

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARTHREX, INC.

Petitioner

v.

MEDSHAPE, INC.,

Patent Owner

IPR2025-00053

Patent No. 7,985,222

OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND
MANUFACTURE

PATENT OWNER'S PRELIMINARY RESPONSE

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EXHIBIT LIST

Exhibit	Description
2001	Scheduling Order in <i>Medshape, Inc., et al. v. Arthrex, Inc.</i> , No. 6:24-cv-151 (W.D. Tex)
2002	Defendant's Amended Invalidity Contentions Served November 6, 2024 in <i>Medshape, Inc., et al. v. Arthrex, Inc.</i> , No. 6:24-cv-151 (W.D. Tex)

I. Introduction

Patent Owner Medshape, Inc. (“Medshape” or “Patent Owner”) submits this Preliminary Response to Petitioner Arthrex Inc.’s (“Arthrex” or “Petitioner”) petition for *inter partes* review of U.S. Patent No. 7,985,222 (“the ’222 Patent”).

The Petition first relies on a ground that ignores the plainly required order of steps of claim 1 of the ’222 Patent, namely that there must be at least some inserting into the first fragment *before* stretching the bone device. This is not found in the sole reference used in Ground 1. Further, despite presenting an obviousness ground, the Petition offers no explanation of differences between the art and the claim, much less an explanation of why the reference would be modified by a POSITA. Next, with respect to Ground 2, the Petition relies on disparate references and attempts to pick and choose functionality, which it ultimately combines in a way that makes no sense. These deficiencies are compounded by Petitioner presenting similar prior art to that already presented during prosecution, which is similarly lacking as to the claim element the Examiner found missing.

Finally, the “expert” declaration Petitioner submits purporting to be from Mike Sherman is largely just a word-for-word copy of the Petition itself, confirming that no reliable expert testimony supports the Petition’s faulty conclusions. For these reasons and others discussed herein, the Board should deny institution

II. Petitioner Does Not Establish a Reasonable Likelihood of Success.

Petitioner cannot shoulder its burden of establishing that the references it cites disclose or suggest each element of the sole independent claim.

A. Petitioner Fails to Carry its Burden with Respect to Ground 1.

The Petition fails to carry its burden with respect to Monassevitch. The Petition points to three different embodiments in Monassevitch as allegedly disclosing the claimed method of the '222 Patent—Staple 10, Staple 150, and Staple 200. Each of these embodiments, however, fails to perform the steps of claim 1 in the order in which they are recited and described in the specification. As the Federal Circuit has explained, a claim “requires an ordering of steps when the claim language, as a matter of logic or grammar, requires that the steps be performed in the order written, or the specification directly or implicitly requires” an order of steps. *TALtech Ltd. v. Esquel Apparel, Inc.*, 279 F. App'x 974, 978 (Fed. Cir. 2008); *see also Function Media, LLC v. Google, Inc.*, 708 F.3d 1310, 1320 (Fed. Cir. 2013) (concluding that a claim that recites “processing” an “electronic advertisement” necessarily indicates that “the creation of the ad must happen before the processing begins”). This is the case here.

1) Independent Claim 1 Requires Inserting into the First Fragment Before Stretching.

The claimed methods of the '222 Patent include a critical functional requirement: “creating in a responsive portion of the bone device at least a partial

transformation into a stress-induced martensitic phase via stretching.” Ex. 1001, claim 1. This reflects the entire purpose of the invention—to promote bone healing using dynamic compressive force obtained through the pseudo-elastic properties of shape memory alloys, not temperature mediated shape memory properties. *Id.*, 1:66-2:6. Claim 1 specifies how this is done:

- 1) the bone device is inserted into two pieces of bone, the responsive portion—the portion of the bone device desired to create compressive force—is ***then linearly stretched*** in an environment above the austenite finish (“Af”) temperature of the shape memory alloy, and the bone device is then fixed to a portion of the bone after stretching; and
- 2) the bone device is inserted into a first piece of bone ***then stretched*** and inserted into a second bone piece and then fixed, ***or*** the bone device is inserted into a second piece of bone ***then stretched*** and inserted into the first piece of bone and then fixed.

In any of these examples, the stretching does not occur until after the bone device is inserted into at least one piece of bone. As in *Taltech*, “[t]he logic and grammar of the claim make the requirement of an order clear.” 279 F App’x at 978. That order is: *first*, inserting a bone device (claim 1.1), *second*, stretching the bone device (claim 1.2), and *third*, fixing the bone device (claim 1.3).

2) None of Monassevitch's Embodiments Discloses the Required Order of Steps.

None of the embodiments in U.S. 6,685,708 to Monassevitch discloses the required order of steps of claim 1. Indeed, Petitioner simply ignores this requirement all together. *See* Petition at 27-35. Thus, Petitioner fails to meet its burden.

Petitioner first points to Staple 10, which fails to disclose the order of the steps recited in claim 1. Monassevitch explains that the length (L) of staple 10 is increased (*i.e.*, the staple is stretched) before it is inserted. *See* Ex. 1005, 12:18-29 (Step 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,”); *see also* Petition at 19 (“Once the length is increased, the staple 10 ‘is inserted into bone 38,’ as shown in the Figures 3B-3E below.”); Ex. 1002, ¶73 (“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.”). Thus, to the extent there is stretching at all, insertion and fixation both occur after the purported stretching as opposed to the order required by claim 1 and as described in the ’222 Patent specification.

