Paper No. 14 Date: April 19, 2023

# UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD LIFE SPINE, INC., Petitioner, v. GLOBUS MEDICAL, INC., Patent Owner. IPR2022-01435

Patent 10,137,001 B2

Before KRISTI L. R. SAWERT, CYNTHIA M. HARDMAN, and MICHAEL A. VALEK, *Administrative Patent Judges*.

SAWERT, Administrative Patent Judge.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314
Granting Petitioner's Motion to File Under Seal
37 C.F.R. §§ 42.14, 42.54

### I. INTRODUCTION

Petitioner Life Spine, Inc. requests *inter partes* review of claims 1–11 of U.S. Patent No. 10,137,001 B2 ("the '001 patent," Ex. 1001). Paper 2 ("Pet."). Patent Owner Globus Medical, Inc. filed a Preliminary Response. Paper 9 ("Prelim. Resp."). With our authorization, Petitioner filed a Preliminary Reply and Patent Owner filed a Preliminary Sur-reply. Paper 10 ("Prelim. Reply"); Paper 11 ("Prelim. Sur-reply"). <sup>1</sup>

We have authority under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." After considering the Petition, Preliminary Response, Preliminary Reply, Preliminary Sur-reply, and associated evidence, we institute an *inter partes* review.

The following preliminary findings of fact and conclusions of law are made solely for determining whether to institute review. Any final decision will be based on the full trial record.

### A. Real Parties in Interest

Petitioner and Patent Owner each identify themselves as the real party in interest. Pet. 1; Paper 7 (Patent Owner's First Updated Mandatory Notices), 1.

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<sup>&</sup>lt;sup>1</sup> The Board observes that both parties delete spacing between words, in an apparent effort to circumvent our word count limits. For example, Petitioner uses "EX1001," while Patent Owner uses "Ex-1001." *See, e.g.*, Pet. 1; Prelim. Resp. 3. The parties are cautioned that continuing this practice may lead to a party's brief not being considered. *See* Consolidated Office Trial Practice Guide (Nov. 2019) ("Consolidated TPG"), at 40, *available at https://www.uspto.gov/TrialPracticeGuideConsolidated*.

### B. Related Matters

The parties identify *Globus Medical, Inc. v. Life Spine, Inc.*, 1:21-cv-01445 (D. Del.), as involving the '001 patent. Pet. 1; Paper 7, 1. The parties also identify a number of patent applications related to the '001 patent, i.e., 17/192,231, 17/409,079, 17/410,335, 17/589,029, and 17/931,913. Pet. 1–2; Paper 7, 1. Patent Owner also identifies a number of related *inter partes* review proceedings, i.e., IPR2022-01434, IPR2022-01599, IPR2022-01600, and IPR2023-00041. Paper 7, 1.

# C. The '001 Patent (Ex. 1001)

The '001 patent, titled "Expandable Fusion Device and Method of Installation Thereof," relates to an expandable device for insertion between adjacent vertebrae to facilitate fusion and a method for promoting intervertebral fusion using the expandable device. Ex. 1001, code (54), 1:19–22. According to the Specification, a need exists for a fusion device that is "capable of being installed inside an intervertebral disc space at a minimum to no distraction height and . . . can maintain a normal distance between adjacent vertebral bodies when implanted." *Id.* at 1:57–61. The '001 patent purports to meet this need with a fusion device including first and second endplates and a central ramp capable of moving in a first direction to push the endplates outwardly into an unexpanded configuration. *Id.* at 2:2–6. The fusion device can be placed into a disc space via an endoscopic tube and then expanded into an expanded configuration. *Id.* at 2:6–9.

The Specification describes exemplary expandable fusion devices for installing in an intervertebral disc space to facilitate intervertebral fusion.

*Id.* at 1:65–2:2. One exemplary device is depicted in Figure 50, reproduced below.

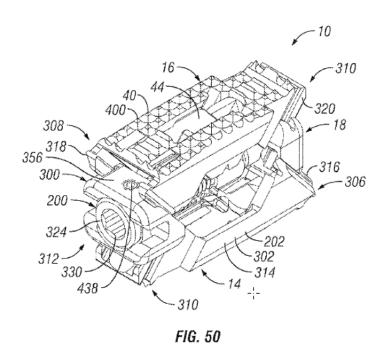


Figure 50 of the '001 patent, reproduced above, is a perspective view of expandable fusion device 10 in an expanded position. *Id.* at 4:46–59, 17:20–21. Expandable fusion device 10 includes first endplate 14, second endplate 16, central ramp 18, actuator assembly 200, and driving ramp 300. *Id.* at 17:21–24. Actuator assembly 200 functions to pull central ramp 18 and driving ramp 300 together, which forces apart endplates 14 and 16. *Id.* at 17:24–28.

