

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

IPR2026-00194
Patent 12,102,368

PATENT OWNER'S PRELIMINARY RESPONSE

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PATENT OWNER'S UPDATED LIST OF EXHIBITS

Exhibit No.	Description
2001	<i>Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.</i> , Initial Complaint, dated May 12, 2025
2002	U.S. Patent No. 9,936,994 to Smith, <i>et al.</i> (the “’994 Patent”)
2003	USPTO Examiner Interview Summary of U.S. Patent Application No. 15/210,426, dated August 16, 2017
2004	U.S. Patent No. 4,159,716 to Borchers
2005	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Chapter 9, Vol. 1, 5th Edition, 2022 (“McGlamry”)
2006	<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
2007	<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
2008	<i>Paragon 28, Inc. and Disior Oy v. Treace Medical Concepts, Inc. and Mios Marketing, LLC</i> Amended Complaint, dated December 18, 2025
2009	U.S. Patent No. 10,856,886 to Dacosta, <i>et al.</i>
2010	U.S. Patent No. 11,696,767 to Dacosta, <i>et al.</i>
2011	Treace Medical Concepts, Inc.'s SEC Form S-1 Registration Statement for Initial Public Offering, dated March 30, 2021

Exhibit No.	Description
2012	Treace Medical Concepts, Inc.'s Initial Public Offering, dated April 22, 2021
2013	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
2014	Treace's Announcement of Grant of Additional U.S. Patent on Instrumented Bunion Correction, dated October 21, 2021
2015	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
2016	Treace's Announcement of Grant of U.S. Patent on Instrumented Bunion Correction, dated January 19, 2022
2017	Treace's Announcement of Expansion of Its Global IP Portfolio with the Grant of Two New U.S. Patents, dated December 19, 2022
2018	Treace's Announcement of Expansion of Market Leading Global IP Portfolio For Bunion And Related Deformities, dated April 19, 2023
2019	Treace's Announcement of New Patent Covering Instrumented Bunion Correction Procedures and Milestone 50th U.S. Patent, dated September 14, 2023
2020	Treace's Announcement of Filing of Patent Infringement Suit Against Zimmer Biomet to Protect Lapiplasty® Bunion Technology, dated June 5, 2025
2021	Treace's Announcement of 100,000 Lapiplasty® 3D Bunion Correction® Patient Milestone Celebration, dated March 25, 2024
2022	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
2023	AlphaSense's November 12, 2024 UBS Global Healthcare Conference Transcript

Exhibit No.	Description
2024	Treace's Announcement of Filing of Patent Infringement Suit To Protect Lapiplasty® Bunion Technology, dated March 28, 2022
2025	Treace's Announcement of Settlement of Lawsuit Against Fusion Orthopedics, dated March 3, 2023
2026	Treace's Announcement of Filing of Patent Infringement and Unfair Competition Suit to Protect Lapiplasty® Bunion Technology, dated October 14, 2024
2027	J.P. Morgan's January 2023 Investor Presentation on Treace Medical Concepts, Inc.
2028	USPTO Additional Discretionary Institution Considerations – U.S. Manufacturing and Small Business Use of AIA Proceedings Memorandum, dated March 11, 2026
2029	Zimmer Biomet Website - Company Overview
2030 [NEW]	Declaration of Daniel C. Farber, M.D. ("Farber Declaration")
2031 [NEW]	<i>Curriculum Vitae</i> of Daniel C. Farber, M.D.
2032 [NEW]	Definition of "Guide" from dictionary.com

I. INTRODUCTION

A. Background

Paragon 28, Inc. (Petitioner) filed a Petition (Paper 1, “Petition” or “Pet.”) requesting *inter partes* review of claims 1–30 of U.S. Patent No. 12,102,368 (Ex. 1001, “’368 Patent”).

The Petition is based on allegation, not evidence. The fundamental failing of the Petition is its failure to properly address the recited “bone positioning guide,” which appears 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. 18. This is followed by Petitioner’s conclusory mapping to a Weber clamp in McGlamry and Kartalian’s reduction forceps, accompanied by naked allegations that those instruments satisfy the recited bone positioning guide because a surgeon can use them to move bones. Pet. 34–37, 61–65.

This is far below what is required for institution. *See* 37 C.F.R. § 42.104(b)(3) (petition must identify how each challenged claim is to be construed); 37 C.F.R. § 42.104(b)(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 insufficient to establish obviousness).

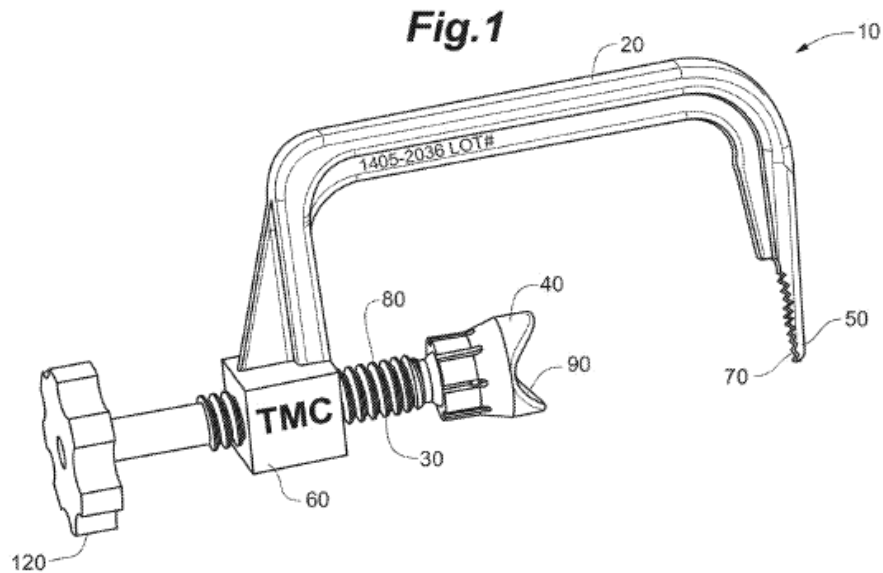
Neither the claim construction nor the prior art mapping presented by Petitioner addresses the “guide” feature, let alone the “configured to” language, of the recited bone positioning guide in a meaningful way. And Dr. Neufeld’s testimony simply parrots the same conclusory assertions presented in the Petition in a failed attempt to transform attorney argument into evidence.

