

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PARAGON 28, INC.,  
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.,  
Patent Owner.

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PGR2026-00017  
Patent 12,268,397

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**PATENT OWNER'S PRELIMINARY RESPONSE**

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**PATENT OWNER'S UPDATED LIST OF EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>
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. 12,349,941 to Dayton, <i>et al.</i> (the “‘941 Patent”)
2003	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Chapters 1 and 13, Vol. 1, 5th Edition, 2022 (“McGlamry”)
2004	<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
2005	<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
2006	<i>Paragon 28, Inc. and Disior Oy v. Treace Medical Concepts, Inc. and Mios Marketing, LLC</i> Amended Complaint, dated December 18, 2025
2007	U.S. Patent No. 10,561,426 to Dayton, <i>et al.</i> (the “‘426 Patent”)
2008	Notice of Allowance of U.S. Application No. 18/645,205 (U.S. Patent No. 12,268,397 to Dayton, <i>et al.</i> )
2009	Notice of Allowance of U.S. Application No. 16/593,153 (U.S. Patent No. 10,561,426 to Dayton, <i>et al.</i> )
2010	U.S. Patent No. 10,856,886 to Dacosta, <i>et al.</i>
2011	U.S. Patent No. 11,696,767 to Dacosta, <i>et al.</i>

<b>Exhibit No.</b>	<b>Description</b>
2012	Treace Medical Concepts, Inc.'s SEC Form S-1 Registration Statement for Initial Public Offering, dated March 30, 2021
2013	Treace Medical Concepts, Inc.'s Initial Public Offering, dated April 22, 2021
2014	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
2015	Treace's Announcement of Grant of Additional U.S. Patent on Instrumented Bunion Correction, dated October 21, 2021
2016	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
2017	Treace's Announcement of Grant of U.S. Patent on Instrumented Bunion Correction, dated January 19, 2022
2018	Treace's Announcement of Expansion of Its Global IP Portfolio with the Grant of Two New U.S. Patents, dated December 19, 2022
2019	Treace's Announcement of Expansion of Market Leading Global IP Portfolio For Bunion And Related Deformities, dated April 19, 2023
2020	Treace's Announcement of New Patent Covering Instrumented Bunion Correction Procedures and Milestone 50th U.S. Patent, dated September 14, 2023
2021	Treace's Announcement of Filing of Patent Infringement Suit Against Zimmer Biomet to Protect Lapiplasty® Bunion Technology, dated June 5, 2025
2022	Treace's Announcement of 100,000 Lapiplasty® 3D Bunion Correction® Patient Milestone Celebration, dated March 25, 2024
2023	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

<b>Exhibit No.</b>	<b>Description</b>
2024	AlphaSense's November 12, 2024 UBS Global Healthcare Conference Transcript
2025	Treace's Announcement of Filing of Patent Infringement Suit To Protect Lapiplasty® Bunion Technology, dated March 28, 2022
2026	Treace's Announcement of Settlement of Lawsuit Against Fusion Orthopedics, dated March 3, 2023
2027	Treace's Announcement of Filing of Patent Infringement and Unfair Competition Suit to Protect Lapiplasty® Bunion Technology, dated October 14, 2024
2028	J.P.Morgan's January 2023 Investor Presentation on Treace Medical Concepts, Inc.
2029 [NEW]	Declaration of Daniel C. Farber, M.D. ("Farber Declaration")
2030 [NEW]	<i>Curriculum Vitae</i> of Daniel C. Farber, M.D.

## I. INTRODUCTION

### A. Background

Paragon 28, Inc. (“Petitioner”) filed a Petition (Paper 1, “Petition” or “Pet.”) requesting post grant review of claims 1–30 of U.S. Patent No. 12,268,397 (Ex. 1001, “‘397 Patent”).

The Petition should be denied because Petitioner has not established that it is more likely than not that any challenged claim is unpatentable. The written description challenges fail because Petitioner imports claim limitations that neither the claim language nor the intrinsic record compels. The enablement challenges fail because Petitioner bypasses the *Wands* factor analysis entirely. The obviousness challenges fail for a fundamental reason that pervades the entire Petition: Petitioner proposes combining a freehand fusion procedure at the tarsometatarsal (TMT) joint with a cutting guide designed for an entirely different surgical objective at an entirely different joint (the metatarsophalangeal (MTP) joint), and then asks the Board to accept that a skilled surgeon would have viewed this combination as an obvious modification with a reasonable expectation of success. Petitioner fails to identify any teaching in McGlamry suggesting dissatisfaction with its freehand Lapidus procedure that would have prompted one skilled in the art to look at cutting guides for the Lapidus procedure.

The two references Petitioner combines do not share a common surgical

context. McGlamry describes the Lapidus arthrodesis procedure (a fusion of the first metatarsal to the medial cuneiform at the TMT joint), where the objective is permanent bony union and correction of the underlying deformity. Augoyard describes an ancillary cutting instrument designed to prepare bones for insertion of a total MTP joint prosthesis (a joint replacement procedure at a different joint entirely). These are not minor variations on a common theme. Fusion and joint replacement are fundamentally different surgical objectives that drive fundamentally different instrumentation requirements. In joint replacement, the cutting geometry is dictated by the prosthetic implant's dimensional requirements, not by a bone-positioning decision made intraoperatively like in a Lapidus procedure. Augoyard's guide system is designed around the MTP joint replacement, not TMT fusion.

The anatomical location of the procedure compounds this mismatch. The TMT joint, where McGlamry's Lapidus procedure is performed and where the '397 Patent's claims are directed, involves preparation of the metatarsal and cuneiform surfaces for fusion. Augoyard's guide, by contrast, is designed to prepare the metatarsal and phalanx at the MTP joint for prosthetic implantation. The bones involved, the joint geometry, the alignment objectives, and the fixation strategies differ between the two procedures. As discussed below, Petitioner offers no meaningful analysis explaining how Augoyard's implant-geometry-driven guide architecture (designed for the MTP joint and optimized around prosthetic component

dimensions) would translate to the TMT joint fusion workflow the claims require.

These location and objective differences are not incidental. They go to the issue of whether a skilled artisan would have had any reason to look to Augoyard when confronted with the challenges of Lapidus joint preparation, and whether such a skilled artisan would have expected success in adapting Augoyard's system to an entirely different surgical context. The claimed procedure requires a specific shared-pin guide architecture that coordinates bone cutting geometry across the metatarsal and cuneiform, with an intraoperative alignment step to establish the fusion position. Petitioner identifies nothing in Augoyard's implant-driven workflow that teaches or suggests that architecture. And nothing in McGlamry, which was aware of cutting guide technology used in other surgical contexts, suggests that a skilled surgeon would have looked to an MTP joint replacement guide to address the challenges of TMT fusion. The Petition's obviousness challenges are a product of hindsight, not of the prior art.

**B. The '397 Patent**

The '397 Patent is part of a continuity chain tracing back to an initial 2015 filing. With that filing, Treace Medical Concepts, Inc. ("Patent Owner") disclosed bunion correction methods to control cutting alignment, thus improving accuracy and reproducibility relative to preexisting techniques. The specific claims of the '397 Patent are directed to bone cutting for bunion correction surgery using a guided

cutting system.

C. **Illustrative Claim**

Claim 1 is representative for the issues discussed in Patent Owner's Preliminary Response ("POPR") and is reproduced below:

1. A bunion correction method comprising:
  - positioning a first bone cutting guide slot over a portion of a metatarsal to be cut;
  - attaching the first bone cutting guide slot to the metatarsal with a first fixation pin inserted into the metatarsal and a second fixation pin inserted into the metatarsal, the first fixation pin and the second fixation pin being positioned distally of the first bone cutting guide slot;
  - inserting a cutting member through the first bone cutting guide slot to cut the portion of the metatarsal;
  - adjusting an alignment of the metatarsal relative to a *cuneiform* separated from the metatarsal by a joint to establish a moved position of the metatarsal;
  - positioning a second bone cutting guide slot over a portion of the cuneiform to be cut, the second bone cutting guide slot being attached to the metatarsal by at least the first fixation pin inserted into the metatarsal and the second fixation pin inserted into the metatarsal, the first fixation pin and the second fixation pin being positioned distally of the second bone cutting guide slot;
  - inserting the cutting member through the second cutting slot to cut the portion of the *cuneiform*; and

causing the metatarsal to *fuse* to the *cuneiform* in the moved position.

Ex. 1001, 10:60–11:18 (emphasis added).

**D. Evidence and Asserted Grounds**

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

<b>Claims Challenged</b>	<b>35 U.S.C. §</b>	<b>Reference/Basis</b>
1–30	112(a)	Written Description
1–30	112(a)	Enablement
1–2, 4–10, 12–20, 22–30	103	McGlamry (Ex. 1005), Augoyard (Ex. 1007)
11	103	McGlamry, Augoyard, DaCosta (Ex. 1014)

Petitioner submits a Declaration from Steven K. Neufeld, M.D. Ex. 1002 (“Neufeld Declaration”). Patent Owner submits a Declaration from Daniel C. Farber, M.D. Ex. 2029. This POPR additionally addresses Petitioner’s citations to Haddad (Ex. 1013), Weinstein (Ex. 1015), and Alchermes (Ex. 1023).

**II. ANALYSIS**

**A. Legal Standards**

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

claims challenged in the petition is unpatentable.” 35 U.S.C. § 324(a).

**B. Level of Ordinary Skill in the Art**

Petitioner contends that because the patent includes both surgical procedures and mechanical devices, a hypothetical person of ordinary skill in the art would have a combination of these two skill sets. Pet. 18–19. 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 19.

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. Nevertheless, Petitioner does not explain how its definition provides a reference point that would alter the Petition's assertion of obviousness and instead concedes it does not. *See* Pet. 19 ("Petition does not turn on this specific definition of the level of ordinary skill.").

