

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

PGR2026-00020
Patent 12,268,428

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	<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. 10,342,590 to Bays, <i>et al.</i> (the “’590 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 [NEW]	37 C.F.R. 1.321(a) Statutory Disclaimer covering Claim Nos. 1–7, 12–20, and 25–27 for U.S. Patent No. 12,268,428
2026 [NEW]	Declaration of Daniel C. Farber, M.D. ("Farber Declaration")
2027 [NEW]	<i>Curriculum Vitae</i> of Daniel C. Farber, M.D.
2028 [NEW]	McGlamry's Comprehensive Textbook of Foot and Ankle Surgery, Chapters 9 and 13, Vol. 1, 5th Edition, 2022 ("McGlamry")
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. 12,268,428 (Ex. 1001, “’428 Patent”). Patent Owner subsequently disclaimed claims 1–7, 12–20, and 25–27. Ex. 2025. The features of the disclaimed claims are still relevant to the extent a pending claim depends from a disclaimed claim (*e.g.*, claim 8 includes the features of disclaimed claim 1). *See Raytheon Technologies Corp. v. General Electric Co.*, 993 F.3d 1374 (Fed. Cir. 2021).

Claims 8–11, 21–24, and 28–30 are the only remaining claims at issue for the institution decision. *See* 37 C.F.R. § 42.207(e) (“No post-grant review will be instituted based on disclaimed claims.”). The disclaimer noted above was made to simplify the issues for this proceeding and highlight the fundamental deficiencies in the Petition for the remaining claims.

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 is recited in all pending 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. 25. This is followed by Petitioner’s conclusory mapping to a clamp in McGlamry, followed by

a naked allegation that the clamp is the recited bone positioning guide because it can be used to move bones. Pet. 49–50.

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) and (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 challenge presented by Petitioner addresses the “guide” feature. 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.

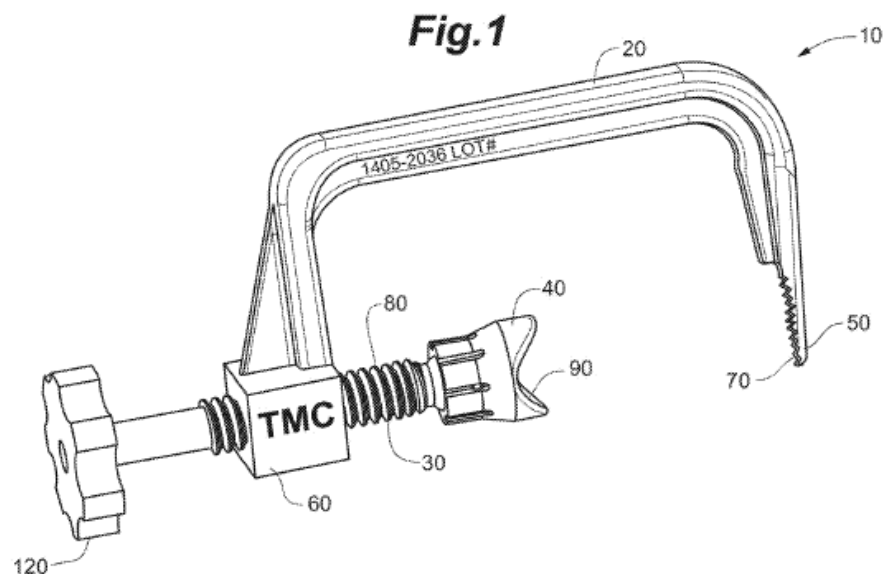
Accordingly, the Board has sufficient reason to deny institution based on Petitioner’s failure to meet its burden. The following discussion further elaborates on the Petition’s failings, evaluating in detail the relevant portions of the Petition and testimony.

B. The ’428 Patent

The ’428 Patent relates to an instrumented surgical technique for bunion correction. The ’428 Patent describes an instrumented correction system used in its surgical technique including an instrument positioned between the first and second

metatarsal, a bone preparation guide, a bone positioning guide, and at least one fixation device. The system helps achieve precise, reproducible bunion deformity correction and fusion of the metatarsal with the cuneiform in the corrected position. This 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.

