

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

DECLARATION OF MIKE SHERMAN

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I. ENGAGEMENT AND COMPENSATION

1. My name is Mike Sherman. I am the President and CEO of MB Innovations, Inc. Our offices are located in the New Memphis Building at 516 Tennessee Street, Suite 215, Memphis TN 38103. My *curriculum vitae* is attached as Ex. 1003. I am submitting this declaration at the request of counsel for Petitioner Arthrex, Inc. to provide my opinion with respect to the unpatentability of U.S. Patent No. 7,985,222 (“the ’222 Patent”) in the above-captioned matter. The following is based on my personal knowledge and experience as well as my review of the documents in this case as listed below. I am being compensated for my time in preparing this declaration at my standard hourly rate, and my compensation is not dependent upon my opinions or the outcome of the proceedings.

II. QUALIFICATIONS

2. I have more than thirty-five years of experience in the medical device industry, including more than twenty-five years of direct experience developing orthopedic devices and products. Throughout my career, I have held roles ranging from product development engineer to executive leadership and have been a key player in driving new technology at one of the largest orthopedics companies in the world, Medtronic Sofamor Danek.

3. I obtained a Bachelor of Science in Biomedical Engineering from Rensselaer Polytechnic Institute in 1983 and a Masters of Science in Biomedical

Engineering from the University of Texas Southwestern Graduate School of Biomedical Sciences in 1984. As part of my Masters' program, I wrote a thesis titled *Biomechanical Factors Affecting Fracture Stability and Femoral Bursting in Closed Intramedullary Rod Fixation of Femur Fractures*.

4. After completing my Masters, I accepted a position as a Biomedical Engineer at Synthes (USA). I worked at Synthes from 1985–1989 and was promoted to Associate Product Manager and Product Development Engineer during that time. While at Synthes, I worked in orthopedic trauma product development and developed and commercialized canulated screws, fixation rods, and spinal instrumentation systems. I also had product management responsibility and was involved in preparing regulatory submissions and interacting with the FDA.

5. Following Synthes, I worked at Smith & Nephew from 1989–1991 as a Senior Product Development Engineer. In that role, I worked extensively on external fixation devices and worked closely with key opinion leaders to develop and launch new orthopedic components.

6. From early 1991 to late 2006, I worked at Medtronic Sofamor Danek, where I held the positions of Senior Engineering Manager, Danek; Director of Product Development, Sofamor Danek; Group Director of Product Development, Sofamor Danek; and Vice President of Technology Development, Medtronic

Sofamor Danek. In those roles, I developed and commercialized numerous implants, instruments, and surgical methods for orthopedic procedures, including trauma. As Vice President of Technology Development, I was involved in both technical and business diligence and led a team that identified and drove new technologies for addressing challenging clinical problems.

7. My development efforts have led to a number of inventions that incorporate shape-memory alloy technology and nitinol specifically. I am a named inventor on at least four (4) shape memory alloy staple patents, six (6) minimally, invasive spinal instrumentation component patents, and two (2) super-elastic plate patents, all of which involve the use of nitinol.

U.S. Patent No.	Title
5,728,098	Multi-angle bone screw assembly using shape-memory technology
5,954,725	Multi-angle bone screw assembly using shape-memory technology
6,132,434	Multi-angle bone screw assembly using shape-memory technology
6,210,413	Connecting apparatus using shape-memory technology
6,287,311	Multi-angle bone screw assembly using shape-memory technology
6,293,949	Superelastic spinal stabilization system and method
6,299,613	Method for the correction of spinal deformities through vertebral body tethering without fusion
6,325,805	Shape memory alloy staple
6,616,669	Method for the correction of spinal deformities through vertebral body tethering without fusion
6,761,719	Superelastic spinal stabilization system and method
6,773,437	Shape memory alloy staple

8. From 2006–2015, I was a Partner in a venture capital firm, MB Venture Partners, LLC. In that role, I led numerous early-stage investments and

served on portfolio company boards for organizations in the medical and orthopedic device field. I also aided a precision medical device manufacturer, launched medical device startups, and created or aided numerous orthopedics companies.

9. While at MB Venture Partners, I founded MB Innovations Inc. (“MBI”) in 2011 serving as the Executive Chairman. Since November of 2016 I have operated MBI as its President & CEO. MBI is a medical device design, development, and consulting firm providing outsourced product development and strategic services to clients, primarily in the musculoskeletal sector. Specifically, MBI develops implants and instruments for spinal procedures, orthopedic trauma, foot and ankle procedures including trauma, joint replacement systems and sports medicine products for soft tissue repair around joints.

10. My work in orthopedic research, development, and commercialization has led to over 125 issued U.S. patents. The devices and methods I helped develop have been used in thousands of patients worldwide. I also have numerous publications, including publications related to the field of orthopedics.

11. I have been a member of the Orthopedic Research Society since 1987. From 1984–1999, I was a member of the American Society of Mechanical Engineers. I am also a member of the American Society of Testing and Materials, and, since 1999, I have been a member of the North American Spine Society. In

2001, I was awarded the Medtronic Technical Contributor of the Year award for my work on the SEXTANT® Percutaneous Rod Insertion System. That same year, I was inducted into the Bakken Society, an honor society at Medtronic that represents the highest recognition for technical achievement offered by the company.

12. Further details of my qualifications and experience are set forth in my *curriculum vitae*, attached hereto as Exhibit 1003.

III. MATERIALS REVIEWED

Exhibit No.	Description
1001	U.S. Patent No. 7,985,222 (“222 Patent”)
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”)

IV. LEGAL STANDARDS

13. In forming my opinions and considering the subject matter of the ’222 Patent and its claims in light of the prior art, I am relying on certain legal principles that counsel explained to me. My understanding of these concepts is summarized below.

A. Claim Construction

14. I have been informed that the United States Patent and Trademark Office interprets claim terms in an *inter partes* review proceeding under the same claim construction standard that is used in a United States federal court. I have been informed that under this standard, the meaning of claim terms is considered from the viewpoint of a person of ordinary skill in the art (“POSITA”) at the time of the alleged invention.

15. I have been informed that claim terms are generally given their ordinary and customary meaning as understood by one of ordinary skill in the art

in light of the specification and the prosecution history pertaining to the patent. I have been informed, however, that claim terms are generally not limited by the embodiments described in the specification.

16. I have been informed that in addition to the claims, specification, and prosecution history, other evidence may be considered to ascertain the meaning of claim terms, including textbooks, encyclopedias, articles, and dictionaries. I have been informed that this other evidence is often less significant and less reliable than the claims, specification, and prosecution history.

B. Obviousness

17. I have been informed that a patent claim can be unpatentable under 35 U.S.C. § 103(a) if it is obvious. A claim is unpatentable for obviousness if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having ordinary skill in the art to which the subject matter pertains. I further have been informed that a hypothetical person of ordinary skill in the art is assumed to know and have all relevant prior art in the relevant subject matter covered by the patent at issue and all analogous prior art.

18. I have been informed that obviousness does not require that every element of the claim be in a single prior art reference. Instead, claim elements can be described in different prior art references, so long as there is motivation or sufficient

reasoning to combine the references and a reasonable expectation of success in achieving what is set forth in the claims.

19. I have been informed that one must consider the claim “as a whole” when evaluating obviousness. This consideration must be made from the perspective of the hypothetical person of ordinary skill in the relevant art, and that such perspective must be considered as of the “time the invention was made.”

20. I have been informed that in considering the obviousness of a claim, one must consider the scope and content of the prior art, the level of ordinary skill in the art at the relevant time, the differences between the prior art and the claim, and any “secondary considerations.”

21. I have been informed that “secondary considerations” include real-world evidence that can tend to make a conclusion of obviousness either more probable or less probable. For example, the commercial success of a product embodying a claim of the patent could provide evidence tending to show that the claimed invention is not obvious. To understand the strength of the evidence, one would want to know whether the commercial success is traceable to a certain aspect of the claim not disclosed in a single prior art reference (a “nexus”). One would also want to know how the market reacted to disclosure of the invention and whether commercial success might be traceable to things other than innovation, for example, the market power of the seller, an advertising campaign, or the existence

of a complex system having many features beyond the claims that might be desirable to consumers. One would also want to know how the product compared to similar products not embodying the claim. I have been informed that commercial success evidence should be reasonably commensurate with the scope of the claim, but that is not necessary for a commercial product to embody the full scope of the claim.

22. Other kinds of secondary considerations are possible. For example, evidence that the relevant field had a long-established, unsolved problem or need that was later provided by the claimed invention could be indicative of non-obviousness. Evidence that others had tried but failed to make an aspect of the claim might indicate that the art lacked the requisite skill to do so. Evidence of copying the patent owner's products before the patent was published might also indicate that its approach to solving a particular problem was not obvious. Evidence that the art recognized the value of products embodying a claim, for example, by praising the named inventors' work, might tend to show that the claim was non-obvious.

23. I further have been informed that prior art references can be combined where there is an express or implied rationale to do so. Such rationale might include an expected advantage to be obtained, or might be implied under the circumstances. For example, a claim is likely obvious if design needs or market

pressures existing in the prior art make it natural for one or more known components to be combined where each component continues to function in the expected manner when combined (i.e., when there are no unpredictable results). A claim is also likely unpatentable where it is the combination of a known base system with a known technique that can be applied to the base system without an unpredictable result. In these cases, the combination must be within the capabilities of a person of ordinary skill in the art.

24. I have been informed that when considering obviousness, one must use hindsight and refer to teachings in the specification of the patent itself. One may, however, refer to portions of the specifications admitted to being prior art, including the “BACKGROUND” section.

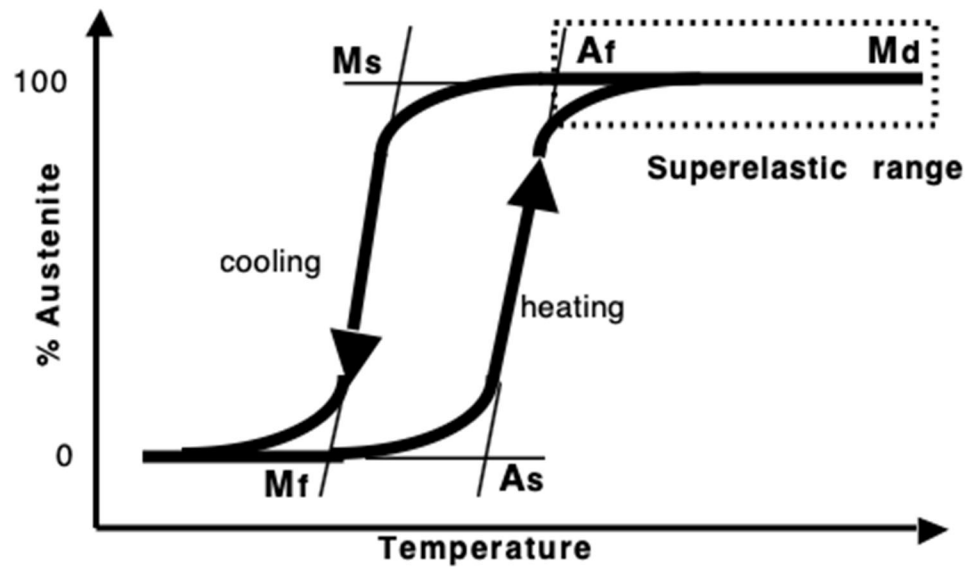
V. BACKGROUND OF THE TECHNOLOGY

25. Shape memory alloys are alloys that possess an ability to “remember” their physical shape, such that they can revert back to their original shape after the material has been deformed. The ability of shape memory alloy (SMA) to remember its shape stems from its ability to exist and transform between two different phases of crystalline structures: austenite and martensite. The martensite state exists at lower temperatures while the austenite state exists at higher temperatures.

26. The transformation between the austenite and martensite states can be affected in two ways: (1) by temperature or (2) by mechanical stress. When cooled to low temperatures, an SMA will transform from a generally rigid austenite state to a soft martensite state. The SMA can then be deformed while in the softer martensitic state and, upon application of heat, the SMA will transform back into the more rigid austenite state and revert to its original shape. This transformation through the use of temperature is referred to as the “thermal shape memory effect.”

27. Alternatively, when an SMA in an austenitic state is mechanically stressed (for example, by bending or stretching), the SMA will transform from an austenitic state to a stress induced martensitic state. When the stress is relieved, the SMA reverts to the austenitic state and recovers its original shape. 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.”

28. Another unique characteristic of SMAs is that they exhibit a hysteresis characterized by five (5) specific temperatures: M_s , M_f , A_s , A_f , and M_d .



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

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

29. As pertinent to the issues here, superelasticity (which involves the formation of stress-induced martensite) occurs when the SMA is stressed at a temperature above A_f and in the range between A_f and M_d . Ex. 1009, p. 2 (“superelasticity only occurs over a relatively narrow temperature range just above the A_f temperature - optimum performance is found at the A_f temperature, and steadily deteriorates until the M_d temperature, at which all indications of superelasticity have vanished.”); Ex. 1011, Section 2.3.6 (“superelasticity appears in a temperature range from near A_f and up to M_d ”); Ex. 1012, p. 2 (“If a stress is applied to a shape memory alloy in the temperature range between A_f and a maximum temperature M_d , martensite can be stress-induced.”)

30. One well-known shape memory alloy is Nitinol, which is a composition of nickel and titanium. Nitinol was developed by the US Navy at the Naval Ordinance Laboratory in 1959. 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 well known that Nitinol is biocompatible in humans. Ex. 1010, p. 235 (“Nitinol, a nearly equiatomic composition of nickel and titanium, is one of very few alloys that is both superelastic and biocompatible”); Ex. 1008, p. 1 (“[Nitinol's] thermo-mechanical characteristics and its biocompatibility has allowed its use across many medical and surgical specialties...”). In fact, the biocompatibility of Nitinol was

understood to be “similar to or better than that of stainless steel.” Ex. 1011, Abstract.

31. 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. 1010, p. 235 (“the narrow temperature range within which Nitinol’s superelasticity is exhibited includes body temperature”). Indeed, one typical Nitinol alloy that was being used for medical applications was a composition that had superelastic properties both at room and body temperature. Ex. 1008, p.12 (“The vast majority of nitinol components being used in current medical device applications (including some FDA-approved permanent implants or stents) are manufactured from the very typical 50.8% Ni alloy composition. This alloy has well documented superelastic characteristics at room and around body temperature making it an ideal candidate.”).

32. 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. Ex. 1016, p. 104; Ex. 1008, p.1. Such applications included self-compressing devices for fracture fixation, such as bone plates, marrow nails, splints, staples, and the like. 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 in the former Soviet Union 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).

VI. THE ’222 PATENT

A. Technical Background

33. 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 a shape memory material, such as nickel titanium (also referred to as 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.

34. 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 ’222 patent depicts several examples of bone devices using a shape memory alloy, including a “bone screw” (*see* Figs 1-3), a “plate,” (*see* Figs. 4-7), and a “bone nail,” (*see* Fig. 8), and purports that these devices “can provide sustained compression.” *See, e.g., Id.*, 4:36-40 (“Embodiments of the present invention include bone fixation devices, including plates, bone nails such as intramedullary nails, bone screws, and the like, that can provide sustained compression (spontaneous dynamic compression) across a bone fracture over time.”).

B. Claimed Invention

35. Claim 1 of the ’222 patent, which is the only independent claim, recites a method as follows:

A method, comprising:

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;

wherein the bone device comprises a shape memory alloy having an austenite finish temperature;

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;

after performing the stretching, fixing the second portion of the bone device to the second bone fragment; and

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

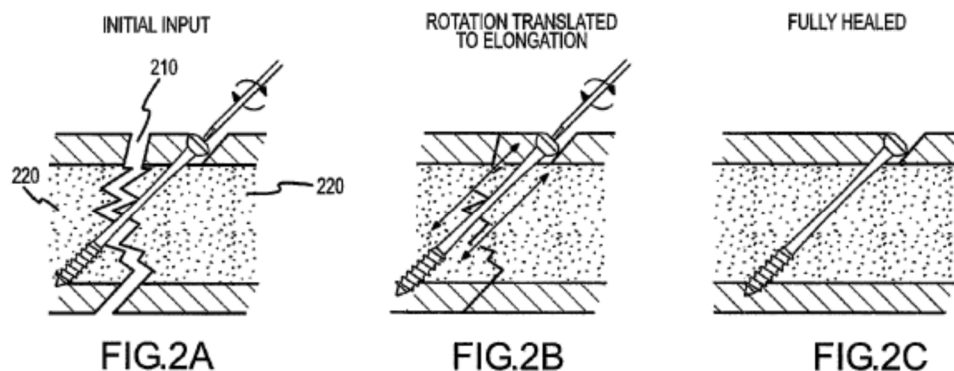
36. The '222 patent also includes dependent claims 2-10, all of which depend directly or indirectly from claim 1 and provide more details on certain steps of the claimed method, including the sequence or temperatures at which steps may occur or about the structure of the bone device.

C. Prosecution History

37. Claim 1 of the '222 patent issued from 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 (2/18/10 Non-Final Rejection). 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 newly added limitation. *Id.*, pp. 88-89 (8/19/10 Response).

38. The Examiner also rejected the claims under 35 U.S.C. § 112 because, according to the Examiner, the specification did not contain a written description of the claimed subject matter. *Id.*, pp. 107-108 (2/18/10 Non-Final Rejection). 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 (8/19/10 Response). 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 (8/19/10 Response).



39. Applicant also asserted that the method described in relation to Figs. 2A–2C performed the “fixing” and “stretching” limitations that are recited in

issued claims 1 and 3 (originally claims 47 and 49). With regard to 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 (8/9/10 Response). Then, with regard to 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 (8/9/10 Response).

40. Likewise, Applicant also asserted that the other claims that depended from claim 1 (original claim 47) were also supported by the specification. *Id.*, pp. 63-64 (3/22/11 Response), 96-97 (8/9/10 Response).

41. The Examiner allowed claim 1 and its dependent claims in view of the above-described arguments. *Id.*, pp. 72-73 (1/24/11 Final Rejection); *see also* p. 35 (Notice of Allowance). However, the Examiner maintained his written description rejection with respect to the other pending claims 27-35, 37, and 38. *Id.* The Applicant ultimately cancelled those other claims. *Id.*, pp. 60-65 (3/22/11 Response). As such, the only independent claim that issued was claim 1.

VII. THE PRIOR ART

A. Monassevitch

42. Monassevitch (Ex. 1005) was filed on February 28, 2001, and issued on February 2, 2004. Monassevitch was not cited during the prosecution of the '222 patent.

B. Bolesky

43. Bolesky (Ex. 1006) was filed on July 27, 1979, and issued on June 30, 1981. Bolesky was not cited during the prosecution of the '222 patent.

C. Hoffman

44. Hoffman (Ex. 1007) was filed on June 12, 1990, and issued on July 30, 1991. Hoffman was not cited during the prosecution of the '222 patent.

VIII. PERSON OF ORDINARY SKILL IN THE ART

45. In rendering the opinions set forth in this declaration, I was asked to consider the patent claims and the prior art through the eyes of a person of ordinary skill in the art, which I have been informed is sometimes referred to by the acronym "POSITA" (person of ordinary skill in the art), as of the time of the alleged invention, which I understand here to be April 21, 2004 (the filing date of provisional application No. 60/563,952).

46. I have been informed that the factors considered in determining the ordinary level of skill in a field of art include the level of education and experience of persons working in the field, the types of problems encountered in the field, the

teachings of the prior art, and the sophistication of the technology at the time of the alleged invention.

47. I have been informed that a person of ordinary skill in the art is not a specific real individual, but instead is a hypothetical individual having the qualities reflected by the factors above. I have been informed that a person of ordinary skill in the art would also know the teachings of the prior art, including the art cited below.

48. Based on my education, experience, and knowledge of problems encountered in the field, a person of ordinary skill in the art (“POSITA”) at the time of the alleged invention of the ’222 patent (April 2004) 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.

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

50. I believe I would meet (or exceed) this definition and would have met this definition in the relevant timeframe. I have also worked with and supervised many individuals who would meet this definition, including at or before the date of filing of the '222 patent. My testimony is offered from this perspective.

IX. CLAIM CONSTRUCTION

A. “Bone Fragment”

51. It is my understanding that, 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.” It is my understanding that the Patent Owner also contends that the term “bone fragment” should be given its plain and ordinary meaning. But it is my understanding that 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 be interpreting “bone fragment” more

broadly to include intact bones as well as pieces of broken bone. I have not been asked to render an independent opinion on this claim term, nor do I believe that analyzing the properness of either party's interpretation to be necessary for my analysis here. This is because, as I explain below, the prior art I discuss in both grounds 1 and 2 below plainly discloses procedures that are used for fixation between two parts of a broken bone. Accordingly, my opinions would remain the same regardless of which party's interpretation of "bone fragment" is applied.

B. "Substantially In An Austenitic Phase"

52. 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." It is my understanding that, in the district court litigation, Arthrex contends that these claims are indefinite. It is my understanding that Patent Owner contends that the claims should be given their plain and ordinary meaning, but has not provided what it believes to be the plain and ordinary meaning. However, it is my understanding that Patent Owner, in its infringement contentions, has applied the claim terms in a way that indicates that a shape memory alloy is substantially in an austenitic phase if only part of the austenitic shape memory alloy is transformed to martensite due to the recited step, or if the shape memory alloy is above the austenite finish temperature (in which

case it would be fully austenitic) prior to the recited step. I have been asked to use Patent Owner's apparent interpretation.

X. OPINIONS ON UNPATENTABILITY

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

53. As described below, it is my opinion that each limitation of claims 1-2 and 5-10 is rendered obvious by Monassevitch. More specifically, in the overview and claim mapping sections below, I describe several Monassevitch embodiments that I believe independently teach each limitation of claims 1-2 and 5-10.