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

**C. Claim Construction**

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

Petitioner proposes a claim construction for "attached/attaching." Pet. 20–28. Petitioner also proposes a construction for "moved position." Pet. 28–29. Patent

Owner does not believe there is a need to expressly construe any particular claim term. *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). Nevertheless, Patent Owner addresses the proposed constructions in the event the Board deems it necessary for its institution decision.

**1. attached/attaching**

Petitioner’s proposed construction for “attached/attaching” does not affect the obviousness challenge, as Petitioner proposes a narrowing construction for purposes of supporting its written description challenge. Pet. 33–36. Patent Owner addresses the proposed “attached/attaching” construction to show that Petitioner has not established that a direct attachment is required. To the extent Petitioner’s § 112 theories depend on importing a “direct attachment” requirement, Petitioner bears the burden to show that limitation is compelled by the claim language or by a clear lexicography/disavowal in the intrinsic record.

Petitioner contends that “the specification demonstrates that, in the ’397 patent, ‘attached’ and its variants refer to direct connections between components, not indirect relationships.” Pet. 20. Petitioner alleges that “[a] POSA would understand, in the context of a surgical method as claimed in the ’397 patent, that ‘attached’ refers to a direct physical connection, not an attenuated series of indirect

relationships.” Pet. 25 (citing Ex. 1002 ¶ 40).

Paragraph 40 of the Neufeld Declaration states: “when I use the words ‘attached’ or ‘attaching’ in the context of foot or ankle surgery, I am referring to a direct connection of one structure to another (e.g., a ligament to a bone), sometimes using a device such as a screw.” That is, Dr. Neufeld attests to his *personal use* of the term and does *not* even allege that this is the understanding of the term by *other POSAs* in the field or in the context of the specification or claim language. Petitioner therefore asks the Board to adopt a narrowing construction of “attached/attaching” without any supporting expert opinion on how a POSA would understand that term in light of the specification.

Petitioner attempts to impose its preferred meaning by citing various Federal Circuit decisions without any detailed analogy to the specific fact patterns in those cases. Pet. 28 (citing *Jurgens v. McKasy*, 927 F.2d 1552, 1560–61 (Fed. Cir. 1991); *Searfoss v. Pioneer Consolidated Corp.*, 374 F.3d 1142, 1149–50 (Fed. Cir. 2004). In *Jurgens*, the court explained, for example, that “the quoted claim limitations literally require a direct series connection between neck, hoop, and spike. That is the meaning which the reexamination examiner ascribed to the limitation.” *Jurgens*, 927 F.2d at 1561. And in *Searfoss*, the court explained that “a construction of the word ‘connect’ to include ‘indirect’ and non-rigid connections (such that the canvas cover itself could be the connection between the tension bail and the extension leg

assembly) is problematic because it would lead to a reading of the claim such that the cover (as the actuation means) is exerting a downward force upon itself.” *Searfoss*, 374 F.3d at 1150. These cases are tied to their specific facts and do not support a general construction as Petitioner appears to allege.

Notably, Petitioner does not identify anything that requires a diversion from the plain and ordinary meaning of “attached/attaching.” The Board and the Federal Circuit have found that the ordinary and customary meaning of the terms “attached/attaching” do not carry a requirement for direct attachment. *See, e.g., Repro-Med Systems, Inc. v. EMED Technologies Corporation*, IPR2015-01920, Paper 65 at 16 (PTAB 2017)<sup>1</sup> (“the ordinary and customary meaning of the term ‘in attachment to’ encompasses both direct and indirect attachment”) (citing *Southco, Inc. v. Fivetech Tech. Inc.*, 611 F. App’x 681, 686 (Fed. Cir.), cert. denied, 136 S. Ct. 587 (2015)). In *Southco*, the Federal Circuit expressly stated: “the ordinary meaning of ‘attached’ includes both direct and indirect attachment.” 611 F. App’x at 686<sup>2</sup>; *see also Wash World, Inc. v. Belanger Inc.*, 131 F.4th 1360, 1372 (Fed. Cir.

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<sup>1</sup> *Repro-Med Systems* was decided during the time when the broadest reasonable interpretation was used for claim construction, but that difference in construction does not affect the relevance of the particular citation to this proceeding.

<sup>2</sup> In *Southco* the Federal Circuit agreed with the lower court that the term “attached” was limited to direct attachment in that case. *See Southco, Inc.*, 611 F. App’x at 686. In that case, however, certain language in the claim itself made it clear that “attached” was limited to direct attachment. *Id.* Claims of the ’397 patent do not include language that would limit “attached/attaching” to direct attachment,

2025) (holding that “dependingly mounted from the carriage” did not require direct attachment because “[i]n general, a structure can be ‘dependingly mounted’ from another structure either by being attached directly to it . . . or by being attached indirectly to it,” and nothing in the claim language suggested otherwise).

Petitioner does not allege that anything in the claims themselves limits “attached/attaching” to direct attachment or that Patent Owner acted as its own lexicographer or disavowed certain claim scope. “Absent a clear disavowal or contrary definition in the specification or the prosecution history, the [claim] is entitled to the full scope of its claim language.” *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004). Petitioner attempts to limit the terms “attached/attaching” beyond their ordinary and customary meaning by reading in particular embodiments from the specification. But “[e]mbodiments in the specification—even if there is only one embodiment—cannot limit the scope of the claims absent the patentee’s words or expressions of manifest exclusion or restriction.” *Apple Inc. v. Wi-LAN Inc.*, 25 F.4th 960, 967 (Fed. Cir. 2022).

Petitioner points to the specification’s use of “supported” and implies that this usage demonstrates a deliberate lexicographic contrast with “attached.” Pet. 26. But “supported” is used to describe the secondary guide member’s relationship to the

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as was found to be present in the patent at issue in *Southco*.

bridge rails, which is a different structural relationship (*i.e.*, between a guide and its carrier rails, not between a guide and a bone). *See, e.g.*, Ex. 1001, 6:49–55. The fact that the specification uses “supported” for one structural relationship does not establish that “attached” was redefined to require direct bone contact in a different structural relationship. Petitioner identifies no statement in the specification that the inventors used these terms in deliberate contrast to one another or that “attached” in the context of guide-to-bone connection was intended to carry a narrower meaning than its ordinary scope.

For at least these reasons, the Board should reject Petitioner’s attempts to unduly limit the meaning of “attach/attached.”

**2. moved position**

With respect to “moved position,” Petitioner proposes that it refers to the final alignment of the metatarsal that is maintained for fusion. Pet. 28–29. Even under Petitioner’s construction, however, the claims do not require that the moved position be established irrevocably before the cuneiform is cut, nor does any intrinsic statement limit the sequence in which the adjustment and cutting steps must occur. The proposed construction for “moved position” therefore does not need to be reached to resolve the institution decision in favor of Patent Owner in view of Petitioner’s failure to establish its non-enablement position even with its proposed construction. Nevertheless, Patent Owner addresses it as needed in connection with

Petitioner's order-of-procedure enablement theory.

Petitioner contends that “[t]he term ‘moved position’ (and its variant ‘moved position of the metatarsal’) should be construed to mean the position of the metatarsal relative to the cuneiform that is established by the recited adjusting step and in which the metatarsal is eventually fused to the cuneiform.” Pet. 29. According to Petitioner, “[t]he claims thus treat ‘moved position’ as a single, defined position: the alignment created by the adjusting step and later maintained for fusion.” *Id.*

Patent Owner disagrees that the recitation of “the moved position” excludes intervening movement between the position after “adjusting” and the position for fusion. The claims recite “adjusting an alignment of the metatarsal relative to a cuneiform . . . to establish a moved position of the metatarsal” and “causing the first metatarsal to fuse to the first cuneiform in the moved position.” Ex. 1001, 10:60–11:18; *see also id.* at 12:54–13:19, 14:13–48. The claims do not require that the moved position be established irrevocably or that fusion occurs without any subsequent repositioning. *See Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) (refusing to impose a negative limitation where there was no “express disclaimer or independent lexicography in the written description that would justify adding that negative limitation”).

Petitioner contends that its “reading is consistent with the specification’s description of positioning the bones ‘as desired’ and then holding that position while

a plate is applied across the joint.” Pet. 29 (quoting Ex. 1001, 7:46–50, 10:26–39).

The portion of column 7 quoted by Petitioner states:

In the embodiments described, cuts are made to bone with respect to the cutting guide, and the bones can be positioned for an additional surgical step, such as bone plating, after the cuts have been made.

Ex. 1001, 7:46–50.

The portion of column 10 quoted by Petitioner states:

When the bone 230 and/or bone 240 have been cut and positioned as desired, the bone cutting guide 20 can be removed. In some embodiments, the cutting guide 20 is temporarily removed from the fixation pins and cut bone is removed from the area. In certain embodiments, an auto graft or other compound is delivered to the area of the bone cuts. Optionally, the guide may then be reset on the bones over the fixation pins and the shaft 100 can be translated within the cavity to adjust the relative position of the bones (*e.g.*, to compress them together). The securing component 90 can [] then be fixed within the securing aperture so the shaft is again fixed relative to the support 30. A bone plate may optionally be applied across the joint while the bones are held in the longitudinally fixed position by the cutting guide.

*Id.* at 10:26–39. But neither passage supports the limiting construction advanced by Petitioner.

Petitioner points to nothing in the claim language, specification, or prosecution history that expressly excludes intervening movement between the

“adjusting” step and the fusion step. Where the claims are silent on a restriction, that restriction cannot be imported. *Omega Eng’g*, 334 F.3d at 1323.

**D. Petitioner’s Written Description Challenge**

Petitioner contends: (1) all claims lack written description for requiring direct attachment of the second cutting guide slot (Pet. 33–36); (2) claims 3 and 21 lack written description for reciting the negative limitations “without the first bone cutting guide slot being positioned over the portion of the metatarsal to be cut” (*id.* at 37–38); and (3) claim 14 lacks written description for encompassing cutting the metatarsal after the cuneiform (*id.* at 38–39).