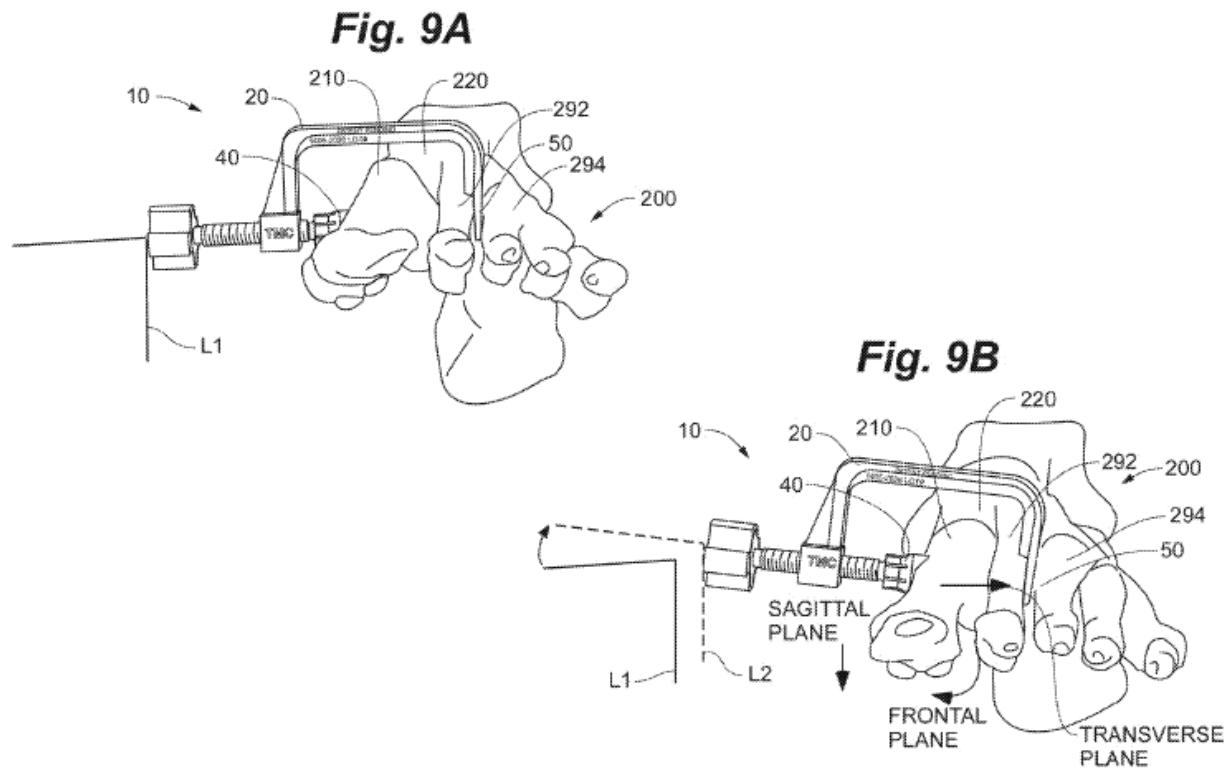
Figure 1 from the '428 Patent is reproduced below.



"F[igure] 1 is a side perspective view of a bone positioning guide." Ex. 1001, 5:25–27. The '428 Patent explains: "When the mechanism is actuated it causes a first bone engaged with the bone engagement member [40] to move to correct an alignment in more than one plane with respect to a second bone in contact with the tip [50]." *Id.*

