

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

PGR2026-00022
Patent 12,274,481

PATENT OWNER'S PRELIMINARY RESPONSE

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PATENT OWNER'S UPDATED LIST OF EXHIBITS

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2001	<i>Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.</i> , Initial Complaint, dated May 12, 2025
2002	<i>Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.</i> , Joint Stipulation and Proposed Order to Extend Stay, dated December 1, 2025
2003	<i>Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.</i> , Joint Stipulation and Proposed Order to Stay, dated September 12, 2025
2004	<i>Paragon 28, Inc. and Disior Oy v. Treace Medical Concepts, Inc. and Mios Marketing, LLC</i> Amended Complaint, dated December 18, 2025
2005	U.S. Patent No. 10,849,670 to Santrock, <i>et al.</i> (the “’670 Patent”)
2006	U.S. Patent No. 10,856,886 to Dacosta, <i>et al.</i>
2007	U.S. Patent No. 11,696,767 to Dacosta, <i>et al.</i>
2008	Treace Medical Concepts, Inc.'s SEC Form S-1 Registration Statement for Initial Public Offering, dated March 30, 2021
2009	Treace Medical Concepts, Inc.'s Initial Public Offering, dated April 22, 2021
2010	J.P. Morgan's Analyst Report entitled "A Differentiated Solution for the Large, Poorly Treated Bunion Market; Initiating at OW and \$37 PT", dated May 18, 2021
2011	Treace's Announcement of Grant of Additional U.S. Patent on Instrumented Bunion Correction, dated October 21, 2021

Exhibit No.	Description
2012	Treace's Announcement of Grant of U.S. Patent and Allowance of U.S. Patent Application on Bone Positioner Technology for Bunion Correction, dated November 30, 2021
2013	Treace's Announcement of Grant of U.S. Patent on Instrumented Bunion Correction, dated January 19, 2022
2014	Treace's Announcement of Expansion of Its Global IP Portfolio with the Grant of Two New U.S. Patents, dated December 19, 2022
2015	Treace's Announcement of Expansion of Market Leading Global IP Portfolio For Bunion And Related Deformities, dated April 19, 2023
2016	Treace's Announcement of New Patent Covering Instrumented Bunion Correction Procedures and Milestone 50th U.S. Patent, dated September 14, 2023
2017	Treace's Announcement of Filing of Patent Infringement Suit Against Zimmer Biomet to Protect Lapiplasty® Bunion Technology, dated June 5, 2025
2018	Treace's Announcement of 100,000 Lapiplasty® 3D Bunion Correction® Patient Milestone Celebration, dated March 25, 2024
2019	Stephen Inc.'s Analyst Report entitled "TMCI's Device Superiority Is Winning The War on Bunions, Initiating EW/V Due To Valuation", dated April 10, 2023
2020	AlphaSense's November 12, 2024 UBS Global Healthcare Conference Transcript
2021	Treace's Announcement of Filing of Patent Infringement Suit To Protect Lapiplasty® Bunion Technology, dated March 28, 2022
2022	Treace's Announcement of Settlement of Lawsuit Against Fusion Orthopedics, dated March 3, 2023
2023	Treace's Announcement of Filing of Patent Infringement and Unfair Competition Suit to Protect Lapiplasty® Bunion Technology, dated October 14, 2024

Exhibit No.	Description
2024	J.P. Morgan's January 2023 Investor Presentation on Treace Medical Concepts, Inc.
2025	USPTO Additional Discretionary Institution Considerations – U.S. Manufacturing and Small Business Use of AIA Proceedings Memorandum, dated March 11, 2026
2026	Zimmer Biomet Website - Company Overview
2027 [NEW]	Declaration of Daniel C. Farber, M.D. ("Farber Declaration")
2028 [NEW]	<i>Curriculum Vitae</i> of Daniel C. Farber, M.D.
2029 [NEW]	Definition of "Guide" from dictionary.com

I. INTRODUCTION

A. Background

Paragon 28, Inc. (Petitioner) filed a Petition (Paper 1, the “Petition” or “Pet.”) requesting post grant review of claims 1–30 of U.S. Patent No. 12,274,481 (Ex. 1001, “’481 Patent”).

The Petition is based on allegation, not evidence. A fundamental failing of the Petition is its failure to properly address the recited “bone positioning guide,” and more specifically its actuation caused by “rotating a knob connected to a threaded shaft of the bone positioning guide . . . to correct the bunion deformity,” which is recited in all challenged claims.

The Board is presented with a conclusory assertion by Petitioner merely stating that “[t]he plain and ordinary meaning of ‘bone positioning guide’ is a ‘device that is designed to move bone(s).’” Pet. 20. This is followed by Petitioner’s conclusory assertion that “Kartalian’s instrument in the combination satisfies ‘bone positioning guide’ under the plain and ordinary meaning, as it is a type of tenaculum/tong and is used to position bones, including moving the metatarsal in the transverse plane.” *Id.* at 29. These conclusory statements are incorrect, and effectively read the word “guide” out of each independent claim.

A further failing of the Petition is its conclusory treatment of the recited “rotating” step found in each claim. *See, e.g.*, Ex. 1001, 18:17–22 (“rotating a knob

connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and . . . to correct the bunion deformity”). The Petition relies on Kartalian’s “locking clamp” as purportedly disclosing this feature, but does not reconcile its position with Kartalian’s express description that its “locking clamp” is used to hold the instrument in position *once final alignment has been achieved*, not to guide the movement of bones with respect to each other. As for the actual claimed “rotating” step, Petitioner points to no disclosure for this step and instead relies on a conclusory statement from its expert, unsupported by any evidence.

This is far below what is required for institution. *See* 37 C.F.R. § 42.202(b)(3) (petition must identify how each challenged claim is to be construed), (4) (petition must identify how the construed claim is unpatentable); *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (petitioner cannot meet its burden through conclusory statements); *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (conclusory expert testimony is insufficient to establish obviousness).

