end in the bone. *Id.* ¶170. Then, nut 9 of Bolesky would be tightened to stretch the shape memory alloy rod. *Id.* Selecting between the fixation approaches of Bolesky and Hoffman would have been a simple matter of design choice, and a POSITA would have recognized that either approach can be used with predictable results. *Id.*

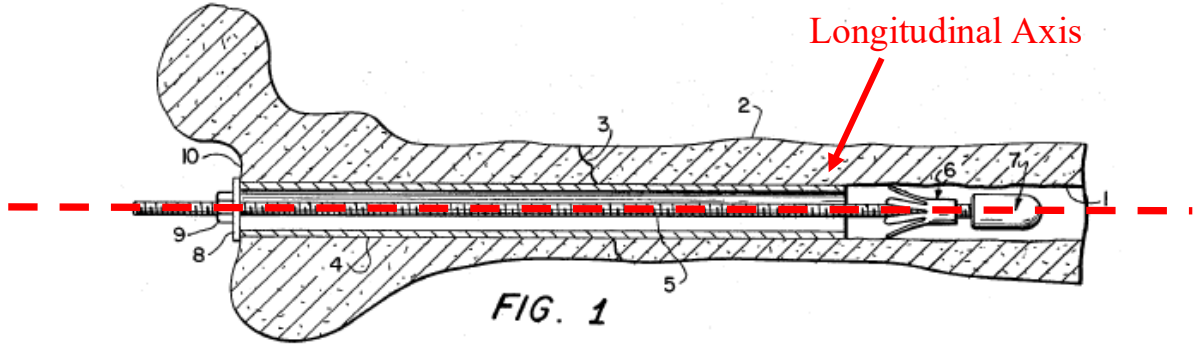
A POSITA would also understand that the SMA would have **an austenite finish temperature**. Ex. 1002, ¶171. As explained above, all SMAs, including Nitinol, are characterized by a number of transformation temperatures. *See supra* Section IV.A. One of these is the austenite finish temperature (A_f), which is the temperature above which the transformation of martensite to austenite is complete. *Id.*, Ex. 1002, ¶171.

- xi. [1.3] creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis;

As discussed above, it would have been obvious to modify the fixation device of Bolesky as described above to include a rod made from an SMA, like Nitinol. Because the modified rod would be stretched to create stress-induced martensite (as described more below), which results in compression being applied to the bone, a POSITA would recognize that the modified rod represents a “responsive portion.” Ex. 1002, ¶¶172-173.



As Bolesky teaches, rod 5 is tensioned by tightening nut 9. Ex. 1006, 3:56-4:12. This causes the responsive portion to be stretched **along the longitudinal axis** of the device. Ex. 1002, ¶174.



A POSITA would also recognize that longitudinally stretching modified rod 5 in the Bolesky device would **create at least a partial transformation into a stress-induced martensite phase.** *Id.*, ¶175. As Hoffman describes, Nitinol is an SMA capable of exhibiting superelasticity when implanted in the human body. *See supra* Section IV.A and element [1.2]; Ex. 1007, 1:60-2:17; 5:4-17. Indeed, as Hoffman teaches, “**stretching the shape memory metal in the austenitic phase**” results in the formation of “**stress-induced martensite.**” Ex. 1007, 5:12-17; *see also* 2:10-17. Thus, a POSITA would understand that implementing a shape memory rod in Bolesky will preferably result in the creation of stress-induced martensite when the rod is stretched. Ex. 1002, ¶175.

Moreover, as discussed above, Nitinol can be tailored to ensure its austenite finish temperature is below body temperature. Ex. 1002, ¶176. A POSITA would