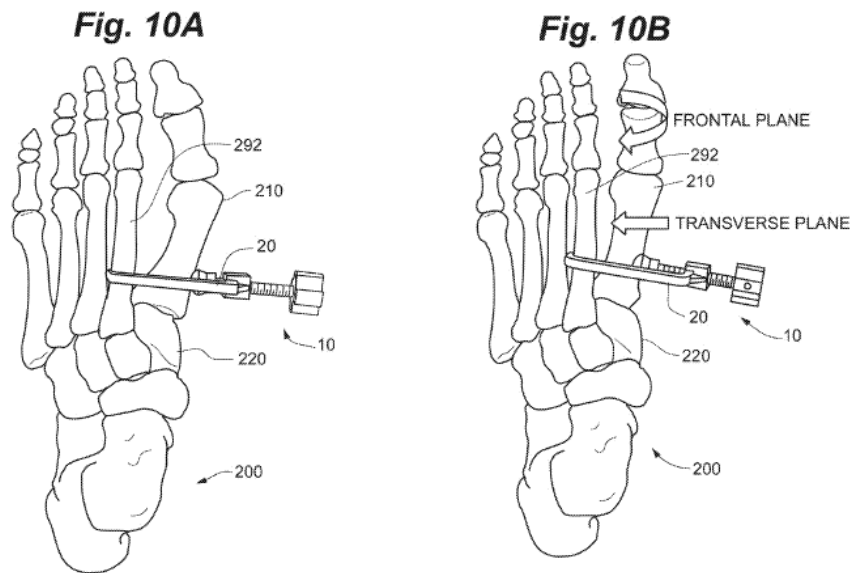
at 5:33–36.

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, 10:14–16. “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 10:17–19. Actuation of the bone positioning guide provides correction in at least one plane. In one example, “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.” *Id.* at 10:21–24. “[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 10:25–29. 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 10:29–34.

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, 12:9–13. “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 12:13–20.

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 the bones of the foot as explained above. *See* Ex. 1001, 10:20–24 (“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 8 is representative for the issues discussed in this POPR. A modified version of claim 8 is reproduced below to include the features of disclaimed claim 1

that are included in claim 8 by its dependency from original claim 1 (features of original claim 8 in bold/italics):

8. An instrumented surgical technique for treating a bunion deformity,
the instrumented surgical technique comprising:
inserting an instrument between a first metatarsal and a second
metatarsal adjacent to the first metatarsal;
with the instrument inserted between the first metatarsal and the
second metatarsal, cutting an end of the first metatarsal;
moving the first metatarsal in at least one plane to treat the bunion
deformity;
cutting an end of a medial cuneiform opposing the end of the first
metatarsal; and
after moving the first metatarsal in at least one plane to treat the
bunion deformity, fixating a moved position of the first metatarsal
relative to the medial cuneiform using at least one bone fixation
device;
*wherein moving the first metatarsal in at least one plane comprises
moving the first metatarsal relative to the second metatarsal in a
transverse plane by applying a force to the first metatarsal with a
bone positioning guide and thereby reducing an intermetatarsal
angle between the first metatarsal and the second metatarsal.*

Ex. 1001, 26:8–24, 61–67.

D. Evidence and Asserted Grounds

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

following grounds (the “Pending” column indicates claims remaining subject to the respective challenge):

Claims Challenged		35 U.S.C. §	Reference/Basis
Original	Pending		
1–3, 6–8, 10–13, 16, 17	8, 10, 11	102	McGlamry (Ex. 1005)
1–3, 6–8, 10–13, 16, 17	8, 10, 11	103	McGlamry
1–3, 6–13, 16, 17	8–11	103	McGlamry and Davidson (Ex. 1006)
4, 5, 14, 15, 17–21, 23–30	21, 23, 24, 28–30	103	McGlamry and Fallin (Ex. 1007)
4, 5, 14, 15, 17–30	21–24, 28–30	103	McGlamry, Davidson, and Fallin
17	None	103	McGlamry and Tyber (Ex. 1008)
17	None	103	McGlamry, Davidson, and Tyber
17	None	103	McGlamry and DaCosta (Ex. 1013)
17	None	103	McGlamry, Davidson, and DaCosta
1–7, 12–14, 16, 18–20, 25, 27	None	103	Fallin and Davidson

Petitioner submitted a Declaration from Steven K. Neufeld, M.D. Ex. 1003 (“Neufeld Declaration”). Patent Owner submits a Declaration from Daniel C. Farber, M.D. Ex. 2026.

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. 21. 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.” Pet. 22.