Petitioner also relies on Staple 150, which fails for similar reasons. Monassevitch explains that the length span of staple 150 is deformed and thus increased and then inserted into the bone to provide fixation. Ex. 1005, 13:3-11 (“[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.”); *see also id.*, 13:32-33 (“staple 150 may be employed to provide bone fixation”). In fact, as Petitioner explains, “staple 150 is inserted into first and second bone fragments such that the first straightedge 30 (first portion) is in contact with the first bone fragment 40 and the second straightedge 30 (second portion, which is different from the first portion) is in contact with the second bone fragment 46.” Petition, 21-22. Accordingly, staple 150 is deformed and then inserted and fixed at the same time—not in the order of steps recited in claim 1.

Petitioner’s reliance on staple 150 is further deficient because, as shown below, Staple 150 is never stretched, much less “stretch[ed] ... along the longitudinal axis,” as is required. Instead, as shown below, staple 150 is ***bent***.

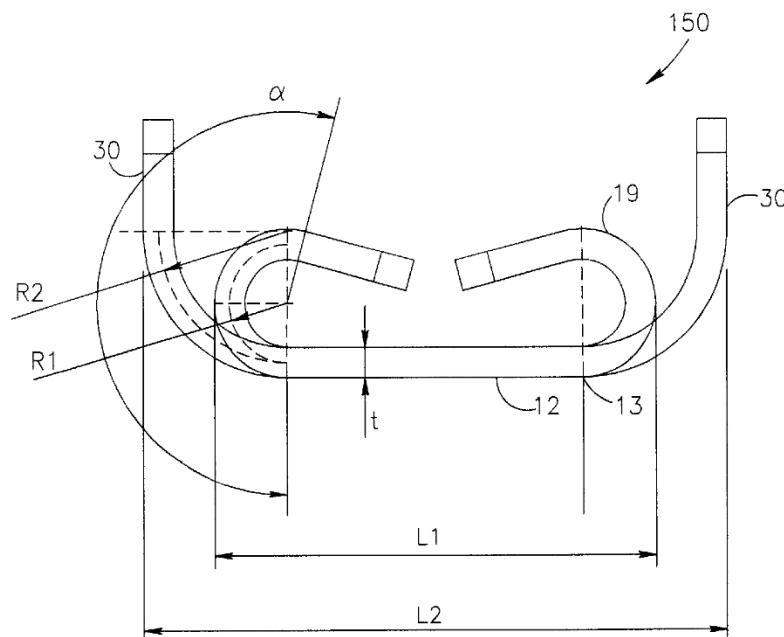
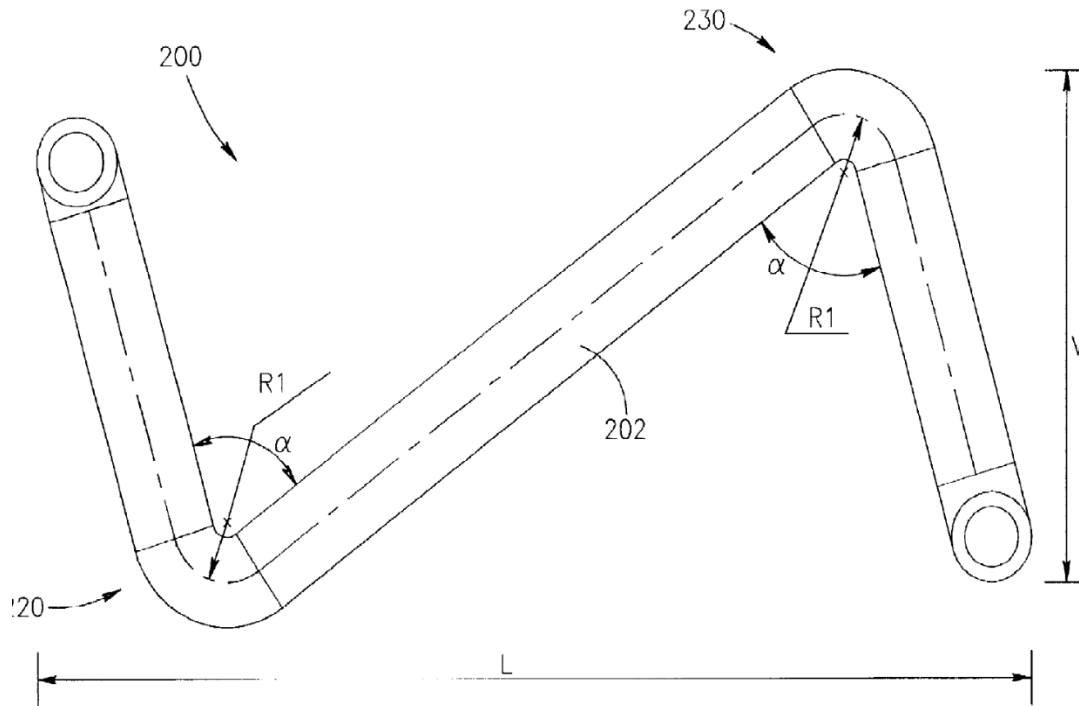


FIG. 8

Ex. 1005, Fig. 8. And, as Figs. 9A-C confirm that stresses create angles of deformation. *See id.*, col. 7:65-67 (“illustrate, in a table format, the percentage of plastic deformation that is encountered when *the curvature of an element is varied*, for the staple of FIG. 8.”). The specification otherwise confirms that there is bending, not stretching, describing with respect to Figure 8 that “[b]ending points 13 are the points at which semicircular end sections 19 begin.” *Id.*, col. 8:38-40. Simply put, bending or curving is not stretching. *See e.g.*, Ex. 1002, ¶27 (distinguishing between “bending or stretching”); ¶65 (noting that “staple 150 is deformed prior to insertion”); ¶97 (“staple 150 is plastically deformed so that α becomes 90°.”)