Petitioner ignores Kartalian’s description of its locking clamp, and Dr. Neufeld’s testimony simply parrots the same conclusory assertions presented in the Petition in a failed attempt to transform attorney argument into evidence. In short, the Petition does not identify where Kartalian teaches the specific claimed step, and

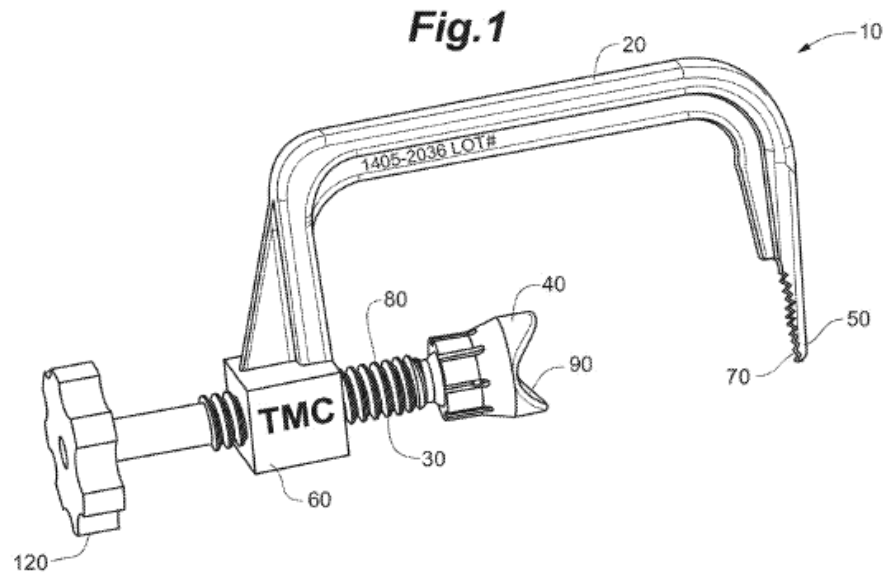
Dr. Neufeld's testimony does not supply that missing disclosure. And neither the claim construction nor the challenge presented by Petitioner addresses the recited "guide" feature.

Accordingly, the Board has sufficient reason to deny institution based on Petitioner's failure to meet its burden. The following discussion further elaborates on the Petition's failings, evaluating in detail the relevant portions of the Petition and testimony.

B. The '481 Patent

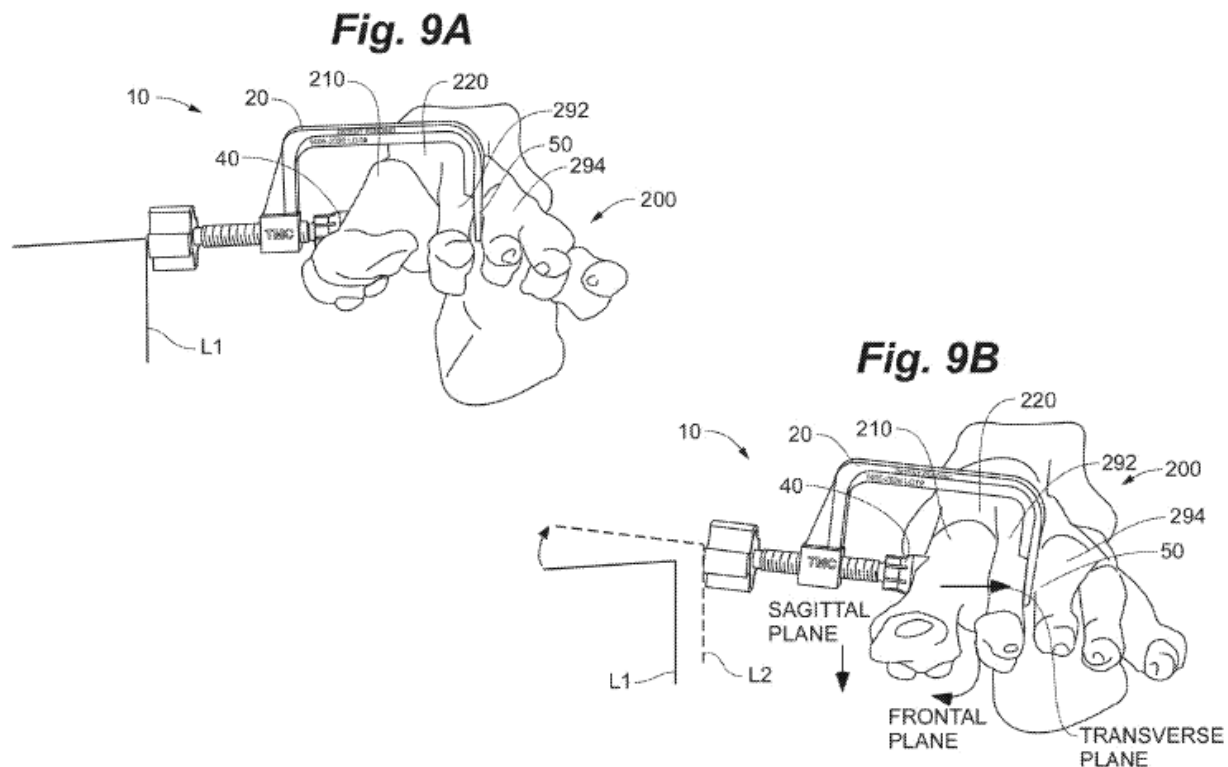
The '481 Patent relates to an instrumented surgical technique for bunion correction. The '481 Patent describes an instrumented correction system used in its surgical technique including a bone preparation guide, a bone positioning guide, and a fixation device. The system enables precise, reproducible bunion deformity correction, providing the corrected metatarsal position for fusion with the cuneiform. Patent Owner's Preliminary Response ("POPR") focuses on the Petition's treatment of the recited "bone positioning guide," including its actuation by "rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal . . . to correct the bunion deformity," as the deficiencies in the Petition regarding those features are adequate for the Board to deny institution.

Figure 1 from the '481 Patent is reproduced below.