Figure 52 of the '001 patent is reproduced below.

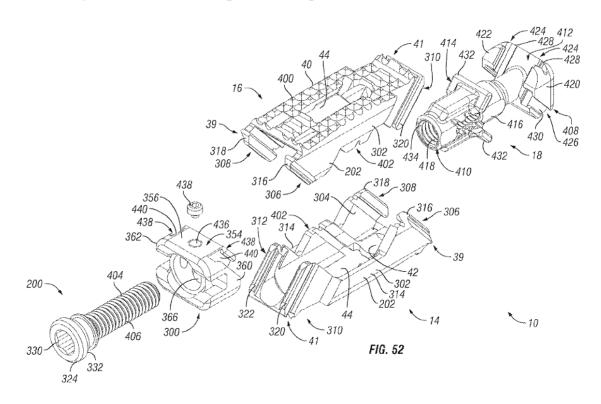


Figure 52, reproduced above, is an exploded view of expandable fusion device 10. *Id.* at 4:53–55. Central ramp 18, which has first end 408 and second end 410, includes first expansion portion 412, second expansion portion 414, rod-receiving extension 416, and longitudinally-extending through bore 418. *Id.* at 19:5–10. Rod-receiving extension 416 is threaded to receive threading of extension 404 of actuator assembly 200. *Id.* at 19:51–54. Driving ramp 300 includes bore 366 sized to receive extension 404. *Id.* at 19:61–63. Actuator assembly 200 includes head portion 324 with rim 332, which engages contact surface 368 of driving ramp 300. *Id.* at 19:67–20:3.

In operation, expandable fusion device 10 is seated into an intervertebral disc space. *Id.* at 20:44–45. An instrument is used to engage head portion 324 of actuator assembly 200. *Id.* at 20:47–48. Rotating

actuator assembly 200 in a first direction pulls central ramp 18 linearly towards driving ramp 300 and pushes driving ramp 300 linearly towards central ramp 18. *Id.* at 20:49–57. Ramped portions of central ramp 18 and driving ramp 300 push against corresponding ramped portions of endplates 14 and 16, which forces the endplates outward into an expanded position. *Id.* at 20:58–60, 21:12–18.

The Specification also describes an exemplary technique for endoscopically inserting the expandable fusion devices into the intervertebral disc space between adjacent vertebrae. *Id.* at 5:26–51, 21:60–22:61. An access path to the intervertebral disc space is created, for example, by using a posterolateral approach. *Id.* at 21:62–65. The expandable fusion device 10 is placed into the intervertebral disc space and expanded to the desired height. *Id.* at 22:28–30. A bone graft or similar bone-growth inducing material is then introduced around or within the expandable fusion device 10. *Id.* at 5:53–55, 22:30–32.

# D. Challenged Claims

Petitioner challenges all 11 claims of the '001 patent. Claims 1 and 10 are independent. Claim 1, reproduced below with bracketed and bolded lettering added,<sup>2</sup> is illustrative:

- 1. [pre] A surgical method comprising:
- [a] creating an access path to an intervertebral disc space; inserting an expandable implant into the disc space,
- [b] wherein the expandable implant comprises: a first endplate having a pair of first tongues;

<sup>&</sup>lt;sup>2</sup> For ease of reference, we use the same bracketed lettering Petitioner uses in the Petition. *See* Pet. 7–48, 122–123.

[c] a second endplate opposed to the first endplate, the second endplate having a pair of second tongues;

[d] a central ramp positioned between the first endplate and the second endplate, [e] wherein the central ramp comprises a first end and a second end, [f] wherein the second end includes a first ramped portion configured to engage a portion of the first endplate and a second ramped portion configured to engage a portion of the second endplate, and [g] a third ramped portion configured to engage a portion of the first endplate and a fourth ramped portion configured to engage a portion of the second endplate positioned between the first and second ends, [h] wherein the central ramp has a longitudinal bore, and [i] wherein the first ramped portion has a pair of first grooves, each of the first grooves sized to receive one of the first tongues, and [j] wherein the second ramped portion has a pair of second grooves, each of the second grooves sized to receive one of the second tongues;