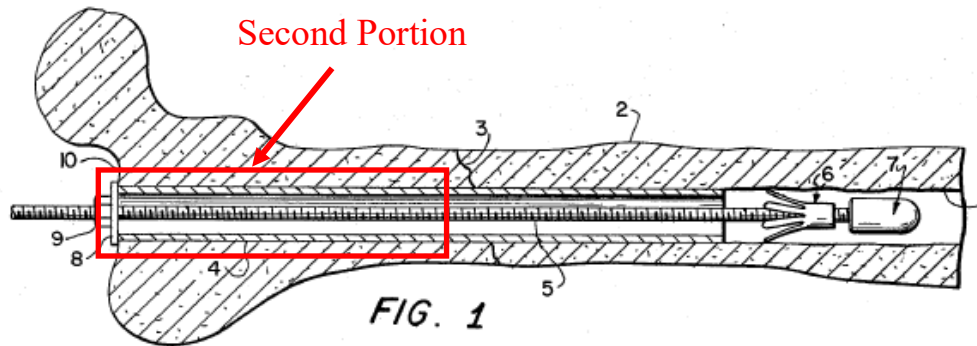
have found it obvious to select the properties and dimensions of the Bolesky rod 5 such that the tensioning of nut 9 in Bolesky is sufficient to stretch at least a portion of the rod into its superelastic range (to create stress-induced martensite). *Id.* And doing so was well within the knowledge and capabilities of those skilled in the art at the time. *Id.*

Alternatively, as described above in element [1.2], it would also have been obvious to substitute the fixation approach of Bolesky with the fixation approach of Hoffman. And, in that regard, Hoffman expressly teaches that its fixation approach **stretches the rod in the longitudinal direction so as to create stress-induced martensite** in the tensile member/rod. Ex. 1007, 5:4-28; Ex. 1002, ¶177. Accordingly, the combination of Bolesky and Hoffman renders this element obvious. Ex. 1002, ¶177.

xii. [1.4] after performing the stretching, fixing the second portion of the bone device to the second bone fragment; and;

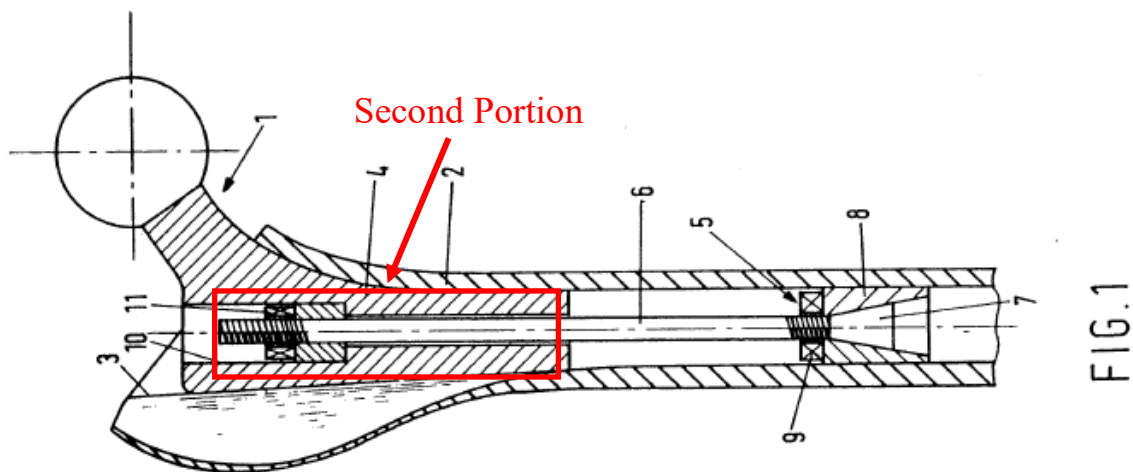
Bolesky teaches that when nut 9 is turned, “movement of gripper unit 6 ... causes the tips 13 of the fingers to penetrate the wall of canal 1” and “actuates gripper unit 6 into the fully engaged condition.” Ex. 1006, 3:61-64. This results in fixing the first portion of the device to the first bone fragment. Ex. 1002, ¶178. The continued tightening of nut 9 then causes rod 5 to be stretched. Ex. 1007, 3:66-4:4. (“As such penetration increases...a force is developed which tensions rod 5.”).

When tightening of nut 9 is complete, the second portion of the device is fixed. Ex. 1002, ¶178. Thus, a POSITA would understand that, in Bolesky, the step of “**fixing the second portion of the bone device to the second bone fragment**” occurs **after** rod 5 has been **stretched**. *Id.*



This is also consistent with the prosecution history. As discussed in Section IV.C, the Applicant overcame a written description rejection by arguing that the limitation of fixing after stretching was practiced by the screw embodiment of the '222 patent. Ex. 1004, pp 88-98 (8/19/10 Response). Applicant asserted that even though the threaded end of the screw is already engaged within the second bone fragment upon insertion, the threaded end is not “in the fixed position” until the screw is done being turned, i.e. when “the stretching/elongation has completed.” Ex. 1004, p. 95 (8/19/10 Response). Under this same reasoning, nut 9 of Bolesky is “in the fixed position” when it is done being turned, i.e., when the stretching/elongation of the rod is completed. Ex. 1002, ¶179.