Petitioner also contends that staple 200 discloses claim 1, but this also fails. Monassevitch explains that staple 200 “may be employed to provide bone fixation, while it is in a stress-induced martensite state.” Ex. 1005, 14:20-28, 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.”). Staple 200, thus, is likewise deformed and then inserted and fixed while the deformation occurs. This is distinct from the claims of the ’222 Patent and its accompanying specification.

Further, as with staple 150, staple 200 is never stretched as the claim requires, but instead bent. As shown below, the staple 200 is bent to “straighten[], or partially straighten[] at least one curvature 220, or curvatures 220 and 230.”



Ex. 1005, Fig. 10. As explained above, bending is not stretching, and thus staple 200 fails to meet the claim for this additional reason.

As the '222 Patent describes, stretching of the bone device must occur after some insertion has occurred. *See, e.g.,* Ex. 1001, 5:32-41, 6:37-57. Yet, in each of the embodiments described in Monassevitch, the bone device is first stretched and then inserted and fixed into bone at the same time. This distinction is fatal to the Petition. None of the embodiments described in Monassevitch disclose the order of steps required by claim 1 of the '222 Patent, and thus, Petitioner fails to meet its burden.

3) Petitioner's Single Reference Obviousness Ground Never Identifies Any Missing Claim Element or Motivation to Modify the Single Reference.

Petitioner's ground based on Monassevitch is couched as obviousness. To support a finding of obviousness, the Petitioner must address certain factual issues, which among other things, include "differences between the prior art and the claims at issue." *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17 (1966). Petitioner fails to identify any such difference between Monassevitch and the claims, and similarly never identifies any motivation to modify Monassevitch to fill that gap. This is improper. "[A] patent can be obvious in light of a single prior art reference *if it would have been obvious to modify that reference* to arrive at the patented invention." *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361 (Fed. Cir. 2016) (emphasis added). But Petitioner never provides any such modification.

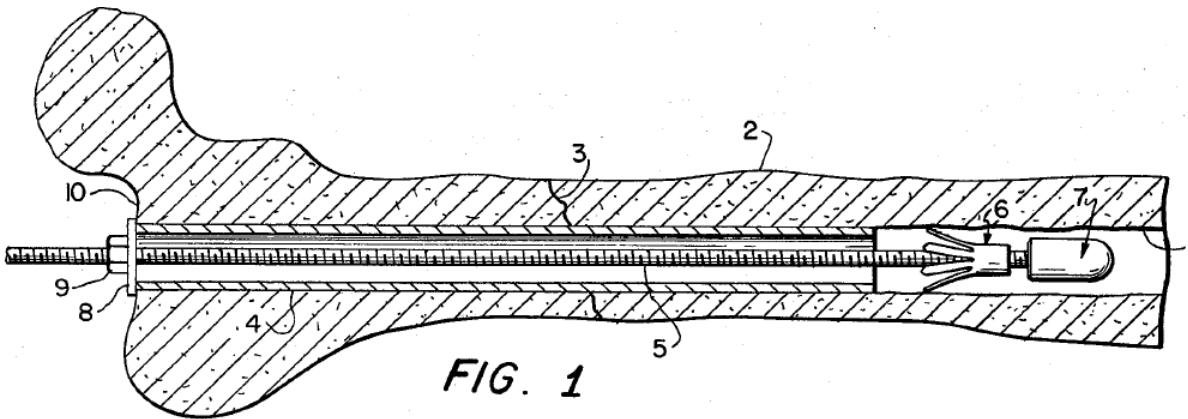
This weakness is critical here, where the claims require a specific order of steps and that order of steps is not disclosed in the single reference, Monassevitch, a deficiency which the Petition wholly ignores. *See supra*. Rather than grappling with this fundamental deficiency in the art, the Petition instead invites the Board to divine what is missing and modify the reference to address any missing elements. The Board should decline Petitioner's invitation and find that Petitioner failed to carry its burden for the reasons explained above. *See Minkin v. Gibbons, P.C.*, 680 F.3d 1341, 1351 (Fed. Cir. 2012) (explaining "anticipation and obviousness are

separate conditions of patentability, requiring different tests and different elements of proof”); *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1364 (Fed. Cir. 2008) (“The tests for anticipation and obviousness are different.... [O]bviousness requires analysis of secondary considerations of nonobviousness, while secondary considerations are not an element of a claim of anticipation.”).

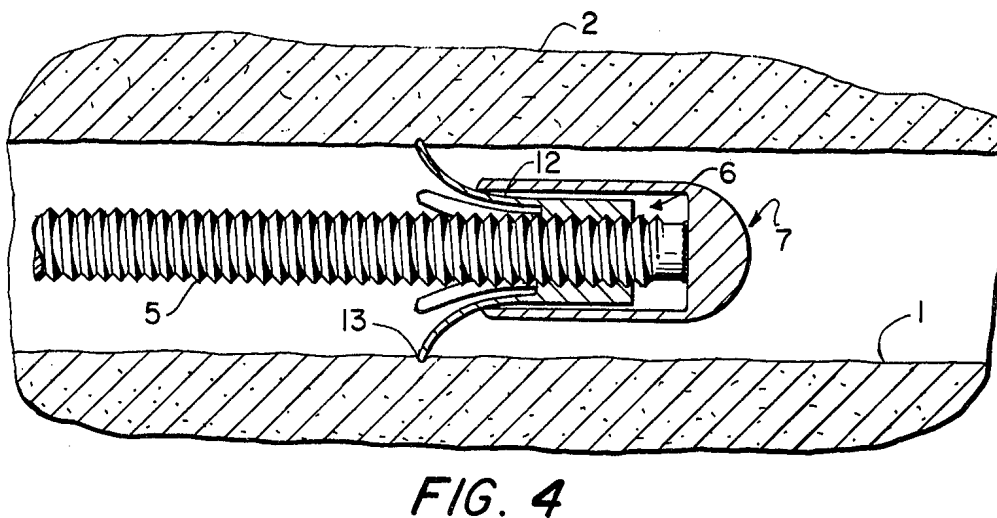
B. Petitioner Fails to Carry its Burden with Respect to Ground 2