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 ’368 Patent

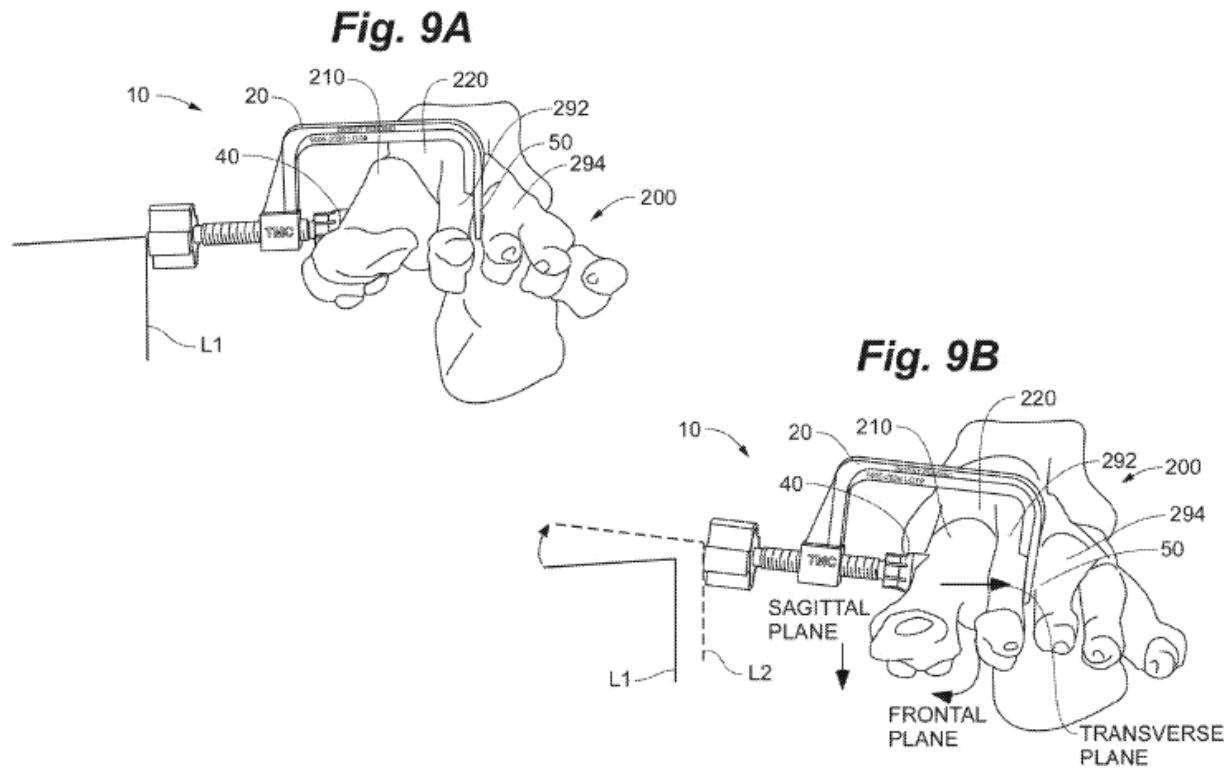
The ’368 Patent relates to a system for bunion correction. The ’368 Patent describes an integrated instrumented correction system including a bone preparation guide, a bone positioning guide, and at least one fixation device. The system achieves precise, reproducible correction in multiple planes, including both the transverse and frontal planes, 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,” as the deficiencies in the Petition regarding that element are sufficient to deny institution.

Figure 1 from the ’368 Patent is reproduced below.



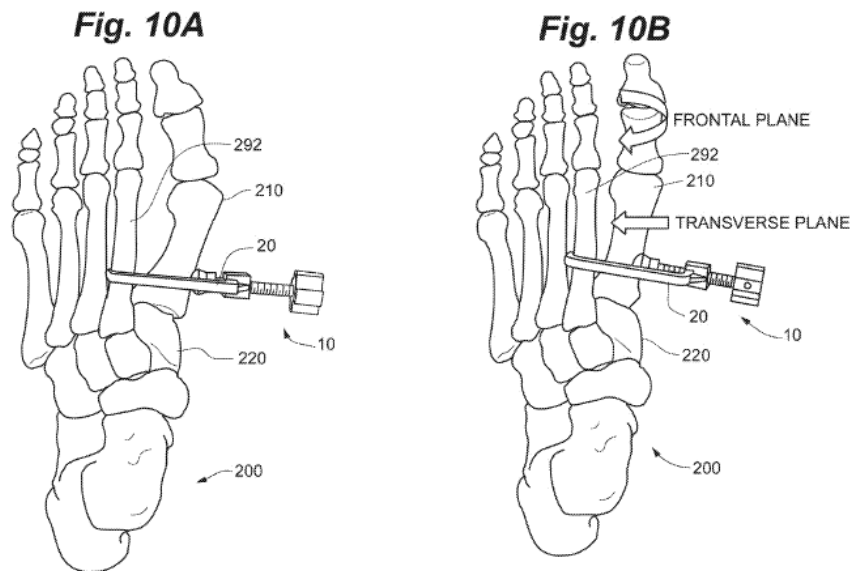
“F[igure] 1 is a side perspective view of a bone positioning guide.” Ex. 1001, 3:21–22. “When the mechanism is actuated it causes a first bone engaged with the bone engagement member to move to correct an alignment in more than one plane with respect to a second bone in contact with the tip,” including a correction “about an axis in a frontal plane.” *Id.* at 5:31–37.

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, 9:62–64. “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 10:65–67. “[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 10:1–4. “[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 10:5–9. 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 10:9–14.

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, 11:57–61. “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 11:64–12:1.

That is, the bone positioning guide 10 is designed to provide the multi-plane correction itself, simply 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 being rotated, this is the result of the controlled motion of that guide from turning the knob and the interactions of the guide geometry with the foot as explained above. *See* Ex. 1001, 9:67–10:4 (“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. A metatarsal bunion correction system comprising:
a bone preparation guide comprising a body defining a guide surface configured to be positioned over a proximal end of a first metatarsal and/or a distal end of a medial cuneiform, the guide surface being configured to guide a tissue removing instrument for cutting the

proximal end of the first metatarsal and/or the distal end of the medial cuneiform;
a bone positioning guide configured to move the first metatarsal to treat a bunion deformity by at least:
moving the first metatarsal in a transverse plane to reduce an intermetatarsal angle between the first metatarsal and a second metatarsal, and
rotating the first metatarsal in a frontal plane; and
at least one fixation device positionable across a tarsal-metatarsal joint separating the first metatarsal from the medial cuneiform, the at least one fixation device being configured to fixate a moved position of the first metatarsal relative to the medial cuneiform for fusion.

Ex. 1001, 18:43–61.