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. 22 (“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 “fulcrum” (Pet. 23–25), “bone positioning guide” (*id.* at 25–26), and “bone fixation device” (*id.* at 26). 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. 25 (citing Ex. 1003 ¶¶ 74–78). 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:

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 [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 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 device (bone positioning *guide*) dictates the movement of the bone for the 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 is fully supported by and consistent with the intrinsic record. The '428 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, 10:21–29. The correction is dictated by the geometry of the device. *Id.* at 12:13–20. 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 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

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

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.

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."

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. 25–26. 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. 25. 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. 25–26); and (2) the “generally C-shaped configuration” from column 5 (*id.* at 26). As explained further below, Petitioner misreads the first category. The tenaculum/tong language at column 7, lines 23–37, 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. The tenaculum/tong discussion in the ’428 Patent identifies an example component of the bone positioning guide, not the guide itself. And while the ’428 Patent describes the C-shaped configuration from column 5 as an example of 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.

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 7 as describing a free-standing bone positioning guide, when in fact it describes a possible component of a bone positioning guide. *See* Ex. 1001, 7: 23–37.

Claim 8 recites:

moving the first metatarsal in at least one plane comprises moving the first metatarsal relative to the second metatarsal in a transverse plane by applying a force to the first metatarsal with a ***bone positioning guide*** and thereby reducing an intermetatarsal angle between the first metatarsal and the second metatarsal.

Ex. 1001, 26:62–67 (emphasis added). Similar features are recited in claims 21 and 28. *See id.* at 28:20–24, 29:1–6. 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 ’428 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.

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.

D. Petitioner’s Challenges

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. 49–51, 57–59, 70, 93, 96–97. Specifically, Petitioner relies on the same discussion related to claim 8 and McGlamry for the bone positioning guide features throughout the challenges. Pet. 49–51.

Claim 8 recites:

moving the first metatarsal in at least one plane comprises moving the first metatarsal relative to the second metatarsal in a transverse plane by applying a force to the first metatarsal with a ***bone positioning guide*** and thereby reducing an intermetatarsal angle between the first metatarsal and the second metatarsal.

Ex. 1001, 26:62–67 (emphasis added). Similar features are recited in claims 21 and 28. *See id.* at 28:20–24, 29:1–6.

According to Petitioner:

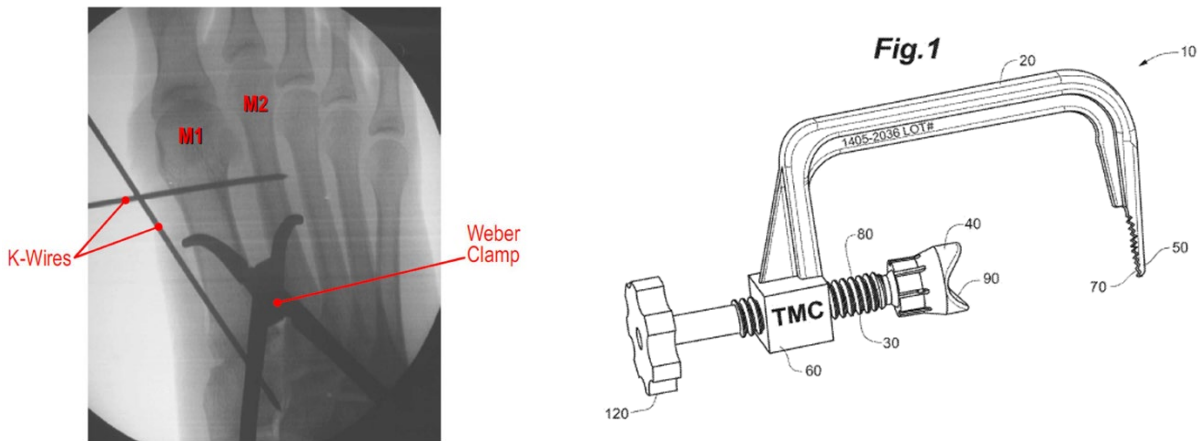
McGlamry discloses this additional limitation. Ex.1003, ¶¶124-128.