Petitioner’s Ground 2 proposes a combination of U.S. 4,275,717 to Bolesky with U.S. 5,035,712 to Hoffman. Petitioner fails to establish a reasonable likelihood of success in establishing a motivation to combine these references. Indeed, a POSITA would recognize that there is no motivation.

The Petition relies on Bolesky as a primary reference. Bolesky describes a “fixation device adapted for use within the medullary canal of a fractured tubular bone.” Ex. 1006, Abstract. Bolesky’s device includes a “threaded rod 5” along with a “gripper unit 6” that is inserted into the medullary canal of a femur. *Id.*, 1:6-65. The threaded rod 5 includes a washer 10 and a nut 9 on the opposite end from the gripper unit 6, as shown below.



The nut is subsequently tightened in order to draw together the two pieces of bone and mend break 3 (shown above). The gripper unit 6 “comprises an internally threaded hub 11, which has its threads operatively engaged with the threads of rod 5, and a plurality of outwardly concave, springy resilient gripper fingers 12 which are equally spaced in a circular series concentric with the rod.” *Id.*, 3:21-27. As the nut is tightened these “springy resilient gripper fingers 12” “have pointed free ends adapted for penetrating engagement with the osseous tissue surrounding the medullary canal.” *Id.*, 3:28-30.



Id., Fig. 4. As is evident from their name—and shown in Figure 4 above—the “springy resilient gripper fingers 12” are resilient and compress the two pieces of bone together. In other words, the springs/fingers exert force to compress the two bone fragments.

The Petition acknowledges that Bolesky is silent as to shape memory material and purports to rely on Hoffman to cure this deficiency. But Hoffman operates on an entirely different principle for a different purpose, using temperature modulated shape memory metal in a thin rod to “secure a prosthesis in a prepared bone.” *See* Ex. 1007, 2:19-25; 4:10-26. As explained above, Bolesky’s “springy resilient gripper fingers 12” already solve the identified problem—providing continuous force across a bone break. The Petition identifies no reason why a POSITA would use an additional spring system—in the form of shape memory metal—in addition to the “springy resilient gripper fingers 12” of Bolesky.

There is no reason for such a combination, nor would a POSITA make this combination. First, the problem is already solved by the springy resilient gripper fingers 12. This alone is sufficient to confirm that there is no motivation for a POSITA to make the combination. *Runway Safe LLC v. Engineered Arresting Systems*, IPR2015-01921, Paper 9 at 7-8 (P.T.A.B. Feb. 29, 2016) (finding no motivation to combine prior art where the alleged improvement from the secondary reference was already present in the primary reference).

Second, the inclusion of additional force from a temperature modulated shape memory material would have potentially detrimental outcomes through providing additional force as well as tissue damage for changing temperatures. Such additional pressure could overpressure the repair site, hindering bone growth, or overpressure the “springy resilient gripper fingers 12” detrimentally driving them into the wall of the medullary canal.

Third, the force to engage the springy resilient gripper fingers 12 is provided by the nut 9, and the Petition never suggests replacing this nut with a temperature modulated shape memory material as allegedly suggested by Hoffman—“a rod stretched at a low temperature, below the transition point of the metal in question, will return to its original length when heated to above the transition point...[w]hen this shrinkage is prevented, a shape recovery stress is built up in the metal” and “tie member 6 is stretched by tightening nut 11 at a temperature higher than the body temperature.” Ex. 1007, 2:1-9; 5:18-22. Petitioner’s purported expert Mr. Sherman provides no help, as his declaration, in particular with respect to motivation to combine, is nearly a word-for-word copy of the Petition and thus offers no credible support. *See infra* Section IV. Thus, Petitioner fails to carry its burden with respect to Ground 2.

In any event, Bolesky is designed for an entirely different purpose—temperature modulated internal tensioning to secure a prosthetic joint. This is

different from Hoffman, which does not use any shape memory material at all, as Petitioner acknowledges. But is further irrelevant to the claims of the '222 Patent, which does not recite temperature change, but instead a constant temperature. *See* '222 Patent, claim 1 (“wherein the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy.”). The Petition never explains how or why such a device would be used to modify a device for fixing bone fragments, in particular where the problem was already solved. This is precisely the piecemeal analysis that the Federal Circuit prohibits. In essence, the Petition breaks the invention down into its component parts and picks the missing features from various references and, guided by hindsight and using the claims as a template, combines them together to conclude summarily and improperly that such combination would have been obvious.

“In short, this case involves nothing other than an assertion that because two ... systems were disclosed in a prior art reference and were therefore ‘known,’ that satisfies the motivation to combine analysis. That is an error as a matter of law. It does not suffice to simply be known. A reason for combining must exist.” *Virtek Vision Int’l ULC v. Assembly Guidance Sys., Inc.*, 97 F. 4th 882 (Fed. Cir. 2024). The Petition fails to establish such a motivation and thus fails to establish obviousness.