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
1–2, 4–20	103	McGlamry (Ex. 1007) and Fallin (Ex. 1005)
1–30	103	McGlamry, Fallin, and Kartalian (Ex. 1006)
3, 21–30	103	McGlamry, Fallin, and Schmuck (Ex. 1028)
3, 21–30	103	McGlamry, Fallin, Kartalian, and Schmuck
7	103	Any of Grounds 1–2 and Jenkins (Ex. 1029)
23	103	Any of Grounds 2–4 and Jenkins

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. 2030.

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. § 316(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 “show[] that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a).

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. 16. 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.* at 16–17.

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. 17 (“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 an *inter partes* 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. § 42.100(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. 18–19), “fixation device” (*id.* at 19), “temporary fixation device” (*id.* at 19–20), “tissue removing instrument” (*id.* at 20), and “a mechanism configured to move the bone engagement member and the tip relative to each other” (*id.* at 20–21). 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).

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. 18 (citing Ex. 1003 ¶ 84). 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 unsupported self-serving allegation. The cited testimony from Dr. Neufeld does not help. That testimony simply states:

It is my opinion that a person of ordinary skill in the art would understand that the plain and ordinary meaning of “bone positioning guide” is a “device that is designed to move bone(s).” I do not seek to specifically construe “bone positioning guide” in this proceeding as the claims would have been obvious whether the term is construed or is accorded a plain and ordinary meaning.

Ex. 1003 ¶ 74. 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 which 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 terms in “bone positioning guide” are not complicated. And the claims further recite that the “bone positioning guide” is “***configured to move*** the first metatarsal to treat a bunion deformity by at least: moving ***the first metatarsal in a transverse plane*** to reduce an intermetatarsal angle between the first metatarsal and a second metatarsal, ***and*** rotating the first metatarsal ***in a frontal plane.***” Ex. 1001, 18:51–56 (emphasis added); *see also id.* at 20:16–21 (claim 21 reciting similar features).

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”

¹ A copy of the definition can be found in Exhibit 2032.

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 device (bone positioning *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 Must Produce the Claimed Multi-Plane Correction

This construction is fully supported by and consistent with the intrinsic record. The '368 Patent describes the bone positioning guide as a device that, when actuated by a mechanism (*e.g.*, by turning knob 120) corrects bone alignment in more than one plane. Ex. 1001, 9:67–10:4. Thus, the correction is dictated by the design and geometry of the device itself. *Id.* at 11:61–12:1. This is the defining characteristic of a “guide”: the device’s structure constrains and directs the path of motion. A clamp 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 bone positioning “guide” under the plain and ordinary meaning.

The specification repeatedly attributes the correction to the guide’s actuation and geometry. 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 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 governs how the bone moves. The claims require the latter.

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."

d. The "Configured To" Language Requires Structural Features to Produce the Recited Movements.

The claim language itself further confirms this construction. Claim 1 recites a bone positioning guide "configured to move the first metatarsal to treat a bunion deformity by at least: moving the first metatarsal in a transverse plane to reduce an intermetatarsal angle . . . and rotating the first metatarsal in a frontal plane." Ex. 1001, 18:51–56. Claim 21 recites a similar limitation. *See id.* at 20:61–21. The use of "configured to" requires that the structure of the device be specifically designed to perform the recited movements. *See In re Giannelli*, 739 F.3d 1375, 1379 (Fed. Cir. 2014) ("configured to" requires that the structure be designed to perform the recited function). A generic compression clamp that a surgeon may happen to position in a way that incidentally assists a manually performed reduction is not "configured to" move bone in multiple planes in the required sense. The device's structure must be the source of the guided movement.

Petitioner fails to even acknowledge, let alone properly address, the “configured to” language. 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 based on its unsupported alleged meaning of “bone positioning guide.” That omission is especially significant at institution because Petitioner cannot establish a reasonable likelihood of prevailing by ignoring claim language that materially defines the required structure.

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

Petitioner provides additional contentions related to § 112(f). Pet. 18–19. The Board need not reach Petitioner’s §112(f) contentions for two independent reasons. First, Petitioner does not affirmatively assert that § 112(f) applies. Rather, it raises the construction only “[t]o the extent the term were construed under § 112(f).” Pet. 18. 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 7 (Pet. 18); and (2) the “generally C-shaped configuration” from column 5 (*id.* at 19). As explained further below, Petitioner misreads the first category. The tenaculum/tong language at column 7, lines 20–34 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, that correspondence does not help Petitioner because the tenaculum/tong discussion in the ’368 Patent identifies an example component of the bone positioning guide, not the guide itself.

Although the ’368 Patent describes the C-shaped configuration from column 5 as an example of a bone positioning guide, Petitioner makes no attempt to explain how a Weber clamp is equivalent to that structure to regulate the direction or path of bone movement. Moreover, Petitioner entirely ignores the recitation that the “bone positioning guide” is “configured to move the first metatarsal” in both the “transverse plane” and the “frontal plane.”

To the extent “bone positioning guide” needs to be expressly construed, the intrinsic record confirms the meaning set forth above by Patent Owner (*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 do not 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 7 as describing a free-standing bone positioning guide, when in fact it describes a possible mechanism for a bone positioning guide, not a bone positioning guide itself. Consistent with the plain and ordinary meaning of “guide,” the claims require a device whose structure directs or regulates the bone’s path of movement in both the transverse plane and the frontal plane (the specific movement specified by the “configured to” language), not merely a device capable of applying force to a bone without any regulated direction or path of bone movement.

f. The Proper Construction

The specification of the ’368 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 to 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 and fails to even acknowledge that the claims specify that the bone positioning guide is *configured to* guide bone movement in both the transverse plane and the frontal plane.

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 a bone (*i.e.*, the structure of the device (bone positioning *guide*) dictates the movement of the bone) along with the specific directed motion required by the “configured to” language.

D. Petitioner’s Challenges

Claims 1 and 21 are the only independent claims in the ’368 Patent. All of Petitioner’s challenges fail for the same reason. They each rely on the overly broad construction of “bone positioning guide” discussed above. *See* Pet. 34–37 (Ground 1/Claim 1), 61–65 (Ground 2/Claim 1), 75–76 (Ground 2/Claim 21), 81–82 (Ground 3/Claim 21—relying on Ground 1 arguments regarding Claim 1), 84 (Ground 4/Claim 21—relying on Ground 2 arguments regarding Claim 1).

As shown below, every asserted ground relies on either McGlamry’s Weber clamp or Kartalian’s forceps instrument as the bone positioning guide recited in the claims. Because neither device satisfies the bone positioning guide limitation under

the proper construction, all grounds fail and institution should be denied as to all challenged claims.