**1. direct attachment—all claims**

Petitioner’s contentions regarding alleged lack of written description for the claims with respect to the purported “direct attachment” requirement rise and fall with the claim construction of “attached/attaching.” *See* Pet. 33–36 (arguing lack of written description based on a requirement of direct attachment)<sup>3</sup>. Because Petitioner has not established that the claim construction it advances is required, the § 112(a) challenge fails.

Nevertheless, the independent claims recite that the second bone cutting guide slot is “attached to the metatarsal by at least the first fixation pin . . . and the second fixation pin.” Ex. 1001, 11:8–10. The preposition “by” describes the mechanism of

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<sup>3</sup> Petitioner does not allege overbreadth.

attachment through the fixation pins already placed in the metatarsal, not a requirement that the second guide have its own independent bore directly into bone. The specification describes the fixation pins extending through the support and into the metatarsal, and describes the secondary guide member as positioned along the bridge rails relative to those same pins. Ex. 1001, 8:1–12. Figures 9 and 13 from the '397 Patent are reproduced below.

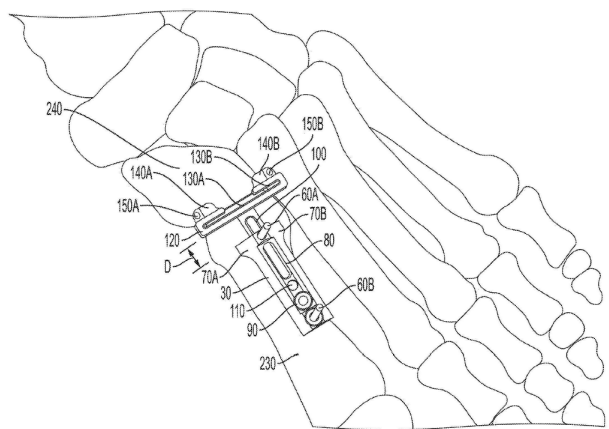


FIG. 9

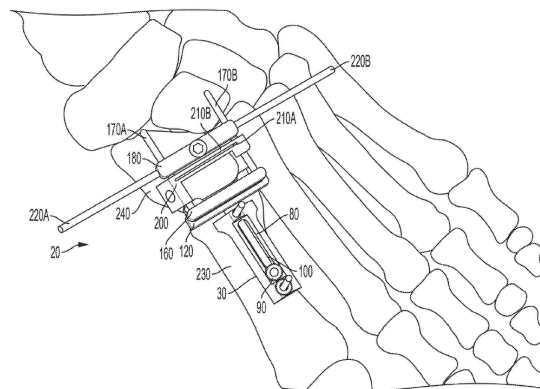


FIG. 13

Figures 9 and 13 illustrate fixation pins 60A, 60B, bridge rails 170A, 170B, and first and second guides 120, 200.

According to Petitioner, “[a] POSA, reading the ’397 patent, would recognize (i) a first guide assembly that can be attached to bone ([Ex. 1001], 7:64–8:7), and (ii) a separate secondary guide member 200 that sits on rails and may be locked to those rails (*id.*, 6:50–51, 7:8–10). In contrast, the patent contains no disclosure that the secondary guide member 200—and therefore the second bone cutting guide slot—is directly attached to the metatarsal, let alone by the same metatarsal fixation

pins that *attached the first bone cutting guide slot.*” Pet. 36 (emphasis added).

The Petition contradicts itself. For example, as seen above, the Petition expressly acknowledges that the first bone cutting guide slot is attached to bone. The specification explains, for example, that “[i]n one embodiment, the support 30 can include a first fixation aperture 50A and a second fixation aperture 50B, each of which can extend through the support 30.” Ex. 1001, 4:1–3. The specification explains: “In some applications, a location of the main guide member 120 relative to the longitudinal axis of the bone 230 can be adjusted without necessitating movement of the support 30. To accomplish this, the shaft 100 at least partially within the inner cavity 40 can be translated relative to the support 30 as shown in the perspective view of FIG. 9.” Ex. 1001, 8:25–30.

As seen above, the specification contemplates even the first cutting guide slot being attached to bone via the fixation pins using intervening components (*i.e.*, the shaft 100 within inner cavity 40), which Petitioner acknowledges provides the “attachment” to bone. Yet Petitioner inexplicably contends that the second cutting guide slot is not “attached” to bone via the fixation pins because of use of intervening elements for the connection therebetween. This internal contradiction further highlights Petitioner’s failure to establish lack of written description.

2. **without the first bone cutting guide slot being positioned—claims 3 and 21**

Petitioner contends: “As written, [claims 3 and 21] require[] that, at the time the cutting member is inserted through the second bone cutting guide slot to cut the cuneiform, the first bone cutting guide slot is (1) no longer positioned over the portion of the metatarsal to be cut and (2) not configured to receive the cutting instrument.” Pet. 37.

Petitioner fails to show that the specification lacks support for the “without” limitation. Even if a requirement of subsequent movement was read into the claim, the specification expressly contemplates moving the first bone cutting guide slot. *See, e.g.*, Ex. 1001, 8:50–53 (“In some embodiments, the main guide member 120 can be used to make additional cuts. In such embodiments, the securing component 90 can be loosened and the shaft 100 can be translated within the cavity to a desired position.”). But subsequent movement is not required.

In one example, the ’397 patent discloses that the metatarsal is cut using the first bone cutting guide slot (Ex. 1001, 9:8–10) and the cuneiform is then cut using the second cutting guide slot (*id.* at 9:16–22). In the cited example, there is no indication that a portion of the metatarsal remains to be cut at the time the cuneiform cut is performed. In the example noted above, once the metatarsal cut is completed, the first slot is no longer positioned over any “portion of the metatarsal to be cut.”

Petitioner does not identify a reason why the claim requires moving the first bone cutting guide slot so it is positioned over a portion of the TMT remaining to be cut and does not establish a lack of written description under § 112(a).

Petitioner contends that after the metatarsal cut is performed, bridge component 160 is inserted into the first cutting guide slot, rendering the first slot “no longer configured to receive a cutting instrument” while it “remains positioned over the portion of the metatarsal.” Pet. 37–38. But this argument depends on reading “portion of the metatarsal to be cut” as referring to a still-uncut target that persists after the metatarsal cut is complete over which the first bone cutting guide slot would be positioned. That reading is not compelled by the claim language.

The phrase “portion of the metatarsal to be cut” identifies the portion that is cut during the recited step, not a condition that must remain after the step is performed. In other words, once the metatarsal cut has been performed, there is no longer a “portion of the metatarsal to be cut” over which the first slot could be positioned, regardless of whether bridge component 160 has been inserted. The bridge insertion itself is entirely consistent with the negative limitation. The specification’s disclosure of an example in which bridge component 160 occupies the first slot after the metatarsal cut is direct evidence that the first slot can transition from a cutting function to a bridging function once the metatarsal cut is complete. Ex. 1001, 9:8–12. This confirms possession of a configuration in which the first slot

is no longer configured to receive a cutting instrument at the time the second guide is used. Petitioner's challenge is undermined by the specification's own disclosed workflow.

Petitioner has not identified any written description gap. After the metatarsal cut is completed, Petitioner has not shown that any "portion . . . to be cut" remains, and thus has not shown the specification fails to convey possession of the claimed "without" condition. To the contrary, once the cut is complete, the first slot would be positioned over a void space created by the cut.

**3. encompassing cutting the metatarsal after the cuneiform—claim 14**

Petitioner argues that claim 14 lacks written description because the specification describes cutting the metatarsal before the cuneiform, whereas claim 14 recites inserting the cutting member through the first bone cutting guide slot to cut the metatarsal after cutting the cuneiform. Pet. 38–39. But Petitioner's argument improperly assumes that the disclosed sequence is exclusive and that the specification must expressly describe every permissible order of otherwise disclosed steps. That is not the written description standard. Petitioner bears the burden to show that the specification affirmatively limits the inventors' possession to one mandatory sequence, but Petitioner identifies no intrinsic statement that the described order is required, essential, or exclusive.

The '397 patent discloses the structural components involved in both cuts and describes how each cut is performed. Ex. 1001, 9:8–22; 9:52–10:11; 6:26–28; 6:51–55. Petitioner does not contend that the specification fails to describe how to perform either cut, nor does it identify any disclosure stating that the metatarsal must be cut first or that reversing the order is excluded. Instead, Petitioner relies solely on the fact that one embodiment describes a particular order of operations and does not even allege that the claim language requires a particular order. But that does not require Petitioner's narrow reading of the claims. *See Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342–43 (Fed. Cir. 2001) (describing a two-part test to determine whether order is required: (1) look to the claim language to determine if, as a matter of logic or grammar, they must be performed in the order written; and (2) if not, look to the rest of the specification to determine whether it directly or implicitly requires such a narrow construction); *see also Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369–70 (Fed. Cir. 2003) (applying the same test).

Notably, the specification's description uses permissive language (*e.g.*, “can” and “optionally”) in describing aspects of the guide assembly and workflow, underscoring that Petitioner has not established that the disclosed sequence is a rigid requirement rather than an example implementation. *See* Ex. 1001, 8:40–10:11. Petitioner also does not identify any disclosure that makes the metatarsal-first order “critical” to the described guide system (*e.g.*, a statement that the system only

functions if the metatarsal is cut first, or that the cuneiform cut cannot be performed first using the disclosed components).