However, to the extent that the Patent Owner may argue that any limitation is missing from any one embodiment, I believe it would also be reasonable and 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.

1. Overview of Monassevitch

54. Monassevitch is directed to “a bone staple formed of a shape-memory alloy and an apparatus associated with the staple” where “[t]he apparatus deforms the staple by increasing its span length and facilitating its insertion into bone tissue.” Ex. 1005, Abstract; *see also Id.*, 1:6-9 (“The present invention relates generally to staples for bone fixation, formed of shape-memory-alloys (SMA) and other biocompatible metals and alloys. The present invention relates in particular

to SMA staples of adjustable length spans.”); 3:54-56 (“It is an aim of the present invention to provide apparatus and method for adjusting the lengths spans of SMA staples for bone fixations, prior to their insertion into the bone.”).

55. Monassevitch explains that the reason for using a shape memory alloy for the staple is due to the phase structure of shape memory alloys:

The reason for the shape memory is found in the phase structure of the alloy. Most metals deform by atomic slip. Dislocations and atomic planes slide over one another and assume a new crystal position. In the new position, the crystal has no memory of its order prior to the deformation. With increased deformation, there is generally a work hardening effect, in which the increased tangle of dislocations makes additional deformation more difficult. This is the case even when the increased deformation is in the direction of restoring the crystal to its original shape. However, for shape memory alloys, both transitions between the austenitic and martensitic phases and deformation in the martensitic phase change lattice angles in the crystal, uniformly for the whole crystal. The original austenitic lattice structure is “remembered” and can be restored.

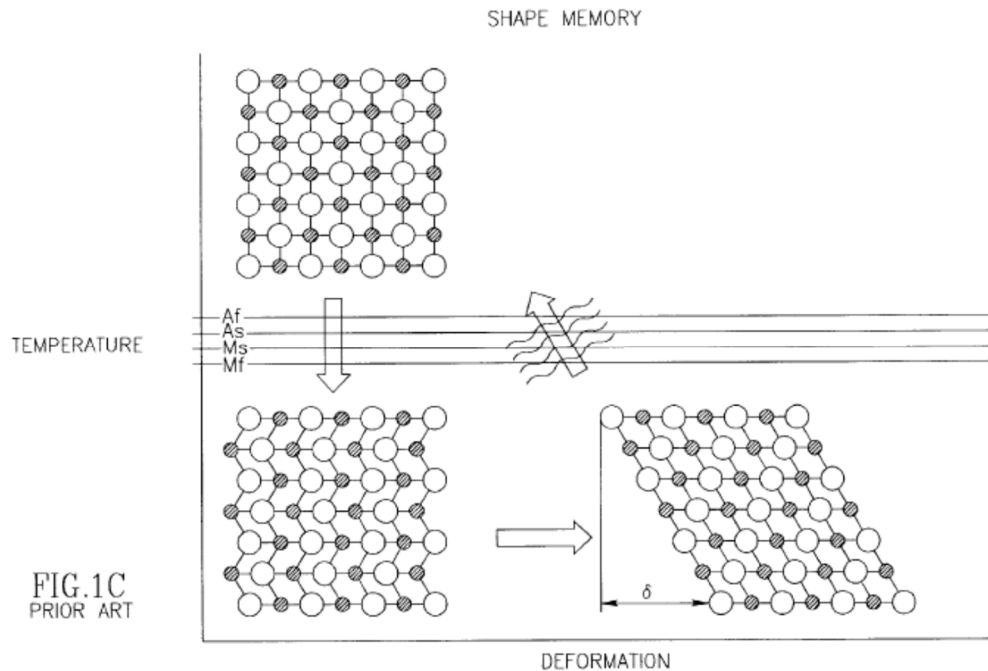
Id., 1:47-61.

56. Monassevitch explains that there are two different properties of shape memory alloys. With reference to Figure 1C (shown below), Monassevitch explains:

in the austenitic phase, the crystal has a cubic structure, and the atoms in the lattice are arranged generally at right angles to each other;
when the austenitic crystal is cooled to a martensitic phase, a twinned lattice structure is formed;
when the twinned martensitic crystal is deformed by an amount no greater than δ , the twinned structure is “stretched” so that the atoms in the lattice are arranged generally at oblique angles to each other, wherein the oblique angles are determined by the amount of deformation; and

when the deformed martensitic crystal is heated, the crystal resumes its cubic structure, wherein, again, the atoms in the lattice are arranged generally at right angles to each other.

Id., 1:62-2:12.

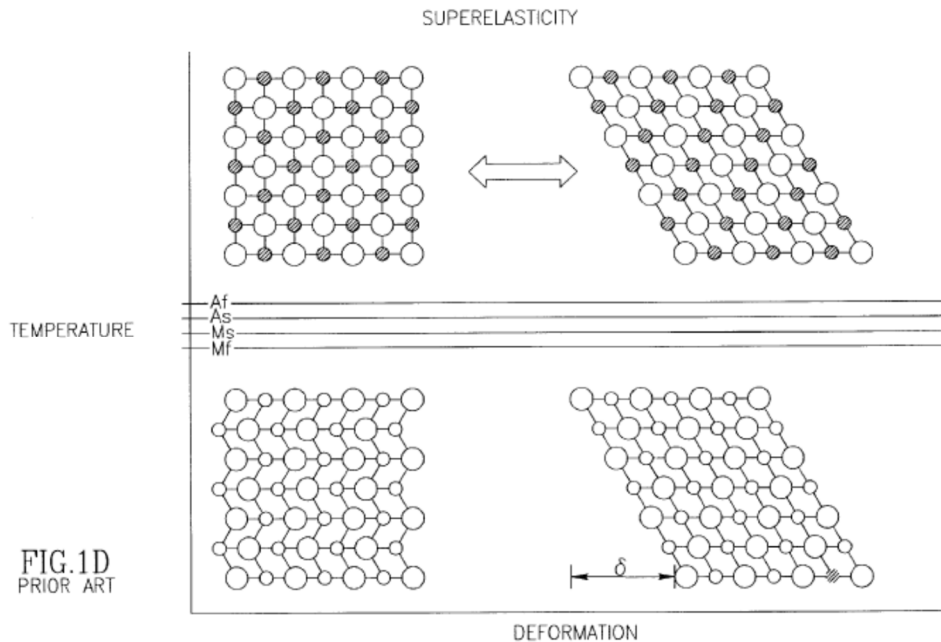


57. Monassevitch also explains that, as illustrated in Fig. 1D (shown below), shape-memory alloys possess super-elastic properties such that when deformed at temperatures above the austenite finish temperature (A_f), the shape-memory alloy will form stress-induced martensite when under stress, but will then revert to its austenitic phase and its original shape when the stress is removed:

Another property that can be imparted to SMA elements, under proper heat treatment and working conditions, 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.** When the stress is removed, the SMA element will **return to the austenitic phase and to its memorized shape in the austenitic phase.** Super-elasticity is also referred to as rubber-band like

property, because the SMA element behaves like a rubber band or a spring, deforming under stress and resuming its original shape when the stress is removed. However, this property is **present only above the temperature A_f** , and only when it is specifically imparted to an SMA element, by proper heat treatment and working conditions.

Id., 2:13-27.¹



58. Monassevitch discloses numerous embodiments of shape memory alloy staples and methods for using them for fracture fixation. Pertinent to my analysis here are three embodiments that are taught as using the superelastic property of the shape memory alloy staple. As discussed below, in each of these embodiments, a shape memory alloy staple is inserted into two bone fragments to provide bone fixation and stabilize a bone fracture. And in each of these three embodiments, the insertion method takes advantage of the superelastic property of

¹ Emphasis is added throughout unless otherwise noted.

the shape memory alloy by stretching the shape memory alloy staple to create stress-induced martensite. *See, e.g., Id.*, 3:54-56 (“It is an aim of the present invention to provide apparatus and method for adjusting the lengths spans of SMA staples for bone fixations, prior to their insertion into the bone.”); 5:31-35 (“...said step of 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.”).

First Embodiment

59. In one embodiment, Monassevitch describes a method using staple 10, as depicted in Fig. 3A. *Id.*, 12:10-12 (“As seen in FIG. 3A, staple 10, preferably of standard dimensions, having standard web length span L, and straightedges 30 is provided.”). As Monassevitch explains, “staple 10 is formed of titanium-nickel, shape-memory alloy.” *Id.*, 17-19.

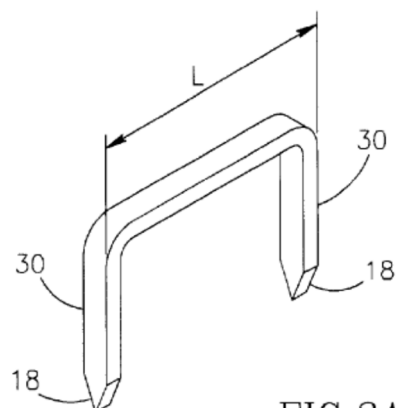


FIG.3A

60. The two straightedges 30 of the staple 10 are designed to be inserted into bore pairs 50 formed in a first bone fragment 40 and a second bone fragment 46. Monassevitch teaches that “[a]s seen in FIG. 3B, 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.”). *Id.*, 12:13-17; *see also* 9:24-36.

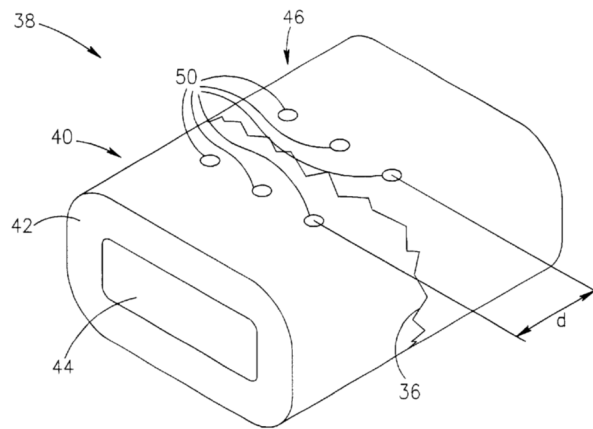
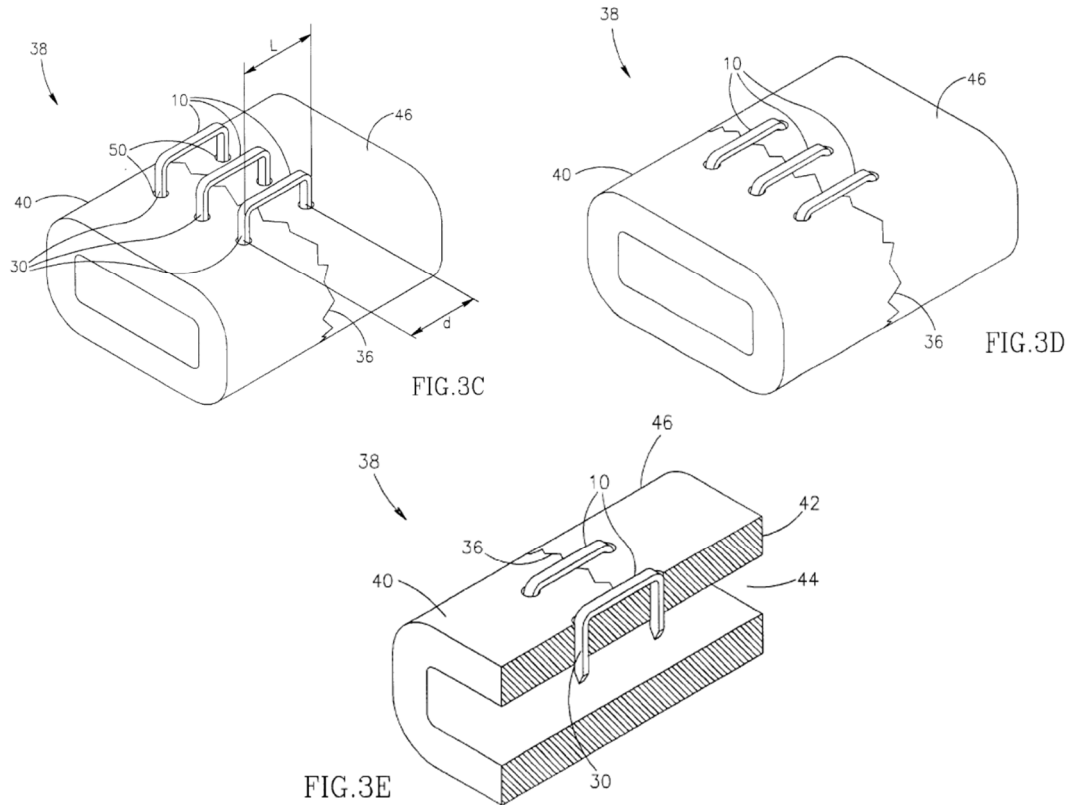


FIG.3B

61. Monassevitch teaches that “[w]here $d > L$, the surgeon (not shown) will adjust the length span L of staple 10 by increasing it” using any of the apparatuses taught in the specification. *Id.*, 12:18-20. Thus, “[a]s seen in FIGS. 3C-3E, staple 10 of adjusted length span L , so that L is equal to d , is inserted into bone 38.” *Id.*, 12:21-22.



62. As a result of the stretching, Monassevitch explains that: “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.” *Id.*, 12:23-25. A POSITA would appreciate that this bone fixation is the result of the compression generated across the fracture interface 36 after staple 10 is released from the apparatus used to perform the stretching (for example, apparatus 60, 90, 100 or 140 (*see Id.*, 12:5-8)) and permitted to return itself to its pre-deformed state.

63. I note that, while the term “plastic deformation” has been used in the art to refer to deformation that is not reversible, Monassevitch refers to plastic

deformation as including deformation that is capable of inducing a stress-induced martensite state in a shape memory alloy, such that the alloy can revert its original shape when the stress is removed. *See, e.g.*, 2:15-18 (“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.”); 5:31-35 (“said step of 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.”); 15:60-61 (“plastically deforming the staple includes *plastically deforming* the staple by reversible martensitic deformation”); 15:67-16:3 (“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.”).

Second Embodiment

64. In another embodiment, Monassevitch describes a staple 150, which is illustrated in Fig. 8 below. *See* Ex. 1005, 12:59-62. “Staple 150 includes web 12 of a length L_1 , thickness t and two semicircular end sections 19 of a radius R_1 , measured as the inner radius plus half thickness t .” *Id.*, 62-65.

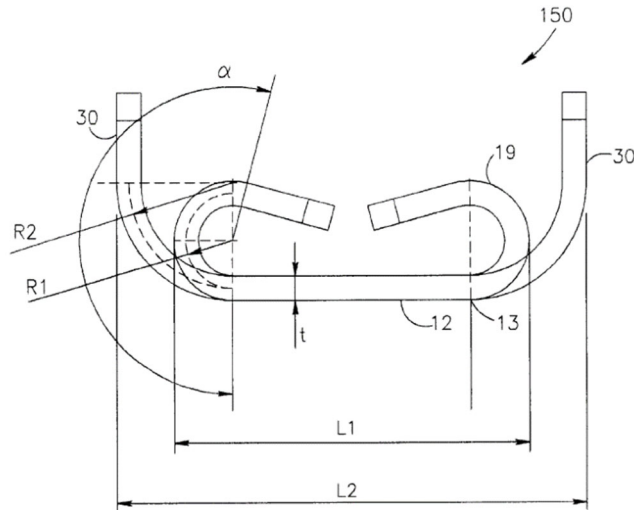


FIG. 8

65. Monassevitch teaches that staple 150 is deformed prior to insertion—for example, using an apparatus such as described in relation to Figs. 5A and 5B—to simultaneously “form straightedges 30, to facilitate insertion into the bone” and “increase the length span L1 to a length span L2.” *Id.*, 13:3-11.

66. Monassevitch teaches that “staple 150 possess [sic] superelasticity and the plastic deformation is performed while staple 150 is fully austenitic, to form stress-induced martensite.” *Id.*, 13:25-28. Thus, Monassevitch explains: “[i]n 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.” *Id.*, 13:29-34. A POSITA would appreciate that this bone fixation is the result of the compression generated across the fracture interface 36 after staple 150 is released from the apparatus being used

to perform the stretching (for example, apparatus 90 (*see Id.*, 14:10-11)) and permitted to return itself to its pre-deformed state

Third Embodiment

67. In yet a third embodiment, Monassevitch describes a staple 200, illustrated in Fig. 10A below. *Id.*, 13:64-66. Monassevitch explains that “[i]n 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 α .” *Id.*, 13:66-14:1; *see also* FIGs. 10A-B. Like staples 10 and 150, Monassevitch teaches that staple 200 is elongated to increase the length span and form stress-induced martensite in the staple prior to insertion. *Id.*, 14:5-12, 14:19-27. Specifically, Monassevitch teaches that “[p]referably, length span L of staple 200 may be increased by straightening, or partially straightening at least one curvature 220, or curvatures 220 and 230.” *Id.*, 14:5-7.

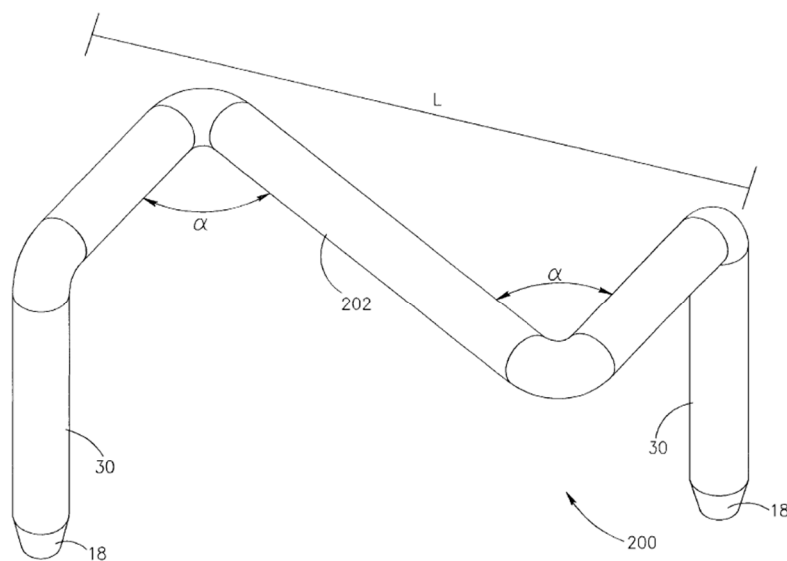


FIG.10A

68. Monassevitch further teaches that, like staples 10 and 150, “staple 200 posses [sic] superelasticity and the plastic deformation is performed while staple 200 is fully austenitic, to form stress-induced martensite.” 14:20-22. Thus, similar to staples 10 and 150, Monassevitch explains: “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.” *Id.*, 14:23-28. And like staples 10 and 150, a POSITA would appreciate that the bone fixation is the result of the compression generated across the fracture interface 36 after staple 200 is released from the apparatus being used to perform the stretching (for example, apparatus 210 (*see Id.*, 14:29-35)) and permitted to return itself to its pre-deformed state.

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

69. To the extent the preamble is limiting, Monassevitch teaches a method of bone fixation. *See Id.*, 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 a method of using staple 10”); 12:59-13:34 (describing a method of using staple 150); 13:62-14:35 (describing a method of using staple 200) *see also* 5:35-37; 6:18-20; 6:58-60; 7:46-48; 9:4-10:6; 16:4-5.

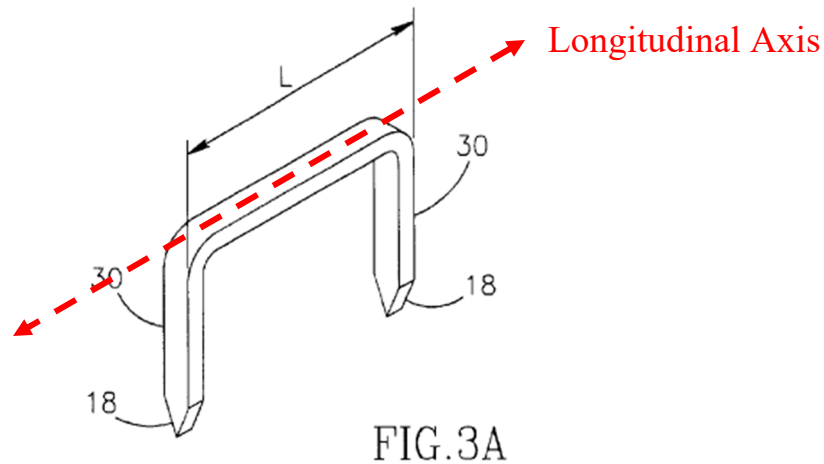
3. [1.1] inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment, wherein the inserting causes a first portion of the bone device to contact the first bone fragment and causes a second portion of the bone device to contact the second bone fragment, the second portion different from the first portion

70. As explained below, it is my opinion that Monassevitch teaches at least three embodiments that perform, or render obvious, the method recited in claim 1. One embodiment involves a method for inserting staple 10; a second embodiment involves a method for inserting staple 150; and a third embodiment involves a method for inserting staple 200.