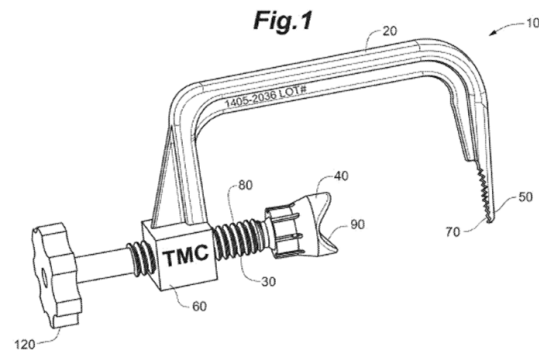
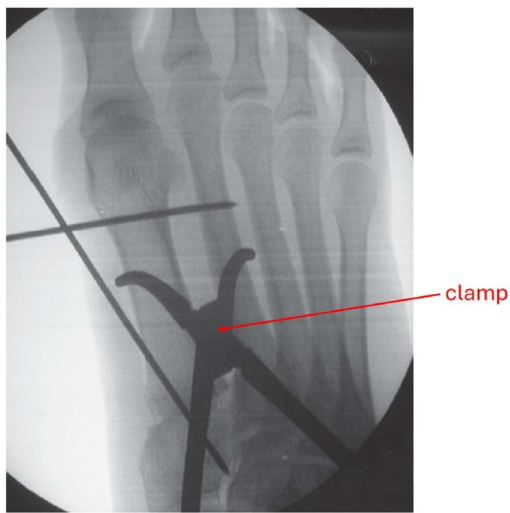
1. Grounds Based on McGlamry Teaching a “bone positioning guide”

Petitioner contends that McGlamry renders a bone positioning guide configured to move the first metatarsal in a transverse plane and a frontal plane obvious. Pet. 34 (citing Ex. 1003 ¶¶ 137–146). According to Petitioner: “McGlamry discloses repositioning the first metatarsal in multiple planes as part of its procedure” and “that a Weber clamp can be used to move the metatarsal in the transverse plane and rotate it in the frontal plane.” Pet. 34 (citing Ex. 1007, 325–326; Ex. 1003 ¶¶ 138–139). But the Petition does not identify any structure in McGlamry meeting the claimed bone positioning guide, and instead asserts functional possibility (*i.e.*, alleging that known tools *could be used* and manipulated by a surgeon to provide bone movement in the claimed manner). That is not enough. The claim requires a “bone positioning guide” that is “configured to” move the first metatarsal in the recited manner, not merely any instrument that a surgeon might manipulate in a way that could move a bone.

a. Structural Contrast Between the Claimed Guide and the Weber Clamp

Petitioner provides an annotated image of McGlamry’s Weber clamp on page 34 of the Petition, which we have reproduced below on the left, next to an example

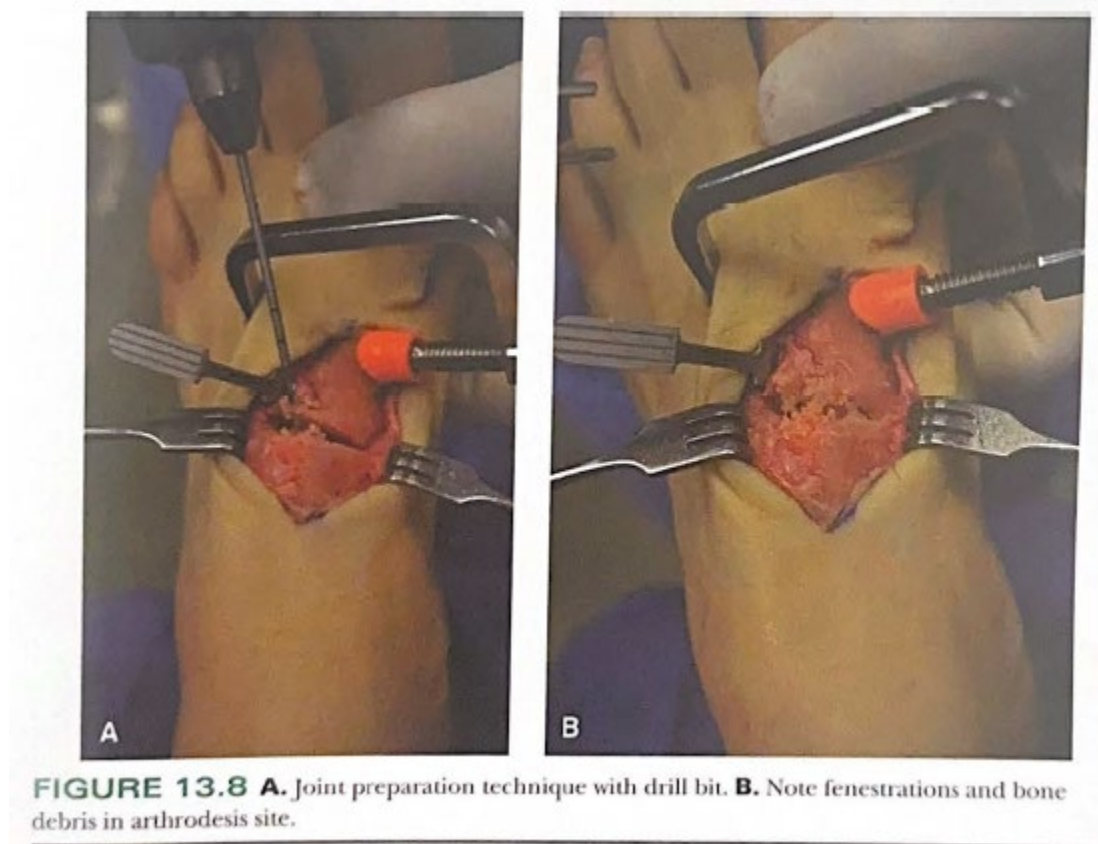
bone positioning guide from the '368 Patent on the right.



The structural contrast between these two devices is stark and dispositive. The bone positioning guide (right) taught by the '368 Patent includes a geometry that constrains and directs the path of bone movement when the knob is turned, correcting the metatarsal in multiple planes. The Weber clamp (left) is a manually operated compression device: two arms that the surgeon closes around the bone by squeezing (akin to the operation of a pair of pliers). Nothing in the Weber clamp's structure regulates or directs the direction of bone movement to correct a bunion deformity. The surgeon chooses where to place the clamp, how much force to apply, and how to manipulate the secured bones, which may move together rather than in relation to one another. The clamp does not guide anything. That is precisely the distinction the word "guide" captures, and precisely the distinction Petitioner's construction erases.