[k] a driving ramp positioned between the first endplate and the second endplate, [l] wherein the driving ramp comprises a first end and a second end, [m] wherein the second end includes a first angled portion configured to engage a portion of the first endplate and a second angled portion configured to engage a portion of the second endplate, [n] wherein the driving ramp has a non-threaded longitudinal through bore extending from the first end to the second end of the driving ramp, [o] the longitudinal bore of the of the [sic] central ramp and the nonthreaded longitudinal through bore of the driving ramp are coaxially aligned;

[p] an actuator insertable through the driving ramp, [q] wherein a portion of the actuator extends through the non-threaded longitudinal through bore of the driving ramp and the longitudinal bore of the central ramp, [r] the actuator is disposed and remains within the non-threaded longitudinal bore, and the actuator is movable with respect to the central ramp and the driving ramp, and [s] wherein the actuator is configured to translate the driving ramp such that the second end of the driving ramp is moved closer to the second end of

the central ramp to thereby cause expansion of the first endplate and the second endplate;

[t] wherein the first tongues and the second tongues are configured to move within corresponding first grooves and second grooves to expand and compress the expandable implant;

[u] wherein the third ramped portion and the fourth ramped portions extend outwardly from a rod receiving extension of the central ramp; and

[v] introducing bone graft material adjacent the expandable implant.

Ex. 1001, 23:4-60.

Challenged independent claim 10 is similar to claim 1, but broader in scope. Specifically, claim 10 does not recite a "non-threaded longitudinal through bore" for the driving ramp found in limitations [n] through [r] of claim 1. *Compare id.* at 23:34–45 (claim 1), with id. at 24:45–50 (claim 10). Additionally, claim 10 does not recite the step of "introducing bone graft material" found in limitation [v] of claim 1. *Compare id.* at 23:59–60 (claim 1), with id. at 24:63 (claim 10).

Challenged claims 2–9 and 11 depend directly or indirectly from independent claim 1 and recite additional features, including with respect to the access path (claim 2), the actuator (claims 3 and 4), the number of expandable implants (claims 6–9), and the driving ramp (claim 11). *Id.* at 23:61–24:14, 24:64–25:2.

E. Evidence

Petitioner submits evidence including:

Evidence	Exhibit No.
Declaration of Troy D. Drewry	1002
KR 20-0290058 (September 26, 2002) ("Chung") <sup>3</sup>	1005
Olmos et al., U.S. Patent Publication 2008/0140207 A1 (published June 12, 2008) ("Olmos")	1006
U.S. Patent Publication 2007/0270968 A1 (published November 22, 2007) ("Baynham")	1007

# F. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–11 are unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. § <sup>4</sup>	Reference(s)/Basis
1, 3, 4, 10	102(b)/103(a)	Chung
2, 5–9, 11	103(a)	Chung with knowledge of the person of ordinary skill in the art or Olmos
1–10	103(a)	Chung with Baynham or Baynham and Olmos

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<sup>&</sup>lt;sup>3</sup> Exhibit 1005 includes a certified English translation on pages 1–12 and the original Korean document on pages 13–22. When citing Chung herein, we refer to the page numbers indicated by the six-digit page numbering scheme applied at the bottom center of the exhibit. For convenience we drop the lead-in zeros.

<sup>&</sup>lt;sup>4</sup> The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended several provisions of 35 U.S.C., including §§ 102 and 103. The '001 patent claims benefit to two applications, both of which were filed before the effective date of the applicable AIA amendments. Ex. 1001, code (63). Thus, we refer to the pre-AIA versions of 35 U.S.C. §§ 102 and 103. Our decision would be the same were we to apply the AIA version of the statutes.

Claim(s) Challenged	35 U.S.C. § <sup>4</sup>	Reference(s)/Basis
1–11	102(b)/103(a)	Olmos
1–9, 11	103(a)	Olmos, Chung

Pet. 3. Patent Owner disputes Petitioner's asserted grounds of unpatentability. *See generally* Prelim. Resp. Patent Owner supports its contentions with the Declaration of Brad Culbert (Ex. 2001), among other evidence.

### II. ANALYSIS

# A. Discretionary Denial Under § 325(d)

The parties dispute whether the Board should discretionarily deny the Petition under 35 U.S.C. § 325(d). Prelim. Resp. 8–29; Pet. 118–121; Prelim. Reply 1–5; Prelim. Sur-reply 4–5.