The level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Petitioner’s own expert does not contend that performing the cuts in the claimed order would require any modification to the disclosed guide system or identify any technique the specification fails to describe. Ex. 1002 ¶¶ 179–181; *See Bilstad v. Wakalopulos*, 386 F.3d 1116, 1126 (Fed. Cir. 2004) (holding that in “the mechanical world—a fairly predictable field—it is wholly conceivable that [a disclosed species] may convey to one skilled in the art” possession of the broader claimed subject matter, and faulting the Board for failing to analyze predictability of the field before finding written description deficient).

Where the same disclosed components perform the same disclosed operations, but in a different sequence, a person of ordinary skill in a mechanical field would understand the inventor to have possessed that ordered method. *See Bilstad*, 386 F.3d at 1125–26. The claim recites the same two cutting operations using the same disclosed guide architecture. Petitioner does not demonstrate that a person of ordinary skill would understand the specification to limit the inventors’ possession

to a single, mandatory order of cuts, nor does it identify any teaching that performing the cuts in the claimed order is inconsistent with the disclosed system.

Under these circumstances, Petitioner's reliance on *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336 (Fed. Cir. 2005) is misplaced. *See* Pet. 33. *LizardTech* addressed a fundamentally different written description failure than Petitioner identifies here. There, the specification disclosed only one specific method for achieving a claimed result, yet the claim covered all possible methods of achieving that result including methods nowhere described in the specification. *LizardTech*, 424 F.3d at 1344–45. The patentee claimed an entire genus of solutions while having disclosed only a single species, leaving skilled artisans without any basis to understand the inventor had possessed the unclaimed solutions. *Id.* Petitioner does not make that showing here.

Petitioner does not identify any claim element that lacks a corresponding disclosure, any structural component absent from the specification, or any cutting technique that the specification fails to describe. Nor does Petitioner identify any statement in the specification characterizing the described order as the invention itself, as essential to the disclosed system, or as the only sequence with which the disclosed guide architecture is compatible. Even Dr. Neufeld testifies that “the ’397 patent does not disclose any advantage to cutting the bones in a particular order.” Ex. 1002 ¶ 180. This is not the kind of affirmative limiting characterization that

serves as the basis for *LizardTech* and the cases it relies upon. *LizardTech*, 424 F.3d at 1344–45; *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998) (finding written description deficient where the specification “specifically distinguishes the prior art as inferior and touts the advantage of the [disclosed] shape,” leaving no basis to find possession of generic shapes).

At most, Petitioner shows that the specification’s example proceeds in one order. That showing is insufficient. *LizardTech* does not stand for the proposition that a single illustrative sequence in an example forecloses all other orderings of the same disclosed operations using the same disclosed structures, particularly where the order of steps is not required. Petitioner has not carried its burden to show that the specification fails to reasonably convey to a person of ordinary skill that the inventors possessed the method recited in claim 14.

**E. Petitioner’s Enablement Challenge**

Petitioner contends: (1) all claims lack enablement because the specification discloses only a single integrated guide system and does not enable a broader genus of methods using disassociated first and second guides (Pet. 40–48); and (2) all claims lack enablement because the specification does not enable the cutting and adjusting steps in orders other than the one described (*id.* at 48–50). Petitioner has not established either contention.

Petitioner attempts to invoke *Amgen v. Sanofi*, 598 U.S. 594 (2023) for an

unduly narrow enablement requirement. Pet. 39–40. *Amgen* stated that “[i]f a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent’s specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims.” *Id.* at 610. But *Amgen* went on to explain: “That is not to say a specification always must describe with particularity how to make and use every single embodiment within a claimed class.” *Id.* at 610–611. “[I]t may suffice to give an example (or a few examples) if the specification also discloses ‘some general quality . . . running through’ the class that gives it ‘a peculiar fitness for the particular purpose.’” *Id.* at 611. “[A] specification may call for a reasonable amount of experimentation to make and use a patented invention. What is reasonable in any case will depend on the nature of the invention and the underlying art.” *Id.* at 612.

*Amgen* addressed functional genus claims in an unpredictable biochemical art, where the claims covered an essentially unlimited universe of antibody structures, and the specification left skilled artisans to engage in research-level “trial and error” to discover which molecules would work. *Amgen*, 598 U.S. at 600, 610–15. That context bears no resemblance to the present claims. *See In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991) (“Where, as here, a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of

disclosure will be greater than, for example, the disclosure of an invention involving a ‘predictable’ factor such as a mechanical or electrical element.”); *In re Bowen*, 492 F.2d 859, 862 (C.C.P.A. 1974) (“In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws.”)

The challenged claims here recite a surgical method employing defined structural components (*i.e.*, fixation pins inserted at specified anatomical locations and guide slots positioned relative to those pins) to perform bone cuts in combination with alignment adjustment. Ex. 1001, 10:60–11:18. This is a mechanical and surgical instrumentation context, not a functional genus of unpredictable chemical species. Accordingly, enablement does not require exhaustive disclosure of every permutation within the claim scope, but only sufficient information to allow a POSA to practice the invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The key word is “undue,” not experimentation.

Petitioner identifies no evidence that orthopedic cutting guide design is an unpredictable art akin to antibody engineering or that practicing the claimed structural relationships would require the type of research program condemned in *Amgen*. Instead, Petitioner’s own obviousness analysis, though misplaced, characterizes cutting guide technology as adaptable across different procedures,

anatomies, and approaches, and asserts that a POSA would have had a reasonable expectation of success in modifying such systems. Pet. 52–57. That is, Petitioner itself asserts that this field operates under predictable structural principles, further underscoring why *Amgen* does not control here. Absent proof of undue experimentation across the claim scope, Petitioner’s reliance on *Amgen* is misplaced.

In determining whether undue experimentation would have been required to make and use an invention, the following factors are considered:

- (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

*Wands*, 858 F.2d at 737. Petitioner presents no evidence on the quantity of experimentation required, the predictability of the art, or any specific failures a POSA would encounter. Its failure to do so reflects that the factors do not support Petitioner’s enablement challenges.

**1. disassociated first and second guides—all claims**

Petitioner contends that “the ’397 Patent’s written description only teaches a single species in which both cuts are provided by multiple bone cutting guides connected to each other through a bridge and rails.” Pet. 40–41. According to Petitioner: “The patent nowhere discloses, or even meaningfully contemplates, an

embodiment in which the claimed “first guide” and “second guide” are not associated with each other through other components and are independently attachable to and removable from the metatarsal at separate times.” *Id.* at 41.

Petitioner does not provide the proper analysis (*i.e.*, no weighing of the *Wands* factors, and no conclusion tethered to them). Instead, Petitioner provides a bullet-pointed list of hypothetical design questions a POSA might face when constructing entirely separate standalone guide devices, which are not even tied to the claims. *See* Pet. 46.

Dr. Neufeld does not opine on the quantity of experimentation a POSA would need to undertake, does not identify specific failures a POSA would encounter, does not address the predictability of foot and ankle surgical device design as a field, and does not compare the hypothesized experimentation to the level of skill in the art. He does not testify that a POSA would be required to engage in trial-and-error experimentation rising beyond clinical judgment within the skill of a POSA. This is not an undue experimentation analysis.

Petitioner does not identify any embodiment within the scope of the claims that could not be practiced by a POSA or demonstrate that any such embodiment would require more than adaptation of known surgical guide structures consistent with the ordinary skill level of a POSA. Petitioner’s failure to apply *Wands* through competent evidence is sufficient to defeat its non-enablement theory on this record.

Petitioner’s enablement challenge also rests on the premise that the independent claims encompass a “broad genus” of methods using any two structurally unrelated guides, while the specification teaches only a narrow integrated species. Pet. 40–41. Petitioner then invokes *Amgen* to argue that this asserted mismatch between claimed scope and disclosed embodiments renders the claims unenabled. This theory fails because the claims are not genus claims in the *Amgen* sense, and the specification fully enables any method falling within their actual scope.

Here, each independent claim recites a surgical method with specific, concrete structural requirements: fixation pins inserted into specific bones at specific positions relative to the cutting guide slots, a particular adjustment step, and a fusion step. These limitations do not define an open-ended functional class. Instead, they describe a specific operative technique with defined structural parameters. The “genus” Petitioner alleges by hypothesizing “completely distinct devices . . . from different manufacturers” (Pet. 43) is created by Petitioner, not a genus created by the claim language. Petitioner does not identify any actual claim language that untethers the second guide from the structural pin relationship expressly recited in the claims.

Petitioner also misreads the claims. The independent claims require the second bone cutting guide slot to be “attached to the metatarsal by at least the first fixation pin . . . and the second fixation pin” inserted into the metatarsal. Ex. 1001, 11:8–10.

This is not a functional limitation open to unlimited structural variation. Rather, it is a structural recitation. Petitioner fails to establish that a POSA reading this limitation would not understand that the second guide slot's compatibility with, and location relative to, the metatarsal pins that anchored the first guide. Petitioner likewise fails to show that the specification's disclosed pin-based architecture and secondary guide slot positioning leave a POSA unable to make and use the claimed method without undue experimentation. Petitioner fails to establish that the specification's disclosure of the bridge-and-rails assembly, in which the secondary guide member is positioned relative to the metatarsal through exactly this pin-based architecture, fails to fully enable a POSA to practice the claimed method without undue experimentation.

Petitioner argues that because the claims do not expressly require the bridge-and-rails architecture, they must encompass "individual blocks or jigs" with no structural relationship to one another. Pet. 46. But the enablement inquiry asks whether a POSA can make and use the invention as claimed without undue experimentation, not whether every conceivable structure that might technically satisfy the claim language in the abstract could be built without guidance. *See Wands*, 858 F.2d at 737. Petitioner presents no evidence that designing a second guide compatible with the recited fixation pin configuration would require more than the ordinary skill and standard design judgment possessed by a POSA. Petitioner does not contend that a POSA would be unable to make and use the claimed method

as described in the specification. Instead, Petitioner argues that the claims might theoretically encompass additional configurations the specification does not describe in detail. That theoretical breadth, without proof of undue experimentation across the claim scope, does not establish a lack of enablement.