McGlamry itself confirms this distinction. The '368 Patent's bone positioning guide is a device whose structure guides how a bone moves to correct the deformity. By contrast, the cited McGlamry passages describe surgeon-directed manual reduction, with a Weber clamp used only as a tool to “assist, increase, or maintain” a reduction selected and controlled by the surgeon. Ex. 1007, 325–326. That is not a disclosure of a guide configured to regulate or direct the progressive motion of a bone being repositioned in the claimed manner. Rather, it is disclosure of a generic reduction clamp used during a manual bunion correction procedure.

The contrast is further exemplified by the later, non-prior-art McGlamry's Comprehensive Textbook of Foot and Ankle Surgery, 5th Edition (Ex. 2005, “McGlamry 5th Edition”). There, the authors explain that “[t]hree-dimensional correction can be made easier . . . with specialized guides and jigs.” Ex. 2005, 300. McGlamry 5th Edition thus distinguishes generic manual tools from “specialized guides and jigs” used to facilitate three-dimensional correction. That later discussion is consistent with Patent Owner's construction and underscores what is missing from the 4th Edition relied on by Petitioner (*i.e.*, any disclosure that the Weber clamp itself is a specialized guide whose structure directs or regulates the correction path). Figure 13.8 of McGlamry 5th Edition depicts an example of such a specialized guide and is reproduced below.



Ex. 2005, 303. The guide structure shown above is actually a commercial embodiment of Patent Owner's bone positioning guide shown in Figure 1 of the '368 Patent, which McGlamry 5th Edition explains provides the additional benefit of guided correction. *See* Ex. 2005, 300. McGlamry 5th Edition therefore draws precisely the line that Petitioner's construction erases: generic reduction clamps on one side, a specialized bone positioning guide instrument on the other. McGlamry's own authors, writing after the procedure matured through the advancement of Patent Owner, understood that a Weber clamp is not a bone positioning guide. The Weber clamp relied upon by Petitioner lacks the geometric configuration that produces the

guided, multi-plane correction described in the '368 patent and recited in the claims.

Dr. Farber confirms this understanding, testifying that a Weber clamp is understood in practice as a generic reduction/compression clamp that transmits surgeon-applied forces, not as an instrument whose geometry itself constrains a predefined multi-planar correction path. *See* Ex. 2030 ¶ 23; *see also id.* at ¶ 26 (explaining that “express recommendation and disclosure of specialized guides and jigs [in McGlamry’s 5th Edition] is consistent with a POSA’s understanding that a Weber clamp is not a guide or jig and would therefore, not be understood as a device that regulates or directs progressive motion or action to move bones”).

b. McGlamry Describes Manual Reduction, Not a Guide-Directed Correction

Petitioner refers to McGlamry’s further discussion of the Weber clamp, contending:

McGlamry explains that the Weber clamp (bone positioning guide) is used to “assist, increase, or maintain the reduction.” Ex.1007, 325-326. Thus, McGlamry discloses that the Weber clamp is configured to move the first metatarsal in a transverse plane to reduce an intermetatarsal angle between the first metatarsal and a second metatarsal and rotate the first metatarsal in a frontal plane. Ex.1003, ¶¶138-142; *see also* Ex. 1015, 1112 (disclosing that a lateral force applied to the first metatarsal both reduces the IMA and corrects a hallux valgus deformity). McGlamry discloses that this reduction treats the bunion deformity. Ex.1007, 324-26; Ex.1003, ¶¶138-142.

Pet. 35–36. As Petitioner acknowledges, McGlamry states that “a large Weber clamp may be used to assist, increase, or maintain the reduction.” Ex. 1007, 325. But Petitioner’s subsequent conclusion that “[t]hus, McGlamry discloses that the Weber clamp is configured to move the first metatarsal in a transverse plane to reduce an intermetatarsal angle between the first metatarsal and a second metatarsal and rotate the first metatarsal in a frontal plane” has no evidentiary support.

The portions of McGlamry cited by Petitioner (Ex. 1007, 325–26) discuss a surgeon manipulating the first metatarsal by hand, not using a guide to regulate or direct the movement of the first metatarsal. *See id.* at 325 (“Once the surgeon has the hallux, sesamoid, and metatarsal rotated to a neutral desirable position (frontal plane reduction), and the first metatarsal sagittal plane corrected, the surgeon can use his or her thumb against the first metatarsal to manually reduce the first intermetatarsal angle in the transverse plane. The primary surgeon must ensure that the first metatarsal is in the desired position, which is essentially rotated out of valgus, and parallel with the second metatarsal in both the transverse and sagittal planes.”).

That passage is fatal to Petitioner’s mapping. It identifies the surgeon, not the Weber clamp, as the actor performing the reduction. McGlamry says *the surgeon* first *rotates* the metatarsal to a desired frontal-plane position, then *manually reduces* the first intermetatarsal angle with the surgeon’s thumb, and ensures the metatarsal

is in the desired position. Ex. 1007, 325. Only after describing those surgeon hand-controlled steps does McGlamry state that, “[i]n many cases, a large Weber clamp may be used to assist, increase, or maintain the reduction.” *Id.* at 325–326. “Assist, increase, or maintain” is not the same as a guide configured to perform the claimed movement itself.

Indeed, McGlamry warns that “[w]hen using the large Weber clamp, the surgeon must be sure not to change the sagittal plane relationship between the first and lesser metatarsals.” Ex. 1007, 326. That admonition reinforces that the Weber clamp is not a specialized guide whose structure directs or regulates controlled correction in the transverse plane and frontal plane. Instead, the Weber clamp is a generic clamp susceptible to causing undesired bone movement during manual manipulation by the surgeon. The warning in McGlamry is the opposite of what one would expect if the Weber clamp were a bone positioning guide in the claimed sense. The fact that McGlamry specifically warns surgeons to guard against unintended sagittal-plane movement while using the Weber clamp confirms that the clamp has no structural feature that constrains or directs the path of bone movement as claimed. It is precisely the absence of such structural features that necessitates the warning.

As discussed above, McGlamry 5th Edition confirms that when authors sought to describe instruments that facilitate guided correction, they identified “specialized guides and jigs,” and specifically presented Patent Owner’s claimed

bone positioning guide, not a Weber clamp. *See* Ex. 2005, 300. That distinction reinforces that McGlamry’s own sequence of surgeon-controlled steps, with a generic clamp used only to assist or maintain a manually performed reduction, is not a disclosure of a bone positioning guide in the claimed sense.

Petitioner’s own fallback theory exposes the flaw in its mapping. Petitioner contends that “even if McGlamry did not disclose that the Weber clamp rotates the metatarsal in the frontal plane, it would have been obvious to employ the Weber clamp” that way. Pet. 36. That is a tacit acknowledgment that the cited McGlamry passage does not actually disclose frontal-plane rotation as Petitioner first attributes to it.