(a) Embodiment #1 – Staple 10

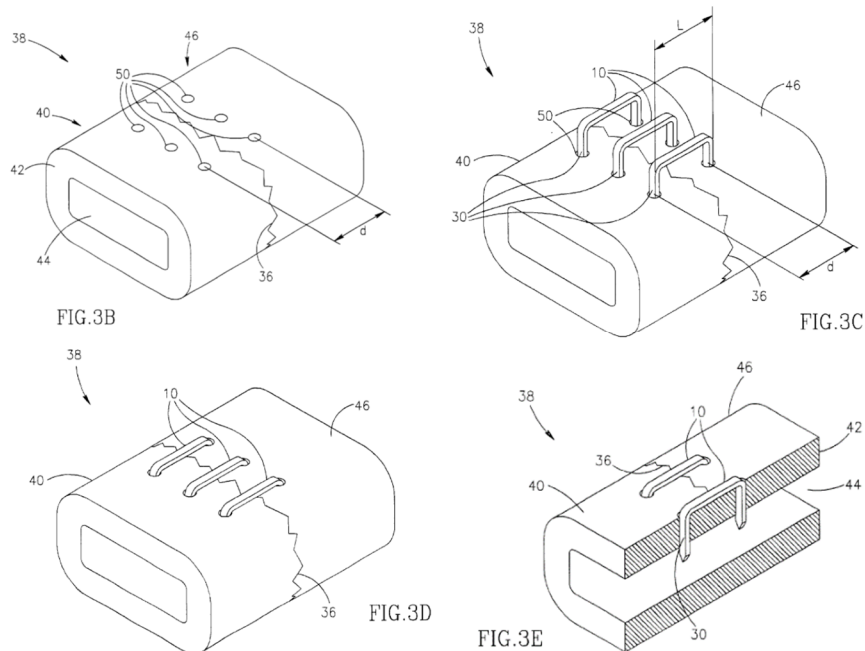
71. In one embodiment, Monassevitch discloses a **bone device** in the form of staple 10, as depicted in Fig. 3A below. *Id.*, 12:5-12:12. The staple 10 has a **longitudinal axis** that extends along the long end of the staple as I have illustrated by the dashed red line. A POSITA would understand that this is the longitudinal axis of the device. Staple 10, and bone fixation staples in general, are longer than they are wide. And this is how the embodiments of Monassevitch are depicted, with the lengthwise direction of the staple designated as “L.” *See, e.g.*, FIGS. 2A-2C, 3A; *see also* 8:22-26; 12:30-58 (teaching that staples can have varying length spans, including length spans from a 6mm length span L to 100mm length span L). Therefore, POSITA would appreciate the longitudinal axis of staple 10 is as I’ve depicted it below. Notably, this is also consistent with how

orthopedic fixation bone staples are traditionally manufactured; i.e. using a wire or bar manufactured by being drawn or extruded in a longitudinal direction and then bent into a desired shape.



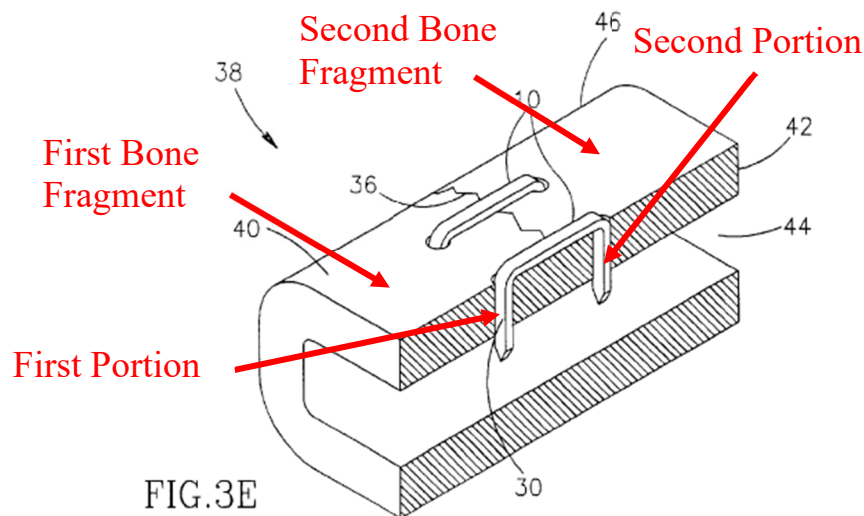
72. I note that, although Monassevitch uses the term “longitudinal axis” in the specification, it does so only in the context of describing Apparatuses 60, 90, and 100, which are used for increasing the length span of the staple. In relation to those Apparatuses, the longitudinal axis is depicted parallel to the z-axis of the coordinate system in figures 4A, 5A, and 11A, and extends along the length (i.e. “longitudinal axis”) of Apparatuses 60, 90, and 100. Monassevitch does not expressly depict the longitudinal axis of staple 10 (or any other staple embodiments that are discussed below). However, for the reasons explained herein, a POSITA would have understood that the longitudinal axis to be as I have depicted.

73. Monassevitch teaches that staple 10 is **inserted into a first bone fragment and a second bone fragment**. As shown in Fig. 3B below, 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.”) *Id.*, 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. Monassevitch further teaches that “[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 has been increased, the staple 10 “of adjusted length span L , so that L is equal to d , **is inserted into bone 38**,” as shown in Figs 3C through 3E below. *Id.*, 12:21-22; *see also* 16:43-46 (“A method of bone fixation, which includes the steps of: drilling at least one pair of bores across a fracture interface of a bone ... inserting the staple into the bores”).



74. 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**. Staple 10 has two straightedges 30, and Monassevitch teaches that inserting the staple 10 into the bore pairs 50 formed in the first bone fragment 40 and the second bone fragment 46 places each of the straightedges in contact with the respective bone fragments. *Id.*, 12:5-23; *see also* 9:52-57 (“As seen in FIG. 3D, staples 10 are fully inserted into bone...As seen in a cross-sectional view of bone 38, in FIG. 3E, staples 10 are inserted so that legs 14 penetrate cortical bone tissue 42 and straightedges 30 protrude from cortical bone tissue 42 into cancellous bone tissue 44”). Thus, as depicted below, a first straightedge 30 represents the claimed first portion (which contacts a first bone fragment 40) and the second straightedge 30 of the staple 10 represents the claimed

second portion (which contacts a second bone fragment 46). A POSITA would appreciate that this contact is enhanced when the bone staple 10 is released from the apparatus being used to do the stretching (for example, apparatus 60, 90, 100 or 140 (*see Id.* 12:5-8)) and attempts to return to its pre-lengthened state. The **second portion is different from the first portion.**



75. Thus, it is my opinion that the above-described embodiment of Monassevitch discloses staple 10 as an example of the claimed “bone device,” and the procedure for using staple 10 involves “inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment,” where the insertion “causes a first portion of the bone device to contact the first bone fragment” and a different “second portion of the bone device to contact the second bone fragment.”

(b) Embodiment #2 – Staple 150

76. Monassevitch discloses another embodiment of a **bone device** in the form of staple 150, shown below. *See Ex. 1005, 12:61-63.* Like staple 10, staple 150 has a **longitudinal axis** as I have depicted with the dashed red line below. A POSITA would understand that this is the longitudinal axis of staple 150 for the same reasons I discussed above for staple 10.

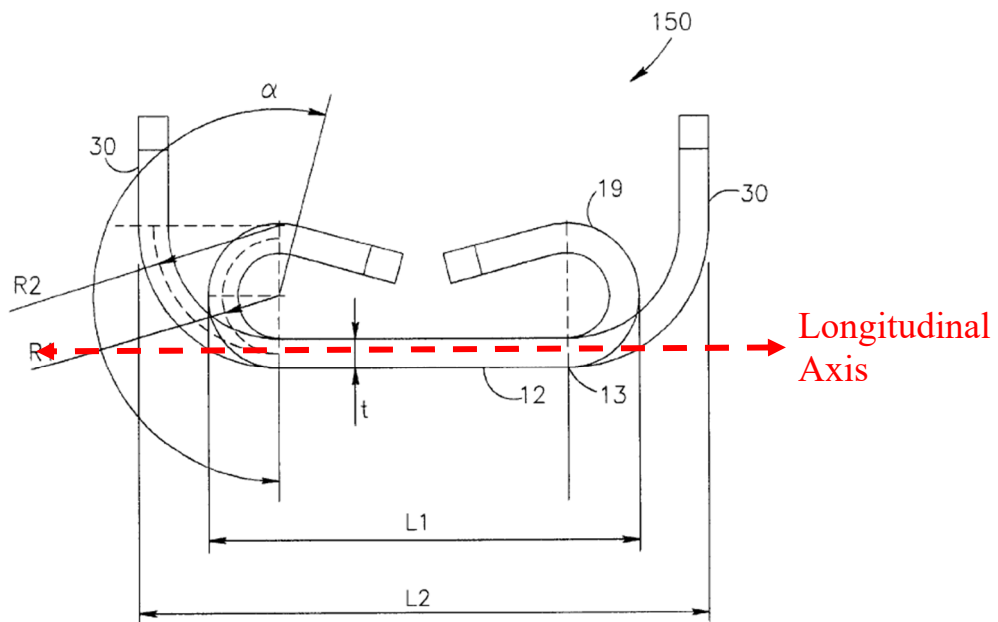


FIG. 8

77. 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.** As Monassevitch teaches: “staple 150 is plastically deformed to simultaneously achieve the following: 1. form straightedges 30, to **facilitate insertion into the**

79. Thus, it is my opinion that the second embodiment described above, using staple 150, involves “inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment,” where the insertion “causes a first portion of the bone device to contact the first bone fragment” and a different “second portion of the bone device to contact the second bone fragment.”

(c) Embodiment #3 – Staple 200

80. Monassevitch also discloses a third embodiment that discloses a **bone device** in the form of staple 200, which is shown below in Figures 10A and 10B. 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.

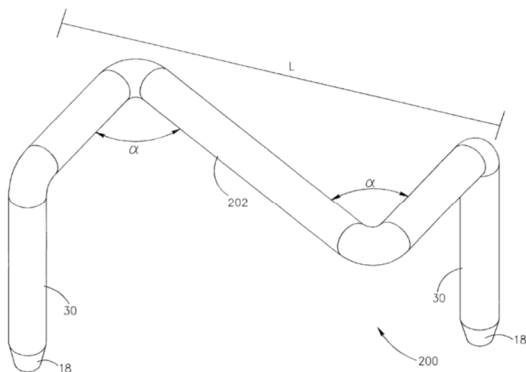


FIG. 10A

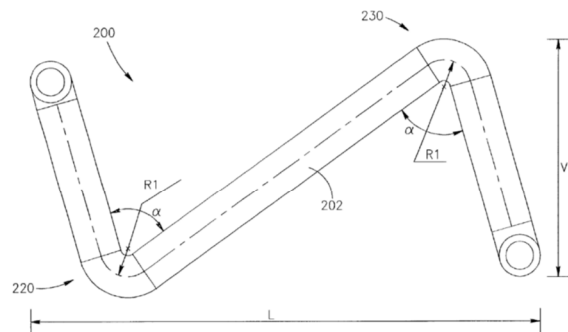


FIG. 10B

81. Staple 200 has a **longitudinal axis** as I have depicted in the top-down view of staple 200 (Fig. 10B) with the dashed red line below. For staple 200, which has additional curvatures 220 and 230, the longitudinal axis would be defined by the central line of the staple in the lengthwise direction. This is consistent with how Monassevitch defines the length L of staple 200. It is consistent with how Monassevitch depicts the longitudinal axis of apparatus' 60, 90, and 100; i.e. as being along the central line in the lengthwise direction. *Id.*, 10:19-21, 10:66-67, 11:30-31; Figs. 4A, 5A, and 6A. And it is consistent with the long axis of staple 200 when the staple is in a fully stretched position. Notably, it is also consistent with how the '222 patent appears to define the longitudinal axes of screw 100 (a bone screw) and bone fixation device 400 (a bone plate). For instance, Fig. 3D is identified in the '222 specification as a "longitudinal cross-sectional view of the bone screw depicted in Fig. 3A," Ex. 1001, 3:50-51. And Fig. 5C is identified in the specification as "a longitudinal cross-sectional view" of the bone fixation device 400 from Fig. 5A. *Id.*, 3:65-66. Both examples depict the "longitudinal cross-sectional view" as along the lengthwise direction of the implant.

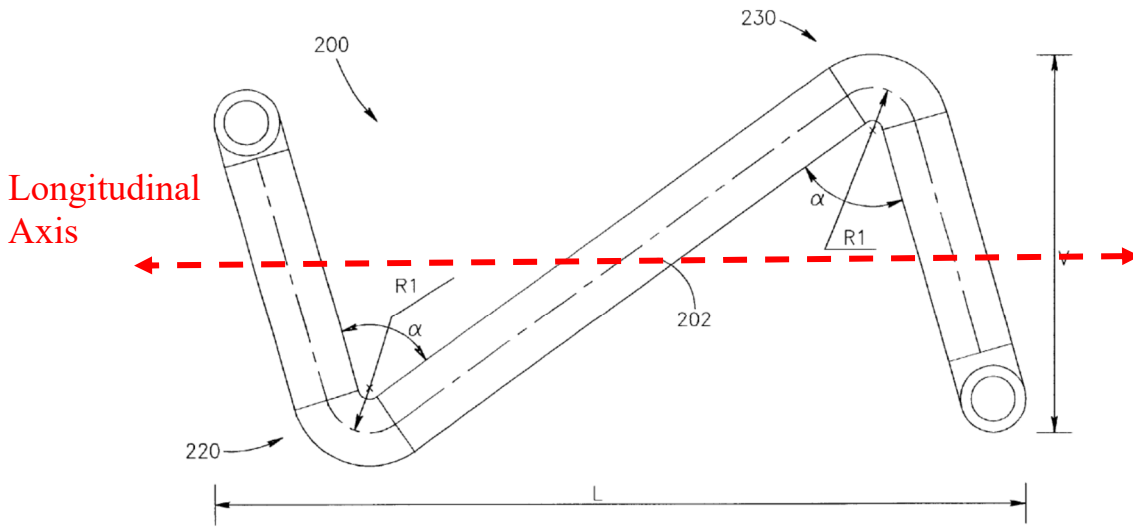
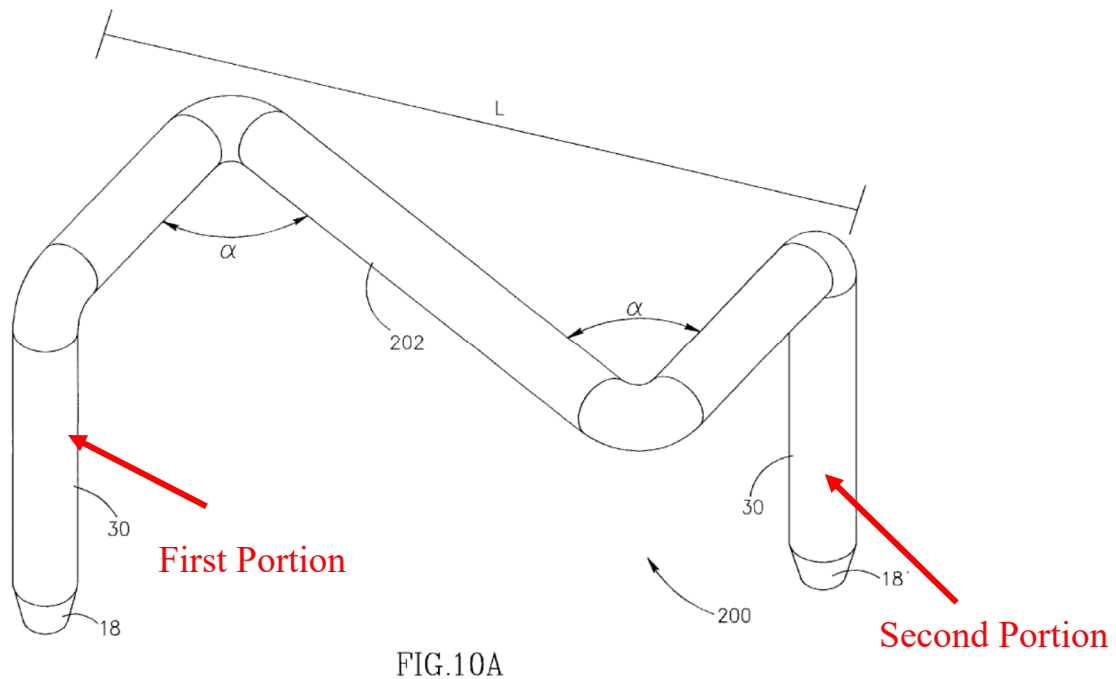


FIG. 10B

82. Like staples 10 and 150, staple 200 is **inserted into a first bone fragment 40 and a second bone fragment 46**. Ex. 1005., 14:23-28 (“staple 200 may be employed to provide bone fixation, while it is in a stress-induced martensite state”). As with staples 10 and 150 discussed above, a first straightedge 30 of staple 200 is the claimed **first portion** and the second straightedge 30 of the staple 200 is the claimed **second portion**. 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 of staple 200) is **in contact with the first bone fragment 40** and the second straightedge 30 (second portion of staple 200, which is **different from the first portion**) is **in contact with the second fragment 46**.



83. Thus, similar to the embodiments discussed above, it is my opinion that the third embodiment of Monassevitch using staple 200 also discloses a method that involves “inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment,” where the insertion “causes a first portion of the bone device to contact the first bone fragment” and a different “second portion of the bone device to contact the second bone fragment.”

4. [1.2] wherein the bone device comprises a shape memory alloy having an austenite finish temperature

84. For each of the first, second, and third embodiments described above, Monassevitch teaches that the staple (10, 150, and 200) is made of **a shape-memory alloy**. *Id.*, 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**

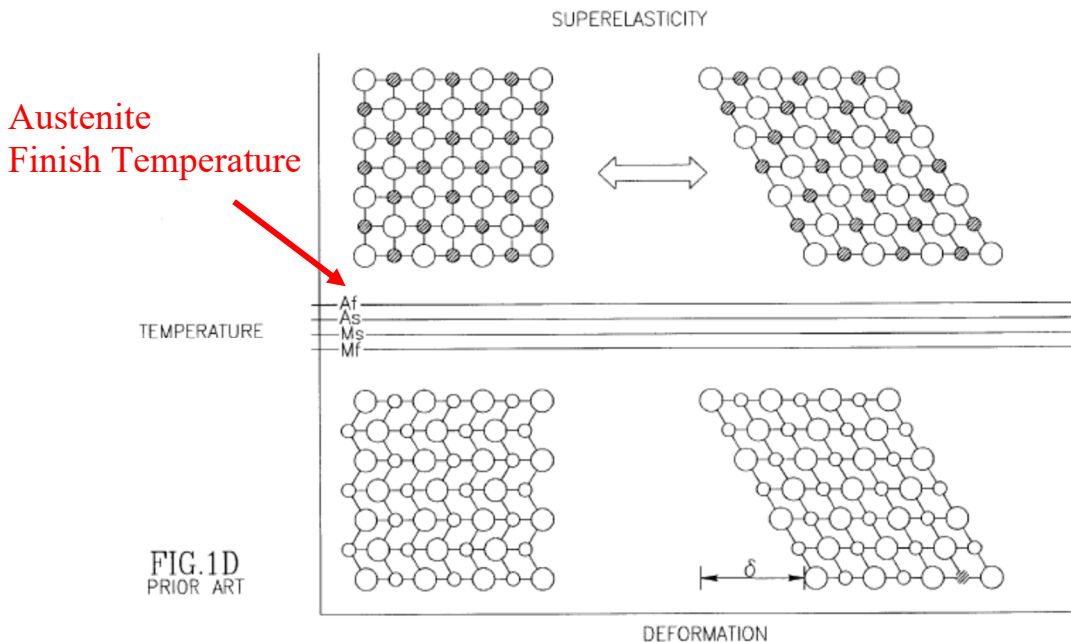
fixations, prior to their insertion into the bone.”); 4:35-36 (“[I]n accordance with the present invention, said **staple is formed of an SMA alloy**.”); 8:18-19 (“Preferably, staple 10 is **formed of titanium-nickel, shape-memory alloy....**”); 12:28-29 (“staple 10 may be used to provide bone fixation, **while in a stress-induced martensite state**”); 12:61-62 (“**In its austenitic shape**, staple 150 is similar to staple 10.”); 14:7 (“[S]taple 200 is **formed of a shape-memory alloy**.”); 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...**”).

85. A POSITA would also understand that the shape memory alloy used for any of staples 10, 150, or 200 would have **an austenite finish temperature**. As explained above, all shape memory alloys, including Titanium-nickel (also known as Nitinol), are characterized by a number of 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. Indeed, 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.” *Id.*, 2:16-18; *see also* 5:20-24 (“[T]he staple is formed of a shape-memory alloy having a fully martensitic phase within a first temperature range, and having a fully austenitic phase within a second temperature range, which is higher than the first temperature range...”). As shown below, Monassevitch also depicts the

austenite finish temperature A_f in relation to Fig 1D (labeled as prior art), which illustrates the transformation of a shape memory alloy from the fully austenitic phase to the stress-induced martensitic phase. *Id.*, 2:28-30 (“FIG. 1D Schematically illustrates a typical cyclic transformation of a super elastic alloy, at a constant temperature above the temperature A_f . The transformation between the austenitic phase and a stress-induced martensitic phase is brought about by stress and is eliminated when the stress is removed.”). Additionally Monassevitch teaches:

As seen in FIG. 3F, in accordance with the first embodiment of the present invention, in the body, staples **10** warm up to body temperature and become fully austenitic, resuming their memorized shape of FIG. 2A or 2B, and clamping bone fragments **40** and **46** together. Preferably, staples **10** have been imparted with super-elasticity, so as to provide dynamic osteosynthesis of the bone fragments. In accordance with the second embodiment of the present invention, staples **10** must be locally heated to a temperature above A_f (FIG. 1A), which may be for example, 42-45° C., for transforming staples **10** to the fully austenitic phase. When fully austenitic, staples **10** resume their memorized shape and clamp bone fragments **40** and **46** together. The memorized shape is maintained in the body, even when body temperature is below A_f (FIG. 1A) *Id.*, 9:58 - 10:5.