Petitioner's own obviousness challenge further undermines its enablement challenge. In arguing that a POSA would have been motivated to incorporate Augoyard's guide system into McGlamry's Lapidus procedure, Petitioner repeatedly characterizes cutting guide technology as adaptable across procedures and anatomies and asserts that a POSA would have had a reasonable expectation of success in making such modifications. *See, e.g.*, Pet. 56. And Dr. Neufeld testifies that "a POSA would have recognized that cutting guides can be readily adapted across procedures and anatomies." Ex. 1002 ¶ 93.

Those assertions necessarily depend on the premise that guide design and adaptation fall within predictable structural principles and the ordinary skill in the art. Having argued that a POSA would reasonably expect such adaptations to succeed for purposes of § 103, it is inconsistent for Petitioner to also contend that practicing the claimed scope would require undue experimentation under §112. The Petition offers no explanation reconciling these positions. At minimum, Petitioner offers no coherent explanation for why the same adaptation it deems workable enough to support a reasonable expectation of success would nevertheless require

undue experimentation to practice across the claim scope.

For at least these reasons, Petitioner fails to establish that the claims lack enablement based on “disassociated first and second guides.”

**2. order of procedure—all claims**

Petitioner also alleges lack of enablement because the specification purportedly does not enable the cutting and adjusting steps in any order other than the one described. Pet. 48–50. In particular, Petitioner argues that the specification fails to enable a method in which the adjustment step occurs between the two cutting steps (*i.e.*, the metatarsal is cut, the bones are moved to the fused position, and then the cuneiform is cut). *Id.*

Petitioner’s argument conflates the order in which steps appear in the claim with a requirement that those steps be performed in that order. *See Interactive Gift*, 256 F.3d at 1342 (Fed. Cir. 2001) (“unless the steps of a method [claim] actually recite an order, the steps are not ordinarily construed to require one.”). As discussed above, the independent claims do not expressly require any particular sequence for the cutting and adjusting steps. Petitioner acknowledges this, citing *Interactive Gift*, 256 F.3d at 1342, for the proposition that method steps are not ordinarily construed to require a particular order absent express claim language. Pet. 48. Having acknowledged that the claims impose no required order, Petitioner then argues that the specification’s description of one order fails to enable the claim. Enablement

must be evaluated against the claim as properly construed. To the extent the claims do not require a particular sequence, disclosure of one operative sequence is sufficient to enable the claimed method.

Additionally, and independently, Petitioner acknowledges that the specification discloses that the fixating structure 180 and shaft 100 can be used to “compress[] or expand[] the space between the bones 230 and 240 as needed” after the fixation pins 220A, 220B are seated in the cuneiform and before the secondary guide member 200 is used to perform the cuneiform cut. Pet. 49 (citing Ex. 1001, 9:39–51, 9:63–64). Petitioner dismisses this as a “temporary manipulation to facilitate cutting, not the final ‘moved position’ in which fusion occurs.” *Id.* But Petitioner does not demonstrate, through application of the *Wands* factors or expert testimony, that a POSA would be unable to perform the claimed adjustment step at that stage of the procedure without undue experimentation.

Nevertheless, even under Petitioner’s construction of “moved position” as the final alignment maintained for fusion, Petitioner does not demonstrate that a POSA would be unable to establish that final alignment before completing the cuneiform cut. The claims do not specify when alignment relative to the cuneiform must be established. Petitioner offers no evidence, and Dr. Neufeld provides no testimony, that a POSA could not perform that adjustment as alleged by Petitioner, or that doing so would require undue experimentation.

Petitioner offers no evidence that performing such an adjustment prior to completing the second cut would require experimentation beyond the ordinary skill and clinical judgment possessed by a POSA. Petitioner offers no evidence that a POSA would not understand how to perform this step based on the specification. Petitioner identifies no undue experimentation.

As with its first enablement theory, Petitioner provides three bullet points alleging what the specification purportedly fails to disclose (Pet. 50). But those bullet points are unsupported attorney argument. Dr. Neufeld does not opine on whether a POSA in the field of foot and ankle surgery would be unable to determine how to adjust the metatarsal relative to the cuneiform prior to completing the second cut, or whether such a POSA would face difficulty aligning a cuneiform cut after such an adjustment. Nor does he apply the *Wands* factors to this theory. Petitioner fails to establish that a skilled foot and ankle surgeon would not exercise exactly this kind of intraoperative judgment. Petitioner has not established through competent evidence that a POSA would face undue experimentation in performing the claimed methods.

Petitioner's obviousness challenge again undercuts its enablement challenges. Petitioner's obviousness challenge assumes that a POSA would have had a reasonable expectation of success modifying surgical workflows to incorporate guide-assisted cutting. Pet. 52–56. Yet in its enablement challenge Petitioner

suggests that performing cutting and adjustment steps in alternative sequences raises unresolved concerns. Pet. 48–50. It is inconsistent for Petitioner to allege that a field is sufficiently predictable to support a reasonable expectation of success under § 103 while simultaneously requiring undue experimentation to practice the claimed method under § 112. Petitioner identifies no evidence bridging that gap. Petitioner offers no coherent explanation for why the workflow changes it asserts are workable enough to support reasonable expectation of success would nevertheless require undue experimentation to practice.

In fact, Petitioner’s own expert testimony is directly inconsistent with its order-of-procedure enablement theory. In his § 103 analysis of claim 14, for example, Dr. Neufeld testifies that performing the metatarsal and cuneiform cuts in an alternative order would be “predictable” and a matter of “surgeon preference.” Ex. 1002 ¶¶ 179–181. Petitioner offers no explanation reconciling Dr. Neufeld’s § 103 testimony with its § 112 enablement theory, and none is apparent. Absent evidence that the claimed method cannot be practiced without undue experimentation across its scope, Petitioner has not met its burden.

For at least these reasons, Petitioner fails to establish that the claims lack enablement based on the “order of procedure.”

**F. Petitioner’s Obviousness Challenges**

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the

claimed invention and the prior art are such that the claimed invention as a whole would have been obvious at the time of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved based on underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in the record, objective evidence of non-obviousness. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17–18 (1966). Obviousness requires that a petitioner establish both (1) a reason to combine or modify the prior art and (2) a reasonable expectation of success in doing so. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016). Conclusory assertions are insufficient.

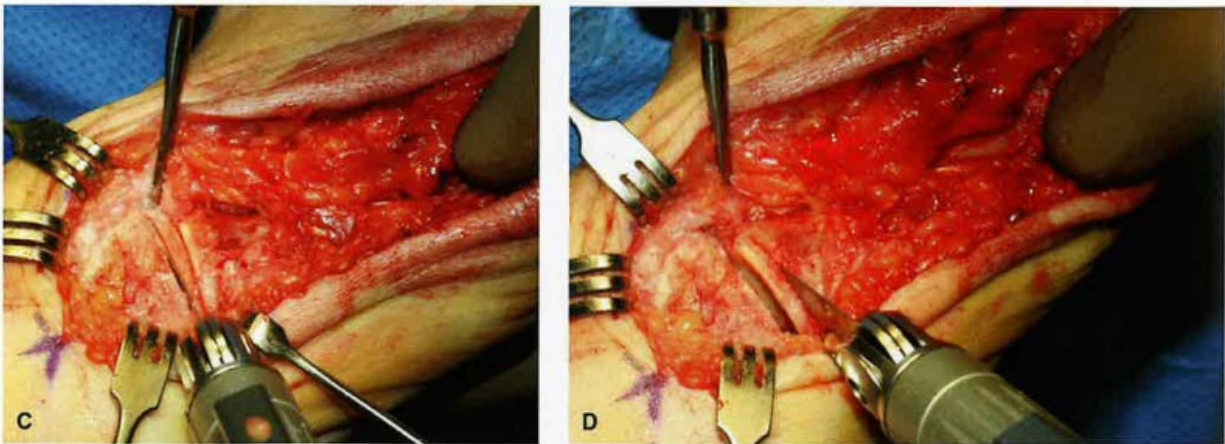
**1. Claim 1**

***a. Background***

Petitioner cites McGlamry as teaching a Lapidus procedure and proposes modifying that procedure to include a cutting guide like Augoyard's. Pet. 51–69. Notably, McGlamry describes a freehand procedure that has been performed since the 1930's. Ex. 1005, 322. Petitioner repeatedly alleges that “it would have been obvious to use a cutting guide like Augoyard's to perform McGlamry's bunion correction method by positioning the first bone cutting guide slot over the proximal

portion of the first metatarsal that McGlamry discloses should be cut.” Pet. 59 (citing Ex. 1002 ¶¶ 103–105); *see also* 60, 62, 63, 65, 68. Dr. Neufeld’s testimony repeatedly parrots the Petition without offering further evidence-based analysis.

Petitioner’s citations to McGlamry are generally related to cutting the proximal end of the metatarsal (Pet. 60 (citing Ex. 1005, 324)) and cutting the distal end of the cuneiform (Pet. 63 (citing Ex. 1005, 324)) for a fusion procedure. Figures 55.7C and 55.7D in McGlamry, reproduced below, illustrate similar cuts in progress using McGlamry’s freehand technique.



The figure reproduced above illustrates cuts being performed on the cuneiform (55.7C on left) and on the metatarsal (55.7D on right). Figure 14 of the '397 Patent is reproduced below to illustrate the location of cuts as claimed.