Nothing in the cited McGlamry passage states that the Weber clamp itself functions as a guide, let alone rotates the first metatarsal in the frontal plane. Nothing in the cited passage identifies any structure of the Weber clamp that regulates or directs the claimed path of movement. And nothing in the cited passage equates a generic reduction clamp that may “assist, increase, or maintain” a reduction with the claimed “bone positioning guide.” The Petition simply leaps from the existence of a clamp to the conclusion that the clamp satisfies the bone positioning guide limitations. That is precisely the sort of unsupported attorney argument and inferential leap that cannot substitute for an evidentiary showing tied to an identified structure in the prior art.

Dr. Farber testifies that, from a surgeon's perspective, McGlamry's sequence describes surgeon-controlled reduction and stabilization, and that a POSA would not read the cited Weber-clamp passage as disclosing an instrument whose structure itself performs multi-planar correction, such as intermetatarsal angle reduction and frontal-plane derotation. *See* Ex. 2030 ¶¶ 22–24. Accordingly, to the extent expert testimony is needed to appreciate the deficiencies in Petitioner's position, Dr. Farber's testimony establishes that a POSA would not view McGlamry's Weber clamp as a bone positioning guide.

c. Dr. Neufeld's Testimony Does Not Supply the Missing Disclosure

Petitioner's citation to Dr. Neufeld's testimony is a failed attempt to convert attorney argument into evidence. Dr. Neufeld provides no reason to believe that McGlamry's Weber clamp is a bone positioning guide. *See* Ex. 1003 ¶¶ 124–128. To the contrary, Dr. Neufeld's testimony provides further support that the Weber clamp is *not* a bone positioning guide. *See id.* (repeatedly discussing the Weber clamp simply as a clamp used to hold bone and move bone).

Dr. Neufeld's testimony underscores the deficiency in the Petition rather than curing it. Like the Petition, he opines that “[e]ven if McGlamry does not disclose that the Weber clamp rotates the metatarsal in the frontal plane, it would have been obvious to use the Weber clamp to rotate the metatarsal in the frontal plane.” Ex. 1003 ¶ 143 (emphasis added).

In making this allegation of obviousness, Dr. Neufeld does not identify any teaching in McGlamry directing a surgeon to use the Weber clamp to perform frontal-plane derotation. Instead, he offers his own after-the-fact mechanical theory: because the first metatarsal is asymmetric and because *the surgeon could alter clamp placement or push/pull on the clamp*, the clamp purportedly *could* generate frontal-plane rotation. Ex. 1003 ¶¶ 143–145. But those are expert-imagined possibilities crafted through the lens of Patent Owner’s claim language, not disclosures from McGlamry. The Petition may not fill a disclosure gap with unsupported expert reconstruction.

Moreover, Dr. Neufeld’s theory confirms rather than cures the structural deficiency. His theory rests on the surgeon’s own actions (*e.g.*, altering clamp placement, applying push/pull force) as the source of frontal-plane rotation. This is not a “guide.” It is the surgeon, not the device structure, providing the directional motion. As explained above, a bone positioning guide has structure that regulates or directs the path of bone movement. Dr. Neufeld’s theory describes a device whose structure plays no directional role at all. It is entirely the surgeon’s choices that determine where the guide is placed and what movement occurs. As Dr. Farber explains, “clamp placement and user-applied push/pull forces are surgeon-generated inputs, not properties of Weber clamp’s device structure, and therefore do not convert such a generic clamp into a “guide” configured to produce the claimed

correction of the '368 patent.” Ex. 2020 ¶ 25.

And the later McGlamry 5th Edition makes clear that when authors sought to facilitate multi-planar correction, they described Patent Owner’s claimed guide, not manipulation of a generic Weber-clamp\.. Ex. 2005, 300; *see also* Ex. 2030 ¶ 26 (explaining that “express recommendation and disclosure of specialized guides and jigs [in McGlamry’s 5th Edition] is consistent with a POSA’s understanding that a Weber clamp is not a guide or jig and would therefore, not be understood as a device that regulates or directs progressive motion or action to move bones”). Dr. Neufeld’s theory thus does not arise from McGlamry’s teachings, but from impermissible hindsight-driven reconstruction.

d. Exhibit 1015 Does Not Cure the Defect

The Petition’s parenthetical citation to Exhibit 1015 is also unhelpful and further exemplifies the conclusory nature of the Petition. That parenthetical is an allegation without further explanation that the exhibit “disclos[es] that a lateral force applied to the first metatarsal both reduces the IMA and corrects a hallux valgus deformity.” Pet. 36 (citing Ex. 1015, 1112). Based on the lack of explanation in the Petition, it is unclear how this relates to the recited “bone positioning guide” that is “configured to move the first metatarsal . . . in a transverse plane . . . and rotat[e] the first metatarsal in a frontal plane.” Ex. 1001, 18:51–56.

Exhibit 1015 states: “The metatarsus primus varus and hallux valgus

deformities may now be simultaneously corrected by applying a laterally directed force to the metatarsal head.” Ex. 1015, 1112. Petitioner identifies no disclosure of a bone positioning guide, let alone a bone positioning guide configured to move the first metatarsal in both a transverse plane and a frontal plane.

At most, Exhibit 1015 says that a laterally directed force can simultaneously correct certain deformities. It does not disclose any guide. It does not disclose a structure that regulates or directs progressive motion or action. And it does not explain how a Weber clamp in McGlamry becomes the claimed guide. The Petition’s parenthetical citation to Exhibit 1015 therefore does not cure its deficiencies.

e. Petitioner’s Fallback Obviousness Theory Confirms the Disclosure Gap

Petitioner’s fallback theory on pages 36–37 confirms the missing disclosure. The Petition argues that, even if McGlamry did not disclose Weber-clamp frontal-plane rotation, it would have been obvious to employ the Weber clamp that way because a clamp engaged across adjacent metatarsals can transmit not only compressive force but also torsional movement. Pet. 36–37. But that is not an argument about what McGlamry discloses. It is an expert-driven theory of how a surgeon supposedly could use a generic clamp. The Board should not allow Petitioner to convert a missing disclosure into an “obvious to use it that way” assertion.

This same deficiency pervades the asserted combinations. The Petition later

characterizes substitution of another instrument for McGlamry's Weber clamp as "nothing more than the substitution of one known element for another with predictable results." Pet. 64. That framing only underscores that McGlamry's Weber clamp is a generic background tool, not the claimed specialized guide. A theory that one known instrument could be substituted for another does not show that the original instrument already disclosed the claimed structure.