86. Thus, in my opinion, a POSITA would understand—based both on the teachings of Monassevitch and/or the knowledge of a POSITA— that the shape memory alloy used for staples 10, 150, and 200, as described above, would have an austenite finish temperature.



5. [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

87. For each of the three embodiments discussed above, Monassevitch teaches creating at least a partial transformation into a stress-induced martensitic phase in a responsive portion of the staple by stretching the staple along its longitudinal axis.

(a) Embodiment #1 – Staple 10

88. Monassevitch discloses **stretching** the length span L of staple 10 such that the deformation results in the shape memory alloy 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

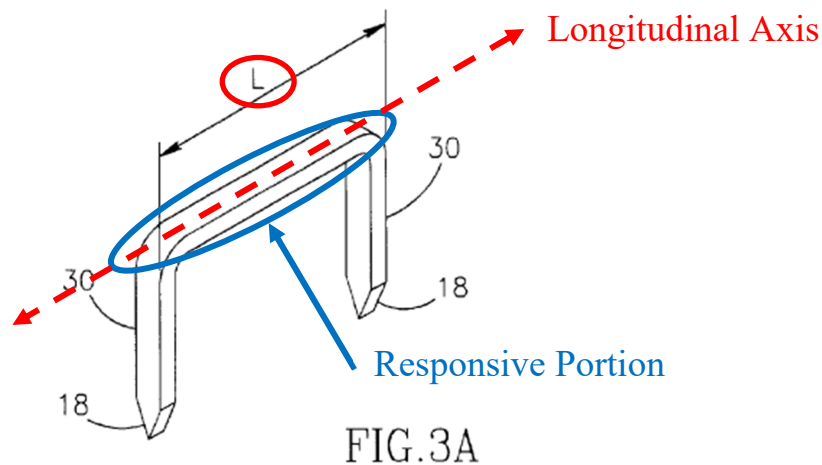
4. As seen in FIGS. 3C-3E, staple 10 of adjusted length span L, so that L is equal to d, is inserted into bone 38.

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**.

Id., 12:18-29; *see also* 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.”); 15:35-50 (“A method of increasing a length of a staple, which includes the steps of ... plastically deforming the staple, to increase its length span.”); 15:60-61 (“plastically deforming the staple includes plastically deforming the staple by reversible martensitic deformation”); 15:67-16:3 (“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.”). In view of these teachings, a POSITA would understand (or at least find it obvious) that the stretching of length span L results in the creation of **at least a partial transformation into a stress-induced martensitic phase** within the length span L of the staple.

89. Because the length span L of staple 10 is made of a shape memory alloy and designed to be lengthened in order to create stress-induced martensite (so as to then provide compression to the bone when the staple is inserted), it is my opinion that a POSITA would recognize that the length span L represents a

“**responsive portion**” of staple 10. *See also* Ex. 1001, 2:21-23 (“The responsive zone is adapted to apply a desired pressure to the bone when coupled thereto”). And, as illustrated below, the lengthening of the span L (and so 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**. *See also* Ex. 1005., 12:5-8 (explaining that the stretching of span L can be performed using “any of apparatus 60 (Fig. 4A), apparatus 90 (Fig. 5A), apparatus 100 (Fig. 6A), or apparatus 140 (Fig. 7)”).



90. I note that claim language does not require the responsive portion to be of any certain shape or dimension. Although the '222 patent states that the “responsive element or responsive zone, in a preferred embodiment, has a smaller cross sectional area than the non-responsive part” (Ex. 1001, 10:7-9), it is my understanding that claims are not limited to preferred embodiments. Indeed, similar language, “responsive zone,” is used with reference to the “middle section

814” of another embodiment shown in Figure 8 in which a rod 800 has a constant cross-sectional area. *Id.*, 8:20-28. The claim language also does not require that the “responsive portion” be defined as commensurate with the portion of the device that is being stretched. As such, one could also choose to define a “responsive portion” as some subset of span L, or to include portions of straightedges 30 along with span L. But how one ultimately decides to perform the box-drawing exercise with regard to the “responsive portion” does not alter my analysis because, under any of these approaches, it is my opinion that the responsive portion would still be stretched along the longitudinal axis of the device so as to create in the responsive portion at least a partial transformation into a stress-induced martensitic phase.

(b) Embodiment #2 – Staple 150

91. The second embodiment of Monassevitch relating to staple 150 likewise discloses 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.

92. 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.**”

Id., 13:25-34.

93. To create the stress-induced martensite in staple 150, Monassevitch teaches that the staple 150 is deformed by **stretching** the staple both to form straightedges 30 and to lengthen the length span of the staple from length L1 to length L2:

[S]taple 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., 13:4-9; *see also* 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 (“A method of increasing a length of a staple, which includes the steps of ... plastically deforming the staple, to increase its length span.”); 15:60-61 (“plastically deforming the staple includes plastically deforming the staple by reversible martensitic deformation”); 15:67-16:3 (“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.”); 16:43-65 (“A method of bone fixation, which includes the steps of...plastically deforming the staple, reversibly in its martensitic phase ...to increase the length span of the web to a desired value”); 17:3-7 (“physically deforming the staple, reversibly, in its martensitic phase, includes plastically deforming the staple in a stress-induced martensitic phase at a temperature range of the fully austenitic phase.”).

94. A POSITA would understand (or at least find it obvious) that such deformation would create at least a partial transformation into a stress-induced martensite phase in **a responsive portion** of the staple, as depicted below. A POSITA would also understand that the depicted portion represents a responsive portion because, as explained above, this portion is comprised of a shape memory alloy possessing superelasticity, and the stress caused by stretching is imparted within this region to create at least a partial transformation into stress-induced martensite, such that this portion will exhibit superelasticity and provide compression to the bone when the staple is inserted.

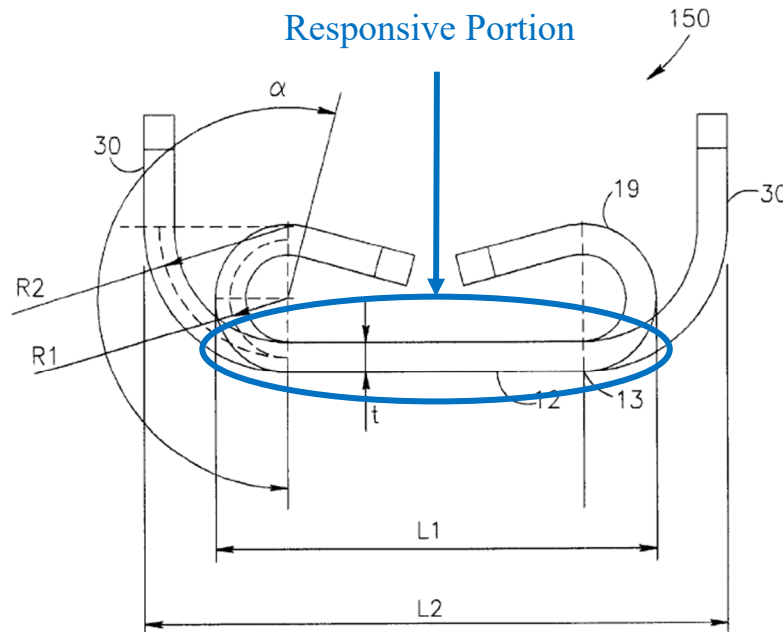


FIG. 8

95. The stretching that results in the creation of stress-induced martensite in the responsive portion of staple 150 occurs “**along the longitudinal axis**” of the device. As Monassevitch explains, the deformation described above for staple 150 “can be achieved, for example, by apparatus 90,” which is depicted in Fig. 5B below. *Id.*, 13:10-11. Monassevitch teaches that this device is used to increase the length span of staple 150 from length L1 to length L2. *Id.*, 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. Thus, a POSITA would recognize that the direction of the stretching of staple 150 is along the longitudinal axis of the staple.

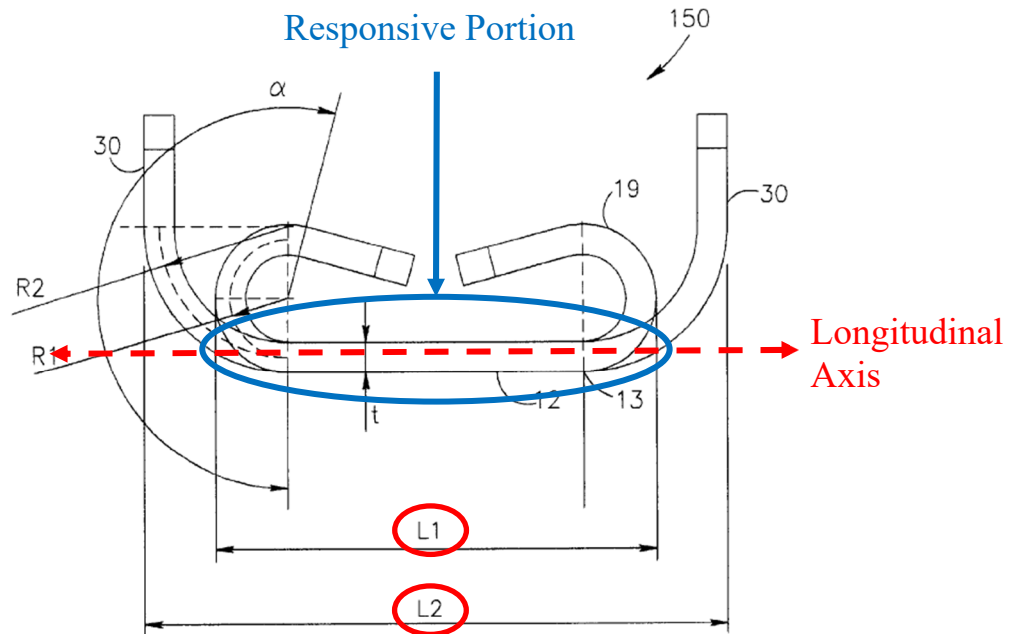


FIG. 8

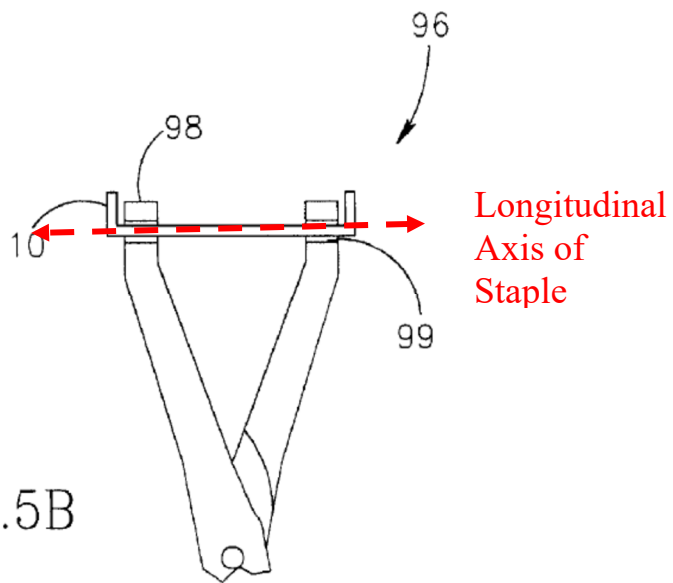


FIG. 5B

96. I note that the claim does not require stress-induced martensite to be created in every part of the responsive portion. Here, depending on how much staple 150 is stressed, it would be obvious to a POSITA that stress-induced

martensite may be created along the entire responsive portion (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). In either instance, at least a partial transformation into a stress-induced martensitic phase is created in the responsive portion.

97. I also note that the claim does not require that a device only have one responsive portion. For instance, a POSITA would recognize that the above-described deformation of staple 150 would also result in the deformation in the ends of section 19 of staple 150 as well as in the depicted responsive portion. *See* Ex. 1005, 2:16-18 (“Preferably, each semicircular end section 19 has an angle α associated there with, measured from point 13, wherein is generally greater than 90° . Preferably, staple 150 is plastically deformed so that α becomes 90° . When this happens, a new radius of curvature, R_2 , is generated, and the length span of web 12 increases from L_1 to L_2 .”). As a result, stress-induced martensite may also be created outside of what I have depicted as the “responsive portion.” However, claim 1 only requires that at least a partial transformation into a stress-induced martensitic phase be created “in a responsive portion.” I understand that “a responsive portion” can be one or more responsive portions so long as at least one responsive portion satisfies the remaining claim limitations. Thus, in my opinion,

the above-described embodiment of Monassevitch staple 150 teaches creating in a responsive portion at least a partial transformation into a stress-induced martensitic phase (by stretching the responsive portion along the longitudinal axis of the device) regardless of whether there is additional stress-induced martensite that is formed in other portions of staple 150.

(c) Embodiment #3 – Staple 200

98. Like with staples 10 and 150, 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.

99. Monassevitch teaches that the stress-induced martensite is created by **stretching** the staple 200 to lengthen span L. 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.” *Id.*, 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. 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.

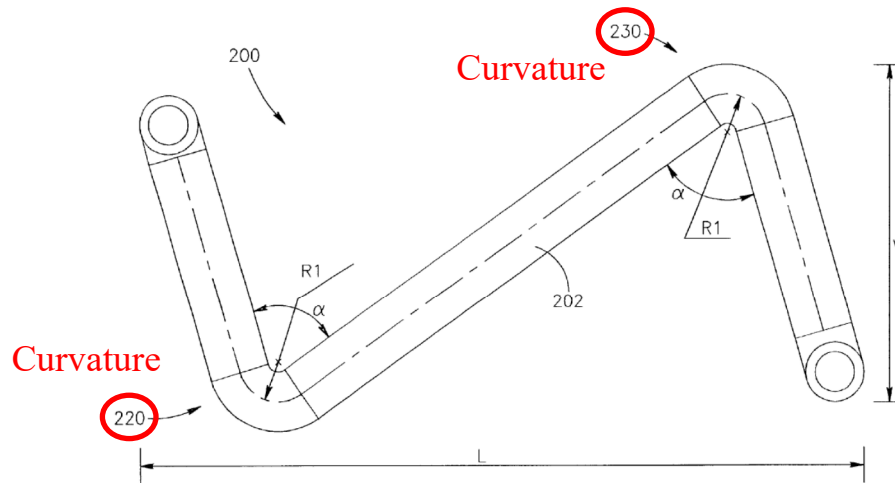


FIG. 10B

100. Thus, in my opinion, this embodiment 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**. As I have depicted below, a responsive portion of the staple is highlighted in blue, as this portion includes the 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). 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.” *Id.*, 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. *See also id.*, 14:29-35 (describing apparatus 210 for increasing the length span L of web 202 of staple 200).

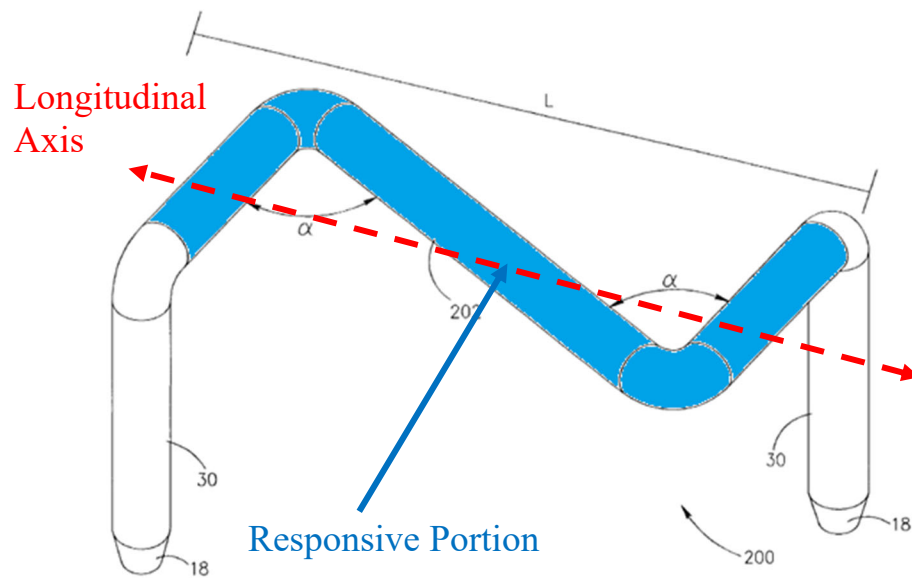


FIG.10A

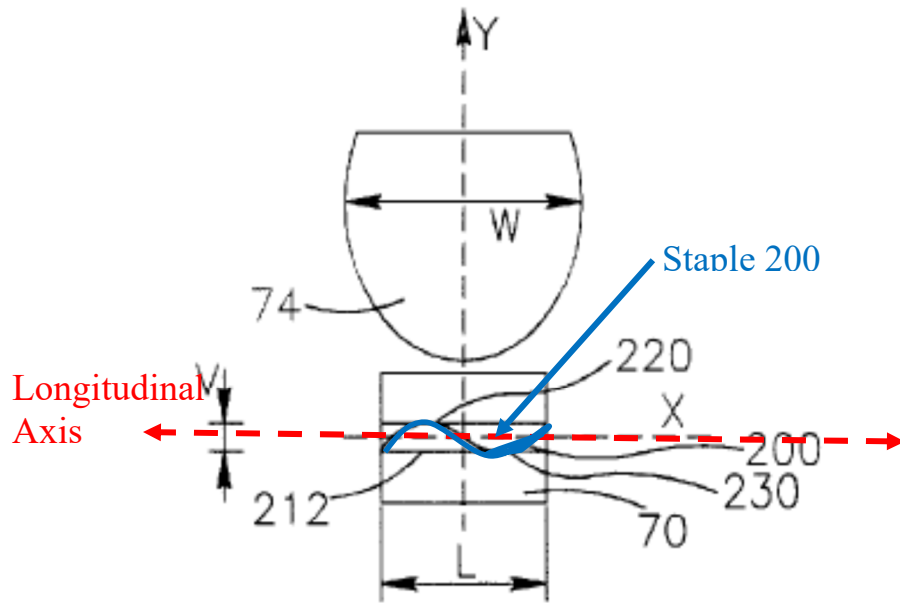
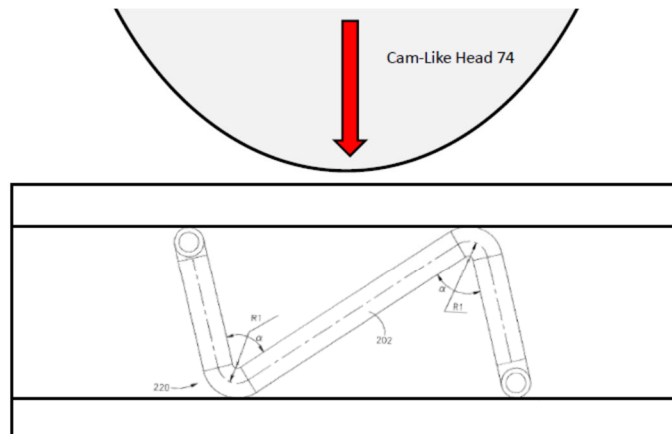


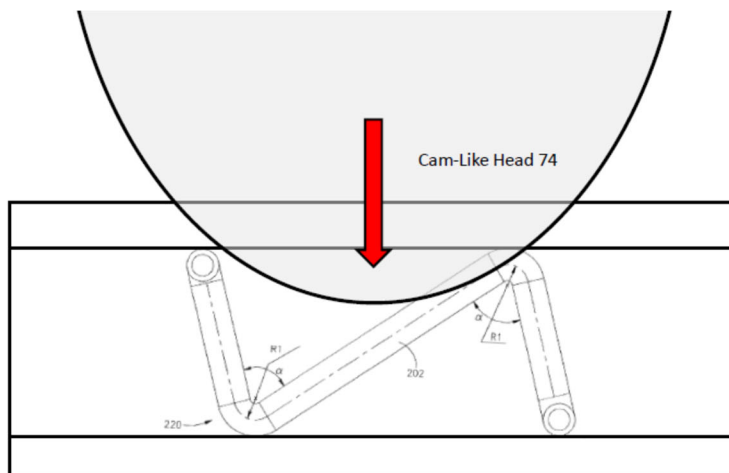
FIG.11C

101. The following series of images, which I prepared, help illustrate how a POSITA would understand the operation of apparatus 210 and how it performs the stretching of length span L of web 202 of staple 200 in the longitudinal direction in order to create at least a partial transformation into a stress-induced martensitic phase in the responsive portion. I note that these images are for exemplary purposes to illustrate the manner in which stretching occurs, and are not intended to be to scale, nor to depict the amount of preferable deformation described in Monassevitch.

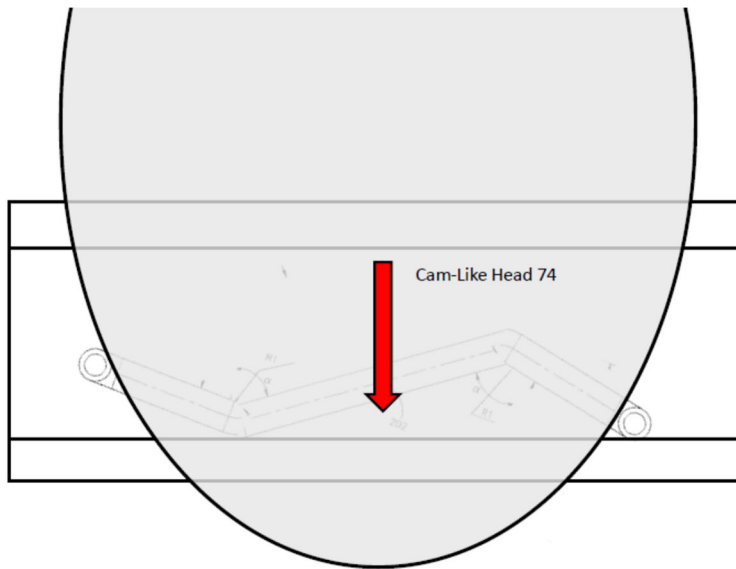
Cam-Like
Head in Open
Position



Cam-Like
Head Slides
Towards
Staple 200
Coming into
Contact With
At Least One
Straightedge
30



Cam-Like
Head Slides
Between
Straightedges
30 Forcing
them Apart to
Increase
Length Span L
of Staple 200



6. [1.4] after performing the stretching, fixing the second portion of the bone device to the second bone fragment; and

102. For each of the three embodiments discussed above, Monassevitch teaches and/or suggests fixing the second portion of the bone device to the second bone fragment after performing the stretching.