# 1. Legal Standard

Section 325(d) provides that the Director<sup>5</sup> may "reject the petition" if "the same or substantially the same prior art or arguments previously were presented to the Office." The Board analyzes this issue under a two-part framework:

(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of [the] first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6, 8 (PTAB Feb. 13, 2020) (precedential).

<sup>&</sup>lt;sup>5</sup> The Board institutes trial on behalf of the Director. 37 C.F.R. § 42.4(a).

In analyzing whether the same or substantially the same art or arguments were previously presented to the Office, we consider factors including: (i) the similarities and material differences between the asserted art and the prior art previously presented to the Office; (ii) the cumulative nature of the asserted art and the prior art previously evaluated by the Office; and (iii) the extent of the overlap between the arguments made before the Office and the manner in which the petitioner relies on the prior art or the patent owner distinguishes the prior art. *See id.* at 8–10.

In analyzing whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims, we consider factors including: (iv) the extent to which the asserted art was evaluated by the Office, including whether the prior art was the basis for rejection during examination; (v) whether the petitioner has pointed out sufficiently how the Office erred in its evaluation of the asserted prior art; and (vi) the extent to which additional evidence and facts presented in the petition warrant reconsideration of prior art or arguments. *See id*.

### 2. Analysis

There is no dispute that Olmos and Baynham were before the Office. *See* Pet. 118 (acknowledging that "Baynham was listed . . . in certain IDS filings" and "[t]he Examiner rejected pending claims over Olmos in seven office actions"); Prelim. Resp. 9. Accordingly, Olmos and Baynham are "[p]reviously presented art." *Advanced Bionics*, IPR2019-01469, Paper 6, at 7–8 (indicating that "previously presented art" includes "art made of record by the Examiner").

Chung, however, stands on different footing. There is no dispute that Chung was not before the Office, and thus is not the "same" art previously

presented to the Office. *See* Pet. 126; Prelim. Resp. 23 (acknowledging that "Chung was not before the Office"). *Advanced Bionics*, IPR2019-01469, Paper 6, at 13–14. Patent Owner argues, however, that Chung is cumulative of Olmos and thus "substantially the same" as art that was before the Office. Prelim. Resp. 23.

We are not persuaded that Chung is cumulative of Olmos. Patent Owner presents a table purporting to show that Petitioner's mapping of Chung to the challenged claims is similar to Petitioner's mapping Olmos to the challenged claims. See Prelim. Resp. 12–20. This mapping, Patent Owner argues, "demonstrates that Chung is 'substantially similar' to Olmos and therefore cumulative." Id. at 12. Petitioner, however, maps Olmos to the challenged claims in a materially different manner than the Examiner mapped Olmos to the claims during prosecution. As one example, Patent Owner itself points out that Petitioner maps Olmos's "elevated guide 232/272" to the claimed "rod receiving extension," whereas the Examiner never made this mapping. Id. at 20. Instead, according to Patent Owner, the Examiner allowed the claims over Olmos once "rod receiving extension" was added to independent claim 1. Id. at 6-7; see also id. at 26 ("[I]t is clear that the Examiner never considered guide 232/272 to be an 'extension,' which is precisely why the Examiner allowed the '001 Patent claims over Olmos when 'rod receiving extension' was added to the independent claims."); Advanced Bionics, IPR2019-01469, Paper 6, at 15 (in analyzing whether Charvin and Zimmerling are "substantially the same art," "review[ing] whether Petitioner relies on Charvin in substantially the same manner as the Examiner cited Zimmerling during prosecution such that

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Charvin discloses substantially the same information as Zimmerling in relevant part").

We also find that "the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art" are different. *Advanced Bionics*, IPR2019-01469, Paper 6, at 9 n.10. The *Advanced Bionics* framework "reflects a commitment to defer to previous Office evaluations of the evidence." *Id.* at 9. Here, however, the Office did not evaluate Chung or the arguments Petitioner presently advances based on Chung in its prior consideration of Olmos. Thus, based on the totality of the evidence presented, we are not persuaded that Petitioner's similar mapping of Chung and Olmos to the challenged claims—where that mapping differs from the Examiner's mapping of Olmos to applicant's claims—compels a conclusion that Chung is cumulative of Olmos.

Four out of five grounds advanced in the Petition include Chung, a reference that was not before the Examiner. And Petitioner uses Chung differently than the Examiner used the allegedly cumulative reference, Olmos. Accordingly, we find that the first part of the *Advanced Bionics* framework is not met with respect to the grounds that include Chung. *See, e.g., Halliburton Energy Servs., Inc. v. U.S. Well Servs., LLC*, IPR2021-01036, Paper 12 at 19–20 (PTAB Jan. 19, 2022); *Advanced Bionics*, IPR2019-01469, Paper 6 at 10.