III. Institution Should Be Denied Under Section 325(d)

A. The Applicant Overcame Similar Art During Prosecution, Weighing in Favor of Denial Under § 325(d).

The Board should exercise its discretion to deny institution under § 325(d) because the Petition presents “the same or substantially the same prior art or arguments previously ... presented to the Office,” 35 U.S.C. § 325(d), and because Petitioner failed to meet its burden to show material error with respect to such art or arguments. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) (precedential) (“*Advanced Bionics*”); *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph) (“*Becton*”).

Under *Advanced Bionics*, the Board first considers “whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office.” IPR2019-01469, Paper 6 at 7-8. If “either condition of [the] first part of the framework is satisfied,” the Board then considers “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Id.* at 8. “If the petitioner fails to show that the Office erred, the Director may exercise his discretion not to institute *inter partes* review.” *Id.* (citing *Becton*, IPR2017-01586, Paper 8 at 24).

Here, institution should be denied because substantially the same prior art and arguments previously were presented to the Office, the Examiner correctly resolved them, and Petitioner makes no allegations to the contrary.

1) Part 1 of *Advanced Bionics*: The Prosecution History of the '222 Patent Considered Substantially the Same Prior Art and Arguments Petitioner Presents.

As explained above, the prior art relied upon by the Petition does not disclose every element of the claims. And the same flaws in the prior art relied upon in the Petition are found throughout the art addressed during the '222 Patent's prosecution. This weighs against institution. *See Juniper Networks, Inc.*, 2018 WL 1358386, at *4; 35 U.S.C.A. § 325(d) ("In determining whether to institute ... the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.").

With respect to Ground 1, during prosecution of the Application that led to the '222 Patent, the Examiner rejected the claims based on U.S. 5,425,660 to Campbell. *See Ex. 1004* at 88. In response, the Applicant amended the claim to add the claim element "after performing the stretching, fixing the second portion of the bone device to the second bone fragment." *Id.* at 87. Applicant went on to explain that Campbell "does not teach the limitation 'after performing the stretching, fixing the second portion of the bone device to the second bone fragment.'" *Id.* at 88. Thus,

Applicant distinguished the claims over Campbell on the same order of steps basis as described above in Section II.A. The next action by the Examiner indicated that the amended claim (claim 47) was allowable. Ex. 1004 at 71-72. And after cancellation of certain other claims, a Notice of Allowance quickly followed. *Id.* at 30. Thus, Applicant overcame a similar rejection to that presented in Ground 1.

With respect to Ground 2, the Applicant submitted as prior art references that clearly describe shape memory materials as is purportedly described in Hoffman. For example, cited on the face of the '222 Patent is U.S. 4,665,906 (Ex. 1004 at 112), which describes in its 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.” Hoffman purports to describe various shape memory material properties all dependent upon temperature modulation. *See* Ex. 1007, 2:10-17; 4:10-29. Thus, the same type of art was in front of the Examiner and considered. Ex. 1004 at 112. This similarly confirms that denial of institution is appropriate. *Juniper Networks, Inc.*, 2018 WL 1358386, at *4; 35 U.S.C.A. § 325(d) (“In determining whether to institute ... the Director may take into account whether, and reject the petition or request because, the same or ***substantially the same prior art*** or arguments previously were presented to the Office.” (emphasis added)).

In short, the Examiner reviewed and applied similar art to that relied upon in both Ground 1 and Ground 2, the Applicant amended the claims to overcome that

art, and the Examiner allowed the claims. The Petition does not acknowledge the similarity in the references addressed during prosecution, much less attempt to dispute it. Thus, the Petition wholly fails to establish that the prior art cited therein is different than the art cited during prosecution.

The similarity in the art presented in the petition and addressed in detail by the Examiner further counsels against institution. *See Fox Factory, Inc. v. SRAM, LLC*, IPR2016-01876, Paper 8 at 7 (Apr. 3, 2017) (“there are the interests in conserving the resources of the Office and granting patent owners repose on issues and prior art that have been considered previously.”); *Kayak*, No. CBM2016-00075, at *12-13.

2) Part 2 of *Advanced Bionics*: Petitioner Failed to Demonstrate that the Office Erred in a Manner Material to the Patentability of the Challenged Claims.

The second prong of the *Advanced Bionics* test is met because Petitioner completely failed to set forth any evidence of material error committed by the Office. Petitioner does not even address *Advanced Bionics*, much less allege “material error” by the Office. Petition at 52. Accordingly, Petitioner has not, and cannot, meet its burden of establishing that “the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics*, IPR2019-01469, Paper 6 at 7-11. Because Petitioner identifies no material error, the Board should exercise its discretion under

§ 325(d) and deny institution. *See, e.g., ABS Glob., Inc. v. Cytonome/ST LLC*, IPR2021-00306, Paper 13 at 13-14, 16 (P.T.A.B. June 7, 2021).

IV. Petitioner’s Expert’s Declaration Parrots the Petition and Thus the Testimony Provided Therein Should Be Given No Weight.

As noted above, in support of its Petition, Petitioner submits a declaration from its expert, Mr. Mike Sherman. *See* Ex. 1002 (the “Sherman Declaration”). The Sherman Declaration simply parrots the Petition, as opposed to providing any insightful expert opinions and analysis. Thus, the Sherman Declaration should not be entitled to any weight—and, as such, Petitioner has necessarily failed to carry its burden with respect to institution.