Alternatively, for the reasons described in elements [1.2] and [1.3], it would also have been obvious to a POSITA to modify Bolesky to use the fixation approach of Hoffman, which also results in **fixing the second portion of the fixation device to the second bone fragment after performing the stretching**. Hoffman teaches that the tip of the device is first fixed at the distal end by turning nut 9, which pushes segments 8 over the wedge-shaped end part 7. Ex. 1007, 4:62-65. Then, once the tip 5 has been fixed in the bone, “tie member 6 is stretched by tightening nut 11.” Ex. 1007, 5:18-21. Thus, like in Bolesky, the tightening of nut 11 stretches the tie member/rod, such that the second portion of the device (the proximal end) is fixed after stretching/elongation is complete. Ex. 1002, ¶180.



As explained above, it would have been obvious to use either of the fixation approaches in Bolesky and Hoffman, and selecting between the two approaches would be a simple matter of design choice. Ex. 1002, ¶181. And, regardless of

which fixation approach is used, the combination of Bolesky and Hoffman render claim element [1.4] obvious. *Id.*

xiii. [1.5] wherein the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy

Hoffman teaches that, in order to create stress-induced martensite in the SMA rod, the rod is to be stretched while “in the austenitic phase.” Ex. 1007, 5:12-15. Hoffman explains that this effect is due to the “presence of so-called superelasticity.” *Id.*, 1:62-67. Although Hoffman does not expressly discuss the austenite finish temperature of the SMA, it was well known that SMAs exhibit superelasticity (in which stress-induced martensite is formed upon the application of stress) at temperatures above the austenite finish temperature (A_f). *See supra* Section IV.A; Ex. 1002, ¶183. A POSITA would know that the austenite finish temperature (A_f) is the temperature above which an SMA such as Nitinol would be completely transformed from martensite to austenite and thus in the austenitic phase. *Id.*

Indeed, during prosecution of the '222 patent, Applicant acknowledged this fact. *See* Ex. 1004, pp. 95-96 (8/19/10 Response) (“Skilled artisans recognize the austenite finish temperature as the transition temperature (T_1) of shape memory alloys for the purposes of creating pseudo-elastic behavior.”). Thus, a POSITA would understand Hoffman’s disclosure of stretching the rod in an austenitic phase to create stress-induced martensite as disclosing that the stretching is performed **at**

a temperature greater than the austenite finish temperature of the SMA. Ex. 1002, ¶¶182-183.

At a minimum, however, a POSITA would have found it obvious to select an SMA, like Nitinol, having an austenite finish temperature that is below the temperature at which the stretching will occur. Ex. 1002, ¶184. Doing so would ensure that the SMA rod would be austenitic—and so capable of forming stress-induced martensite—when being stretched. *Id.*

xiv. Claim 2

Claim 2 depends from claim 1 and further requires “**wherein stretching the bone device is performed with the bone device substantially in an austenitic phase.**” The device of Bolesky, as modified in view of Hoffman, discloses this limitation for the reasons described above with respect to claim limitations [1.2], [1.3] and [1.5]. In short, as explained above, it would have been obvious to modify the device of Bolesky to use a rod made out of an SMA as taught by Hoffman. And Hoffman teaches that to create stress-induced martensite in the SMA rod, the rod is stretched while “**in the austenitic phase.**”⁴ Ex. 1007, 5:12-15. Accordingly, a