McGlamry discloses moving the first metatarsal in at least one plane relative to the second metatarsal, including movement in a transverse plane to reduce the first intermetatarsal angle, as explained above for claim 1. See §VII.A.1.d, supra; Ex.1005, 325 (“***[T]he surgeon can use his or her thumb against the first metatarsal to manually reduce the first intermetatarsal angle in the transverse plane***”), 809 (Fig. 55.7G).

McGlamry also discloses using instruments to move the first metatarsal in one or more planes, including the transverse plane. See Ex. 1005, 325-326; Ex.1003, ¶125. For example, McGlamry explains that “***a large Weber clamp may be used to assist, increase, or maintain the reduction***” of the first metatarsal. Ex.1005, 325; Ex.1003, ¶125. McGlamry’s Figure 31.5 (below) is an x-ray depicting “a case in which a large Weber clamp was used for reduction of a large [intermetatarsal] angle,” i.e. used to move the first metatarsal toward the second metatarsal in the transverse plane to reduce the angle. Ex.1005, 326.

Pet. 49–50 (emphasis added). As seen above, Petitioner contends that McGlamry teaches the recited structure and does not propose modifications to McGlamry’s Weber clamp to meet the limitation.

Petitioner provides an annotated image of McGlamry’s Weber clamp (Figure 31.5) on page 50 of the Petition, which is reproduced below on the left, next to an example bone positioning guide from the ’428 Patent on the right.