103. With regard to the first embodiment (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**. As explained above with respect to element [1.1], Monassevitch teaches elongating length span L of the staple prior to inserting the staple into the second bone fragment 46. *Id.*, 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. 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 that the force caused by the staple 10 attempting to return to its pre-stretched austenitic shape results in the staple 10, including a second portion of staple 10 as shown below, being further fixed in the second bone fragment 46.

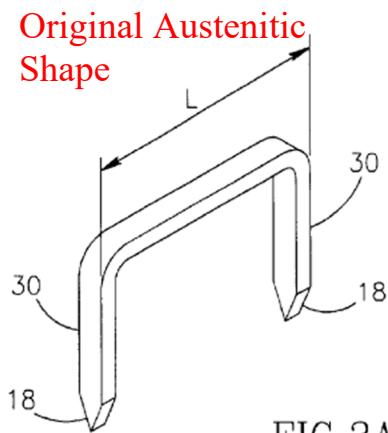


FIG. 3A

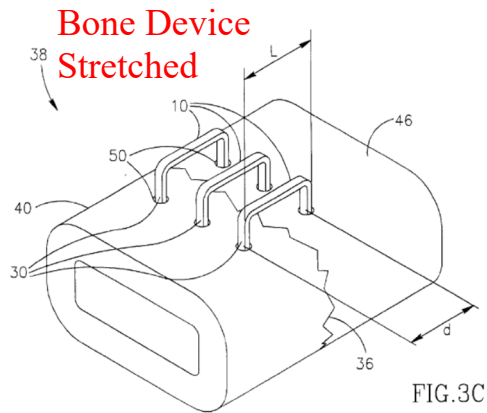


FIG. 3C

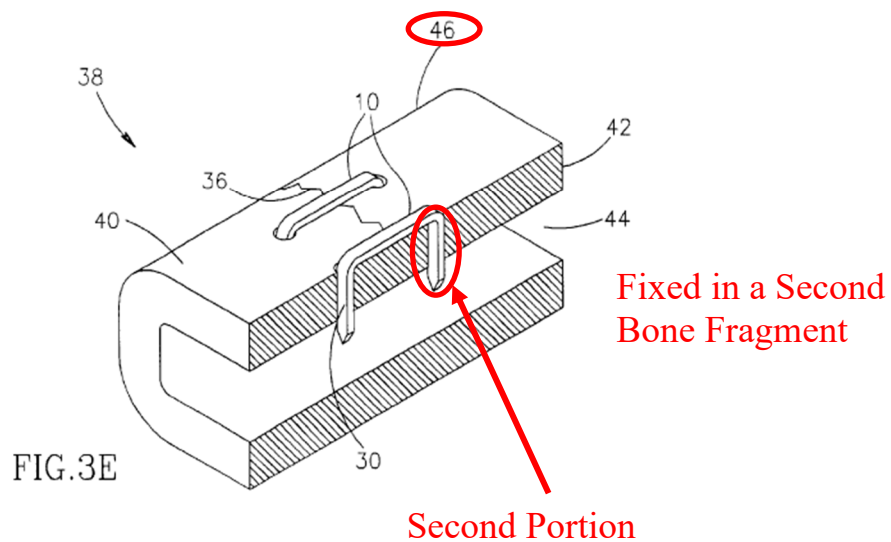


FIG. 3E

104. Likewise, for the second embodiment (staple 150), Monassevitch teaches that the second portion of staple 150 is inserted into and **fixed to the second bone fragment 46 after stretching** (i.e., after the length span of the staple is increased through stretching). *See Id.*, 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 released from the stretching instrument and fixed in the second bone fragment for the same reasons as discussed above for the first embodiment (i.e., the completion of insertion of staple 150 into the bone fixes it to the bone fragment and the force caused by the staple 150 attempting to return to its austenitic shape results in the staple 150, including the second portion of staple 150, being further fixed in the second bone fragment).

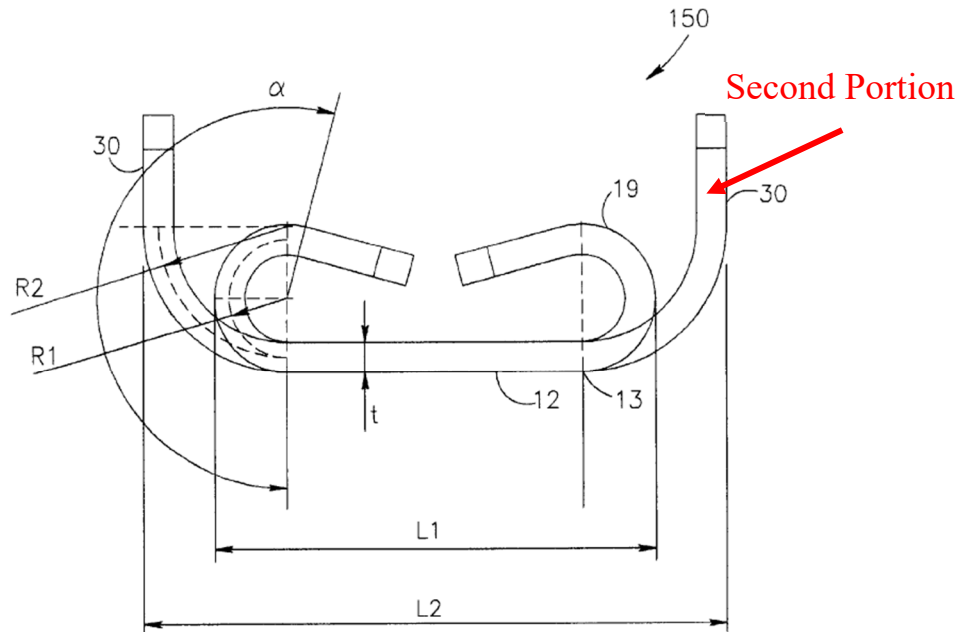
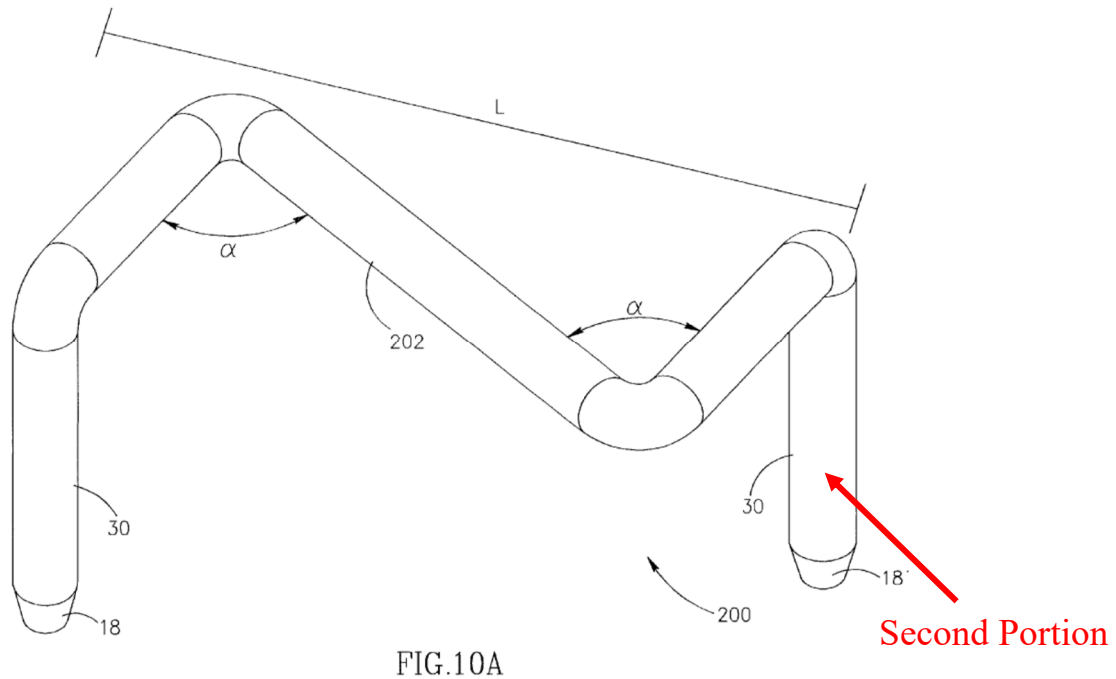


FIG. 8

105. The same is also true for the third embodiment (staple 200). Like staples 10 and 150, Monassevitch teaches that staple 200 is inserted into and **fixed to the second bone fragment 46 after stretching** length span L of the staple. *See Id.*, 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.”). And as with staples 10 and 150 above, a POSITA would understand (or at least find it obvious) that the second portion (as depicted below) 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 the staple 200

attempting to return to its austenitic shape results in the staple 200, including the second portion of staple 200, being further fixed in the second bone fragment).



7. [1.5] wherein the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy.

106. In my opinion, Monassevitch teaches and/or suggests that the creating/stretching step for each of staples 10, 150, and 200 is performed **at a temperature greater than the austenite finish temperature of the shape memory alloy.**

107. As explained above in the section discussing claim element [1.3], for each of the embodiments discussed (i.e., staples 10, 150, and 200), Monassevitch

teaches 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**.

Id., 12:24-29.

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**.

Id., 13:25-34.

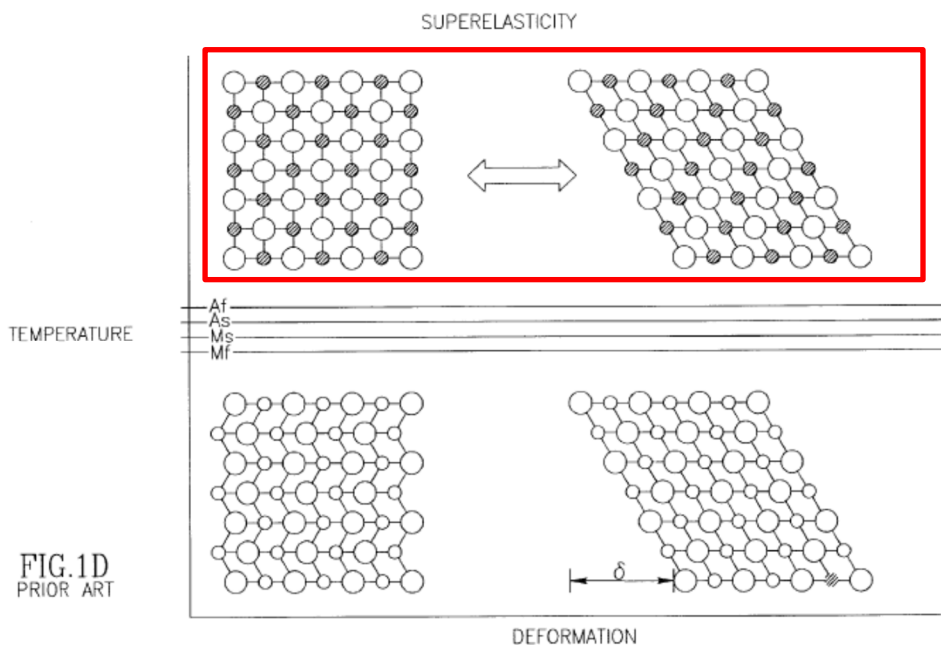
Staple 200 posses [sic] superelasticity and the plastic deformation is **performed while staple 200 is fully austenitic, to form stress-induced martensite**...In other words, staple 200 may be employed to provide bone fixation, while it is **in a stress-induced martensite state**.

Id., 14:20-28.

108. In my opinion, Monassevitch further teaches that the superelastic property of shape memory alloys is exhibited at temperatures above A_f because that is the temperature range at which the shape memory alloy is austenitic and will form stress-induced martensite under stress. *Id.*, 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**). *Id.*, 2:16-25. Monassevitch further illustrates in Fig. D (below) “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. The claims recited in Monassevitch likewise disclose: “A method of increasing a length of a staple, which includes the steps of ... plastically deforming the staple, to increase its length span” (claim 7) where “plastically deforming the staple includes plastically deforming the staple by reversible martensitic deformation” (claim 9) where (“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.**” (*Id.*, 15:35-16:3) and “A method of bone fixation, which includes the steps of...plastically deforming the staple, reversibly in its martensitic phase ...to increase the length span of the web to a desired value” (claim 14) where “physically deforming the staple, reversibly, in its martensitic phase, includes **plastically deforming the staple in a stress-induced martensitic phase at a temperature range of the fully austenitic phase.**” (claim 16) (*Id.*, 16:43-65 17:3-7). Accordingly, it is my opinion that

Monassevitch describes that creating stress-induced martensite in staple 10, 150, and 200 involves stretching the staple at a temperature greater than the austenite finish temperature.



109. Moreover, as explained above in Section V, it was well known that shape memory alloys exhibit superelasticity (in which stress-induced martensite is formed upon the application of stress) at temperatures above the austenite finish temperature (A_f). A POSITA would thus know that the austenite finish temperature (A_f) is the temperature above which a shape memory alloy would be completely transformed from martensite to austenite and thus in the austenitic phase. Indeed, during prosecution of the '222 patent, Applicant acknowledged this fact:

“Para. [0052] states "The PE (pseudoelastic) state is observed when T_a (the surrounding temperature) is greater than T_1 (the transformation

temperature)" for a shape memory alloy. Therefore, the surrounding body temperature will be above/greater than the transformation temperature for the pseudo elastic state. **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."**

Ex. 1004, pp. 95-96 (8/19/10 Response) (explained as part of Applicant's argument as to why claim 48 (which issued as claim 2) was supported by the specification).

A POSITA would thus understand that, in order 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 shape memory alloy.

110. At a minimum, however, it would have been obvious to select a shape memory alloy for staples 10, 150, and 200 having an austenite finish temperature that is lower than the temperature at which the staple would be stretched (operating room temperature). For the reasons discussed above, doing so would ensure that that shape memory alloy staple would be austenitic—and so capable of forming stress-induced martensite—when being stretched.

8. Claim 2

111. 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.” Each of the three embodiments described above teach stretching the staple while it is substantially in an austenitic phase.

112. The intrinsic record of the '222 does not use the phrase nor provide an explanation as to what it means to stretch the bone device with it “*substantially* in an austenitic phase.” However, in addressing a 112 rejection during prosecution, the Applicant provided the below argument as to why this claim limitation was supported by the specification.

“Body temperature will be the surrounding temperature of the osteosynthetic device after the device is inserted into the patient. Para. [0034] states "In one embodiment, the fixation devices, such as screw 100, are machined from a shape memory material such as Nitinol that is thermally treated to exhibit pseudo-elasticity at body temperature." Para. [0052] states "The PE (pseudoelastic) state is observed when T_a (the surrounding temperature) is greater than T_1 (the transformation temperature)" for a shape memory alloy. Therefore, the surrounding body temperature will be above/greater than the transformation temperature for the pseudo elastic state. 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. 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.***”

Ex. 1004, pp. 95-96 (8/19/10 Response). While I do not believe that this explanation helps to clarify the full scope of the claim, Applicant’s statement seems to suggest that a shape memory alloy that is fully austenitic (i.e., at a temperature above the austenite finish temperature such that the alloy has finished its transformation to the austenite phase) would meet the limitation of being

“substantially in an austenitic phase.” Moreover, as I explained above in section IX.B, I have been asked, for purposes of my analysis, to apply Patent Owner’s apparent interpretation; i.e. that a shape memory alloy is substantially in an austenitic phase if only part of the austenitic shape memory alloy is transformed to martensite due to the recited step, or if the shape memory alloy is above the austenite finish temperature (in which case it would be fully austenitic) prior to the recited step. Applying this interpretation, it is my opinion that Monassevitch discloses, or at least renders obvious, this limitation with respect to each of the staple 10, 150, and 200 embodiments for the reasons described above with respect to claim limitations [1.2], [1.3] and [1.5].

113. In short, with regard to the first embodiment (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. As I explained above, because the staple is lengthened to create a stress-induced martensite state, it would be understood (or at least obvious) that the staple is being stretched while it is fully austenitic. *See Id.*, 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.”);

see also 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.**”)

114. Similarly, Monassevitch also teaches that staples 150 and 200 are stretched while fully austenitic. *Id.*, 13:25-34 (“[S]taple 150 posses [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 posses [sic] superelasticity and **the plastic deformation is performed while staple 200 is fully austenitic**, to form stress-induced martensite.”).

115. Accordingly, in my opinion, a POSITA would understand, or at least find it obvious, that the stretching of each of staples 10, 150, and 200 would be performed with the shape memory alloy of the staple being substantially in an austenitic phase.

9. Claim 5

116. 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 (staple 10, 150, and 200), Monassevitch discloses this limitation, or at least renders it obvious, for the reasons described above with respect to claim limitation [1.5] and claim 2.

10. Claim 6

117. 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.**” In my opinion, Monassevitch discloses or at least renders obvious this limitation with respect to each of the three embodiments described above (staple 10, 150, and 200).

118. 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. *See Id.*, 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 claim element [1.5], it would be understood or at least obvious to a POSITA 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 shape memory alloy.

119. Thus, 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**. Indeed, as Monassevitch explains, the “super-elasticity, or Stress-Induced Martensite” property of a shape memory alloy is “**present only above the temperature A_f** .” *Id.* 2:13-27.

11. Claim 7

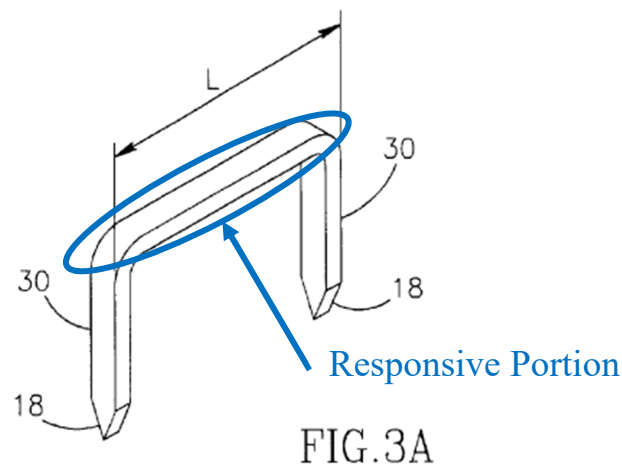
120. Claim 7 depends from claim 1 and further requires “**wherein inserting the bone device into the second bone fragment is performed while the responsive portion is substantially in an austenitic phase.**”

121. As noted above with respect to claim 2, the specification of the ’222 does not use the phrase nor provide guideposts that would give reasonable certainty as to when the insertion of a bone device is “performed while the responsive portion is *substantially* in an austenitic phase.” However, for purposes of my analysis, I have been asked to apply Patent Owner’s apparent interpretation; i.e. that a shape memory alloy is substantially in an austenitic phase if only part of

the austenitic shape memory alloy is transformed to martensite due to the recited step, or if the shape memory alloy is above the austenite finish temperature (in which case it would be fully austenitic) prior to the recited step. Applying this interpretation, it is my opinion that Monassevitch discloses or at least renders obvious this limitation with respect to each of the three embodiments described above (staple 10, 150, and 200), as explained below.

(a) Embodiment #1 – Staple 10

122. Starting with the first embodiment (staple 10), as I have described above, Monassevitch discloses that the length span L of staple 10 is stretched to create stress-induced martensite in a responsive portion of the staple. *See* claim element [1.3]; Ex. 1005, 12:18-29.



123. Monassevitch further teaches that staple 10 can be provided in varying lengths, each of which can stretched to varying lengths for insertion into the bone fragments:

In accordance with a preferred embodiment of the present invention, staples 10 of length spans between 6 and 18 are provided in three length spans, of 4 mm increments, as follows:

1. A Staple of 6 mm length span L, arranged for length spans between 6 and 10 mm.
2. A Staple of 10 mm length span L, arranged for length spans between 10 and 14 mm.
3. A Staple of 14 mm length span L, arranged for length spans between 14 and 18 mm.

Alternatively, staples 10 of length-spans between 5 and 30 are provided in five length spans, of 5 mm increments, as follows:ps [sic]

1. A Staple of 5 mm length span L, arranged for length spans between 5 and 10 mm.
2. A Staple of 10 mm length span L, arranged for length spans between 10 and 15 mm.
3. A Staple of 15 mm length span L, arranged for length spans between 15 and 20 mm.
4. A Staple of 20 mm length span L, arranged for length spans between 20 and 25 mm.
5. A Staple of 25 mm length span L, arranged for length spans between 25 and 30 mm.

Alternatively, staples 10 of length spans between 10 and 100 mm are provided in ten length spans, of 10 mm increments, or in 20 length spans of 5 mm increments.

Alternatively, other length spans and other incremental increases are provided.

Id., 12:30-58; *see also* 8:22-23; 18:23-38.