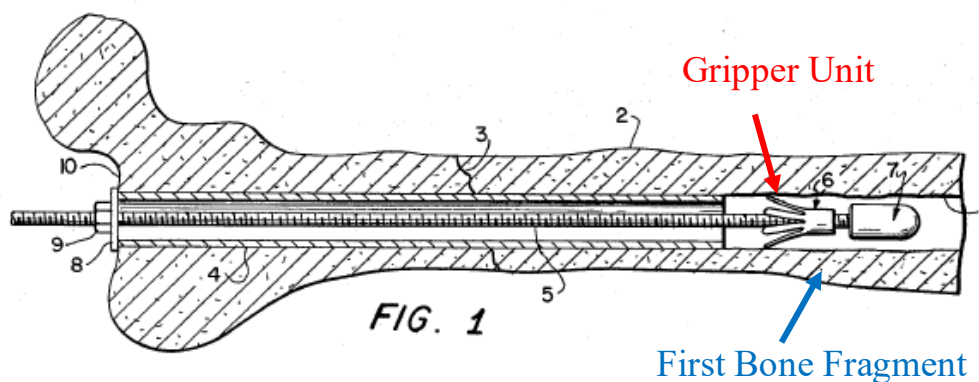
⁴ During prosecution, in addressing a 112 rejection, Applicant argued that this claim was supported by disclosure in the specification that taught stretching

POSITA would understand, or at least find it obvious, that the stretching of the modified bone device would be performed with the SMA portion of the bone device (i.e., the rod) being substantially in an austenitic phase. Ex. 1002, ¶¶185-187.

xv. Claim 3

Claim 3 depends from claim 1 and further requires “**before performing the stretching, fixing the bone device to the first bone fragment.**”

Bolesky teaches this limitation. Ex. 1002, ¶¶189-191. Bolesky teaches that “[a]fter the device has been installed in the bone,” nut 9 is turned to “move rod 5 and gripper unit 6 a predetermined small distance toward the entrance of the canal.” Ex. 1006, 3:56-61.



The tightening of the nut “actuates gripper unit 6 into the fully engaged condition,” as shown in FIG. 3 below. *Id.*, 3:61-63. This occurs because “as the nut

when the shape memory alloy was fully austenitic. Ex. 1004, pp. 94-95 (8/19/10 Response); Ex. 1002, ¶186.

is tightened, movement of gripper unit...causes the tips 13 of the fingers to penetrate the wall of canal 1" which will "resist further movement of the gripper unit relative to the bone." *Id.*, 3:63-4:4.

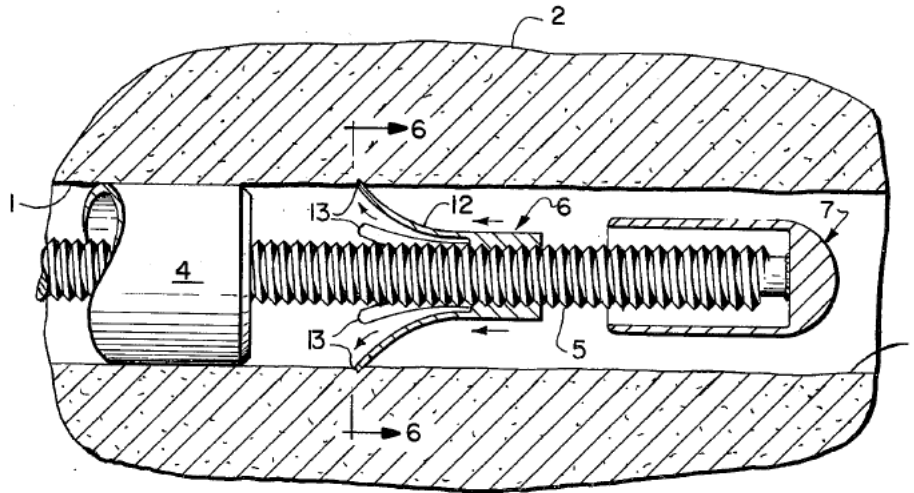
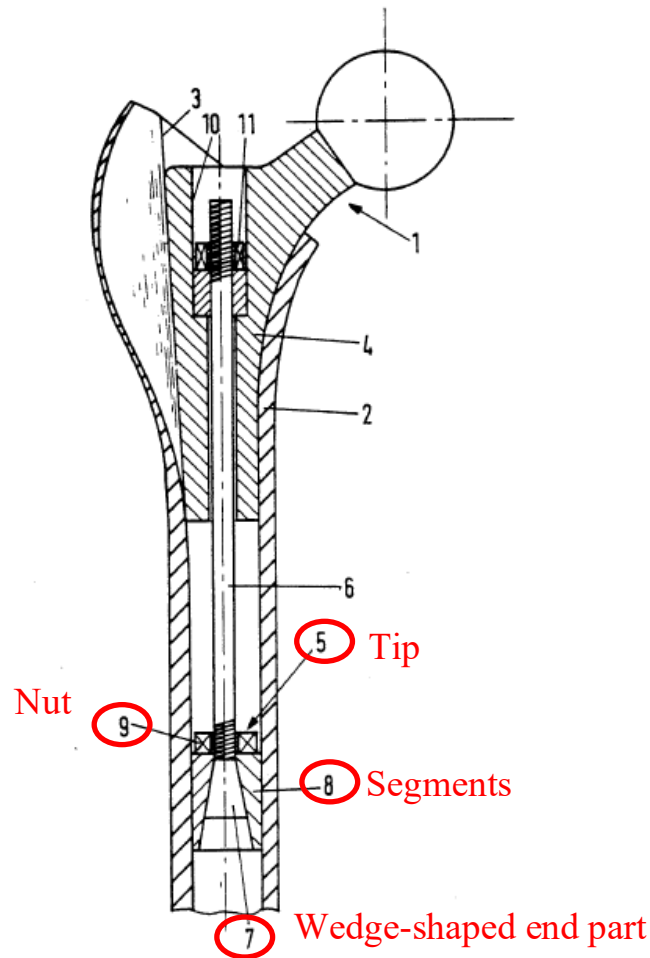