The remaining ground does not include Chung. *See* Pet. 3 (alleging that claims 1–11 are anticipated by, or obvious over, Olmos alone). Under these circumstances, we must "evaluate the challenges and determine whether § 325(d) is sufficiently implicated that its statutory purpose would

be undermined by instituting on all challenges," and if so, "evaluate whether the entire petition should be denied." SAS Q&A's (June 5, 2018), Question/Answer D1.<sup>6</sup> Here, given the requirement to institute on all challenges or none and the fact that Petitioner maps Olmos to the challenged claims in a materially different manner than the Examiner, we determine that § 325(d) is not sufficiently implicated such that its statutory purpose would be undermined by instituting on all challenges.

Additionally, even if the first part of the *Advanced Bionics* framework were met, we would also find that "the Office erred in a manner material to the patentability of challenged claims" under the second part of the *Advanced Bionics* framework. *Advanced Bionics*, IPR2019-01469, Paper 6 at 8. For example, we are persuaded that Petitioner, by showing a reasonable likelihood that at least one challenged claim would have been obvious over Olmos (as discussed below in § II.I), has demonstrated that the Examiner erred by not applying Olmos in the manner Petitioner argues and as supported by Dr. Drewry. *See, e.g., Apple Inc. v. MPH Techs. OY*, IPR2019-00820, Paper 10 at 16–17 (PTAB Oct. 7, 2019); *see also Advanced Bionics*, IPR2019-01469, Paper 6 at 8–9 n.9 (stating that "[a]n example of a material error may include misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims").

For these reasons, and considering the Petition as a whole, we decline to exercise our discretion to deny *inter partes* review under § 325(d).

https://www.uspto.gov/sites/default/files/documents/sas qas 20180605.pdf.

<sup>&</sup>lt;sup>6</sup> Available at

# B. Principles of Law

In an *inter partes* review, "the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). Petitioner ultimately bears the burden of persuasion to prove unpatentability of each challenged claim by a preponderance of the evidence. 35 U.S.C. § 316(e). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). The Board may authorize an *inter partes* review if we determine that the information presented in the Petition and Patent Owner's Preliminary Response shows that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314(a).

Anticipation under 35 U.S.C. § 102 requires that a prior art reference set forth each and every element of a claim as set forth in the claim. *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987); *see also Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (anticipation not only requires that each element of a claim be present in a prior art reference, but also the arrangement or combination of those elements).

A claim is unpatentable as obvious under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said

subject matter pertains. 35 U.S.C. § 103(a) (2006); see also 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) any objective indicia of nonobviousness. Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966). An obviousness determination requires finding a reason to combine accompanied by a reasonable expectation of achieving what is claimed in the challenged patent. Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359, 1367 (Fed. Cir. 2016). "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." KSR, 550 U.S. at 419–20.

C. Level of Ordinary Skill in the Art

We consider the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art at the time of the invention. *Graham*, 383 U.S. at 17–18. Petitioner contends that a person of ordinary skill in the art (sometimes abbreviated herein as "POSITA"):

as of September 3, 2010, would have had a bachelor's degree in mechanical engineering or biomedical engineering and two or more years of experience in biomechanical engineering, biomedical engineering, and/or spinal implant devices. A person could also have qualified as a POSITA with some combination of more formal education (e.g., an M.D.) and less technical experience or less formal education and more

<sup>&</sup>lt;sup>7</sup> Patent Owner does not presently assert objective indicia supporting nonobviousness of the challenged claims. *See generally* Prelim. Resp.; Prelim. Sur-reply.

technical or professional experience in the foregoing fields, and would have had further appreciation of various technical concepts in this field, as explained by Prof. Drewry.

Pet. 5 (citing Ex. 1002 (Drewry Decl.) ¶¶ 31, 43–64). Patent Owner does not presently dispute Petitioner's proposal. Prelim. Resp. 1–2.

Because Petitioner's proposed level of ordinary skill in the art is undisputed on this record, we adopt it for purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (indicating that the prior art itself may reflect an appropriate skill level). Because the claims at issue are directed to a surgical method, the parties are encouraged to address in their papers at trial whether a person of ordinary skill in the art would have had more formal medical training than that required by Petitioner's proposal.