As McGlamry 5th Edition makes clear, when authors sought to describe instruments that facilitate multi-planar correction, they identified "specialized guides and jigs," not a generic clamp used differently. Ex. 2005, 300. Petitioner's fallback obviousness theory therefore highlights, rather than cures, the underlying problem. The relied-upon McGlamry 4th Edition does not disclose the claimed guide, and Petitioner's resort to an assertion that a generic clamp could have been used differently only confirms that deficiency.

f. Conclusion as to McGlamry-Based Grounds

For at least these reasons, Petitioner's challenges based on McGlamry allegedly teaching the recited bone positioning guide lack merit. Petitioner has not shown that McGlamry's Weber clamp is a "bone positioning guide configured to move the first metatarsal to treat a bunion deformity by at least: moving the first metatarsal in a transverse plane to reduce an intermetatarsal angle between the first metatarsal and a second metatarsal, and rotating the first metatarsal in a frontal

plane.” The instrument of McGlamry is only a generic clamp used to assist, increase, or maintain a transverse plane reduction. Correction is left to the hands and skill of the surgeon in the McGlamry technique. The Weber clamp in McGlamry does not provide a structure that regulates or directs the path of that movement. Institution should therefore be denied as to all grounds relying on McGlamry for the bone positioning guide limitation of the claims.

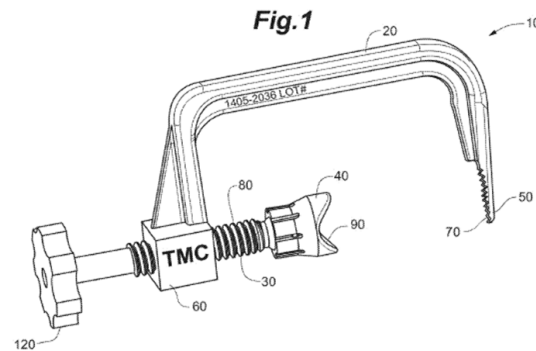
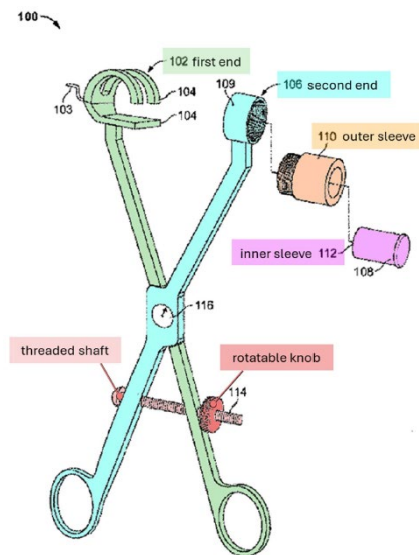
2. **Grounds Based on Kartalian Teaching a “bone positioning guide”**

As shown below, Kartalian’s instrument 100 suffers from the same fundamental deficiency as McGlamry’s Weber clamp: it is a reduction forceps whose structure does not regulate or direct the path of bone movement in the way the claimed guide requires.

a. Kartalian’s Instrument Is a Reduction Forceps, Not a Bone Positioning Guide

Petitioner relies on Kartalian’s instrument 100 as disclosing “an ‘instrument 100’ that ‘may act as reduction forceps to align two bones or reduce the distance between the bones, as desired’ and that ‘allow[s] for correction of any rotational deformity (pronation) when used for surgical correction of a bunion.’” Pet. 62 (quoting Ex. 1006, 9:66–10:3). Petitioner provides a detailed annotated version of Kartalian’s Figure 1 (produced in connection with its connections regarding claim 10, which depends from claim 1) on page 69 of the Petition, reproduced below on

the left, next to an example bone positioning guide from the '368 Patent on the right.



Again, the structural contrast between these two devices is stark and dispositive. Like the Weber clamp, Kartalian's instrument 100 is a reduction forceps (*i.e.*, a device used by a surgeon to apply compressive force across two bones).

The fact that Kartalian's forceps has a threaded shaft and knob does not transform it into a bone positioning guide in the claimed sense. As seen above, Petitioner quotes column 9, line 66 through column 10, line 3 of Kartalian. But Petitioner does not address the discussion immediately following that portion of Kartalian. Notably, the quoted discussion of Kartalian cited by Petitioner discusses surgeon manipulation. Kartalian explains that "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." Ex. 1006, 10:4–6. That is, the rotatable knob and threaded shaft labeled in Petitioner's annotated figure above is simply described as

a locking mechanism to secure the instrument after the surgeon's manual positioning is completed.

The structure of the instrument does not, by virtue of the knob adjustment, produce transverse-plane translation and frontal-plane rotation of the first metatarsal in the manner claimed and described in the '368 Patent. Rather, the surgeon decides where to place the instrument, how to orient it relative to the bones, and what movements to make. The instrument itself does not constrain or direct the correction path.

Kartalian explicitly describes this surgeon-directed quality: the instrument “may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.” Ex. 1006, 9:66–10:3 (emphasis added). The phrase “as desired” reveals that the direction and degree of correction is determined by the surgeon's desire and manipulation, not by any structural feature of the instrument that guides or constrains the bone's path of movement. This is precisely what distinguishes a reduction forceps from a bone positioning guide in the claimed sense.

Petitioner's treatment of Kartalian parallels its treatment of McGlamry. The Petition again does not identify guide-specific structure disclosed in the reference. Instead, it asserts that Kartalian's instrument “functions to position the bones by moving the metatarsal in the transverse plane and rotating it in the frontal plane” and therefore “satisfies ‘bone positioning guide’ under the plain and ordinary meaning.”

Pet. 63. That conclusion depends entirely on Petitioner’s overly broad construction of a guide as any device designed to move bone. It is not an identification of structure in Kartalian that regulates or directs progressive motion or action to move the bone.

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 arrangement that controls realignment in the claimed manner. Instead, Petitioner again relies on the notion that a surgeon *could* use the instrument to achieve the claimed result. That is not disclosure of the claimed guide.

Dr. Farber confirms this understanding, testifying that Kartalian’s instrument would be understood by surgeons as a reduction forceps whose effect depends on surgeon-selected placement and force application, not as a guide that structurally dictates frontal-plane and transverse-plane correction. *See* Ex. 2030 ¶¶ 28–29.

b. Kartalian’s Discussion of Rotational Correction Does Not Establish a Guide

Petitioner relies on Kartalian’s statement that its instrument “allow[s] for correction of any rotational deformity (pronation) when used for surgical correction of a bunion” to argue that the instrument is configured to rotate the first metatarsal in the frontal plane. Pet. 62 (citing Ex. 1006, 9:66–10:3). But this passage does not describe any structural feature of Kartalian’s instrument that directs or constrains the

frontal-plane rotation. The word “allows” is permissive and surgeon-dependent. It is a statement that the device does not structurally prohibit the surgeon from rotating the first metatarsal in the frontal plane. The instrument *allows a surgeon* to affect frontal-plane rotation if the surgeon positions the instrument in a certain way and applies force in the appropriate direction and magnitude. It does not describe a device whose geometry constrains the path of movement such that use of the device produces frontal-plane rotation.