FIG. 3

When the gripper unit is fully engaged, the bone device is **fixed to the first bone fragment**. Ex. 1002, ¶191. The subsequent continued tightening of nut 9 then causes rod 5 to be stretched. *Id.*; Ex. 1006, 3:66-4:12. Accordingly, a POSITA would understand that, in Bolesky, the step of "**fixing the bone device to the first bone fragment**" occurs **before** rod 5 has been **stretched**. Ex. 1002, ¶191.

Alternatively, Hoffman also discloses **fixing the bone device to the first bone fragment before performing the stretching**. Hoffman teaches that the tip 5 of the device is fixed at the distal end by turning nut 9, which pushes segments 8 over the wedge-shaped end part 7. Ex. 1007, 4:62-65. Once the tip 5 has been fixed

in the bone, “tie member 6 is stretched by tightening nut 11.” Ex. 1007, 5:18-21.



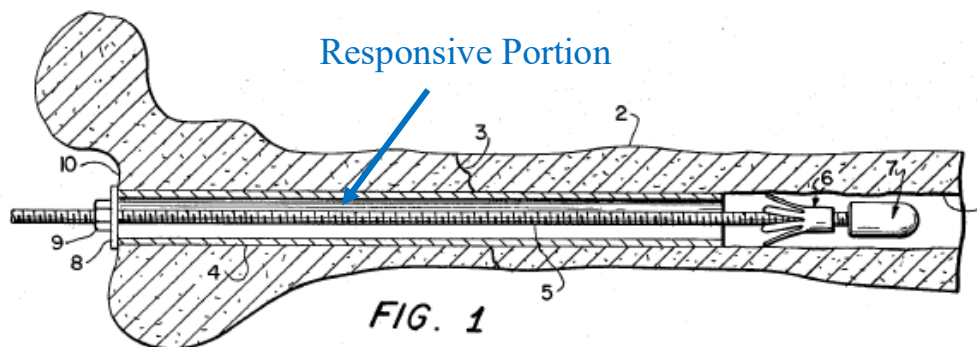
As described above in elements [1.2], [1.3] and [1.4], it would have been obvious to use either of the Bolesky or Hoffman fixation approach, and selecting between the two would be a simple matter of design choice. Ex. 1002, ¶193.

Thus, regardless of which fixation approach is used, claim 3 would have been obvious to a POSITA in view of the combination of Bolesky and Hoffman. *Id.*

xvi. Claim 4

Claim 4 depends from claim 3 and further requires “**holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the bone device to the first bone fragment is performed.**”

As discussed above for claim 1, it would have been obvious to modify the fixation device of Bolesky to use a rod made from an SMA, like Nitinol. And for the reasons described in element [1.3], a POSITA would recognize that the rod, as modified, represents a “**responsive portion.**” Ex. 1002, ¶195.