### D. Claim Construction

In AIA proceedings we interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*; *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc).

Petitioner asserts that the claims do not "require constructions differing from their plain and ordinary meaning." Pet. 5. Patent Owner argues that Petitioner's interpretation of the claim term "rod receiving extension" in Petitioner's discussion of the asserted grounds is contrary to the plain and ordinary meaning of the term and is inconsistent with the Specification. Prelim. Resp. 31–41, 46; Prelim. Reply 2–4.

Patent Owner argues that a "rod receiving extension" (as recited in independent claims 1 and 10) is "a structure that both increases the axial length (i.e., extends) of the central ramp and receives a rod (e.g., the threaded portion of actuator 200)." Prelim. Resp. 34; Prelim. Sur-reply 2. Patent Owner supports this construction by arguing, among other things, that the Examiner "identified the 'extensions' in [Olmos] as various cylindrical structures," and "the specification clearly and consistently identifies a rod-receiving extension as a structure that increases the axial length of the central ramp." Prelim. Resp. 39, 55.

Petitioner responds that Patent Owner's construction "improperly imports features from the specification into the claims." Prelim. Reply 2. Petitioner argues that "rod receiving extension" "is broad and merely requires a longitudinal protrusion on the central ramp that receives a rod." *Id.* Petitioner asserts that "[t]here is no requirement that the extension have a particular shape or that it lengthen the central ramp." *Id.* In support, Petitioner argues that the Specification uses the term "extension' to refer to a myriad of structures." *Id.* (citing Ex. 1001, 6:24–36, Fig. 10; 11:66–12:1, 12:32–35, Fig. 23; 10:27–32, 10:55–11:7, Fig. 24).

On this preliminary record, we do not discern a meaningful difference between the parties' proffered constructions. Both parties agree that the rod receiving extension must "receive a rod," and Petitioner acknowledges that the "rod receiving extension" is "a longitudinal protrusion on the central ramp." Prelim. Reply 2. At most, then, it appears that the parties disagree about the length of the extension. *Compare, e.g.*, Prelim. Resp. 34 (stating that the rod receiving extension must increase or extend the axial length of the central ramp), *with* Prelim. Reply 2 (stating that "[t]here is no

requirement that the extension have a particular shape or that it lengthen the central ramp"). That dispute, however, need not be resolved to apply the prior art in this Decision.

For this Decision, we apply Petitioner's construction of "a longitudinal protrusion on the central ramp that receives a rod." Prelim. Reply 2. The parties are encouraged to further develop the record at trial as to how an ordinarily skilled artisan, at the time of the invention, would have interpreted "rod receiving extension" in light of the disclosure of the '001 patent, and more clearly explain any relevant differences between their interpretations. Any final written decision entered in this case may include a final claim construction based on the full trial record that differs from this preliminary construction, or from any discussion of claim scope provided in our analysis below.

E. Overview of Asserted Prior Art

1. Chung (Ex. 1005)

Chung, titled "A lumbar holder," relates "to a medical device for correcting the back." Ex. 1004, code (54), 2, 4. Chung discloses "a lumbar holder that is inserted between the back bones consisting of the lumbar in order to fix the back bones robustly while freely adjusting the height in order to maintain the appropriate space according to the patient's state." *Id.* at 4.

Figure 1 of Chung, reproduced below, is a perspective view of a lumbar holder. *Id.* at 3.

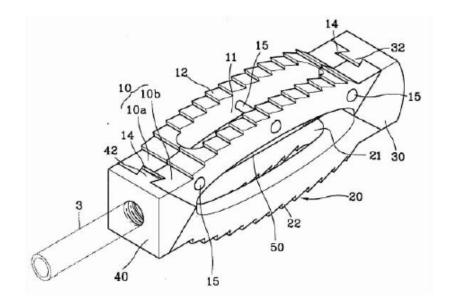


Figure 1 of Chung, reproduced above, depicts main holder bodies 10 and 20, lead wedge 30, and opposing wedge 40. *Id.* at 6.

Figure 2 of Chung, reproduced below, is an exploded view of the lumbar holder in Figure 1 above.