This is the same deficiency identified with respect to McGlamry’s Weber clamp. Both the Weber clamp and Kartalian’s forceps are tools that a skilled surgeon can use to produce bone movement through specific manual techniques. Neither is a guide whose structure regulates or directs the path of that movement.

Petitioner never cites a passage in Kartalian describing a structure for guiding rotational realignment. Instead, it jumps from Kartalian’s statement that the instrument may be used during bunion correction and may “allow” correction of rotational deformity to the conclusion that the instrument itself is the claimed guide. That is the same analytical gap present with respect to McGlamry. Petitioner conflates a surgeon’s ability to use a tool during a procedure with disclosure of a device whose structure is configured to direct the claimed movement.

c. Petitioner’s Substitution Theory Does Not Remedy the Deficiency

Petitioner argues that substituting Kartalian’s instrument for McGlamry’s

Weber clamp “would have been nothing more than the substitution of one known element for another with predictable results.” Pet. 64. This framing confirms that Petitioner views both devices as functionally equivalent reduction forceps. But if Petitioner treats both as functionally equivalent, then Kartalian’s instrument suffers from the same structural deficiency as the Weber clamp. It is a generic bone reduction tool, not a bone positioning guide whose structure directs and constrains the path of bone movement in the claimed manner. Substituting one deficient reference for another does not cure the underlying deficiency.

That substitution theory is particularly revealing because it confirms Petitioner is not identifying any unique guide structure in Kartalian. Instead, Petitioner treats Kartalian as a functionally interchangeable tool that can stand in for McGlamry’s Weber clamp. But a theory that one generic reduction instrument can be swapped for another does not show that either one discloses the claimed guide arrangement.

Petitioner’s interchangeable-tool theory is especially important at institution because it confirms that Petitioner believes one generic reduction instrument can be substituted for another and then treated as the claimed guide under an overly broad functional definition. That premise depends on Petitioner’s construction, not on a specific guide disclosure in Kartalian.

Again, Petitioner’s showing is not that the reference discloses the claimed

guide, but that Petitioner can characterize a known forceps instrument as equivalent once the claim term is stripped of meaningful structural content.

d. Dr. Neufeld's Testimony Does Not Supply the Missing Disclosure

Dr. Neufeld's testimony does not repair the Petition's defects. He supplies the alleged guide functionality through allegations of equivalence and conclusory modifications, asserting that Kartalian's instrument is "identical or at least equivalent" to the claimed bone positioning guide because it performs the positioning and rotational functions "in substantially the same way." Ex. 1003 ¶ 220. He further asserts that a POSA would have been motivated to use Kartalian's instrument in bunion surgery because it includes features "specifically designed for bunion correction procedures" and would have been "desirable." Ex. 1003 ¶ 222. But those assertions do not identify any guide-specific structure disclosed in Kartalian for regulating or directing progressive bone rotation.

Instead, Dr. Neufeld, like the Petition, characterizes Kartalian's instrument as equivalent because a surgeon can use it to position and rotate bone during a procedure. *See* Ex. 1003 ¶¶ 216–228. That testimony rests on allegations of user manipulation and functional similarity, not on disclosed structural features in Kartalian corresponding to the claimed guide arrangement. There is no evidence-based support that the claimed outcome is produced by Kartalian's instrument structure rather than by the surgeon's chosen manipulation of the instrument. As Dr.

Farber explains, “[t]he functions Dr. Neufeld attributes to Kartalian arise, if at all, from user manipulation during surgery, and Kartalian does not disclose structure that would be understood to constrain or guide the claimed multi-planar correction path.” Ex. 2030 ¶ 30.

Dr. Neufeld testifies that “Kartalian’s instrument 100 also includes ‘an automatic angle indicator 116 to provide the surgeon with an estimate of the angle of the bones requiring correction’” and alleges that “[t]his feature would provide the surgeon with additional guidance on the final position of the bone.” Ex. 1003 ¶ 223 (citing Ex. 1006, 10:8–16). But as Dr. Farber explains, this only reinforces the understanding that Kartalian’s instrument 100 is not a bone positioning guide as required by the claims. *See* Ex. 2030 ¶ 30 (“Dr. Neufeld’s discussion of Kartalian’s angle indicator 116 does not transform a tenaculum into a guide. Rather, it further shows that a skilled surgeon would understand Kartalian’s tenaculum as a surgeon-driven manual reduction tool, where the angle indicator simply indicates the manual reduction performed by the surgeon’s manipulation of Kartalian’s tenaculum.”).

e. Conclusion as to Kartalian-Based Grounds

For at least these reasons, Petitioner’s challenges based on Kartalian allegedly teaching the recited bone positioning guide lack merit. Petitioner has not shown that Kartalian’s instrument 100 is a “bone positioning guide configured to move the first metatarsal to treat a bunion deformity by at least: moving the first metatarsal in a

transverse plane to reduce an intermetatarsal angle between the first metatarsal and a second metatarsal, and rotating the first metatarsal in a frontal plane.” The instrument is a surgeon-directed reduction forceps that requires surgeon selection and control how to manually manipulate the instrument. The Kartalian instrument does not provide a structure that regulates or directs the path of that movement. Institution should therefore be denied as to all grounds relying on Kartalian as the disclosure of the bone positioning guide limitation of the claims.

III. CONCLUSION

Because all grounds rely on either McGlamry’s Weber clamp or Kartalian’s instrument as the sole or primary disclosure of the bone positioning guide limitation, and because neither device satisfies that limitation under the proper construction, the Petition fails to establish a reasonable likelihood of prevailing as to any challenged claim.

Because the Petition’s theory of unpatentability depends entirely on an unsupported construction of “bone positioning guide” that reads the term “guide” out of the claim and disregards the “configured to” language, and because no prior art reference under any ground discloses a device whose structure regulates or directs the path of bone movement in the claimed manner, institution should be denied.

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

IPR2026-00194
Patent 12,102,368

Dated: April 13, 2026

Respectfully Submitted,

/Joshua Van Hoven/

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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 8,601 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 13, 2026

/Joshua Van Hoven/
Joshua Van Hoven (Reg. No. 56,786)

Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned certifies that on the 13th 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-IPR-368@morganlewis.com to the below counsel of record for Petitioner per Petitioner’s consent for electronic service (*see* Paper 1 at 91).

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