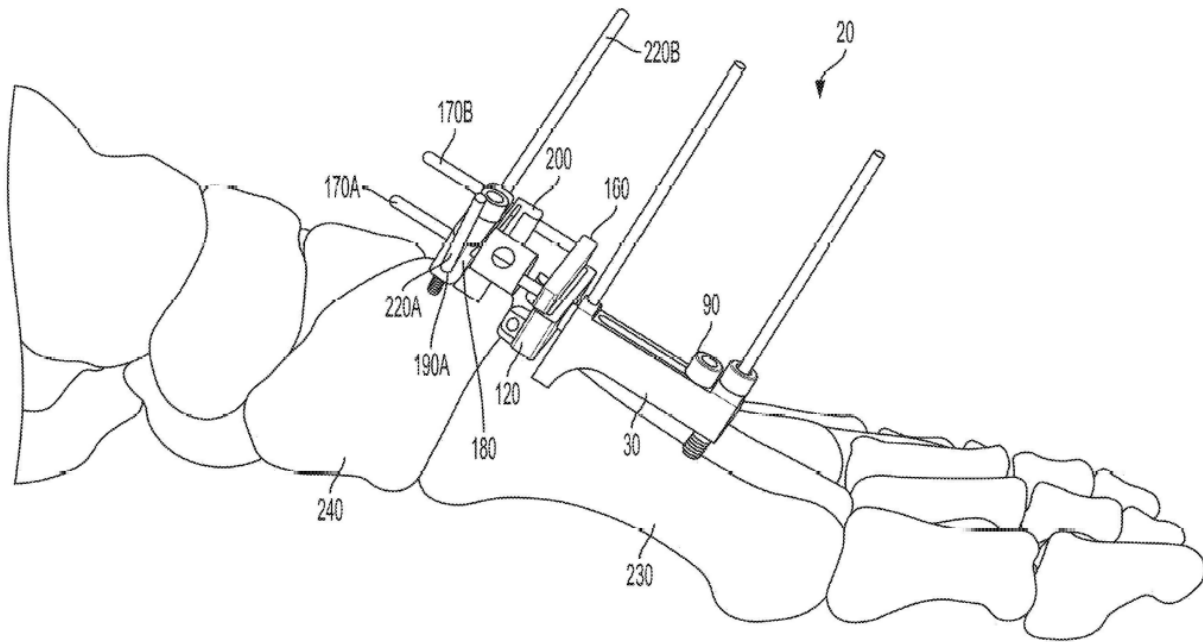


FIG. 14

Figure 14 is a perspective view of the '397 Patent's cut guide positioned over the first tarsometatarsal (TMT) joint (*i.e.*, the joint between the metatarsal 230 and cuneiform 240).

Petitioner provides an annotated version of Augoyard's FIG. 22, reproduced below.

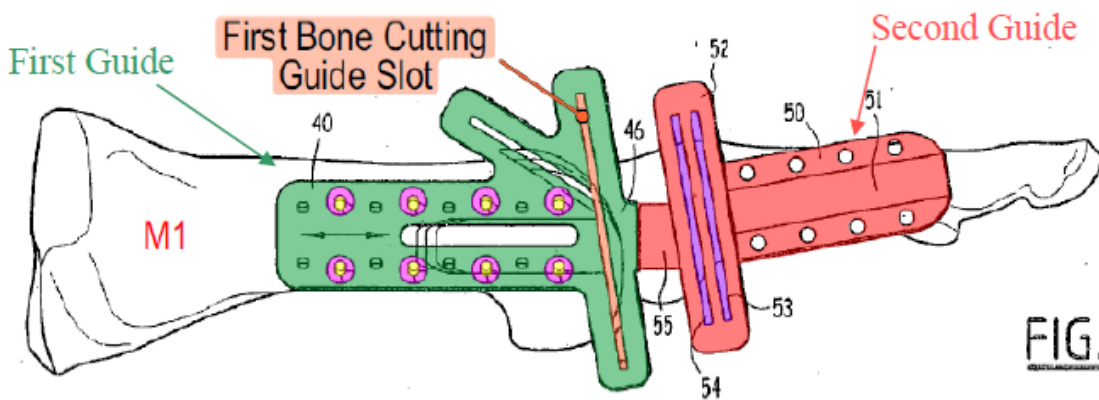


FIG. 22

The figure reproduced above is Augoyard's FIG. 22, which "shows a side view of the ancillary phalangeal cutting instrument positioned on the ancillary metatarsal cutting instrument" (Ex. 1007 ¶ 36), along with Petitioner's annotations labeling the portions of Augoyard's cut guide that purportedly map to the cut guide recited in claim 1. Pet. 59.

Augoyard states that its cut guide "relates to a new total metatarsophalangeal prosthesis, known as a 'cut prosthesis,' in particular for the joint between the first metatarsal bone and the first phalanx of the big toe, as well as ancillary instruments for fitting this prosthesis." Ex. 1007 ¶ 1. Augoyard's cut guide is not described as appropriate for use in a Lapidus bunion correction surgery. In fact, it is for a different purpose (joint prosthesis, *i.e.*, joint replacement, rather than joint fusion) and at a different joint (first metatarsophalangeal (MTP) joint rather than the TMT joint).

Petitioner's challenge rests on whether it would have been obvious to use a cutting guide like Augoyard's, which is for a joint replacement at the MTP joint, in McGlamry's Lapidus procedure, which is for fusion at the TMT joint. *See* Pet. 51–69. Petitioner's contentions fail for multiple reasons.

***b. Petitioner's § 112 and § 103 Theories Are Internally Inconsistent***

Before addressing Petitioner's § 103 challenge in detail, Patent Owner notes a threshold problem that runs through all of Petitioner's grounds. For purposes of § 112, Petitioner contends that guide compatibility and step sequencing cannot be

determined without undue experimentation for a cut guide positioned at the TMT joint. Pet. 40–51. For purposes of § 103, however, Petitioner contends that a POSA would have had a reasonable expectation of success combining disparate guide systems at a different joint for different surgical purposes, and then adapting them to a new surgical workflow. Pet. 56–58. Petitioner offers no explanation reconciling these positions because none exists.

*c. Arguments*

Institution should be denied because Petitioner’s § 103 theory depends on a chain of unsupported hindsight adaptations rather than record-supported teachings. The claims require a specific pin-based guide architecture used in a staged metatarso-cuneiform (*i.e.*, TMT) fusion workflow, not merely the generic use of a cutting guide in bunion surgery.

The Petition does not identify evidence that a POSA would have selected Augoyard’s joint replacement-driven MTP guide system and adapted it to McGlamry’s Lapidus/TMT fusion procedure where the joint is fused and not replaced. Instead, Petitioner relies on generalized assertions that cutting guides improve precision and efficiency, coupled with conclusory expert testimony. Petitioner’s mapping effectively repurposes Augoyard’s phalanx and metatarsal cutting sequence to a different joint and surgical objective than Augoyard describes, and then assumes without record-supported analysis that the claimed shared-pin

architecture and workflow would carry over with a reasonable expectation of success. But even the placement of the cut guide is different (lateral in Augoyard for MTP joint replacement versus dorsal in the '397 Patent for TMT fusion), not to mention the orientation of the cutting guide slots on the portions of the different bones to be cut. *See* Ex. 2029 ¶¶ 33–34 (Dr. Farber describing the differences and explaining why these are significant relative to the proposed use of Augoyard's cut guide for a Lapidus procedure).

As discussed below, McGlamry prescribes a careful freehand technique and radiographic confirmation for Lapidus preparation and does not suggest importing a dual-slot, interconnected guide architecture into that procedure. Nor does Augoyard teach or suggest use of its joint replacement-oriented system in a staged joint fusion workflow which involves a different joint and surgical objective. On this record, Petitioner has not shown it is more likely than not that any challenged claim would have been obvious.

***i. McGlamry Favors Freehand Technique, Not Instrumentation***

Petitioner's rationale begins with the observation that McGlamry emphasizes the importance of precise bone cutting and warns that inaccuracies may lead to complications such as shortening, delayed union, or non-union. Pet. 51–52 (citing Ex. 1005, 324, 329; Ex. 1002 ¶ 82). McGlamry indeed describes joint preparation as “extremely important” and warns of potential complications. Ex. 1005, 324, 329.

But recognition that precision matters does not constitute a teaching or suggestion to abandon the disclosed freehand technique. *See InTouch Techs., Inc. v. VGo Commc'ns, Inc.*, 751 F.3d 1327, 1351 (Fed. Cir. 2014) (reversing invalidity finding where expert “opined that all of the elements of the claims disparately existed in the prior art, but failed to provide the glue to combine these references”).

The relevant question is not whether precision is desirable. It is whether Petitioner supplies a sufficient reason to replace McGlamry’s disclosed freehand preparation technique with Augoyard’s procedure-specific, interconnected, dual-slot architectural system that coordinates cutting geometry across bones through shared fixation pins. *See KSR*, 550 U.S. at 418 (requiring “some articulated reasoning with some rational underpinning” to support combining prior art references in the particular manner claimed).

McGlamry describes the Lapidus fusion procedure using freehand resection and affirmatively presents a careful surgical technique, not instrumentation, as the means of avoiding complications. *See Ex. 1005*, 324 (“the articular joint resection needs to be kept consistent and parallel with the natural occurring anatomy”). McGlamry’s recommended solution to the risk of imprecise cutting is surgeon diligence and time spent on joint preparation, not a guide system. *Id.* (“[a] substantial period of time is spent preparing this joint as this is a vital portion of the procedure”). That is a meaningful teaching.

McGlamry does not characterize the freehand technique as deficient. It does not recommend replacing freehand cuts with a guide system. And it does not suggest attaching interconnected guides across the metatarsal and cuneiform. Petitioner does not identify any evidence that McGlamry contemplated instrumentation as complementary to its disclosed technique. The Petition transforms general surgical caution into an implied directive to redesign the procedure without support. A generalized recognition that precision is important is not a specific reason to restructure the disclosed surgical workflow in the particular manner required by the claims. *See InTouch Techs.*, 751 F.3d at 1351 (“A reason for combining disparate prior art references is a critical component of an obviousness analysis; ‘this analysis should be made explicit.’”).