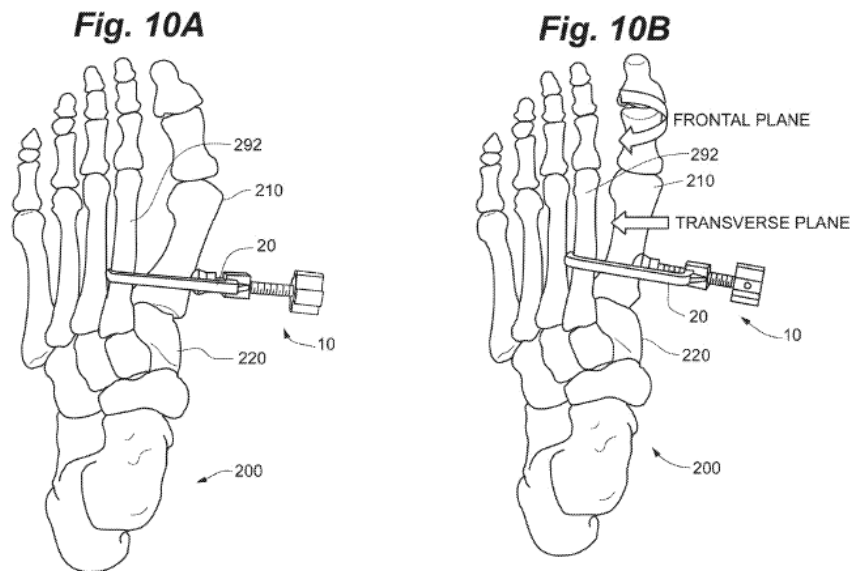
“F[igure] 1 is a side perspective view of a bone positioning guide.” Ex. 1001, 4:46–47. The “bone positioning guide 10 can also include an actuator (*e.g.*, a knob or a handle) 120 to actuate the mechanism, in this embodiment associated with the shaft,” and “the actuator can be useful for allowing a user to rotate the shaft with respect to the main body member 20.” *Id.* at 6:26–31. The ’481 Patent explains: “When the mechanism is actuated it causes a first bone engaged with the bone engagement member to move to correct an alignment in more than one plane with respect to a second bone in contact with the tip.” *Id.* at 4:56–60.

Figures 9A, 9B, 10A, and 10B illustrate the bone positioning guide in operation, and are reproduced below.



“FIG. 9A depicts a foot 200 with an uncorrected bunion deformity, while FIG. 9B depicts the foot 200 with an alignment corrected by the bone positioning guide 10.” Ex. 1001, 9:20–22. “Solid line L1 represents the starting location of the bone positioning guide 10 and dotted line L2 represents the finishing location of the bone positioning guide.” *Id.* at 9:23–25. “[A]s the bone positioning guide 10 is actuated it rotates with the first metatarsal 210 about an axis extending through the frontal plane as it pushes the first metatarsal 210 laterally in the transverse plane and plantarly in the sagittal plane.” *Id.* at 9:26–29. “[T]he position of the first metatarsal 210 is corrected with respect to the second metatarsal 292 generally in three planes by actuating a single bone positioning guide 10 [by rotating a knob] to urge a bone

engagement member 40 toward a tip 50.” *Id.* at 9:30–34. Figures 10A and 10B illustrate the correction from a top view.



“F[igure] 10A shows a top view of a foot 200 with an uncorrected bunion deformity, while F[igure] 10B shows a top view of the foot 200 with an alignment corrected by the bone positioning guide 10, emphasizing the rotational correction in the frontal plane and the lateral correction in the transverse plane.” *Id.* at 9:34–39.

As seen above, “the actuator [knob] 120 [labeled in Figure 1] can be actuated to extend the shaft 30 to reduce the angle (transverse plane angle between the first metatarsal and the second metatarsal) and rotate the first metatarsal about its axis (frontal plane axial rotation).” Ex. 1001, 11:16–20. “The first metatarsal 210 can be properly positioned with respect to the medial cuneiform 220 by moving the bone engagement member 40 with respect to the tip 50,” where “such movement

simultaneously pivots the first metatarsal with respect to the cuneiform and rotates the first metatarsal about its longitudinal axis into an anatomically correct position to correct a transverse plane deformity and a frontal plane deformity.” *Id.* at 11:20–27.

The ’481 Patent describes a guide/actuator arrangement in which actuation of the knob/shaft relationship produces the claimed correction. That is, the bone positioning guide 10 *guides* the bone for the correction itself by turning the knob 120 (*i.e.*, dialing the bunion away). To avoid confusion, it is worth noting that although Figures 9A and 9B show the bone positioning guide itself displaced from one figure to the next, this is the result of the controlled motion of that guide from turning the knob and the interactions of the guide geometry with bones of the foot as explained above. *See* Ex. 1001, 9:25–29 (“As shown, as the bone positioning guide 10 is actuated it rotates with the first metatarsal 210 about an axis extending through the frontal plane as it pushes the first metatarsal 210 laterally in the transverse plane and plantarly in the sagittal plane.”).

C. **Illustrative Claim**

Claim 1 is representative for the issues discussed in this POPR, and is reproduced below:

1. An instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a

bunion deformity, the instrumented surgical technique comprising:
making an incision on a foot to provide access to a tarsal-metatarsal joint;
engaging the first metatarsal with a bone engagement member of *a bone positioning guide*;
engaging the bone positioning guide with a second metatarsal separated from the first metatarsal by an intermetatarsal angle;
cutting an end of the first metatarsal with a tissue removing instrument; *rotating a knob* connected to a threaded shaft *of the bone positioning guide* to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal *to correct the bunion deformity*;
imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity;
cutting an end of a medial cuneiform with the tissue removing instrument;
compressing the first metatarsal together with the medial cuneiform;
and
fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device.

Ex. 1001, 18:4–32 (emphasis added).

D. Evidence and Asserted Grounds

Petitioner asserts that claims 1–30 would have been unpatentable on the

following grounds:

Claims Challenged	35 U.S.C. §	Reference/Basis
1, 3–8, 10, 11, 13, 27, 29	103	McGlamry (Ex. 1004) and Kartalian (Ex. 1005)
2, 9, 14–24, 26, 28, 30	103	McGlamry, Kartalian, and Fallin (Ex. 1006)
1–11, 13–24, 26–30	103	Fallin, Kartalian, and McGlamry
12, 25	103	Fallin, Kartalian, McGlamry, and Tyber (Ex. 1007)
12	103	McGlamry, Kartalian, and Tyber
25	103	McGlamry, Kartalian, Fallin, and Tyber

Petitioner submits a Declaration from Steven K. Neufeld, M.D. Ex. 1003 (“Neufeld Declaration”). Patent Owner submits a Declaration from Daniel C. Farber, M.D. Ex. 2027.