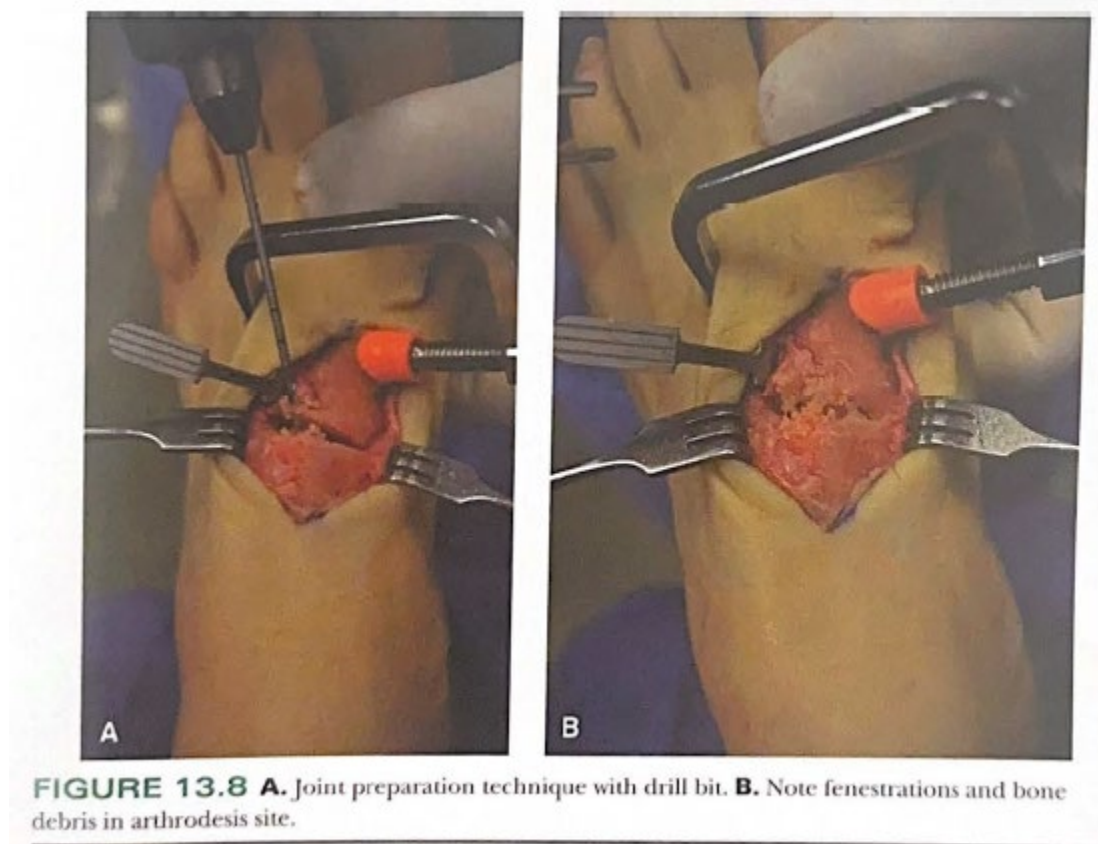


The structural contrast between these two devices is stark and dispositive. The bone positioning guide (right) taught by the '428 Patent includes a geometry that constrains and directs the path of bone movement when the knob is turned. The Weber clamp (left) is a manually operated compression device: 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 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. 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 '428 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 to “assist, increase, or maintain” a

reduction selected and controlled by the surgeon. Ex. 1005, 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 5th Edition (McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, 5th Edition, 2023 (“McGlamry 5th Edition”), Ex. 2028). There, the authors explain that “correction can be made easier . . . with specialized guides and jigs.” Ex. 2028, 300. McGlamry 5th Edition thus distinguishes generic manual tools from “specialized guides and jigs” used to facilitate three-dimensional correction. Figure 13.8 of McGlamry 5th Edition depicts an example of such a specialized guide and is reproduced below.



Ex. 2028, 303. The guide structure shown above is actually a commercial embodiment of Patent Owner's bone positioning guide shown in Figure 1 of the '428 Patent, which the later edition of McGlamry explains provides the additional benefit of guided correction. *See* Ex. 2028, 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.

Dr. Farber's testimony supports this understanding, explaining 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 correction path. *See* Ex. 2026 ¶ 15; *see also id.* at ¶ 17 (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”). And 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).

Patent Owner’s position is further supported by Dr. Farber’s testimony that the Weber clamp’s effect on bone position depends entirely on surgeon-selected placement and applied force, not on any structural feature of the clamp itself, and that a POSA would not understand McGlamry’s Weber clamp passage as disclosing an instrument whose structure performs the claimed correction. *See* Ex. 2026 ¶ 16. 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 and Dr. Neufeld’s

testimony does nothing to rebut that understanding.

The same deficiency carries through to all remaining grounds. For claims 21 and 28 (and their dependents 22–24 and 29–30), Petitioner’s mapping of the bone positioning guide limitation relies on the identical McGlamry Weber clamp analysis. *See* Pet. 93 (claim 21), 96 (claim 28). For the grounds combining McGlamry with Davidson or Fallin, Petitioner makes no independent argument that Davidson’s retractor or Fallin’s cutting guide satisfies the bone positioning guide limitation, as those references are relied upon for other limitations entirely. *See* Pet. 70 (Ground 3, claim 8: “Using an instrument such as Davidson’s retractor in McGlamry’s procedure would not change the manner in which force is applied by the bone positioning guide to the first metatarsal.”). Thus, every remaining ground falls with Petitioner’s Weber clamp mapping for the reasons stated above.

E. Summary

The record addressing the claims remaining in this proceeding is thin. The Board is left with Petitioner’s conclusory allegation that a bone positioning guide is anything that can be used to move bones, which as explained above is an allegation that is unfounded based on the record. The result is Petitioner’s subsequent conclusion that McGlamry’s Weber clamp must be a bone positioning guide despite the fact that it does not regulate the direction or path of bone movement.

Accordingly, Petitioner has not established that it is more likely than not it

will prevail at trial on at least one claim. Every remaining ground relies on the same deficient claim construction allegation, and Weber clamp mapping for the bone positioning guide limitation in claims 8, 21, and 28, from which all remaining dependent claims 9–11, 22–24, and 29–30 depend. The deficiency is fatal to institution as to all pending claims.

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 6, 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 4892 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 6, 2026

/Joshua Van Hoven/

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Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned certifies that on the 6th 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-428@morganlewis.com to the below counsel of record for Petitioner per Petitioner’s consent for electronic service (*see* Paper 1 at 123).

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