Dr. Farber testifies that experienced foot and ankle surgeons were aware of cutting guide technology and made a deliberate clinical choice not to recommend guide instrumentation for Lapidus joint preparation for fusion, reflecting a considered judgment about the technique’s suitability for that specific procedure rather than an oversight. *See Ex. 2029 ¶¶ 19–23, 35.*

McGlamry explains that “[m]alunions associated with the procedure can be avoided with intraoperative radiographs to establish correct positioning in all three planes of motion.” Ex. 1005, 329. McGlamry’s prescribed remedy for the very complication Petitioner invokes is radiographic verification, not a different cutting

method. McGlamry prescribes its own answer to the identified problem. Neither the Petition nor Dr. Neufeld's declaration explains why intraoperative radiographic confirmation, McGlamry's own prescribed solution, was insufficient, or why a POSA would have looked beyond it to Augoyard's interconnected guide structure.

Dr. Farber testifies that intraoperative radiographic confirmation was the recognized standard of care for verifying metatarso-cuneiform alignment in Lapidus fusion at the time of the claimed invention, and that a POSA would have understood it as the established clinical remedy for the malunion risk McGlamry identifies rather than as an inadequate substitute for a guide system. Ex. 2029 ¶¶ 23, 25.

***ii. McGlamry's Own Disclosure of Cutting Guides Elsewhere Weighs Against the Combination and is Confirmed by McGlamry's Subsequent Edition***

McGlamry's own disclosures underscore the absence of a motivation to modify its Lapidus procedure. McGlamry expressly discusses the use of cutting guides in other surgical contexts, including joint replacement-related bone resections that "help the surgeon resect the proper amount of bone and at the proper angles." Ex. 1005, 381–383; *see also* Ex. 1002 ¶ 84 (acknowledging use of cutting guides elsewhere). Thus, McGlamry was plainly aware of cutting guide technology and its potential benefits.

At the same time, McGlamry acknowledges that precise preparation of the

TMT joint in the Lapidus procedure is “extremely important” and that errors in freehand cutting can lead to complications such as shortening, delayed union, and non-union. Ex. 1005, 324, 329. Yet despite recognizing both (i) the availability of cutting guides and (ii) the challenges of freehand bone resection in the Lapidus context, McGlamry does not recommend or even suggest using cut guides in the Lapidus procedure at all, let alone with a dual-slot cutting guide system like Augoyard’s. McGlamry’s authors knew cutting guides existed for foot surgery, knew precise bone cutting mattered in Lapidus procedures, and yet did not recommend a guide. That omission is meaningful and weighs heavily against Petitioner’s assertion that a POSA would have been motivated to apply guide instrumentation in this context.

This conclusion is further reinforced by the subsequent edition of McGlamry itself (which post-dates the ’397 Patent priority date). The fifth edition of McGlamry’s *Foot and Ankle Surgery*, published May 21, 2021<sup>4</sup> expressly states in its *Surgical Pearls for the Lapidus bunionectomy*: “make precise cuts utilizing a cutting jig (preferred by authors),” which is based on Patent Owner’s invention that became the standard for care. Ex. 2003, 300. That express recommendation appears nowhere in the fourth edition on which Petitioner relies.

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<sup>4</sup> After the January 7, 2015 priority date of the ’397 Patent.

The later edition of McGlamry reflects that guide-assisted Lapidus cutting was treated as a refinement worth expressly identifying and recommending. The later edition's adoption of cutting jigs does not confirm what a POSA already knew. If that were true, any subsequent refinement adopted by practitioners would be rendered obvious in retrospect. The relevant question is not whether guide-assisted Lapidus surgery was eventually adopted, but whether the prior art as it existed at the priority date supplied a reason to make that specific modification. The fourth edition, which is the only McGlamry before the Board, did not.

The express identification of guide-assisted cutting as worthy of recommendation in 2021 confirms that the fourth edition (the only McGlamry before the Board) did not supply that recommendation. Petitioner's hindsight reading imparts the later edition's endorsement onto the earlier edition's silence.

***iii. The Petition's Reasoning is Overgeneralized***

Petitioner asserts that a POSA would have been motivated to use Augoyard's guide to simplify the procedure, reduce time under anesthesia, increase repeatability, and reduce complications. Pet. 52–55. These are universal surgical objectives applicable to virtually any orthopedic procedure. And it is not even clear that the purported benefits noted by Petitioner would be attained from using Augoyard's MTP joint replacement cut guide in a Lapidus TMT joint fusion procedure. *See Ex. 2029 ¶ 21–23* (Dr. Farber explaining why the purported benefits do not necessarily

flow from the proposed modifications and describing the difficulties with adapting a cut guide from a different procedure).

If such generalized goals were sufficient to establish a motivation to combine, nearly every surgical technique described in the prior art would be obvious to convert into a guide-based procedure, which the obviousness inquiry is specifically designed to prevent. *KSR*, 550 U.S. at 421. *KSR* did not dispense with the requirement of articulated reasoning. Rather, it reaffirmed that the obviousness analysis must be made explicit and supported by a rational underpinning. *Id.* at 418.

Petitioner invokes the *KSR* rationale that it would have been obvious to apply a known technique to improve a similar method in the same way, arguing that both McGlamry and Augoyard involve a joint between the first metatarsal and an adjacent bone. Pet. 55. But superficial procedural similarity does not establish the required motivation.

Augoyard's guide system is architecturally integrated around implant geometry for a joint replacement procedure, not a fusion procedure. The adjacent bone in Augoyard is the phalanx, while the adjacent bone in McGlamry's Lapidus procedure is the cuneiform. The surgical objective (*i.e.*, implant seating and positioning versus fusion) is fundamentally different. Petitioner does not explain why a POSA would conclude that a guide designed around prosthetic implant geometry at the MTP joint would transfer to a staged fusion workflow at the TMT

joint, or how the shared-pin attachment architecture the claims require would be achieved in that adaptation. The superficial similarity that both procedures involve the first metatarsal and an adjacent bone does not bridge those architectural and workflow differences.

Dr. Farber testifies that from the perspective of a practicing foot and ankle surgeon, MTP joint replacement and TMT fusion are fundamentally different procedures in terms of surgical objective, intraoperative decision-making, alignment strategy, and fixation approach, such that instrumentation developed for one context would not be understood as transferable to the other without procedure-specific redesign. *See* Ex. 2029 ¶¶ 21–22, 30–31, 33–34. Dr. Farber further explains that the intraoperative alignment adjustment required in Lapidus fusion (*i.e.*, positioning the metatarsal relative to the cuneiform to correct the deformity before completing the second cut) has no analog in Augoyard’s implant-driven workflow, where guide geometry is dictated by prosthetic implant requirements rather than by bone positioning decisions, and that a POSA would have recognized this as a fundamental architectural difference rather than a minor modification. Ex. 2029 ¶ 21–23, 25, 31, 33–34.

This is illustrated by the above discussion of the later McGlamry edition itself. Even the reference relied on by Petitioner (McGlamry) did not treat guide-assisted cutting as a given in the edition relied upon. It treated the technique as worthy of

express identification and endorsement only in a later edition. That sequencing is itself evidence of hindsight.

Dr. Farber confirms that guide-assisted Lapidus cutting was not standard or recognized clinical practice at the priority date and that the technique represented a genuine advance in surgical methodology rather than an obvious application of instrumentation tools that were already known and available to foot and ankle surgeons. *See* Ex. 2029 ¶¶ 19, 25, 35.

***iv. The Petition's Reasoning is Not Based on Record Evidence***

Petitioner's motivation theory depends heavily on Dr. Neufeld's declaration, particularly paragraphs 82–92. *See* Pet. 51–56 (citing Ex. 1002 ¶¶ 82–92). Those paragraphs largely restate that precision is important, that cutting guides reduce guesswork, and that a POSA would have recognized benefits from incorporating Augoyard's guide into McGlamry's procedure. The declaration does not identify any passage in McGlamry suggesting dissatisfaction with the disclosed freehand Lapidus technique, nor does it cite any teaching in Augoyard recommending application of its guide to metatarso-cuneiform fusion. Petitioner connects McGlamry's union concerns to Augoyard's specific guide structure based on Haddad's generalized disclosure of complementary bone surfaces, not from any teaching in McGlamry or Augoyard themselves.

The Petition asserts that a POSA would have been motivated to incorporate

Augoyard's dual-slot cutting guide into McGlamry's Lapidus procedure because cutting guides were known to create complementary bone surfaces that "easily and effectively achieve a union through biological healing." Pet. 54 (citing Ex. 1013 ¶ 68). This is the only portion of Haddad Petitioner cites in its discussion of rationale for the proposed modifications. Petitioner additionally cites Haddad in its reasonable expectation of success discussion (addressed further below) as a single parenthetical: "Ex.1013, [0057]-[0058] (describing how the jig and guide can be used in multiple metatarsal procedures and other anatomies, such as the hand)." Pet. 56.

Haddad does disclose a cutting guide (100) coupled to a jig (12), with dual cutting slots (104, 106) configured to guide a surgical saw in cutting opposing bone segments so as to create complementary surfaces that may "easily and effectively achieve a union through normal biological healing." Ex. 1013 ¶ 68. Although Haddad notes that its components may be used independently (Ex. 1013 ¶ 55), the cutting guide's disclosed purpose and entire operational context is primarily presented in connection with Haddad's integrated fixation system. That system is a compression plate and adjustable jig assembly designed to guide placement of the fixation. Petitioner does not assert any teaching where Haddad's cutting guide would be used as a freestanding joint resection technique divorced from that fixation system. Petitioner cites no evidence that a POSA would have understood it that way.