II. ANALYSIS

A. Legal Standards

Petitioner bears the burden of persuasion to prove unpatentability, by a preponderance of the evidence, of the claims challenged in the Petition. 35 U.S.C. § 326(e). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). For purposes of instituting trial, Petitioner must “demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” 35 U.S.C. § 324(a).

B. Level of Ordinary Skill in the Art

Petitioner contends that because the patent includes both surgical procedures and mechanical devices, a hypothetical person of ordinary skill in the art would have a combination of these two skill sets. Pet. 18. Accordingly, Petitioner contends that “a hypothetical person of ordinary skill in the art (“POSA”) would have had [a] medical degree and at least 3 years of surgical experience with foot surgery,” and “would have worked as part of a team and collaborated with a person having a degree in mechanical engineering or a similar engineering discipline, and experience with the design of surgical instrumentation.” *Id.*

The level of ordinary skill in the art is “a prism or lens” through which the prior art and the claimed invention are viewed. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). The person of ordinary skill in the art is a hypothetical person presumed to have known the relevant art at the time of the invention. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In determining the level of ordinary skill in the art, factors considered include the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *Id.*

The level of skill in the art is a reference point for gauging what would have been obvious based on the reference disclosures. *See Okajima*, 261 F.3d at 1355. In

other words, the lens of the level of ordinary skill in the art does not change a prior art's disclosure, though it may change one's understanding of what is disclosed.

Patent Owner disagrees that a POSA would need to have worked as part of a team and collaborated with a person having a degree in mechanical engineering or a similar engineering discipline. But Petitioner does not explain how its definition provides a reference point that would alter the Petition's assertion of obviousness and instead concedes it does not. *See* Pet. 19 ("Petition does not turn on this specific definition of the level of ordinary skill.").

Accordingly, the definition of a POSA provided by Petitioner should not affect the outcome of the institution decision.

C. Claim Construction

In a post grant review, a claim "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.200(b). Under this standard, claims "are generally given their ordinary and customary meaning," as understood by a person of ordinary skill. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (citation omitted).

Petitioner proposes a claim construction for "bone positioning guide" (Pet. 20–21), "fixation device" (*id.* at 21), and "tissue removing instrument" (*id.* at 21–22). The "bone positioning guide" is the only term the Board needs to address to

deny institution in the proceeding. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (confirming that the Board need not construe claim terms where their construction is not material to the dispute).

But even the construction of “bone positioning guide” is not necessary because Petitioner points to no disclosure of Kartalian’s device being “rotat[ed] to push the first metatarsal laterally toward the second metatarsal . . . to correct a bunion deformity” as recited in the claims. Patent Owner addresses the construction of “bone positioning guide” below to the extent the Board finds it necessary to construe this term in order to deny institution in this proceeding.

1. Bone Positioning Guide

a. Petitioner’s Construction Fails to Give Meaning to the Term “Guide”

Petitioner contends that “[t]he plain and ordinary meaning of ‘bone positioning guide’ is a ‘device that is designed to move bone(s).’” Pet. 20 (citing Ex. 1003 ¶¶ 84–89). That is the extent of Petitioner’s construction under the plain and ordinary meaning. But that is no claim construction at all. It is merely an unsupported self-serving allegation. The cited testimony from Dr. Neufeld does not help. That testimony simply states: “A POSA would understand that a ‘bone positioning guide’ is a ‘device that is designed to move bone(s)’ under the plain and ordinary meaning of this term” and “would understand that ‘moving’ a bone, or movement of a bone in the context of the ’481 patent would encompass either translational movement or

rotation of the bone, or a combination of the two.” Ex. 1003 ¶¶ 85–86. There is no support for Petitioner’s proposed construction.

Notably, Petitioner disregards the “guide” aspect of “bone positioning *guide*,” and instead simply reads the term as a “bone positioner.” “A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.” *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005); *see also Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007) (denouncing claim constructions that render phrases in claims superfluous). Petitioner provides no basis for its reading the term “guide” out of the claim.

b. The Plain and Ordinary Meaning of “Bone Positioning Guide” Requires That the Device’s Structure Regulate or Direct the Path of Bone Movement

In construing claims, the focus begins and remains centered on the language of the claims themselves. *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, 749 F.3d 1349, 1354 (Fed. Cir. 2014). The claim terms in “bone positioning guide” are not complicated.

To the extent evidence is needed for the plain and ordinary meaning of “guide,” Patent Owner notes that “guide” is commonly defined as “a device that regulates or directs progressive motion or action.” “Collins English Dictionary — Complete & Unabridged” 2012 Digital Edition © William Collins Sons & Co. Ltd. 1979, 1986 © HarperCollins Publishers 1998, 2000, 2003, 2005, 2006, 2007, 2009,

2012 (<https://www.dictionary.com/browse/guide>) (last accessed March 13, 2026).¹

For purposes of this POPR, Patent Owner will agree that “bone positioning” corresponds to “bone moving.” Accordingly, when addressing the plain and ordinary meaning of the claim language, a “bone positioning guide” is a device that regulates or directs progressive motion or action to move a bone. That is, the structure of the guide dictates the movement of the bone for correction of the bunion deformity.

c. The Intrinsic Record Confirms That the Structure of the Bone Positioning Guide Itself Produces the Claimed Correction

This construction (a device that regulates or directs progressive motion or action to move a bone) is fully supported by and consistent with the intrinsic record. The '481 Patent describes the bone positioning guide as a device that, when actuated by a mechanism (*e.g.*, turning knob 120), corrects bone alignment. Ex. 1001, 9:26–34. The correction is dictated by the geometry of the device. *Id.* at 11:20–27. This is the defining characteristic of a “guide”: the device’s structure constrains and directs the path of motion. A Weber clamp or forceps-like instrument that merely applies compressive force at a location chosen by the surgeon, with no structural feature that regulates the direction or path of bone movement, is not a “guide” under the plain and ordinary meaning of the claim term.

The specification repeatedly attributes the correction to the guide’s actuation

¹ A copy of the definition can be found in Exhibit 2029.

and geometry. Ex. 1001, 9:26–34, 11:20–27. That distinction matters because Petitioner’s prior art theories depend on instruments that a surgeon may use to grab the bone for reduction, not on a disclosed structure that itself guides how a bone moves to correct the bunion deformity.