As the Board has consistently recognized, a declaration that repeats the petition *verbatim* “is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight.” *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9, 2022 WL 3648989, at *6 (P.T.A.B. Aug. 24, 2022) (precedential) (denying institution where Petitioner’s expert “offers only a *verbatim* restatement of the assertion being supported, without any supporting evidence or technical reasoning.”). Simply put, an expert declaration that “merely parrots the Petition” is entitled to “little to no weight.” *E.g., MarkForged Inc. v. Continuous Composites, Inc.*, IPR2022-01431, Paper 7, at 14 (Jan. 18, 2023) (“[Expert’s] declaration testimony on this point is entitled to little to no weight as it merely parrots the Petition.”); *LG Elecs. Inc. v. Jawbone Innovations*,

LLC, IPR2023-01111, Paper 10, at 15 (Jan. 9, 2024) (“Petitioner’s expert merely parrots the Petition.... Thus, Petitioner’s conclusory assertion is unpersuasive.”); *see Content Square SAS v. Medallia Inc.*, IPR2022-00316, Paper 13, at 38 (July 14, 2022) (“Merely repeating an argument from the Petition in the declaration of a proposed expert, does not give that argument enhanced probative value.”); *Man Wah Holdings Ltd. v. Rafeel Sys., LLC*, IPR2019-00616, Paper 7, at 15-16 (Aug. 21, 2019) (“Merely repeating an argument from the Petition in the declaration of a proposed expert does not give that argument enhanced probative value.”).

Such is the case here with respect to the Sherman Declaration. Indeed, with respect to, for example, the purported motivation(s) to combine the disparate prior art references in Ground 2—an area on which expert testimony may be critical—the Sherman Declaration simply restates the attorney argument set forth in the Petition itself, without any meaningful discussion or elaboration, let alone expertise. *Compare* Ex. 1002, ¶¶ 146-148 *with* Petition at 56-58.

One example highlighting the similarity is what Mr. Sherman purports to provide as the motivation to modify the threaded rod of Bolesky to use Nitinol as described in Hoffman. As shown below, Mr. Sherman does not even attempt to conceal that his opinion is nothing more than a copy-paste of the same analysis in the Petition. Much less than develop any credence of credibility, such expert

“testimony” does nothing to help the Board address the prior art or the purported motivations to make the modifications that Petitioner proposes:

Petition at 58	Ex. 1002, ¶148
A POSITA would have a reasonable expectation of success in using a Nitinol rod, as taught in Hoffman, as a substitute for the threaded rod of Bolesky. Ex. 1002, ¶148. A POSITA would have known that Nitinol was biocompatible and a suitable alternative to the stainless steel used in Bolesky. <i>Id.</i> Additionally, the superelastic properties of Nitinol were well known in the art and routinely used by skilled artisans in the design of orthopedic fracture fixation devices. <i>Id.</i> Thus, a POSITA in the relevant timeframe would have had a reasonable expectation of success in combining Bolesky and Hoffman in the manner discussed herein.	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.

As is shown above, the statements, purporting to be about a reasonable expectation of success for the combination is little more than parroting the Petition. Mr. Sherman’s only modifications are to adjust phrases to include statements like “in my opinion.” Put another way, the Sherman Declaration is almost identical to the Petition. But a purported expert merely parroting the Petition cannot give any

insight into what a POSITA may or may not be motivated to do. *See LG Elecs.*, IPR2023-01111, Paper 10, at 15; *Content Square*, IPR2022-00316, Paper 13, at 38.

There are other significant examples with respect to the specific grounds. For example, in addressing Ground 1, and the claim element “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,” Mr. Sherman again almost directly quotes the Petition:

Petition at 34	Ex. 1002, ¶148
Accordingly, a POSITA would understand that this embodiment (staple 200) also discloses or suggests stretching a responsive portion along the longitudinal axis of the staple, such that at least a partial transformation into a stress-induced martensitic phase is created in the responsive portion. Ex. 1002, ¶100. A POSITA would recognize that the portion of staple 200 highlighted in blue below is a responsive portion of the staple because this portion includes a region or regions of the staple (i.e., one or more of the curvatures in the top portion of the staple) that are being deformed and exhibit stress-induced martensite (to provide compression to the bone when the staple is inserted). <i>Id.</i> In addition, Monassevitch teaches that the stretching is performed using apparatus 210, which is “similar in construction and operation to apparatus 60,” for “increasing length span L of web 202 of staple 200.” Ex. 1005,	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.” <i>Id.</i>, 14:29-35; <i>see also</i> 10:6-41 (describing operation of apparatus 60). And as illustrated below, the stretching created

14:29-35; <i>see also</i> 10:6-41 (describing operation of apparatus 60). And as illustrated below, the stretching created by apparatus 210 that causes this deformation and lengthening to occur is performed along the longitudinal axis of the staple 200. Ex. 1002, ¶¶100-101.	by apparatus 210 that causes this deformation and lengthening to occur is performed along the longitudinal axis of the staple 200. <i>See also id.</i> , 14:29-35 (describing apparatus 210 for increasing the length span L of web 202 of staple 200).
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There are numerous other instances where Mr. Sherman's declaration is a near exact copy of the Petition and is being used to purportedly supply something missing from the prior art. Such testimony is "particularly problematic" because it attempts to "supply a limitation missing from the prior art." *Xerox*, 2022 WL 3648989, at *6. Such "declaration testimony is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight." *Id.*

This issue is not isolated to independent claims and continues throughout the claim set, including for example, the passage below addressing claim 5:

Petition at 44	Ex. 1002, ¶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 described above, Monassevitch discloses and/or renders obvious this limitation for the reasons described above with respect to claim	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.

limitation [1.5] and claim 2. Ex. 1002, ¶116.	
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As another example of the Sherman Declaration being an almost exact copy of the Petition, compare Mr. Sherman’s purported testimony at paragraphs 117-119 claiming to analyze the claim 6 with the analysis of that claim at pages 45-46 of the Petition:

Petition at 45-46	Ex. 1002, ¶117-119
Claim 6 depends from claim 1 and further requires “holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the second portion is performed.” Monassevitch discloses and/or renders obvious this limitation with respect to each of the three embodiments described above. Ex. 1002, ¶117. For each of staples 10, 150, and 200, Monassevitch teaches that the staple is not only stretched to create a stress-induced martensitic state, but that it is used to “provide bone fixation” in the stress-induced martensitic state. Ex. 1005, 12:24-29 (“staple 10 may be employed in a plastically deformed state that results from the length-span increase. In other words, the deformed shape that results from the length-span increase is the final shape, and staple 10 may be used to provide bone fixation, while in a stress-induced martensite state”); 13:25-34. (“staple	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). 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. <i>See Id.</i>, 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

150 may be employed **to provide bone fixation, while it is in a stress-induced martensite state**"; 14:20-28 ("staple 200 may be employed **to provide bone fixation, while it is in a stress-induced martensite state.**"). For the reasons discussed above with regard to element [1.5], a POSITA would have understood that, in order to create stress-induced martensite, and thus be in a stress-induced martensite state, the shape memory would be at a temperature greater than the austenite finish temperature of the SMA. Ex. 1002, ¶118.

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

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.

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 Af.**" *Id.* 2:13-27.

Other than the minor differences in verbiage, the two statements are almost entirely the same. Yet another example of parroting is below, addressing whether Monassevitch discloses claim element 8:

Petition at 52	Ex. 1002, ¶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. Ex. 1002, ¶132; <i>see also</i> Ex. 1005, Fig. 3C. As such, for each of the three relevant embodiments, Monassevitch discloses and/or renders obvious this limitation for the same reasons as discussed for claim 7. Ex. 1002, ¶132.	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. <i>See, e.g.</i> 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.

The Petition and Mr. Sherman’s purported expert testimony are replete with other similar examples of Mr. Sherman’s parroting the Petition. *Compare* Petition at 17 (addressing element 1.p) *with* Ex. 1002, ¶69; *Compare* Petition at 21-22 (addressing Staple 150) *with* Ex. 1002, ¶¶77-78; *Compare* Petition at 22 (addressing Staple 200) *with* Ex. 1002, ¶80; *Compare* Petition at 33-34 (addressing Staple 200) *with* Ex. 1002, ¶¶99-100; *Compare* Petition at 36-39 (addressing element 1.4) *with* Ex. 1002, ¶¶103-105; *Compare* Petition at 42 (addressing superelasticity) *with* Ex.

1002, ¶109; *Compare* Petition at 56-57 (addressing motivation to combine) *with* Ex. 1002, ¶146; *Compare* Petition at 60-61 (addressing Bolesky) *with* Ex. 1002, ¶¶153-155; *Compare* Petition at 62-64 (addressing element 1.2) *with* Ex. 1002, ¶¶157-162; *Compare* Petition at 64-66 (addressing Hoffman and SMA) *with* Ex. 1002, ¶¶163-165; *Compare* Petition at 71-74 (addressing element 1.4) *with* Ex. 1002, ¶¶178-181; *Compare* Petition at 76-79 (addressing claim 3) *with* Ex. 1002, ¶¶188-193.

As the Board has explained, “merely repeating conclusory arguments does not help the Board, the trier of fact in this proceeding, understand the evidence or to determine a fact in issue.” *Man Wah Holdings Ltd. v. Rafeel Sys., LLC*, IPR2019-00616, Paper 7, at 15-16 (P.T.A.B. Aug. 21, 2019).

Mr. Sherman’s unhelpful declaration should therefore be given no weight, particularly where it is used to supply a limitation missing from the prior art. *See, e.g., MarkForged*, IPR2022-01431, Paper 7, at 14 (“[Expert’s] declaration testimony on this point is entitled to little to no weight as it merely parrots the Petition.”); *Xerox*, 2022 WL 3648989, at *6. And without expert testimony, Petitioner cannot satisfy its burden of demonstrating that its purported prior art discloses the elements of the challenged claims.

V. Institution Should Be Denied Under the *Fintiv* Factors.

On March 25, 2024, Petitioner was served with a Complaint filed by Patent Owner alleging infringement of the ’222 Patent in *Medshape, Inc., et al. v. Arthrex*,

Inc., No. 6:24-cv-151 (W.D. Tex) (the “Parallel Litigation”). Since that time the Parallel Litigation advanced at pace. Indeed, the parties have already completed claim construction briefing, the Court held a *Markman* hearing on December 5, 2024, and fact discovery began the next day. Ex. 2001. Fact discovery is scheduled to conclude on July 3, 2025 with the close of expert discovery on August 28, 2025, and dispositive motions due shortly thereafter on September 11, 2025.

Defendant has served two sets of invalidity contentions, an initial set served August 15, 2024, and an amended set on November 6, 2024. Those amended invalidity contentions include all the prior art relied upon in the Petition. *See* Ex. 2002 at 13 (Hoffman is chart A-1, Monassevitch is chart A-2, Bolesky is chart A-15). Despite relying on the exact same art relied upon in this Petition and challenging the exact same claims (Ex. 2002 at 1), Petitioner does not include any *Sotera*-type stipulation.

The precedential order in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (“*Fintiv*”) identifies six factors for the Board to consider in deciding whether to exercise discretion to deny institution based on parallel proceedings involving the same patent. As discussed below, application of the present facts to these factors demonstrates that there are strong reasons for exercising discretion to deny institution here.

A. Factor 1 Weighs Against Institution Because a Stay Has Not Been Granted in the Parallel Litigation And there Is No Evidence that a Stay Would Be Granted if this IPR Was Instituted.