Dr. Farber testifies that the general principle that complementary planar bone

surfaces can promote union does not translate into a procedure-specific rationale for replacing McGlamry's freehand Lapidus technique with a dual-slot interconnected guide system. *See* Ex. 2029 ¶ 26. The clinical factors governing union in TMT fusion involve bone preparation quality, fixation stability, and alignment accuracy in combination. *See id.* A POSA would not have understood Haddad's generalized union principle as directing attention to Augoyard's implant-centric guide architecture as a solution to the union concerns McGlamry identifies. *See id.*

The Petition's reasoning can be summarized as follows: (1) precision promotes union (Haddad); (2) McGlamry discusses union risks; therefore (3) a POSA would have modified McGlamry by incorporating Augoyard's specific interconnected guide structure. At each step, the Petition again relies on superficial similarity rather than an articulated analytical link. Petitioner points to the superficial similarity that both Haddad and the claimed method involve cutting guides that create complementary bone surfaces, without addressing the structural and functional differences between Haddad's integrated fixation-system context and the staged Lapidus fusion workflow the claims require.

Even accepting Haddad as evidence of general knowledge that complementary planar bone surfaces can promote union, that principle does not supply the missing link required here. McGlamry already recognizes that precise preparation of the metatarso-cuneiform joint is "extremely important" and prescribes

careful freehand technique and intraoperative radiographic confirmation to avoid complications. Ex. 1005 at 324, 329. Haddad does not suggest that delayed union in Lapidus procedures was understood to stem from inadequacy of freehand resection, nor does it teach that surgeons were motivated to replace established freehand joint preparation with a dual-slot cutting guide system such as Augoyard's. An explanation of why a POSA would have concluded that the union concerns identified in McGlamry warranted replacing its disclosed freehand technique with cut guides (let alone Augoyard's specific interconnected guide system for a different purpose at a different joint) is absent from the Petition and from Dr. Neufeld's declaration alike.

Conclusory expert assertions cannot substitute for record evidence supplying an articulated rationale. Here, Dr. Neufeld does not identify any teaching in McGlamry suggesting dissatisfaction with freehand Lapidus preparation, nor any teaching in Augoyard recommending application of its guide to metatarso-cuneiform fusion. Instead, he relies on Haddad's generalized statement about complementary bone surfaces and then concludes that a POSA would have been motivated to combine the asserted references. That leap is not grounded in the prior art of record or any other evidence submitted by Petitioner.

Dr. Farber directly addresses Dr. Neufeld's motivation to combine opinions and explains why the generalized cutting guide benefits Dr. Neufeld identifies (*e.g.*,

precision, reduced guesswork, procedure simplification) do not constitute a procedure-specific rationale for adapting Augoyard's implant-driven MTP guide system to McGlamry's Lapidus fusion workflow. *See* Ex. 2029 ¶¶ 21–22. Dr. Farber further explains that a POSA familiar with both procedures would not have understood those general benefits as directing attention to Augoyard's specific guide architecture as a solution to the challenges of Lapidus joint preparation. *See* Ex. 2029 ¶ 23.

***v. Petitioner Has Not Established a Reasonable Expectation of Success***

Petitioner uses Weinstein and Alchermes in its reasonable expectation of success contentions to support the proposition that cutting guides are adaptable across procedures and anatomies. Pet. 56–57. But reasonable expectation of success requires more than general adaptability. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (The reasonable expectation of success requirement “refers to the likelihood of success in combining references to meet the limitations of the claimed invention.”).

Neither Weinstein nor Alchermes supplies that basis. Alchermes discloses a surgical instrument for achieving acute angle osteotomy cuts directed to a single-bone cut at the medial surface of the first metatarsal head. Ex. 1023, Abstract; 5:40–48. Petitioner identifies no disclosure of metatarso-cuneiform fusion, joint preparation across two bones, or any fusion methodology. The broad statement that

the instrument is “applicable to such cutting as related to any skeletal elements of the body” (*id.* at 7:44–46), does not supply a procedure-specific understanding that relates Alchermes to a staged two-bone fusion workflow.

Weinstein identifies a Lapidus-type procedure as one that “may benefit” from its osteotomy guide apparatus in a single sentence. Ex. 1015 ¶ 51. Petitioner identifies nothing in Weinstein disclosing a method for performing such a procedure using cutting guides, a sequential cut workflow, an intraoperative alignment step between cuts, or a fusion-specific protocol.

Petitioner does not identify teachings in either reference related to how cutting guides would be configured, positioned, or used in a metatarso-cuneiform fusion workflow, what the expected outcome of such use would be, or why a POSA would have anticipated success in that specific context rather than merely recognizing a theoretical possibility. Petitioner has not established a reasonable expectation of success because the cited reference provides only aspirational language about potential applications without disclosing the specific procedure at issue. *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988) (no reasonable expectation of success where prior art “gave only general guidance as to the particular form of the claimed invention or how to achieve it”).

Augoyard also provides no basis for a reasonable expectation of success. Augoyard’s guide system is designed around a joint replacement workflow for MTP

joint replacement, not a staged fusion procedure requiring intraoperative alignment adjustment between cuts and fusion of the metatarso-cuneiform joint. Pet. 12–14. Petitioner’s own characterization of Augoyard confirms that its guide geometry is dictated by prosthetic implant requirements, not by the bone positioning and fusion objectives that define the claimed procedure. *See* Pet. 12–13 (“Augoyard discloses a prosthesis for replacing the metatarsophanageal (sic) joint and instruments for preparing the bones and placing the prosthesis” and has “interlocking cutting guides ensure precise orientation of the cuts to the metatarsal and phalanx.”). Petitioner identifies nothing in Augoyard that teaches or suggests that its guide system would succeed when extracted from that implant context and applied to a two-bone fusion workflow with an intervening alignment step.

Rather, Augoyard’s specific guide and attachment arrangement is dictated by the geometry of the MTP joint. Dr. Farber testifies that the specific modifications Petitioner characterizes as minor (*i.e.*, reorienting the second guide from phalanx geometry to cuneiform geometry, repositioning the fixation pin relationship from the distal to the proximal metatarsal, and adapting an implant-driven guide to a fusion workflow requiring an intraoperative alignment adjustment between cuts) involve non-trivial surgical and instrumentation design considerations that a POSA would not have expected to resolve without procedure-specific development work. Ex. 2029 ¶¶ 33–34. Dr. Farber further explains that the intraoperative alignment step

between the two cuts (*i.e.*, adjusting metatarsal position relative to the cuneiform to establish the fusion alignment before completing the cuneiform cut) fundamentally changes the surgical workflow in ways that Augoyard’s implant-geometry-driven system does not accommodate. *See* Ex. 2029 ¶¶ 23, 31. Dr. Farber testifies that a POSA would not have had a reasonable basis to expect that Augoyard’s guide system could be adapted to incorporate that step without resolving significant design questions about guide compatibility, pin placement, and slot geometry that the prior art does not address. Ex. 2029 ¶¶ 30–31, 33–34.

The internal inconsistency between Petitioner’s § 112 and § 103 positions, noted above, again undercuts Petitioner’s position here. If, as Petitioner contends for § 112 purposes, guide compatibility requires resolving numerous unresolved structural and geometric design considerations, a POSA would not have had an objectively reasonable expectation of success achieving that same compatibility for § 103 purposes. What Petitioner characterizes as “minor modifications” for § 103 purposes (*i.e.*, reorienting the second guide from phalanx geometry to cuneiform geometry, repositioning the fixation pin relationship from the distal to the proximal metatarsal, and adapting an implant-driven guide to a fusion workflow (Pet. 57)) are precisely the structural and geometric design considerations Petitioner elsewhere characterizes as raising unresolved § 112 questions that a POSA cannot navigate without undue experimentation (*id.* at 40–45).

Petitioner characterizes the same design questions as raising meaningful architectural challenges for § 112 while dismissing them as minor for § 103. This internal inconsistency independently defeats Petitioner's reasonable expectation of success showing.

**2. Claims 2–19**

Claims 2–19 depend from claim 1. Petitioner fails to establish that it is more likely than not that it would prevail at trial on any of these claims for the reasons set forth above regarding claim 1.

**3. Claims 20–30**

Claims 20 and 29 are independent, with claims 21–28 and 30 depending therefrom, respectively. The issues with the challenge to claim 1 identified above are also present in Petitioner's challenges to claims 20 and 29. *See* Pet. 87–90, 94. Petitioner fails to establish that it is more likely than not that it would prevail at trial on any of claims 20–30 for the reasons set forth above regarding claim 1.

**4. Summary**

Petitioner has not carried its burden of showing that it is more likely than not that at least one claim would have been obvious. Petitioner has not articulated a specific, record-supported reason to modify McGlamry's Lapidus procedure in view of Augoyard. Instead, the Petition relies only on generalized surgical goals, conclusory expert testimony, and inferences unsupported by the references. The

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reasonable expectation of success analysis fails independently for the reasons discussed above. The subsequent evolution of McGlamry confirms rather than cures these deficiencies.

For at least these reasons, the Petition fails to establish that it is more likely than not that any claim would have been obvious.

### III. CONCLUSION

For at least the reasons set forth above, Petitioner has failed to establish that it is more likely than not to succeed in its challenges on any claim of the '397 Patent.

Dated: April 1, 2026

Respectfully Submitted,

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**CERTIFICATE OF WORD COUNT**

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this Patent Owner's Preliminary Response complies with the type-volume limitation of 18,700 words provided in 37 C.F.R. § 42.24(a)(1)(ii), (b)(1). The word processing program used to prepare Patent Owner's Preliminary Response indicates that it contains 12,860 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 1, 2026

/Joshua Van Hoven/  
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Counsel for Patent Owner

**CERTIFICATE OF SERVICE**

The undersigned certifies that on the 1 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-397@morganlewis.com to the below counsel of record for Petitioner per Petitioner’s consent for electronic service (*see* Paper 1 at 100).

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