As explained in claim element [1.5], Hoffman teaches, or at least renders obvious, that the responsive portion is stretched at a temperature that is above the austenite finish temperature of the SMA. For the same reasons, a POSITA would also understand that Hoffman teaches, or at a minimum renders obvious, that **the responsive portion is held above the austenite finish temperature of the shape**

memory alloy while the bone device is fixed to each of the bone fragments. Ex. 1002, ¶196-198. That is because the stretching and the fixing steps are both being performed at the same surrounding temperature.

xvii. Claim 5

Claim 5 depends from claim 1 and further requires “**holding the shape memory alloy at a temperature greater than the austenite finish temperature of the shape memory alloy while the stretching is performed.**” The combination of Bolesky and Hoffman renders this limitation obvious for the reasons described above with respect to element [1.5] and claim 2. Ex. 1002, ¶199.

xviii. Claim 6

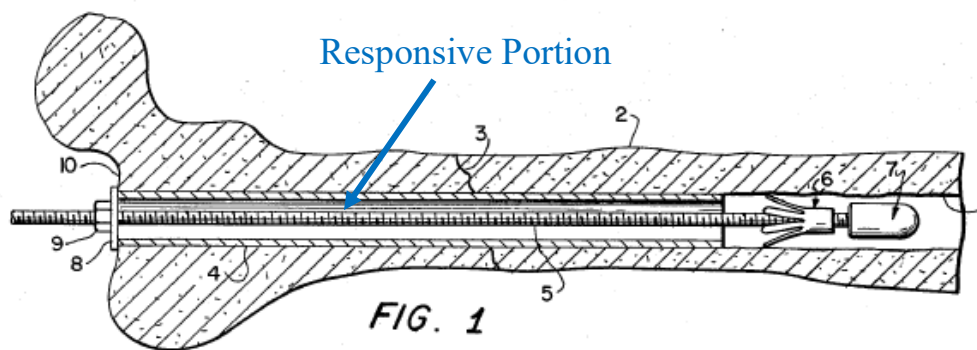
Claim 6 depends from claim 1 and further requires “**holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the second portion is performed.**” The combination of Bolesky and Hoffman renders this limitation obvious for the reasons described above with respect to element [1.5] and claim 4. Ex. 1002, ¶200.

xix. Claim 7

Claim 7 depends from claim 1 and further requires “**wherein inserting the bone device into the second bone fragment is performed while the responsive portion is substantially in an austenitic phase.**” The device of Bolesky, as modified in view of Hoffman, performs this limitation for the reasons described

above with respect to claim limitations [1.2], [1.3] and [1.5], and claim 3 and 4. Ex. 1002, ¶¶201-202.

In short, as discussed above, it would have been obvious to modify the fixation device of Bolesky to use a rod made from an SMA, like Nitinol. And for the reasons described in element [1.3], a POSITA would recognize that the rod, as modified, therefore represents a “**responsive portion.**” Ex. 1002, ¶203.



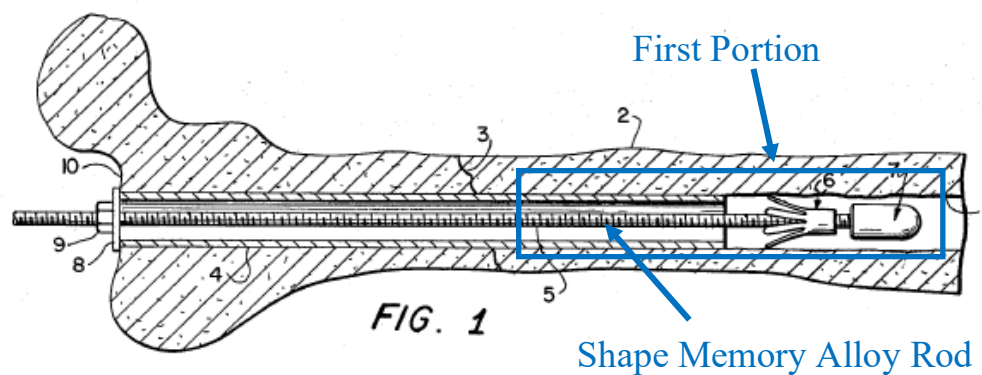
Furthermore, as explained in element [1.5] and claim 2, Hoffman teaches and/or renders obvious that the responsive portion is stretched at a temperature that is above the austenite finish temperature of the SMA (which results in the creation of stress-induced martensite). For the same reasons, a POSITA would also understand that Hoffman teaches, or at a minimum renders obvious, that **inserting the bone device into the bone fragments is performed while the responsive portion is substantially in an austenitic phase.** Ex. 1002, ¶204-205. That is because the stretching and the inserting steps are both being performed in the body and so are both at the same surrounding temperature. *Id.*