124. 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). Take for instance the example of Monassevitch where a staple of 25

mm length span L is arranged for use with length spans between 25 and 30 mm. If the staple is stretched to 30 mm, there may be more stress-induced martensite formed than if the staple were stretched to 26 mm. Accordingly, if the staple is only stretched to only a little above 25 mm, such as 26 mm, then during insertion there may only be a small amount of stress-induced martensite present. In this instance, even though some stress-induced martensite was created, the responsive portion of staple 10 would still be substantially in an austenitic phase. A POSITA would recognize that one potential advantage to a lower level of stretching is the reduced stress in the material and that, depending on the specific application, reducing the overall stress in a structural element, like a bone staple, may have a positive impact the device fatigue performance.

125. Thus, it is my opinion that Monassevitch discloses, or at least renders obvious, staple 10 being inserted into the bone fragments while the responsive portion is still substantially in an austenitic phase.

(b) Embodiment #2– Staple 150

126. As I have 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].

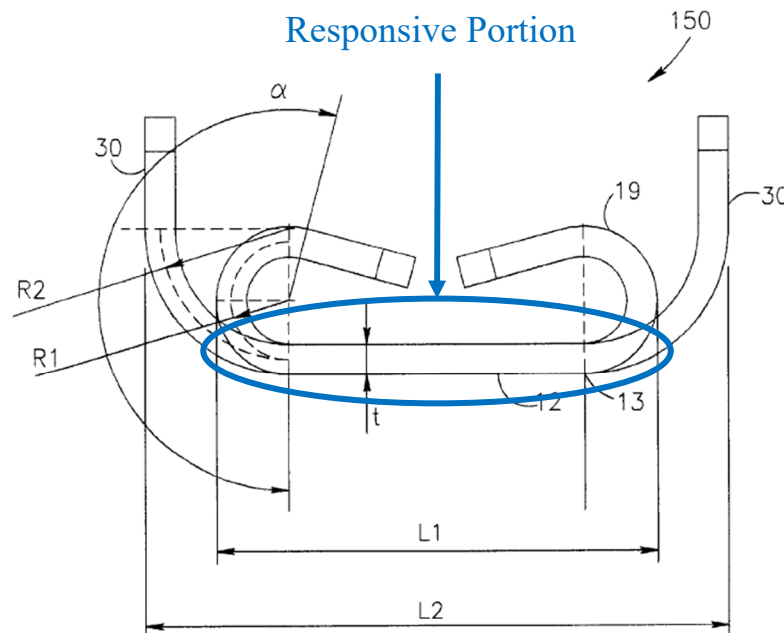


FIG. 8

127. As I also explained with regard to 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). As I explained above, in either instance, at least a partial transformation into a stress-induced martensitic phase is created in the responsive portion. 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.

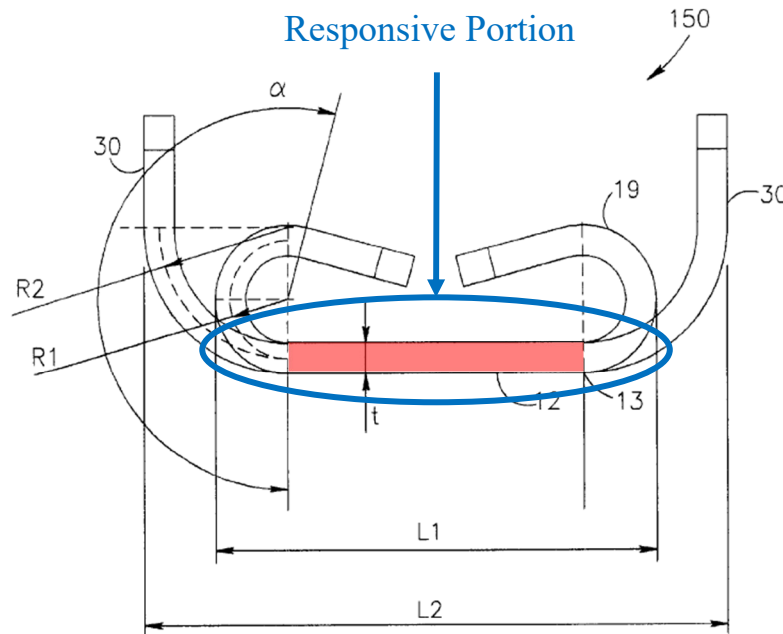


FIG.8

128. Thus, it is my opinion that Monassevitch discloses, or at least renders obvious, staple 150 being inserted into the bone fragments while the responsive portion is still substantially in an austenitic phase.

(c) Embodiment #3– Staple 200

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

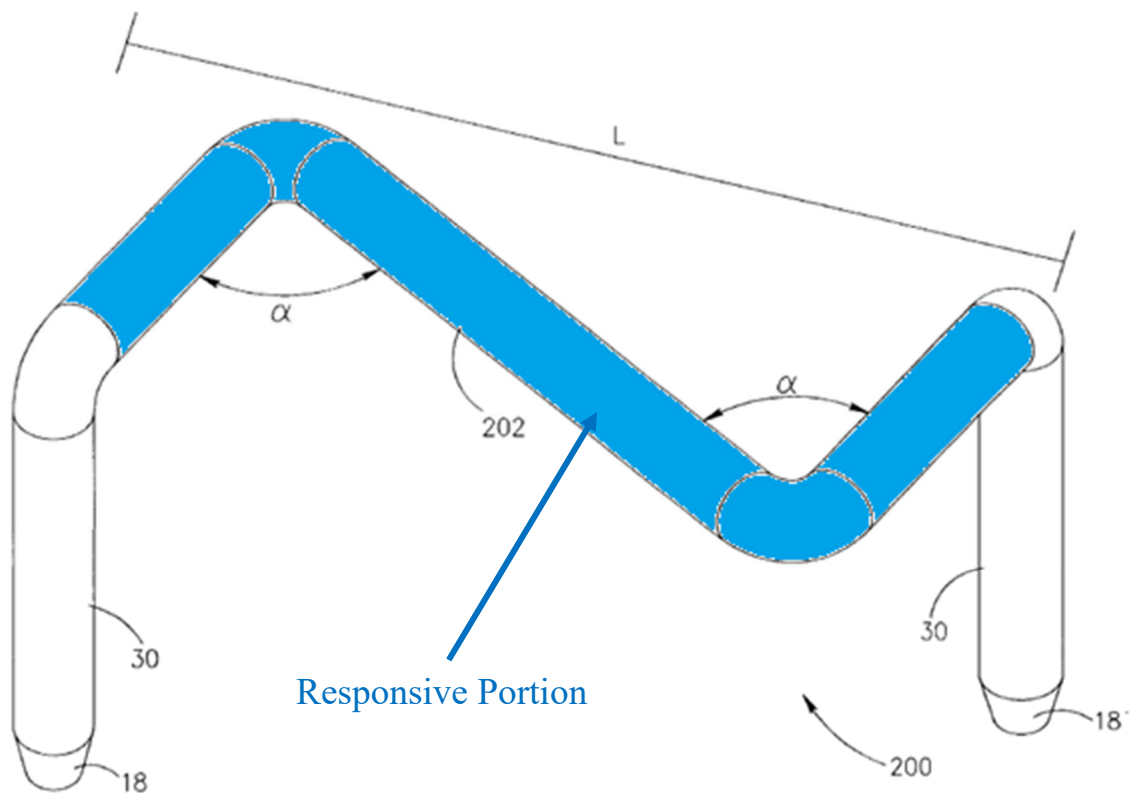


FIG. 10A

130. As I 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]ength span L of staple 200 may be increased by straightening, or partially straightening at least one curvature 220, or curvatures 220 and 230.”). Thus, as I also explained above, 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. As a result, a POSITA would understand

that most of the responsive portion, as depicted in red below, would remain austenitic when the staple is being inserted into the bone.

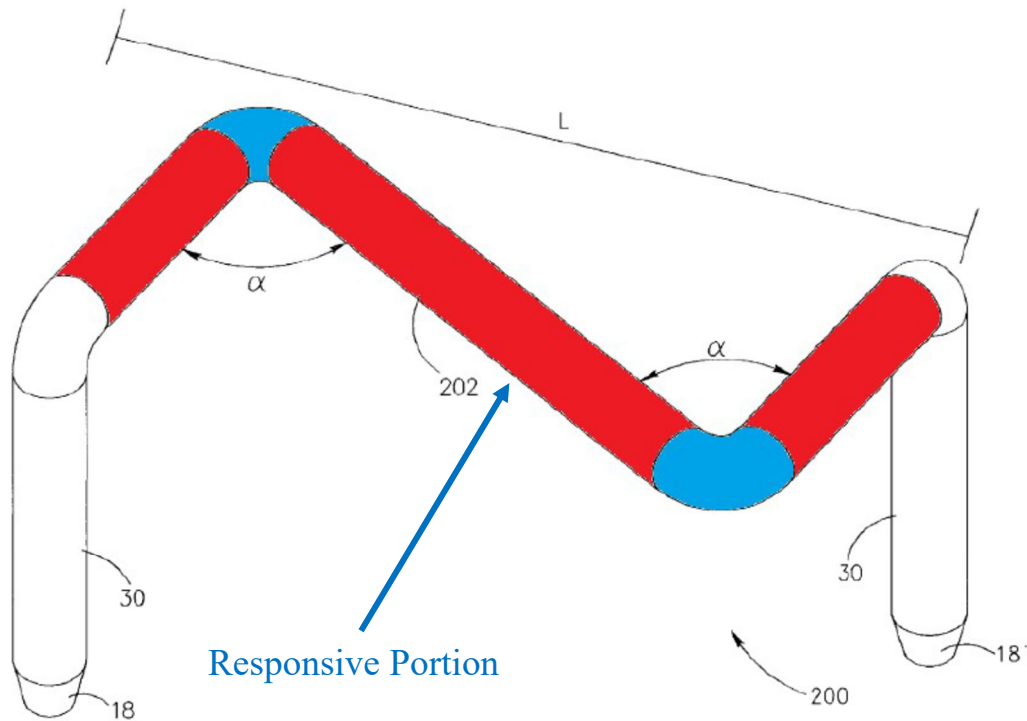


FIG.10A

131. Thus, it is my opinion that Monassevitch discloses, or at least renders obvious, staple 200 being inserted into the bone fragments while the responsive portion is still substantially in an austenitic phase.

12. Claim 8

132. 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. *See, e.g.* Ex. 1005, Fig. 3C. As such, for

each of the three embodiments (staples 10, 150, and 200), it is my opinion that Monassevitch discloses or at least renders obvious this limitation for the same reasons as discussed above for claim 7.

13. Claim 9

133. Claim 9 depends from claim 1 and further requires “**wherein the first portion comprises the shape memory alloy.**” Monassevitch discloses this limitation with respect to each of the three embodiments (staple 10, 150, and 200).

134. Monassevitch teaches that the entirety of each of staples 10, 150, and 200 is made of shape memory alloy. *See Id.*, 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.”); 4:35-36 (“[I]n accordance with the present invention, said staple is formed of an SMA alloy.”). 8:18-19 (“Preferably, staple 10 is formed of titanium-nickel, shape-memory alloy....”); 12:28-29 (“staple 10 may be used to provide bone fixation, while in a stress-induced martensite state”); 12:61-62 (“In its austenitic shape, staple 150 is similar to staple 10.”); 14:7 (“[S]taple 200 is formed of a shape-memory alloy.”); 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...”). Accordingly, the first portion of each of staples 10, 150, and 200 “comprises the shape memory alloy.”

14. Claim 10

135. Claim 10 depends from claim 1 and further requires “**wherein the second portion comprises the shape memory alloy.**” Monassevitch discloses this limitation with respect to each of the three embodiments (staple 10, 150, and 200).

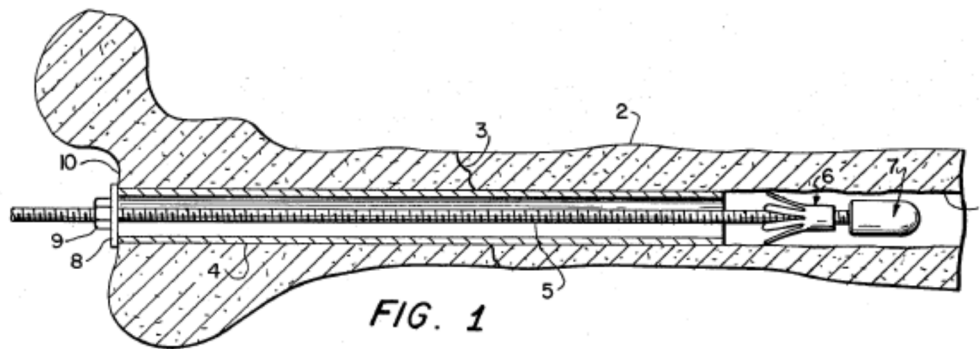
136. Monassevitch teaches that the entirety of each of staples 10, 150, and 200 is made of shape memory alloy. *See Id.*, 3:54-56 (“It is an aim of the present invention to provide apparatus and method for adjusting the length spans of SMA staples for bone fixations, prior to their insertion into the bone.”); 4:35-36 (“[I]n accordance with the present invention, said staple is formed of an SMA alloy.”); 8:18-19 (“Preferably, staple 10 is formed of titanium-nickel, shape-memory alloy....”); 12:28-29 (“staple 10 may be used to provide bone fixation, while in a stress-induced martensite state”); 12:61-62 (“In its austenitic shape, staple 150 is similar to staple 10.”); 14:7 (“[S]taple 200 is formed of a shape-memory alloy.”); 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...”). Accordingly, the second portion of each of staples 10, 150, and 200 “comprises the shape memory alloy.”

**B. Ground 2 – Claims 1-10 are Unpatentable Under 35 U.S.C. §103
As Being Rendered Obvious By Bolesky and Hoffman**

137. As described below, it is my opinion that 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.

1. Overview of Bolesky

138. Bolesky is directed to “a fracture fixation device for use within the medullary canal of a fractured tubular bone.” Ex. 1006, Abstract. In the Background of the Invention, 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. As such, one of the objects 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 that, as illustrated below, includes an “intramedullary nail 4,” a “threaded rod 5,” a “gripper unit 6,” a “nose member 7,” a “washer 8,” and a “nut 9.” *Id.*, 2:61-3:20.



139. To insert this device, a canal 1 in the bone is first reamed. *Id.*, 2:63-65. Next, the threaded rod 5, gripper unit 6 and nose member 7 are inserted through the bored entrance into the medullary canal. *Id.*, 2:65-67. And then the intramedullary nail 4 is inserted over rod 5 so that the nail extends from the entrance of the canal to a point well beyond the fracture location 3. *Id.*, 3:1-4.

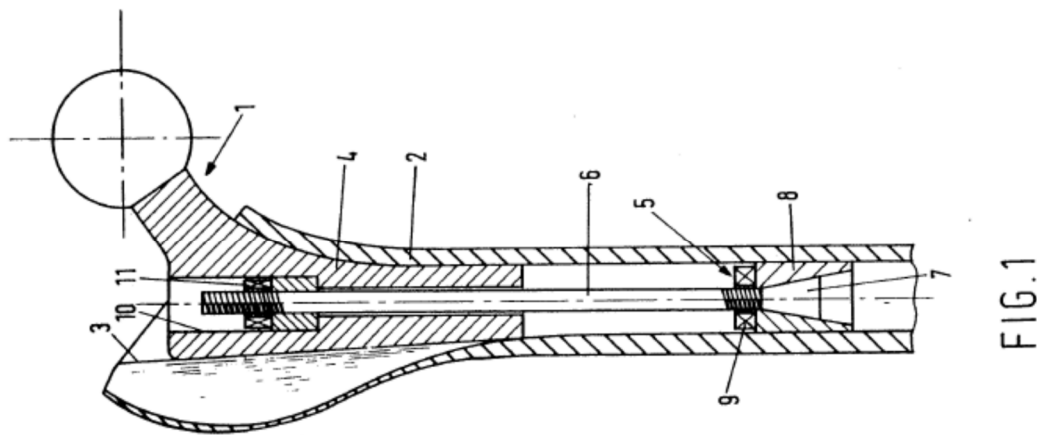
140. Once the device has been inserted into the canal 1, a “nut 9 is turned until washer 8 is snug against the end face of the bone.” *Id.*, 3:56-61. Bolesky teaches that as the nut is tightened, the gripper unit is moved towards the entrance of the canal (i.e. to the left in Fig. 1 above), which causes the tips of the fingers in the gripper unit 6 to “penetrate the wall of canal 1.” *Id.*, 3:63-4:2. As the penetration increases, the fingers will resist further movement of the gripper unit relative to the bone, and so, with the further tightening of the nut, a “force is developed which tensions rod 5.” *Id.* As a result, 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.

The compressive force “secures the bone in a stable condition which promotes osteosynthesis.” *Id.*, 4:9-12.

141. Bolesky states that the “device is to be made out of a biocompatible material, such as 316 Stainless Steel.” *Id.*, 4:62-63.

2. Overview of Hoffman

142. Hoffman discloses a bone device to secure a prosthesis to a section of bone. Ex. 1007, Abstract. As illustrated below, the Hoffman device has a generally similar design to that of Bolesky. The Hoffman device 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 *Id.*, 4:51-5:11.



143. 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. Ex. 1007, Abstract, 1:60-61, 2:18-21. Hoffman explains that, by providing a rod made of a shape memory alloy, the superelastic property of the material can be utilized to create compression (i.e., the shape memory alloy 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.

144. 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. 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 this in the range with a flat distance/stress curve. When the elongation is consumed, the material automatically returns into the austenitic phase.” *Id.*, 5:12-17. Thus, as Hoffman explains, stretching the shape memory material (by tightening nut 11) will take advantage of the superelastic property of the material by causing the shape memory material to become “stress-induced martensite.” *Id.* 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.

3. Overview of My Opinion Concerning Obviousness

145. In my opinion, the combination of Bolesky and Hoffman renders the challenged claims obvious. As explained above, 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 using a shape memory material for the rod. 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 a shape memory alloy. Thus, in my opinion, it would have been obvious to modify the device of Bolesky to use a rod made out of a shape memory alloy and, more specifically, to utilize the superelastic property of the shape memory alloy rod taught by Hoffmann (i.e., by tensioning the rod to create stress-induced martensite) to provide continuous compression across the fracture site.

4. Rationale (Motivation) Supporting Obviousness

146. In the claim mapping below, I provide specific rationales for the combination where appropriate under the relevant claim elements. As an initial matter, however, Bolesky and Hoffman have several important similarities. Both

of these 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. Both devices are designed to be inserted into the marrow canal of the long bone. Both devices provide the compression by tensioning a rod. And both devices create the compression by turning a nut that tensions the rod. As such, a POSITA looking for ways to improve or enhance the compression in the fracture fixation device of Bolesky would naturally look to Hoffmann. A POSITA would have understood that 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.

5. Analogous Art

147. In my opinion, Bolesky and Hoffman are analogous art. They are in the same field of endeavor as the '222 patent. Although Bolesky and the '222 patent address a slightly different issue (fracture fixation) than Hoffman (which is directed to securing a prosthesis to a bone), all three relate to implantable orthopedic devices utilizing compression. *See* Ex. 1006, Abstract; Ex. 1007, Abstract, Ex. 1001, Abstract. Additionally, Bolesky and Hoffman are both pertinent to the problem that the '222 purports to have been addressing; namely maintaining compression across fracture fragments. The '222 patent notes: "Loss

of compression is contrary to the objectives of fracture fixation in general, and osteosynthetic implants in particular. Improvements are desired to help maintain compressive load across the fracture site over a longer period of healing.” *See* Ex. 1001, 1:48-62. Bolesky teaches that: “A still further object is to provide such a device for supporting the fracture in compression.” Ex. 1006, 1:45-48. And Hoffmann teaches: “This invention relates to the attachment of a prosthesis in a bone” using compression where the implant “is given a pre-stress as the prosthesis is being implanted, which pre-stress remains constant within a large range of stretch, the proximal part will always remain biased in the direction of the distal part with a force which contributes to preventing micromovements.” Ex. 1007, 1:4-5, 2:25-30. Thus, all three patents relate to the maintenance of a compression on bone via an orthopedic implant.

6. Reasonable Expectation of Success

148. I understand that it can be important to demonstrate that a POSITA could have pursued the known potential solutions in the art with a reasonable expectation of success. Here, both Bolesky and Hoffman teach structurally similar devices that are inserted within the intramedullary canal of a long bone (like a femur) and held in position using a rod in compression. 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. Nitinol was well known to be

biocompatible (the stated desired characteristic in Bolesky) and a suitable alternative to the stainless steel used in Bolesky. Additionally, the superelastic properties of Nitinol (i.e., the creation of stress-induced martensite by stretching Nitinol above its austenite finish temperature) were also well known in the art and routinely used by skilled artisans in the design of orthopedic fracture fixation devices. Thus, in my opinion, a POSITA in the relevant timeframe would have had a reasonable expectation of success in combining Bolesky and Hoffman in the manner discussed in the overview section above and in the claim mapping below.

7. Secondary Considerations of Non-Obviousness

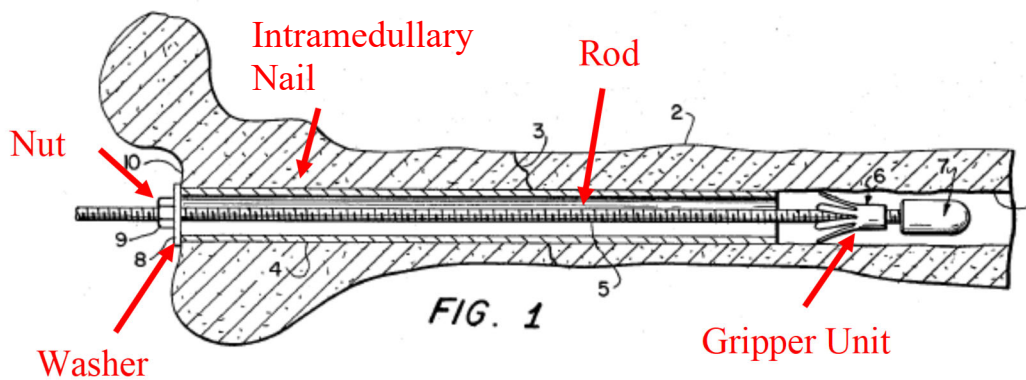
149. I am not aware of any secondary considerations that would make an inference of non-obviousness more likely.