In short, the distinction is not whether a tool can be used while a bone is being moved, but whether the tool’s structure itself regulates or directs progressive motion of how the bone moves to achieve the correction of a bunion. The claims require the latter.

As noted above, Petitioner’s failure to engage in meaningful claim construction at all should be fatal to its position because it cannot meet its burden without its unsupported alleged meaning of “bone positioning guide” that ignores the meaning of the guide limitation.

d. Petitioner’s Section 112(f) Analysis Confirms Rather Than Cures the Deficiency in Its Construction

Petitioner provides additional contentions related to § 112(f). Pet. 20–21. The Board need not reach Petitioner’s §112(f) contentions for two independent reasons. First, the claims do not use the word “means” and Petitioner does not affirmatively assert that § 112(f) applies. Rather, the Petition raises the construction only “[t]o the extent the term were construed under § 112(f).” *Id.* at 20. Petitioner therefore has not overcome the presumption that § 112(f) does not apply where the claim does not use

the word “means.” *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (en banc in relevant part) (presumption against §112(f) where claim term does not use “means”); *Zeroclick, LLC v. Apple Inc.*, 891 F.3d 1003, 1007 (Fed. Cir. 2018) (same).

Second, even if the Board were to consider Petitioner’s § 112(f) analysis, it reveals, rather than cures, the deficiency in Petitioner’s position. Petitioner identifies two categories of corresponding structure: (1) “a tenaculum or tong structure” from column 6 (*id.* at 20); and (2) the “generally C-shaped configuration” from column 4 (*id.* at 21). As explained further below, Petitioner misreads the first category. The tenaculum/tong language at column 6, lines 44–58, describes a possible mechanism for actuating the bone positioning guide, not a free-standing bone positioning guide itself. Accordingly, even accepting that a Weber clamp is a type of tenaculum or that a POSA would have substituted Kartalian’s tenaculum for McGlamry’s Weber clamp, that correspondence does not help Petitioner. The tenaculum/tong discussion in the ’481 Patent identifies an example component of the bone positioning guide, not the guide itself. And while the ’481 Patent describes the C-shaped configuration from column 4 as an example of a bone positioning guide, Petitioner makes no attempt to explain how a Weber clamp or tenaculum is equivalent to that structure that enables the regulating of the direction or path of bone movement.

To the extent “bone positioning guide” needs to be construed, the intrinsic

record confirms the meaning set forth above (*i.e.*, a device that regulates or directs progressive motion or action to move a bone) is consistent with the plain and ordinary meaning, and provides no basis for Petitioner’s broader reading. *See E.I. du Pont de Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1068 (Fed. Cir. 2019) (“[W]e cannot look at the ordinary meaning of [a] term . . . in a vacuum.”); *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1338 (Fed. Cir. 2003) (it is the use of the words in the context of the written description and as used by skilled artisans that reflects the meaning of claim terms). As discussed above in connection with Petitioner’s §112(f) analysis, Petitioner misreads the specification by treating the tenaculum/tong language at column 6 as describing a free-standing bone positioning guide, when in fact it describes a possible actuation component of a bone positioning guide. *See* Ex. 1001, 6:44–58.

Claim 1 recites: “engaging the first metatarsal with a bone engagement member of *a bone positioning guide*,” “engaging *the bone positioning guide* with a second metatarsal separated from the first metatarsal by an intermetatarsal angle,” and “*rotating a knob* connected to a threaded shaft *of the bone positioning guide* to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal *to correct the bunion deformity*.” Ex. 1001, 18:10–14, 17–22 (emphasis added). Similar features are recited in claims 14, 27, and

30. *See id.* at 19:53–20:2, 21:48–60, 22:34–47. Consistent with the plain and ordinary meaning of “guide,” these claims require a device whose structure directs or regulates the bone’s path of movement, not merely a device capable of applying force to a bone.

e. The Proper Construction

The specification of the ’481 Patent provides no reason to divert from the plain and ordinary meaning of bone positioning guide set forth above. And this is not something better left for trial to resolve. This is a fundamental failure of the Petition. Petitioner knew that the term would be at issue and made the decision to address it in the most cursory way possible, simply alleging a meaning with no analysis or meaningful support whatsoever. Moreover, that conclusory construction fails to even give meaning to every term of “bone positioning *guide*” as explained above.

For at least these reasons, “bone positioning guide” should be given its plain and ordinary meaning as a device that regulates or directs progressive motion or action to move bones (*i.e.*, the structure of the device (bone positioning *guide*) dictates the movement of the bones).

As noted above, however, the Board need not adopt Patent Owner’s full construction to deny institution in this proceeding. Even if no express construction is necessary, Petitioner still had to identify where the asserted prior art teaches the claimed guide/actuator relationship and the recited step of rotating a knob connected

to a threaded shaft to cause the claimed lateral displacement and bunion correction. The Petition does not do so.

D. Petitioner's Challenges

All of Petitioner's challenges fail for the same reasons. They each rely on an overly broad and erroneous construction of "bone positioning guide" for a deficient mapping to Kartalian to allegedly teach "rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity," as recited in claim 1 (and similarly in claims 14, 27, and 30). *See* Pet. 26–34, 48–50, 64–65, 77–78, 82–85, 93–94, 99–100, 103–104.

At the outset, Patent Owner notes that the challenged claims are method claims, which means more is required than simply finding a device that might be capable of being manipulated in the claimed manner. *See ParkerVision, Inc. v. Qualcomm Inc.*, 903 F.3d 1354, 1363 (Fed. Cir. 2018). Petitioner fundamentally misapprehends what it must show to establish unpatentability of method claims. The device-based analysis in the Petition does not establish unpatentability of method claims.

As explained below, there is no identified disclosure whatsoever of the claimed method of operation. And Petitioner does not even establish that Kartalian's

device could be operated in the claimed manner.