No stay has even been requested in the Parallel Litigation. In addition, even if this IPR was instituted (which would not occur until on or around April 30, 2025) it is unlikely that the Court (Judge Pulliam) would grant a stay, particularly given the stage of litigation, and that Petitioner has not filed any challenge to the other asserted patent, U.S. 8,491,583. *See generally Continental Intermodal Grp. v. Sand Revolution LLC*, No. 7:18-cv-00147 (W.D. Tex. July 22, 2020) (Judge Albright); *Multimedia Content Mgmt. LLC v. Dish Network*, No. 6:18-CV-00207-ADA (W.D. Tex. May 30, 2018) (Judge Albright) (denying stay). Thus, the first factor weighs against institution.

B. Factor 2 Weighs Against Institution Because the Parallel Litigation Will Likely Have a Trial Around the Projected Statutory Deadline for a Final Written Decision.

As discussed, any institution decision would not occur until on or around April 30, 2025. Thus, the statutory deadline for a final written decision is not until late April 2026. And while there is no trial date currently scheduled in the Parallel Litigation, under the present scheduling order (Ex. 2001) dispositive motions are due by September 11, 2025, which is nearly eight months before the statutory deadline for a final written decision. Indeed, given the current case schedule, it is highly likely

that trial will be scheduled to occur several months prior to any Final Written Decision.

Thus, the current case schedule strongly suggests that trial will occur before a final written decision is issued, and this is confirmed by statistics from the overall jurisdiction. This factor weighs against institution or is, at worst, neutral.

C. Factor 3 Weighs Against Institution Because the Parties Will Have Invested Significant Effort in the Parallel Litigation by the Time the Board's Institution Decision Is Due.

Factor 3 relates to investment in the Parallel Litigation by the court and the parties. *Fintiv*, Paper 11 at 9. This factor is judged from the date of the institution decision, which is expected to be no later than April 30, 2025. *Id.* In the Parallel Litigation, the parties have already exchanged infringement contentions and invalidity contentions and engaged in substantial discovery. *See, e.g.*, Ex. 2002 (DEFENDANT'S FIRST AMENDED DISCLOSURE OF PRELIMINARY INVALIDITY CONTENTIONS). Claim construction briefing is already completed, and the parties held a *Markman* hearing nearly two months ago in early December. *See* Ex. 2001. Further, by the time of any institution decision the parties will have served final invalidity and infringement contentions and the deadline to amend pleadings will have passed, and fact discovery will have been open for almost five months and will close just two months thereafter in early July. *See id.*

Simply put, the parties and the Court have already made a substantial investment in the Parallel Litigation, which will grow even larger by the expected date of the institution in late April. Thus, the third factor weighs against institution.

D. Factor 4 Weighs Against Institution Because there Is Substantial Overlap Between the Parallel Litigation and this IPR

In its Invalidity Contentions in the Parallel Litigation, Petitioner relies on Monassevitch, Bolesky, and Hoffman, which are the same references relied on in this IPR. *See* Ex. 2002 at 13 (charts A-1, A-2, and A-15).

Reference	Claim Chart
Hoffman	A-1
Monassevitch	A-2
Bolesky	A-15

Thus, there is complete overlap in the invalidity grounds between the parallel litigation and the Petition. In such a situation there are particularly strong “concerns of inefficiency and the possibility of conflicting decision” if this IPR is instituted. *Fintiv*, Paper 11 at 12; *see Eclinicalworks, LLC et al. v. Decapolic LLC*, IPR2022-00229, Paper 10 at 13 (P.T.A.B. Apr. 13, 2022) (finding factor 4 weighs strongly in favor of denial where the ground in the Petition was included in the preliminary invalidity contentions in parallel case).

Petitioner falsely states “Petitioner also challenges claims not identified as being asserted in the corresponding litigation.” Petition at 84. This statement is false. The Petition challenges the validity of claim 1-10.

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

Petition at 3. And the same claims are challenged in Petitioner’s invalidity contentions. Ex. 2002 at 1 (“Defendant provides its Preliminary Invalidity Contentions as to Claims 1–10 of U.S. Patent No. 7,985,222”).

Thus, the fourth factor weighs against institution.

E. Factor 5 Weighs Against Institution Because the Patent Owner and the Petitioner Are the Same Parties as in the Parallel Litigation

Patent Owner and Petitioner are the same parties as in the Parallel Litigation.

Thus, the fifth factor weighs against institution.

F. Factor 6 Weighs Against Institution Because there Are No Other Circumstances that Favor Institution, and the Merits of Petitioner’s Challenge is Weak

As discussed above, Petitioner’s challenge is weak. Petitioner misunderstands the required order of steps in the claims and conflates the disclosure of the three cited prior art references. *See* Section II *supra*. Further, Petitioner’s expert provides only a conclusory parroting of the Petition, which should be afforded little weight, to the

extent it is even accepted. *See* Section IV *supra*. Thus, the sixth factor weighs against institution.

All *Fintiv* factors weigh against institution of the IPR. Under §314(a) and, based on the totality of the *Fintiv* factors, institution should be denied.

VI. Conclusion

For all the foregoing reasons, the Petitioner fails to carry its burden, and no proceeding should be instituted.

Dated: January 30, 2025

Respectfully Submitted,

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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this Preliminary Response contains 7,525 words according to the word-processing program used to prepare this paper. The foregoing word count complies with the 14,000 word type-volume limit specified by 37 C.F.R. § 42.24(b)(1).

Dated: January 30, 2025

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Patent Owner's Preliminary Response has been served electronically via email upon the following:

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