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

150. To the extent the preamble is limiting, Bolesky discloses a method for using a “fixation device adapted for use within the medullary canal of a fractured tubular bone.” Ex. 1006, Abstract; *see also* 1:45-48; (“A still further object is to provide such a device for supporting the fracture in compression with the compression forces being uniform about the entire peripheral extent of the fracture.”). Hoffman likewise discloses a method for using a device that is “received in... a marrow cavity” to “secur[e] a prosthesis to a bone.” Ex. 1007, Abstract.

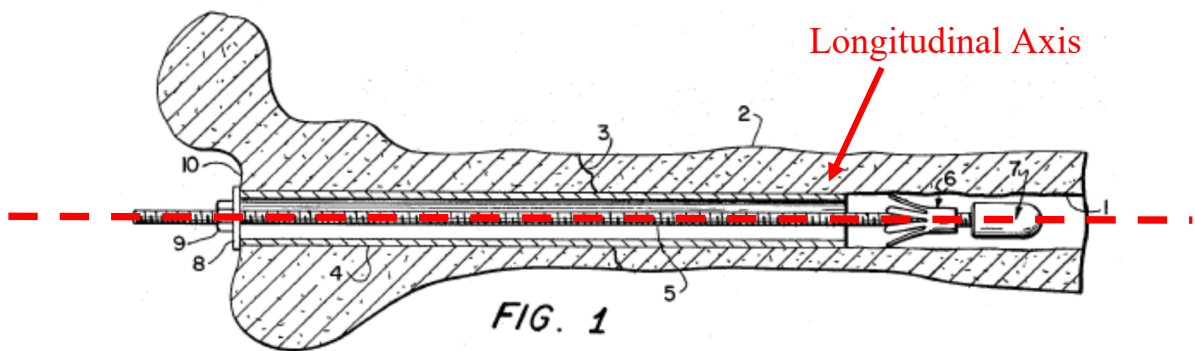
9. [1.1] inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment, wherein the inserting causes a first portion of the bone device to contact the first bone fragment and causes a second portion of the bone device to contact the second bone fragment, the second portion different from the first portion;

151. Bolesky discloses a **bone device** in the form of a “fracture fixation device.” 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.*



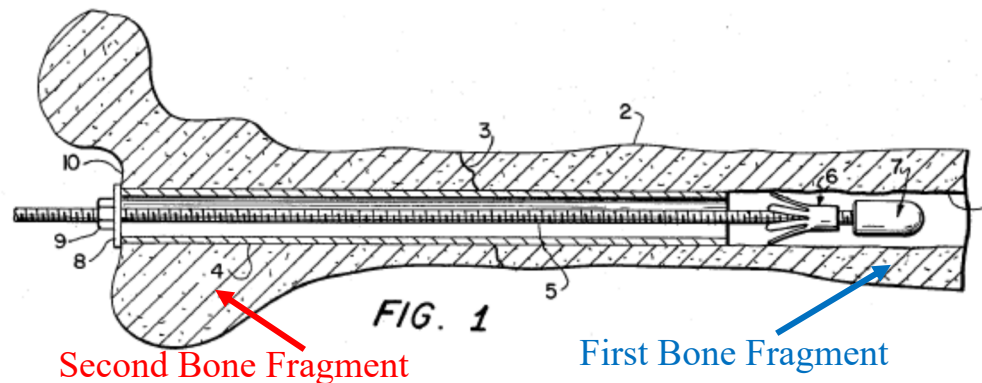
152. The device has a **longitudinal axis** along the length of the device as I have illustrated by the dashed red line below. A POSITA would understand that this is the longitudinal axis for several reasons. First, it would be obvious to a POSITA looking at the implant of Bolesky that the longitudinal axis runs along the length of the threaded rod. Second, the Bolesky device comprises a rod 5 and an intramedullary nail 4, both of which are long cylindrical structures that, when modeled mechanically, are typically characterized as possessing a “neutral axis”

that runs the length of the structure down its center. Third, the Bolesky device is inserted into the medullary canal of the femur or tibia, and a POSITA knows the medullary canal of the femur or tibia runs along their longitudinal axes. Thus it is obvious, reasonable, and logical that the longitudinal axis of the Bolesky device is as I have depicted below.



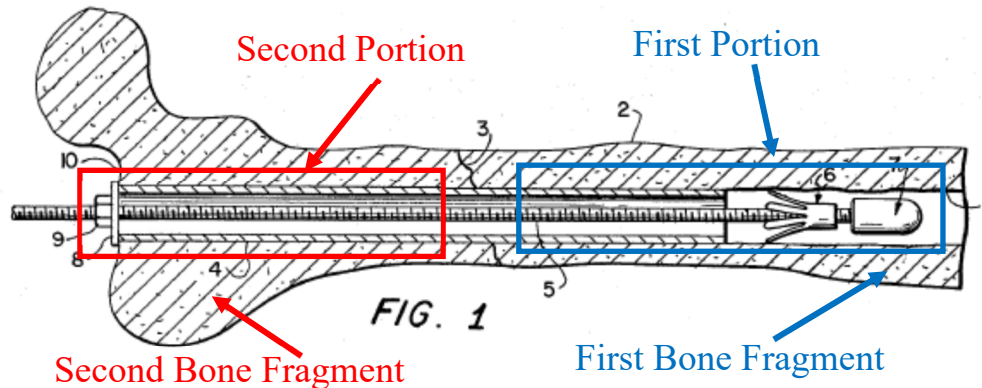
153. Bolesky teaches that the fixation device is **inserted into a first bone fragment and a second bone fragment**. As Bolesky explains, the fixation device is installed “within the medullary canal of a fractured hollow bone, such as the femur and tibia.” Ex. 1006, 1:51-54. Fig. 1 illustrates the device “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. These are both

bone fragments because each of them is a piece of bone that was broken from the original intact femur.



154. 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.

155. 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**. 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. 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.



156. In summary, in my opinion, Bolesky’s fracture fixation device is an example of the claimed “bone device,” and the procedure for inserting Bolesky’s fracture fixation device involves “inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment,” where the insertion “causes a first portion of the bone device to contact the first bone fragment” and a different “second portion of the bone device to contact the second bone fragment.”

10. [1.2] wherein the bone device comprises a shape memory alloy having an austenite finish temperature;

157. 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 is my opinion that it would have been obvious to substitute a different biocompatible material, such as a **shape memory alloy** like Nitinol, for the threaded rod 5 of Bolesky.

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

158. 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.

159. The Bolesky device creates compression by tensioning a rod that spans both sides of a fracture site. 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.” *Id.*, 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) The Use of SMAs To Improve Compression In Medical Devices Was Known

160. Long prior to the filing of the '222 patent, the use of shape memory alloys such as Nitinol in medical devices was well known. By the 1990s, Nitinol was being increasingly used in medical devices and was “becoming one of the materials of choice for many designers and engineers.” Ex. 1008, p.1. Engineers considered it a “staple of their design toolbox.” Ex. 1016, p.104. And physicians were “routinely familiar with both Nitinol and superelasticity.” *Id.*

161. As discussed above in Section V, Nitinol was known to be biocompatible in humans. Ex. 1010, p. 235; Ex. 1011, Abstract; Ex. 1008, p. 1. It was known that the range of temperatures within which Nitinol exhibited superelasticity can be tailored to include room temperature and/or body temperature (i.e., the austenite finish temperature below room temperature and/or body temperature). Ex. 1010, p.235. In fact, one typical Nitinol composition that was being used for many medical devices was known to be superelastic at both room and body temperature. Ex. 1008, p.12.

162. It was also known that Nitinol could provide for the ability to make “self-locking, self-expanding, and self-compressing implants.” Ex. 1011, Abstract; *see also* discussion in Section V above. Indeed, , as far back as 1983 (shortly after I graduated with my undergraduate degree), 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. Ex. 1017, Abstract (“Medical devices which are currently proposed to use elements made from shape memory alloys may be improved by the use of stress-induced martensite alloy elements instead”); 7:35-58 (describing bone plate using superelastic effect); 7:60-8:42 (describing marrow nails using superelastic effect); 9:58-10:24 (describing bone staples and clips using superelastic effect).

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

163. Hoffman discloses a bone device similar to that of Bolesky albeit for the purpose of securing a prosthesis to a section of bone using a shape memory alloy (nitinol) tie member that, when in tension, places the bone in a state of compression. 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.

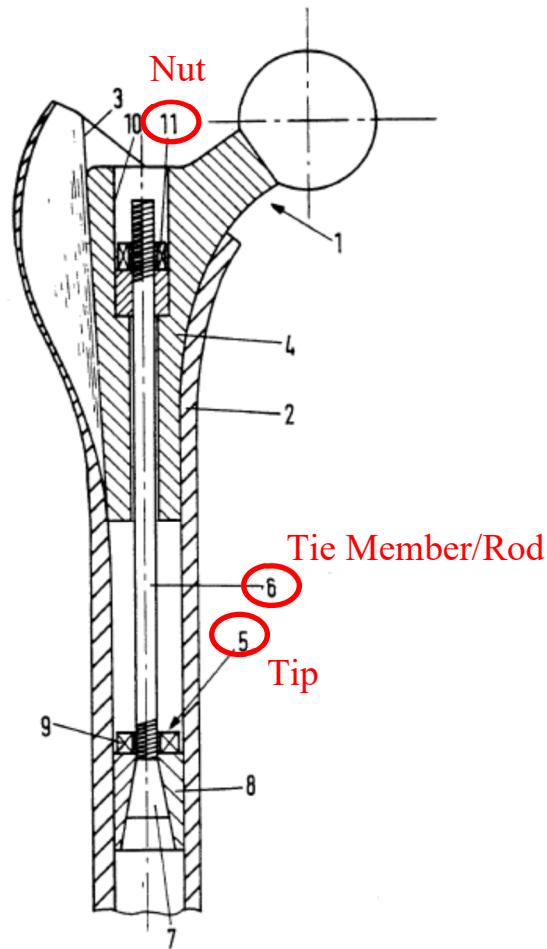


FIG. 1

164. Akin 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. Hoffman teaches that the purpose of using a shape memory alloy 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.

165. In summary, Hoffman discloses an implantable bone device that stretches a shape memory alloy 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. By drawing the proximal part 4 toward the tip 5 creating tension in the rod, this simultaneously compresses the bone.

(d) It Would Have Been Obvious To Modify Bolesky to Use A Rod Comprising A Shape Memory Alloy

166. With respect to the motivation to combine Bolesky and Hoffman, 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 a shape memory alloy “tie-member,” placed in tension, for the purposes of compressing fixed, opposite ends of a bone. Replacing the threaded rod of Bolesky with the shape memory alloy rod of

Hoffman to benefit from the superelastic properties of Nitinol would be an obvious design choice. A POSITA would have a high expectation of success in combining these teaching to create compression across a fracture. Both Bolesky and Hoffman teach structurally similar devices that are inserted within a bone canal (like a femur) for providing compression, and shape memory alloys (like Nitinol) were well known as being capable of providing continuous compression within the body to promote healing.

167. Additionally, a POSITA would have found it obvious to modify Bolesky's fixation device to use a rod made of a shape memory alloy, as taught by Hoffman. As discussed above, the object of Bolesky is to provide compression across a fracture site by tensioning a rod that spans across either side of the fracture. Bolesky states that the device, including the rod, should be made of a biocompatible material, such as stainless steel. Ex. 1006, 4:62-63. A POSITA would have recognized that Nitinol is a suitable "biocompatible material" that can be substituted for stainless steel in applications like the Bolesky rod. In fact, as explained above, the availability and use of Nitinol in medical devices was well known and addressed in the literature. 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 (i.e., by imparting constant compression as a result of the superelastic effects of Nitinol created when

longitudinally stretching the rod). Furthermore, in the context of fracture fixation, a POSITA would have understood that using stress induced martensite to provide compression would represent an improvement over using a tensioned threaded rod as taught by Bolesky. A POSITA would know that when a fractured bone is initially compressed during a stabilization procedure, that compression weakens over time. Additionally, the fracture site tends to resorb slightly during the healing process, further reducing compression. In fact, the '222 patent discusses this in its background as being as high as “thirty-two percent (32%)” reduction of compression over just a two-week period. Ex. 1001 at 1:52-54. The superelasticity of the shape memory alloy rod can accommodate this slight resorption of bone and stress relaxation in the bone, without sacrificing compression across the fracture.

168. The modified device would 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. In either approach, the modified device would operate as follows: After the device has been installed in the bone, nut 9 is turned to move rod 5 and gripper unit 6. As the nut is tightened, movement of gripper unit 6 will cause the tips 13 of the fingers to penetrate the wall of canal 1. As such penetration increases, the fingers 13 of the gripper unit 6 will resist further movement of the gripper unit relative to the bone.

Further tightening of the nut will then tension (i.e., stretch) the rod 5. As taught by Hoffman, stretching the shape memory alloy (Nitinol) rod while at body temperature (when the shape memory alloy is austenitic) will cause stress-induced martensite to be created in the rod. Ex. 1007, 5:4-28. This will in turn create a superelastic effect resulting in a constant force—characterized by Hoffmann as a “flat distance-stress curve”—pulling the two ends of the rod together, thus providing compression across the fracture site. *Id.*, 2:10-17, 5:12-17.

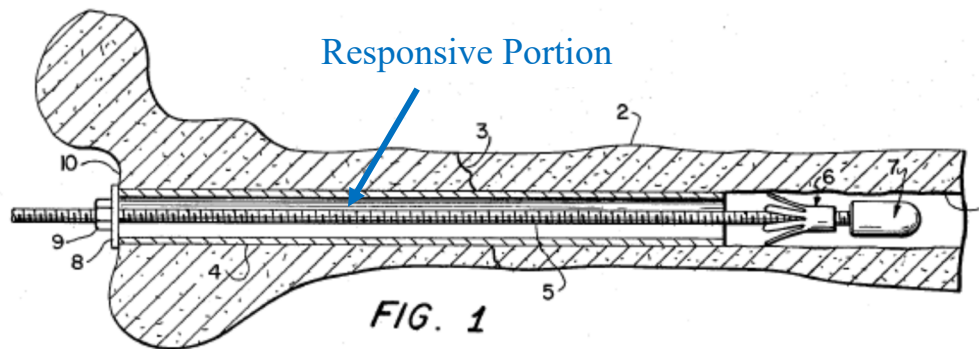
169. Alternatively, it would also have been obvious to further modify Bolesky to use both the rod and the fixation approach of Hoffman, which is expressly disclosed as being used to create stress-induced martensite in a shape memory alloy rod. Hoffman teaches that the “distal end of tie member 6 includes a wedge-shaped part 7, around which a number of segments 8 are arranged.” *Id.*, 4:55-57. Fixing the tip of the device (at the distal end) in the marrow cavity is performed by pushing the segments “over the wedge-shaped end part 7 of the tie member by means of a nut 9 as a result of which the active diameter of the combination of segments is increased.” *Id.*, 4:62-65. Then, when “tip 5 has been fixed in bone 2,” the shape memory alloy “tie member 6 is stretched by tightening nut 11” (at the proximal end). *Id.* 5:18-20. The stretching causes stress-induced martensite to form in the shape memory alloy tie member 6. *Id.*, 5:12-17. Once the tightening of nut 11 is completed, the proximal portion of the device is fixed.

170. It would have been obvious to a POSITA that the Bolesky device could be modified to implement the above-described fixation approach of Hoffman. 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). In this case, the modified distal attachment assembly would be used to fix the distal end in the bone. Then, nut 9 of Bolesky would be tightened to stretch the shape memory alloy rod. 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.

171. A POSITA would also understand that the shape memory alloy would have **an austenite finish temperature**. As explained above, all shape memory alloys, including Nitinol, are characterized by a number of transformation temperatures. One of these is the austenite finish temperature (A_f), which is the temperature above which the transformation of martensite to austenite is complete. Thus, a POSITA would understand that the shape memory alloy used for the Bolesky device, as described above, would have an austenite finish temperature.

11. [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;

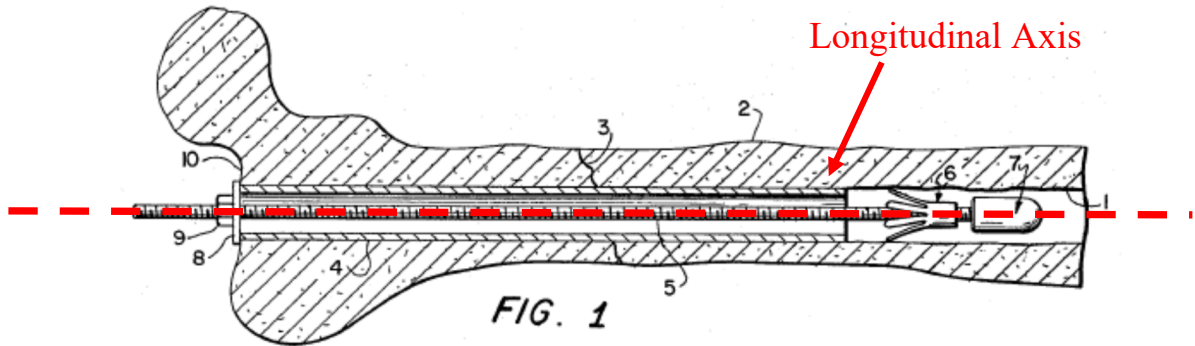
172. As discussed above, it would have been obvious to modify the fixation device of Bolesky to use a rod made from a shape memory alloy, like Nitinol. Because the modified rod would be stretched to create stress-induced martensite (as discussed more below), which results in compression being applied to the bone, a POSITA would recognize that the rod, as modified, represents a **“responsive portion.”** See also Ex. 1001, 2:21-23 (“The responsive zone is adapted to apply a desired pressure to the bone when coupled thereto”).



173. I note that the claim language does not require the responsive portion to be of any certain shape or dimension. Although the '222 patent states that the “responsive element or responsive zone, in a preferred embodiment, has a smaller cross sectional area than the non-responsive part” (*Id.*, 10:7-9), it is my understanding that claims are not limited to preferred embodiments. Indeed, similar language, “responsive zone,” is used with reference to the “middle section

814” of another embodiment shown in Figure 8 in which a rod 800 has a constant cross-sectional area. *Id.*, 8:20-28. I also note that claim language does not require that the “responsive portion” be commensurate with the portion of the device that is made of a shape memory alloy. Although the specification states that “[i]n a preferred embodiment, the responsive zone comprises a shape memory material” (*Id.*, 2:23-25), the open-ended language suggests that the responsive zone may be made of SMA and other materials. The ’222 patent also suggests that the responsive portion can be only a subset of the SMA area. For examples, in relation to the bone screw embodiment, ’222 patent describes a “non-responsive screw portions, such as head 130” (*Id.*, 6:13-20) even though the full “bone screw 100 is formed from nickel titanium, a shape memory alloy referred to as Nitinol” (*Id.*, 4:52-56). As such, one could choose to define the “responsive portion” either as the entire shape memory alloy rod or as some subset of the shape memory alloy rod of which at least a portion is capable of being transformed into a stress-induced martensitic phase via stretching. But how one ultimately decides to perform the box-drawing exercise with regard to the “responsive portion” does not alter my analysis because, in my opinion, the combination of Bolesky and Hoffman renders the ’222 claims obvious regardless of whether the whole shape memory alloy rod, or only a subset of it, is defined as the “responsive portion.”

174. 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.



175. 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**. As explained above, and as described in Hoffman, Nitinol is a shape memory alloy capable of exhibiting superelasticity when implanted in the human body. *See* Section V *supra*; 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 (describing “stretching the rod above its deformation temperature . . . to form stress-induced martensite (SIM)”). Thus, a POSITA would understand that implementing a shape memory

rod in Bolesky will result in the creation of stress-induced martensite when the rod is stretched.

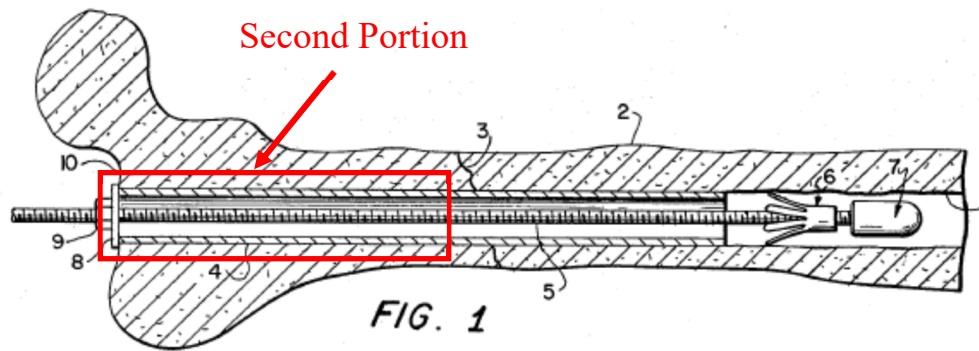
176. Additionally, a POSITA would understand that Nitinol can be tailored to ensure its austenite finish temperature is at or below body temperature. The superelastic range of a component made from a shape memory alloy, like Nitinol, can be selected by altering the material properties of the alloy as well as the dimensions of the device. A POSITA would have selected 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. A POSITA would have been motivated to do so in order to achieve the beneficial superelastic effects that are caused by the creation of stress-induced martensite ensuring a near continuous level of compression across the fracture, even as a small (albeit normal) amount of bone resorptions and stress relaxation in the bone occurs. And doing so was well within the knowledge and capabilities of those skilled in the art at the time.