1. **Rotating a Knob to Correct a Bunion Deformity**

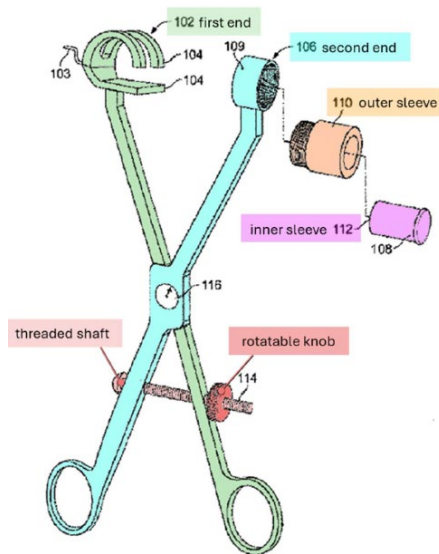
Regardless of whether Kartalian's tenaculum is considered a bone positioning guide (which it is not), there is no teaching identified related to the recitation of "*rotating a knob* connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal . . . *to correct the bunion deformity*." This omission in Kartalian and the Petition is central to institution because the limitation is expressly recited in the challenged claims. This is fatal to the Petition and not something to address at trial.

Petitioner glosses over this limitation at pages 32–34 of the Petition. Petitioner contends that "McGlamry and Kartalian render this limitation obvious." Pet. 32. (citing Ex. 1003 ¶¶ 129–132). The Petition, however, relies on Kartalian as teaching the alleged "knob" to be rotated followed by a conclusory allegation that "[w]hen the instrument is used in McGlamry's procedure and engaged with the first and second metatarsals, a surgeon would rotate the threaded knob to bring the handles toward each other, thereby causing the arm 106 (bone engagement member) to move toward the end 102." *Id.* at 33 (citing Ex. 1003 ¶ 131).

With respect to the alleged "knob," Petitioner contends that "Kartalian's instrument 100 includes a rotatable knob connected to a threaded shaft." Pet. 33.

Petitioner provides an annotated version of Kartalian's Figure 1, which is

reproduced below.



Pet. 33; Ex. 1003 ¶ 130 (reproducing same annotated figure). In the annotated figure above, Petitioner labels Kartalian’s element 114 as a rotatable knob and threaded shaft. But *neither Petitioner nor Dr. Neufeld address Kartalian’s discussion of reference numeral 114* in their treatment of Kartalian’s “rotatable knob.”

Paragraph 131 of Dr. Neufeld’s testimony repeats the conclusory allegation from the Petition reproduced above:

A POSA would understand that rotation of the knob would cause the knob to move down the threaded shaft, thereby causing a reduction of the distance between the first end 102 and the second end 106. This would move the bone engagement member and the tip relative to one another. Accordingly, Kartalian’s IMA reduction mechanism includes a knob connected to a threaded shaft.

Petitioner further contends that:

Kartalian explains that movement of the arm 106 (bone engagement member) toward the end 102 pushes the first metatarsal laterally toward the second metatarsal, reducing the intermetatarsal angle between the two metatarsals: “[t]he instrument 100 may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.” Ex.1005, 9:66-10:3, *see also id.*, 10:46-62 (“After the instrument 100 is placed on the bones and the bone is set in the desired orientation, the reduction or realignment may occur to the desired angle as estimated by angle indicator 116.”); Ex.1003, ¶131.

Pet. 34.² The cited portion of Dr. Neufeld’s testimony again parrots the Petition:

When Kartalian’s instrument is used in McGlamry’s procedure and engaged with the first and second metatarsals, the surgeon would rotate the threaded [k]nob to bring the handles toward each other, thereby causing the arm 106 (bone engagement member) to move toward the end 102. Kartalian explains that the movement of the arm 106 toward end 102 pushes the first metatarsal laterally toward the second metatarsal, reducing the IMA between the two metatarsals. Ex.1005, 9:66-67 (“The instrument 100 may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.”), 10:8-18 (describing operation of the “automatic angle indicator 116” for estimating the IMA between the “bones requiring correction” (the first and second metatarsals)), 10:46-62 (“After the instrument 100 is placed on the bones and the bone is set in the desired orientation, the reduction

² The citation to Dr. Neufeld’s testimony at the end of the block quote appears to be incorrect, as paragraph 132 appears to be the intended citation.

or realignment may occur to the desired angle as estimated by angle indicator 116.”). This IMA reduction corrects the bunion deformity. Ex. 1003 ¶ 132. But neither the Petition nor Dr. Neufeld identifies disclosure from Kartalian stating that rotation of reference numeral 114 causes correction. Instead, the Petition relies on attorney argument and expert assertion to bridge that gap. Neither the Petition nor Dr. Neufeld’s testimony are credible because both Petitioner and Dr. Neufeld fail to provide any evidence to support the purported operation of Kartalian’s clamp and are *directly contradicted by the express disclosure of Kartalian*.

As noted above, although the Petition and Dr. Neufeld both identify Kartalian’s element 114 as the claimed “rotatable knob,” neither address Kartalian’s discussion of element 114. Kartalian discusses element 114 at column 10, lines 4–6. Patent Owner has reproduced the entirety of Petitioner’s contentions above, as well as Dr. Neufeld’s testimony, related to the claim requirement of “*rotating a knob* connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal . . . *to correct the bunion deformity*.” Critically, the Petitioner skips over the most relevant portion of Kartalian’s discussion of element 114.

Kartalian explains: “The instrument 100 may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.” Ex. 1005, 9:66–67.

With respect to element 114 cited by Petitioner, Kartalian states: “instrument 100 may include a locking clamp 114 to hold the instrument 100 in position *once the final alignment of the bones has been achieved.*” *Id.* at 10:4–6. That is, Kartalian expressly states that its clamp is a “locking clamp” used *after* the bones are positioned, not that it is rotated to position the bone as recited in the claims (*i.e.*, “rotat[ed] . . . to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal”).

Petitioner appears to understand Kartalian’s teachings at column 10, lines 4–6 regarding locking clamp 114 in the manner as noted above by Patent Owner. Indeed, when addressing the “bone positioning guide” earlier in the Petition, the Petition itself states that Kartalian’s “instrument includes features for engaging or even *locking* bones during movement of the first metatarsal.” Pet. 28 (citing Ex. 1005, 10:4–6; Ex. 1003 ¶ 112) (emphasis added). That is, Petitioner acknowledges the disclosure of Kartalian’s locking mechanism 114 as being used to lock the instrument 100.