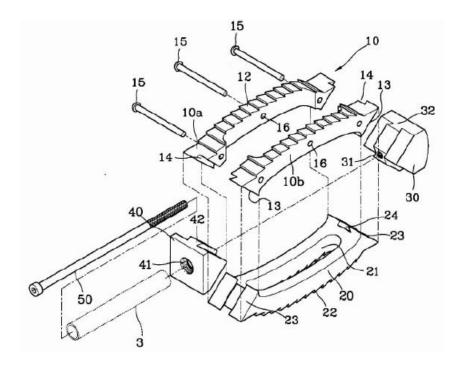


Figure 2 of Chung, reproduced above, depicts groove fastening screw 50, which fastens to screw hole 31 of lead wedge 30. *Id.* at 6. Opposing wedge 40 has penetrating hole 41, which has a raised spot to hold the head of groove fastening screw 50. *Id.* at 7. Tightening or loosening groove fastening screw 50 adjusts the distance between lead wedge 30 and opposing wedge 40, which slide along guiding surfaces 13 and 23 of holder bodies 10 and 20 to widen or narrow the space between the holder bodies. *Id.* at 6–7.

Figure 4 of Chung is reproduced below.

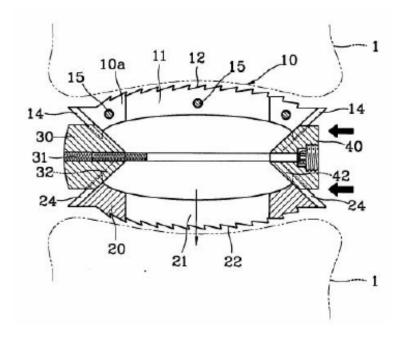


Figure 4 of Chung, reproduced above, is a cross-section view of a lumbar holder inserted between back bones. Chung discloses that, in operation, the lumbar holder is inserted between back bones and a wrench is used to tighten groove fastening screw 50, which brings lead wedge 30 and opposing wedge 40 together such that the wedges push main holder bodies 10 and 20 outward into contact with the back bones. *Id.* at 7. Conversely, loosening groove fastening screw 50 moves lead wedge 30 and opposing wedge 40 apart, which pulls main holder bodies 10 and 20 together. *Id.* 

# 2. Baynham (Ex. 1007)

Baynham, titled "PLIF Opposing Wedge Ramp," relates to "implants to be placed between vertebrae in the spine." Ex. 1007, code (54),  $\P$  3. Baynham discloses a spinal fusion implant for implantation between vertebrae. *Id.*, code (57).

Figure 1 of Baynham is reproduced below.

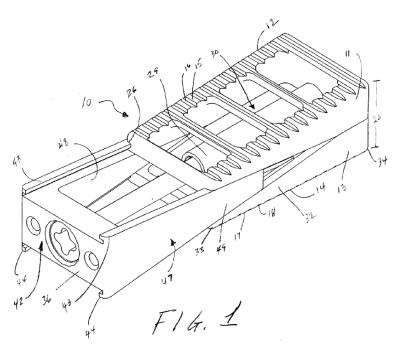


Figure 1 of Baynham, reproduced above, is a perspective view of spinal fusion device 10 comprising upper section 11 with top surface 12 and lower section 13 with bottom surface 14. *Id.* ¶ 22. Distractor 42 is between upper section 11 and lower section 13. *Id.* ¶ 28.

Figure 3 of Baynham is reproduced below.

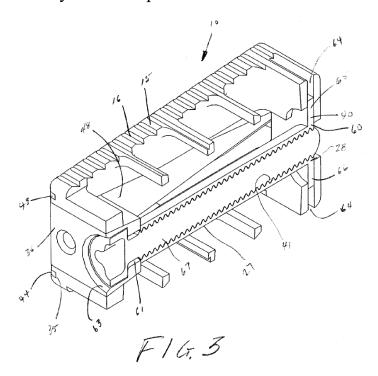


Figure 3, reproduced above, is a cross-section view of spinal fusion device 10 including jack screw 67, which is inserted through bore 61 of disruptor 42. *Id.* ¶ 29. Jack screw 67 engages internal threads in tube 27 of link 40. *Id.* ¶ 25. Tightening jack screw 67 draws disruptor 42 between the upper and lower sections 11 and 13, increasing the distance between sections. *Id.* 

# 3. Olmos (Ex. 1006)

Olmos, titled "Intervertebral Implant," relates to "[a]n adjustable spinal fusion intervertebral implant." Ex. 1006, code (54), (57). Figure 16A of Olmos is reproduced below.