177. Moreover, as described above in the section addressing claim element [1.2], it would also have been obvious to substitute the fixation approach of Bolesky with the fixation approach of Hoffman. In that regard, Hoffman expressly teaches that its fixation approach stretches the rod in the longitudinal direction so as to create a transformation into stress-induced martensite in the tensile

member/rod. Ex. 1007, 5:4-28 (“In this concept, this property is used by stretching the shape memory metal in the austenitic phase, as a result of which it becomes stress-induced martensite.”). Accordingly, the combination of Bolesky and Hoffman renders this element obvious.

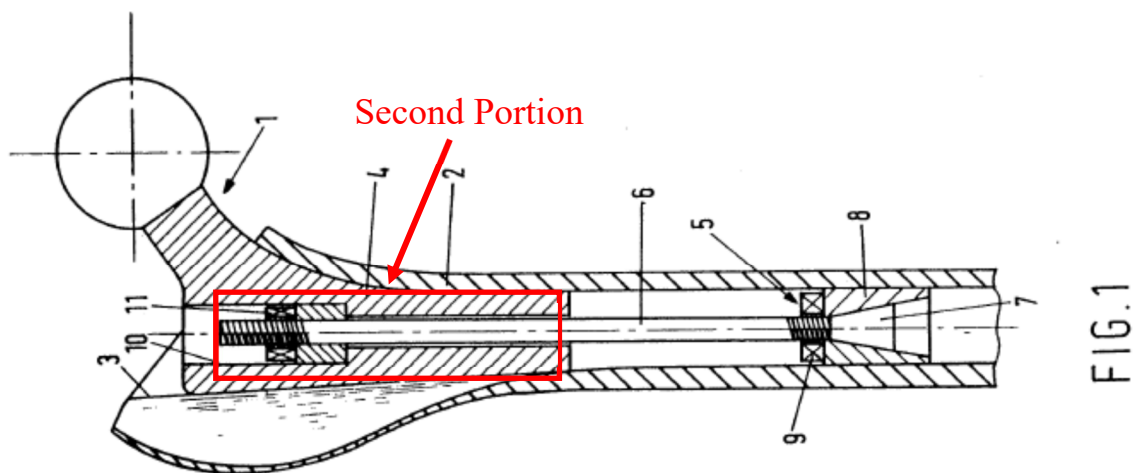
12. [1.4] after performing the stretching, fixing the second portion of the bone device to the second bone fragment; and;

178. 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. The continued tightening of nut 9 then causes rod 5 to be stretched. *Id.*, 3:66-4:4. (“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.”). When tightening of nut 9 is complete, the second portion of the device is fixed. Thus, in my opinion, 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**.



179. This is also consistent with the prosecution history. As discussed in Section VI.C, the Applicant overcame a written description rejection by arguing that the claimed requirement of fixing after stretching was practiced by the screw embodiment described in relation to Figures. 2A-2C of the '222 patent. Ex. 1004, pp 88-98 (8/19/10 Response). According to the patent, the screw—which comprises a shape memory alloy—is inserted into first and second bone fragments, and the continued turning of the screw causes the threaded end of the screw to stretch away from the head end of the screw. Ex. 1001, 5:42-67. 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.

180. Alternatively, Hoffman also discloses **fixing the second portion of the fixation device to the second bone fragment after performing the stretching**. As described, 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.



181. For the reasons described above in elements [1.2] and [1.3], 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. Thus, in my opinion, regardless of which fixation approach is used, claim element [1.4] is obvious.

13. [1.5] wherein the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy

182. As described above with respect to element [1.3], it is my opinion that the combination of Bolesky and Hoffman renders obvious the step of creating at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis. It would thus also have been obvious to a POSITA that the creating step is performed **at a temperature greater than the austenite finish temperature of the shape memory alloy**.

183. As Hoffman teaches, in order to create stress-induced martensite in the shape memory alloy 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 shape memory alloy, it was well known (as explained above in Section V) that shape memory alloys exhibit superelasticity (in which stress-induced martensite is formed upon the application of stress) at temperatures above the austenite finish temperature (A_f). A POSITA would know that the austenite finish temperature (A_f) is the temperature above which a shape memory alloy such as Nitinol would be

completely transformed from martensite to austenite and thus in the austenitic phase. Indeed, during prosecution of the '222 patent, Applicant acknowledged this fact:

“Para. [0052] states "The PE (pseudoelastic) state is observed when T_a (the surrounding temperature) is greater than T_1 (the transformation temperature)" for a shape memory alloy. Therefore, the surrounding body temperature will be above/greater than the transformation temperature for the pseudo elastic state. **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. 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.**” *See* [pros his], pp. 96-97 (8/19/10 Response) (explained as part of Applicant’s argument as to why claim 48 (which issued as claim 2) was supported by the specification).

Ex. 1004, pp. 96-97 (8/19/10 Response). 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 shape memory alloy.

184. At a minimum, however, it would have been obvious when modifying Bolesky as described above, to select a shape memory alloy, like Nitinol, having an austenite finish temperature that is below the temperature at which the stretching will occur (for example, body temperature or room temperature). Doing so would ensure that the shape memory alloy rod would be austenitic—and so capable of forming stress-induced martensite—when being stretched. *See also* Ex.

1007 at 5:21-25 (describing a “maximum elongation is about 6%” at body temperature).

14. Claim 2

185. 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.**”

186. The intrinsic record of the '222 does not use the phrase nor provide an explanation as to what it means to stretch the bone device with it “*substantially* in an austenitic phase.” However, in addressing a 112 rejection during prosecution, the Applicant provided the below argument as to why this claim limitation was supported by the specification.

“Body temperature will be the surrounding temperature of the osteosynthetic device after the device is inserted into the patient. Para. [0034] states "In one embodiment, the fixation devices, such as screw 100, are machined from a shape memory material such as Nitinol that is thermally treated to exhibit pseudo-elasticity at body temperature." Para. [0052] states "The PE (pseudoelastic) state is observed when T_a (the surrounding temperature) is greater than T_1 (the transformation temperature)" for a shape memory alloy. Therefore, the surrounding body temperature will be above/greater than the transformation temperature for the pseudo elastic state. 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. 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.*”

Ex. 1004, pp. 95-96 (8/19/10 Response). While I do not believe that this explanation helps to clarify the full scope of the claim, Applicant's statement seems to suggest that a shape memory alloy that is fully austenitic (i.e., at a temperature above the austenite finish temperature such that the alloy has finished its transformation to the austenite phase) would meet the limitation of being "substantially in an austenitic phase." Moreover, as I explained above in section IX.B, I have been asked, for purposes of my analysis, to apply Patent Owner's interpretation; i.e. that a shape memory alloy is substantially in an austenitic phase if only part of the austenitic shape memory alloy is transformed to martensite due to the recited step, or if the shape memory alloy is above the austenite finish temperature (in which case it would be fully austenitic) prior to the recited step. Applying this interpretation, it is my opinion that 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].

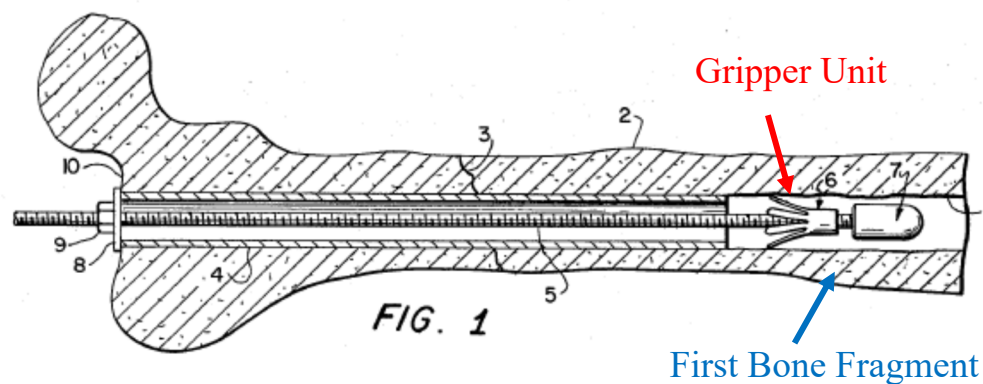
187. In short, as explained above, it would have been obvious to modify the device of Bolesky to use a rod made out of a shape memory alloy as taught by Hoffman and, more specifically, to utilize the superelastic property of the shape memory alloy rod taught by Hoffmann (i.e., by tensioning the rod to create stress-induced martensite) to provide continuous compression across the fracture site. And Hoffman teaches that to create stress-induced martensite in the shape memory

alloy rod, the rod is stretched while “**in the austenitic phase.**” Ex. 1007, 5:12-15. Accordingly, in my opinion, a POSITA would understand, or at least find it obvious, that the stretching of the modified bone device (as described above) would be performed with the shape memory alloy portion of the bone device (i.e., the rod) being substantially in an austenitic phase.

15. Claim 3

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

189. Bolesky teaches this limitation. 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.



190. 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 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.

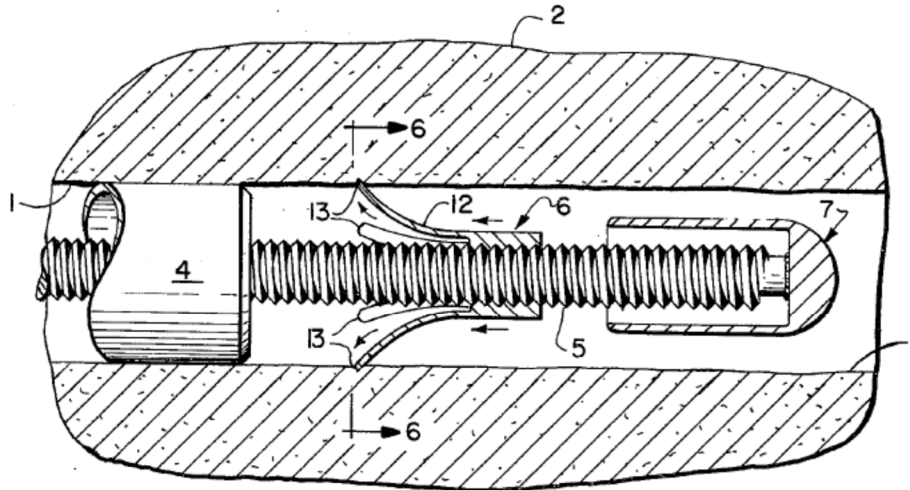


FIG. 3

191. When the gripper unit is fully engaged, the bone device is **fixed to the first bone fragment**. The subsequent continued tightening of nut 9 then causes rod 5 to be stretched, as explained in more detail above with regard to claim 1. *See also Id.*, 3:66-4:12. (“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. The resilient force created by the tightening of the nut 9 against the washer 8 and bone interface 10 in action with the gripper unit penetrating the medullary canal distal to the fracture site effects a positive compressive force at the fracture site. 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.”). 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**.

192. 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 (“For fixing the tip in the marrow cavity, the segments are pushed over the wedge-shaped end part 7 of the tie member by means of a nut 9 as a result of which the active diameter of the combination of segments is increased, by means of a specially designed tool.”). Subsequently, 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, a first portion of the device is fixed in a first bone fragment before stretching/elongation of the rod is performed.

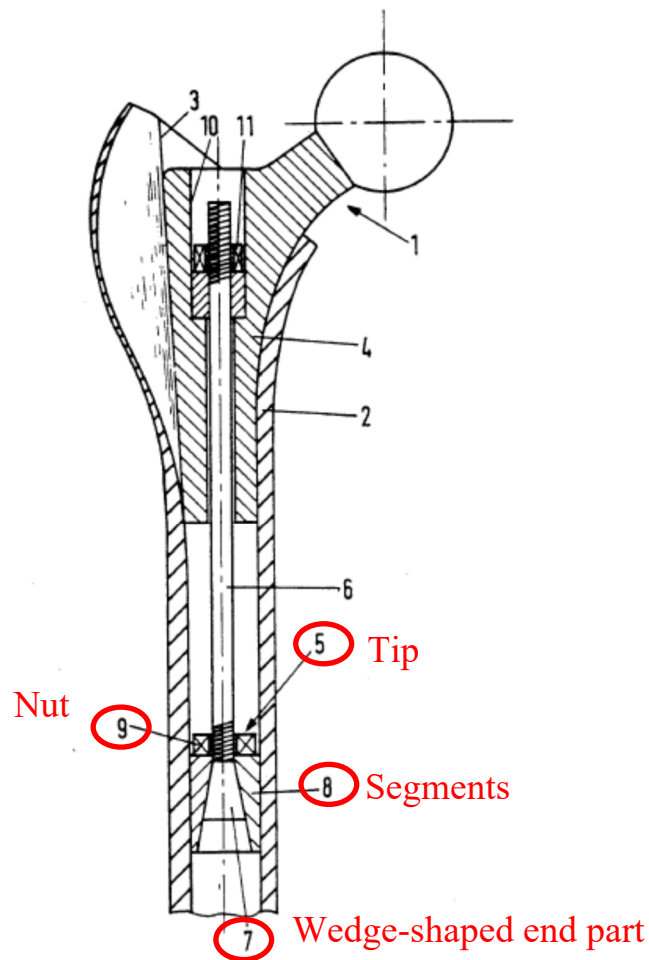


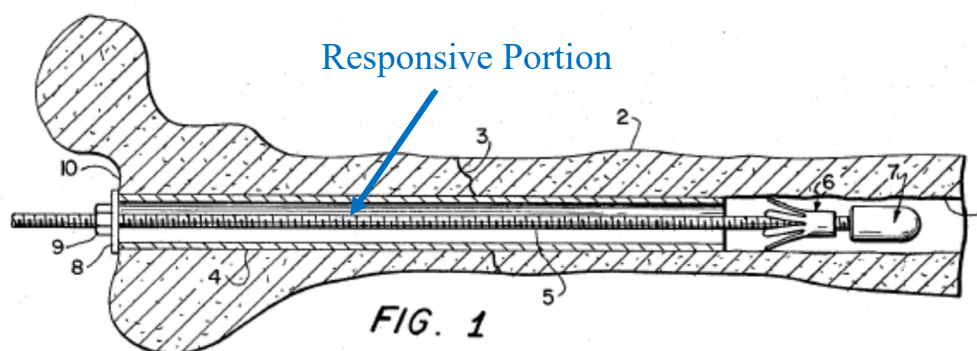
FIG. 1

193. For the reasons previously described above in elements [1.2], [1.3] and [1.4], 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. Thus, in my opinion, regardless of which fixation approach is used, claim 3 is obvious in view of the combination of Bolesky and Hoffman.

16. Claim 4

194. 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.**”

195. As discussed above for claim 1, it would have been obvious to modify the fixation device of Bolesky to use a rod made from a shape memory alloy, like Nitinol. And for the reasons I note above in the section addressing element [1.3], a POSITA would recognize that the rod, as modified, represents a “**responsive portion.**”



196. Furthermore, as I explained with regard to claim element [1.5], Hoffman teaches, or at a minimum renders obvious, that the responsive portion is stretched at a temperature that is above the austenite finish temperature of the shape memory alloy (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 **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. That is because the stretching and the fixing steps are both being performed at the same surrounding temperature.

197. This is also consistent with the prosecution history. When identifying written description support for this claim during prosecution (originally prosecuted as claim 52), the Applicant stated that “[b]ody temperature will be the surrounding temperature of the osteosynthetic device after the device is inserted into the patient.” Ex. 1004, p. 62 (3/2/11 Response). And as I explained above for claim element [1.5], Hoffman taught, or at least rendered obvious, that the austenite finish temperature of the shape memory alloy rod should be below body temperature (so that it is austenitic and capable of creating stress-induced martensite when stretched).

198. Accordingly, it is my opinion that the combination of Bolesky and Hoffman renders obvious the step of 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.

17. Claim 5

199. 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 claim limitation [1.5] and claim 2.

18. Claim 6

200. 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 claim element [1.5] and claim 4.

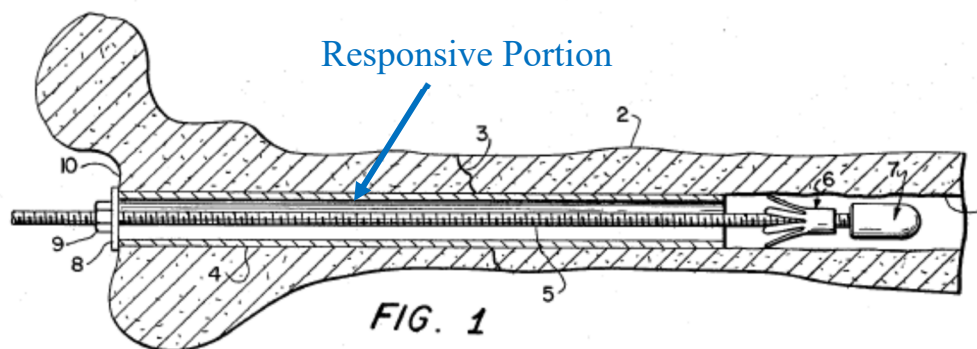
19. Claim 7

201. 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.**”

202. As noted above with respect to claim 2, the specification of the '222 does not use the phrase nor provide an explanation as to what it means to stretch the bone device with it “*substantially* in an austenitic phase.” However, for purposes of my analysis, I have been asked to apply Patent Owner’s interpretation; i.e. that a shape memory alloy is substantially in an austenitic phase if only part of the austenitic shape memory alloy is transformed to martensite due to the recited step, or if the shape memory alloy is above the austenite finish temperature (in which case it would be fully austenitic) prior to the recited step. Applying this

interpretation, it is my opinion that 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.

203. In short, as discussed above, it would have been obvious to modify the fixation device of Bolesky to use a rod made from a shape memory alloy, like Nitinol. And for the reasons stated above in my discussion of claim element [1.3], a POSITA would recognize that the rod, as modified, therefore represents a **“responsive portion.”**



204. Furthermore, as I explained with regard to claim element [1.5] and claim 2, Hoffman teaches, or at a minimum renders obvious, that the responsive portion is stretched at a temperature that is above the austenite finish temperature of the shape memory alloy (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. 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.

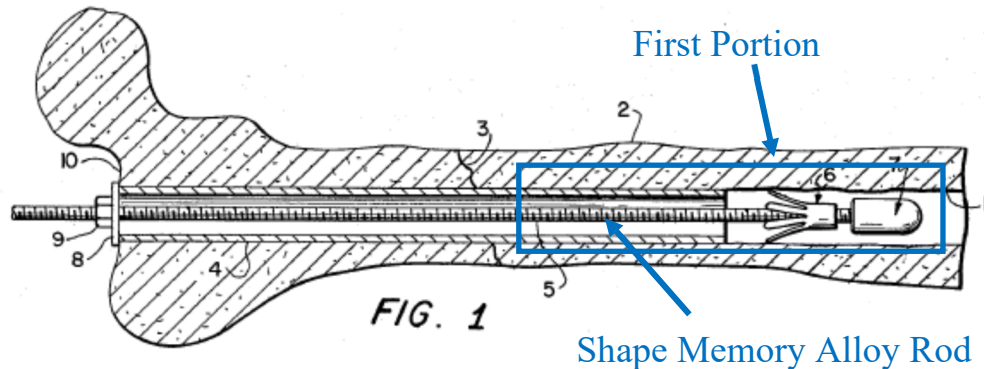
205. Accordingly, it is my opinion that the combination of Bolesky and Hoffman renders obvious that inserting the bone device into the second bone fragment is performed while the responsive portion is substantially in an austenitic phase..

20. Claim 8

206. 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.

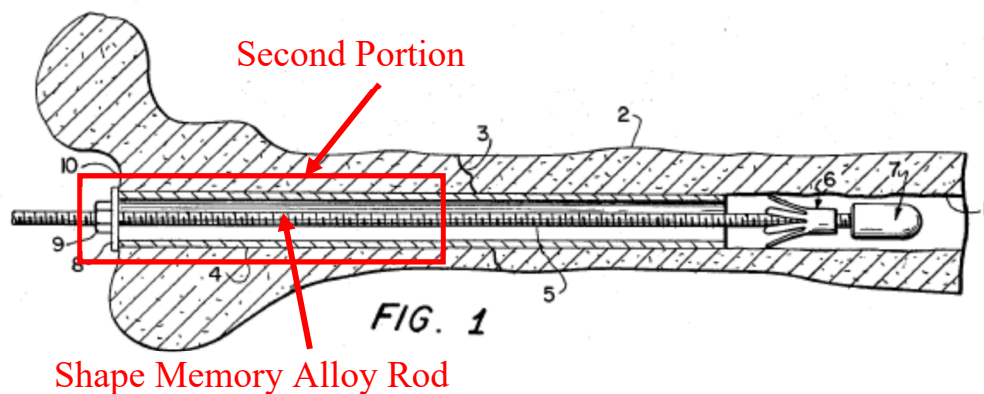
21. Claim 9

207. 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 a shape memory alloy, like Nitinol. Thus, as shown below, the first portion of the bone device comprises shape memory alloy.



22. Claim 10

208. 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 a shape memory alloy, like Nitinol. Thus, as shown below, the second portion of the bone device comprises shape memory alloy.



XI. CONCLUSION

209. For the reasons set forth above, it is my opinion that a POSITA would have understood the subject matter of claims 1-10 of the '222 Patent to have been suggested by the prior art.

210. In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to deposition in this case.

211. I declare that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: October 17th, 2024

Respectfully submitted,

By: 