The cited testimony from Dr. Neufeld goes further, explaining:

Kartalian includes a feature for locking bones during movement of the first metatarsal. [Ex. 1005], 10:4–6 (describing structure to “hold the instrument 100 in position once the final alignment of the bones has been achieved”). This *locking feature would prevent unwanted transverse plane movement after repositioning of the first metatarsal.*

Ex. 1003 ¶ 112. Based on the current record, there is nothing that could support a finding that Kartalian teaches “***rotating a knob*** connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal . . . ***to correct the bunion deformity.***”

As Dr. Farber explains, “Kartalian’s instrument would be understood by surgeons as using the locking clamp 114 in a manner consistent with Kartalian’s disclosure at 10:4–6 (*i.e.*, to lock the clamp in position once the surgeon achieves a desired manual reduction) in the normal course of its operation.” Ex. 2027 ¶ 29; *see also id.* at ¶ 30. Dr. Farber confirms that Kartalian’s instrument would not be understood by skilled surgeons as being actuated by rotating the knob of the locking mechanism 114. *Id.* ¶ 31.

As noted above, the challenged claims are method claims, which means more is required than simply finding a device that might be capable of being manipulated in the claimed manner. *See ParkerVision*, 903 F.3d at 1363. Here, Petitioner has failed to put forth any meaningful argument or evidence that Kartalian’s device is even capable of being operated in the claimed manner, let alone any teaching related to using Kartalian’s device in the recited manner.

Petitioner also provides no meaningful rationale as to why the claimed operation via rotating the knob would have been obvious with Kartalian’s device.

Rather, as noted above, Petitioner simply asserts that “when the instrument is used in McGlamry’s procedure and engaged with the first and second metatarsals, a surgeon would rotate the threaded knob to bring the handles toward each other, thereby causing the arm 106 (bone engagement member) to move toward the end 102.” Pet. 33. According to Petitioner and Dr. Neufeld, “using Kartalian’s instrument instead of McGlamry’s Weber clamp would have been nothing more than the substitution of one known element for another with predictable results” because “[b]oth are a form of a tenaculum and used in similar bunion correction procedures.” Pet. 28 (citing Ex. 1003 ¶ 115). That is, there is no different operation proposed by Petitioner when using Kartalian’s device in McGlamry’s procedure.

Moreover, it is not even clear if Kartalian’s instrument 100 could be operated as claimed. Nor does Petitioner provide any evidence regarding such capability. For example, the friction between the knob on locking clamp and the handle may prohibit such operation from being practical without Kartalian’s instrument 100 first being closed by a surgeon’s hand (*i.e.*, via the typical actuation of forceps by engaging the finger holes at the bottom of the device shown above). We are left only with Dr. Neufeld’s conclusory testimony that contradicts the disclosure of Kartalian.

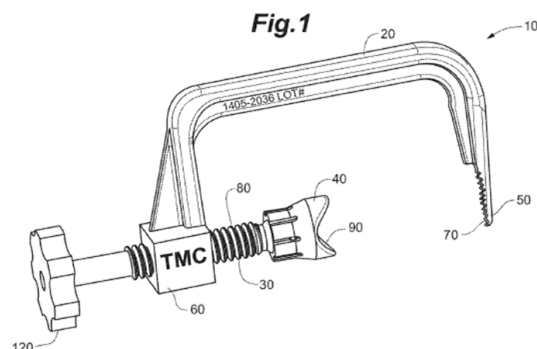
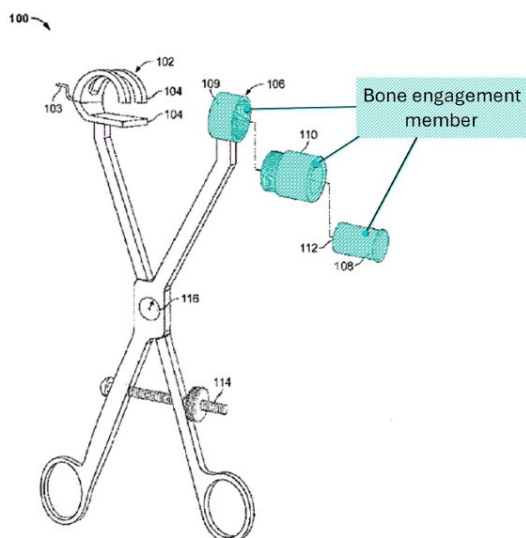
The result is that Petitioner has not established that it is more likely than not to prevail at trial on at least one claim.

2. Neither Kartalian nor McGlamry Teaches a Bone Positioning Guide

To the extent there is any dispute as to whether Kartalian teaches the recitation of bone positioning guide actuation via knob rotation, neither Kartalian nor McGlamry teaches a “bone positioning **guide**” to correct a bunion deformity.

a. Kartalian

Kartalian discusses orthopedic alignment concepts but does not disclose a bone positioning guide, let alone a bone positioning guide operated in the claimed manner. Petitioner relies on Kartalian’s instrument 100 as disclosing the bone positioning guide. Pet. 27 (quoting Ex. 1005, 9:66–10:3). As Petitioner itself states: “Kartalian’s instrument is a tenaculum (forceps).” *Id.* Petitioner provides an annotated version of Kartalian’s Figure 1 on page 27 of the Petition, reproduced below on the left next to an example bone positioning guide from the ’481 Patent on the right.



The cited structures are different, and the Petition does not explain how Kartalian's instrument satisfies the claim language directed to a "bone positioning guide" with the recited guide/actuator relationship. Kartalian's instrument 100 is a reduction forceps (*i.e.*, a device used by a surgeon to apply compressive force across two bones).

Initially, Patent Owner notes that the portion of Kartalian's instrument 100 labeled by Petitioner as a "bone engagement member" is not described as such in Kartalian. Kartalian explains:

[F]irst end 102 may be placed on the distal second bone (second metatarsal) and second end 106 may be placed on the proximal first bone (first metatarsal). The sleeve 108 on the proximal end of instrument 100 may be used as a drill guide. Initially, a first sleeve 108 having an inner diameter 112 in the range of about 3 millimeters (mm) to about 4 mm, which is capable of accommodating a large drill, may be used as a guide to create a tunnel across the proximal first bone in line with the end 102. Subsequently, sleeve 108 is removed and replaced with a new sleeve 108 having a smaller inner diameter 112 in the range of about 1.60 mm to about 2 mm. The new sleeve 108 may then serve as a guide for a smaller diameter drill to make a pilot hole in the distal second bone.