xx. Claim 8

Claim 8 depends from claim 1 and further requires “**wherein inserting the bone device into the first bone fragment is performed while the responsive portion is substantially in an austenitic phase.**” The combination of Bolesky and Hoffman renders this limitation obvious for the reasons described above with respect to claim 7. Ex. 1002, ¶206.

xxi. Claim 9

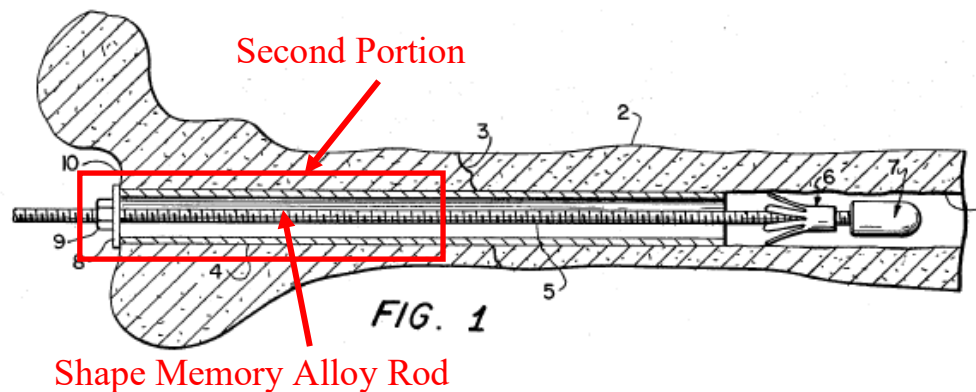
Claim 9 depends from claim 1 and further requires “**wherein the first portion comprises the shape memory alloy.**” As discussed above for claim 1, it would have been obvious to modify the fixation device of Bolesky to use a rod made from an SMA, like Nitinol. Thus, as shown below, the first portion of the bone device “comprises the shape memory alloy.” Ex. 1002, ¶207.



xxii. Claim 10

Claim 10 depends from claim 1 and further requires “**wherein the second portion comprises the shape memory alloy.**” As discussed above for claim 1, it

would have been obvious to modify the fixation device of Bolesky to use a rod made from an SMA, like Nitinol. Thus, as shown below, the second portion of the bone device “comprises the shape memory alloy.” Ex. 1002, ¶208.



IX. THE BOARD SHOULD NOT DISCRETIONARILY DENY UNDER 35 U.S.C. § 314

The Board need not address the factors in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) because the Petition presents a compelling case of unpatentability. Director’s Interim Procedure for Discretionary Denials, at 2 (June 21, 2022) (“the PTAB will not rely on the Fintiv factors to discretionarily deny institution in view of parallel district court litigation where a petition presents compelling evidence of unpatentability.”). However, even if the Board does consider the factors, at least factors 2-4 and 6 weigh strongly against denial because in the corresponding litigation, the Answer was filed on May 23, 2024 with no fact or expert discovery occurring as of this filing and no current

timeline for a trial. Petitioner also challenges claims not identified as being asserted in the corresponding litigation and the merits of the petition are strong.

X. CONCLUSION

Therefore, Petitioner submits that the challenged claims are unpatentable and requests institution of *Inter Partes* Review.

DATED: October 18, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing petition for *inter partes* review, together with all exhibits and other documents filed therewith, was served by Federal Express on October 18, 2024, on the Patent Owner's counsel of record at the U.S. Patent and Trademark Office having the following address:

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CERTIFICATE OF WORD COUNT

The undersigned hereby certifies that the foregoing petition for *inter partes* review contains 13,984 words according to the word processing program used to prepare it.

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