Ex. 1005, 10:49–63. That is, the purported "bone engagement member" is described as a drill guide.

Petitioner attempts to equate Kartalian's tenaculum with the examples of the

bone positioning guide in the '481 Patent. Petitioner contends, for example, that Kartalian's "instrument is identical or at least equivalent to structures identified in the '481 patent for the claimed bone positioning guide discussed in Section V.A." Pet. 29. As discussed above in connection with Patent Owner's claim construction, Petitioner misapprehends the disclosure of the '481 Patent by alleging that the '481 Patent itself discloses a "tenaculum or tong structure" as an example of the bone positioning guide. Pet. 20 (citing Ex. 1001, 6:44–58). This is not accurate.

The '481 Patent explains: "In the embodiment of FIG. 1, bone positioning guide 10 includes a main body member 20 and a shaft 30, and the bone engagement member 40 is connected to the shaft and the tip 50 is connected to the main body member." Ex. 1001, 4:63–66. The '481 Patent provides a number of example actuation mechanisms. *See, e.g., id.* at 5:11–24 ("In some embodiments, the shaft 30 includes threads 80 . . . In other embodiments, the shaft can slide within the main body member . . . In yet other embodiments, the shaft can be moved with respect to the main body by a ratchet mechanism."). The '481 Patent further explains that "bone positioning guide 10 can also include an actuator (e.g., a knob or a handle) 120 to actuate the mechanism." *Id.* at 6:26–28.

Petitioner selectively cites the '481 Patent. Petitioner's cited portion of the '481 Patent explains: "In other embodiments, the mechanism to urge the bone engagement member and the tip towards each other can include a tenaculum or tong

structure.” Ex. 1001, 6:44–46. Contrary to Petitioner’s characterization, this language does not state that “a tenaculum or tong” is itself the bone positioning guide. *See* Pet. 20 (citing Ex. 1001, 6:44–58).

The Petition does not identify any guide-specific structure disclosed in Kartalian. This absence of structural disclosure is important. Kartalian may discuss orthopedic alignment concepts and may disclose an instrument usable during reduction, but Petitioner does not point to any passage describing a guide to perform the method steps claimed for correcting a bunion deformity. Dr. Farber’s testimony supports this understanding of Kartalian’s failure to disclose a bone positioning guide. *See* Ex. 2027 ¶¶ 24–27, 31. Dr. Farber testifies that “[t]he Kartalian instrument is a form of a tenaculum . . . whose structure does not regulate or direct the path of bone movement in the way the claimed guide requires.” *Id.* ¶ 24. Dr. Farber further explains that “Kartalian’s instrument would be understood by surgeons as a reduction forceps whose effect depends on surgeon-selected placement and force application” and that “[t]he functions Dr. Neufeld attributes to Kartalian arise, if at all, from user manipulation during surgery.” *Id.* ¶¶ 25, 26. “[I]t is the surgeon’s hand that dictates the movement of the bones, not the structure of the tenaculum (i.e., the reduction forceps)” of Kartalian. *Id.* ¶ 31.

b. McGlamry

As noted above, Petitioner does not rely on McGlamry teaching a bone

positioning guide. *See* Pet. 26 (alleging that “McGlamry and Kartalian render this limitation obvious” without specifically citing McGlamry as teaching the guide), 29 (alleging that “Kartalian’s instrument in the combination satisfies ‘bone positioning guide’”). For completeness, Patent Owner notes that anything that could be read as an allegation that McGlamry also teaches a bone positioning guide fails for reasons similar to those discussed above relative to Kartalian. *See* Pet. 29 (“The operational principles of Kartalian’s instrument would not be changed when used in McGlamry’s procedure” because “the Weber clamp disclosed by McGlamry performs a similar function.”). The function referenced by Petitioner is clamping for manipulation, not guiding performed by the bone positioning **guide**.

E. Summary

The Petition’s treatment of the recited “rotating” step is insufficient to establish that Petitioner is more likely than not to prevail with respect to at least one claim at trial. Petitioner identifies no disclosure from Kartalian teaching the claimed knob-rotation operation and instead relies on conclusory expert assertion to bridge that gap, without reconciling that theory with Kartalian’s express contradicting description of element 114 as a locking clamp used once final alignment has been achieved.

Moreover, Petitioner’s claim construction reduces “bone positioning guide” to any instrument that can move bone without regard to whether the instrument itself

“guides” that movement, which as explained above, misreads the disclosure of the ’481 Patent regarding a tenaculum or tong structure that is manipulated by the surgeon to move bones. The result is Petitioner’s subsequent (and erroneous) conclusion that Kartalian’s tenaculum must be a bone positioning guide despite the fact that the Petition does not identify where Kartalian teaches the claimed guide/actuator relationship.

There is no dispute raised in the Petition that is better left for resolution at trial. These are institution-stage defects in Petitioner’s current showing, not merely disputes over competing weight of evidence. These are fundamental flaws in the Petition that cannot be cured.

III. CONCLUSION

For at least the reasons set forth above, Patent Owner respectfully requests that the Board deny institution of this post grant review.

Dated: April 22, 2026

Respectfully Submitted,

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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this Patent Owner's Preliminary Response complies with the type-volume limitation of 18,700 words provided in 37 C.F.R. § 42.24(a)(1)(ii), (b)(1). The word processing program used to prepare Patent Owner's Preliminary Response indicates that it contains 6989 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a), (that is, the word count does not include the table of contents, table of authorities, the exhibit list, the certificate of service, or the certificate of compliance).

Dated: April 22, 2026

/Jeremy M. Plenzler/
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Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned certifies that on the 22nd of April, 2026, a complete and entire copy of the foregoing “PATENT OWNER’S PRELIMINARY RESPONSE,” including any exhibits, was electronically served via email to MLB-P28-PGR-481@morganlewis.com to the below counsel of record for Petitioner per Petitioner’s consent for electronic service (*see* Paper 1 at 111).

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