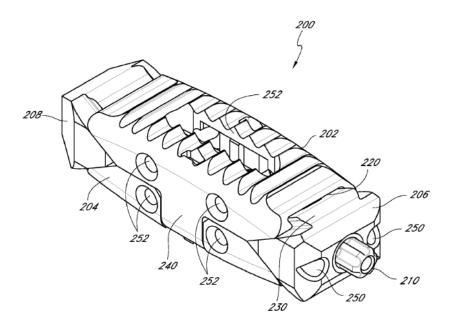


FIG. 16A

Figure 16A of Olmos, reproduced above, is a perspective view of intervertebral implant 200 in an unexpanded state. *Id.* ¶ 152. Implant 200 comprises upper body portion 202, lower body portion 204, proximal wedge member 206, distal wedge member 208, and actuator shaft 210. *Id.* ¶¶ 152, 156. Proximal wedge member 206 includes upper guide member 230 engaging a corresponding slot in upper body portion 202 to enhance stability. *Id.* ¶ 156; *see also id.* (describing that proximal wedge member 208 includes a similar feature).

Figure 18 of Olmos is reproduced below.

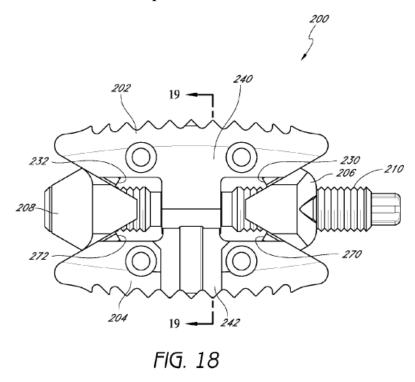


Figure 18 of Olmos, reproduced above, is a side view of intervertebral implant 200 in an expanded state. *Id.* ¶ 168. Actuator shaft 210 includes threads to engage at least one of the proximal and distal wedge members 206 and 208. *Id.* ¶ 159. Rotating actuator shaft 210 causes proximal and distal wedge members 206 and 208 to move towards each other and separate upper and lower body portions 202 and 204. *Id.* ¶ 155. Proximal wedge member 206 includes upper guide member 230 and lower guide member 270 and distal wedge member 208 includes upper guide member 232 and lower guide member 272. *Id.* ¶¶ 156, 167. Olmos discloses that the slots and guide members may have a dovetail shape to ensure secure engagement between the wedge members and the body portions. *Id.* ¶ 167.

F. Ground 1 – Alleged Anticipation by, or Obviousness Over, Chung
For Ground 1, Petitioner asserts that claims 1, 3, 4, 10 are
unpatentable as anticipated by, or obvious over, Chung. Pet. 6–53. Patent
Owner disputes Petitioner's contentions. Prelim. Resp. 31–34, 45–60.

For the reasons discussed below, we determine that Petitioner has not shown a reasonable likelihood of establishing that claims 1, 3, 4, 10 are unpatentable as anticipated by, or obvious over, Chung.

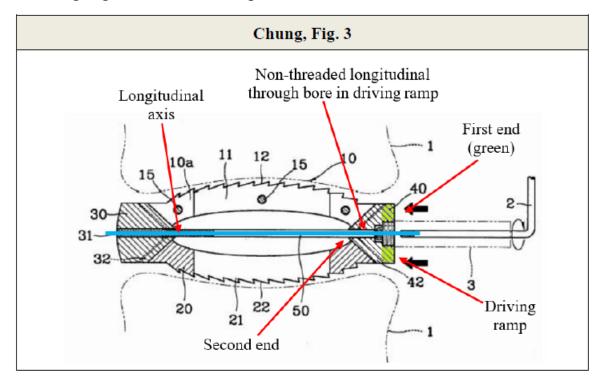
# 1. Independent Claim 1

Petitioner provides a limitation-by-limitation analysis alleging that Chung discloses each and every limitation of challenged claim 1 and therefore anticipates claim 1. *See* Pet. 7–22. As to limitations 1[n] (relating to a "non-threaded longitudinal through bore extending from the first end to the second end of the driving ramp") and 1[u] (relating to "rod receiving extension of the central ramp"), Petitioner provides additional analysis alleging that these limitations also would have been obvious over Chung. *Id.* at 37–38 (limitation 1[n]), 47–48 (limitation 1[u]). At this stage of the proceeding, Patent Owner disputes only Petitioner's contentions regarding limitations 1[n] and 1[u]. *See* Prelim. Resp. 29–60, 91–94. We discuss those below.

a. Limitation 1[n]: the driving ramp has a non-threaded longitudinal through bore extending from the first end to the second end of the driving ramp

The parties dispute whether Chung teaches limitation 1[n], which recites that "the driving ramp has a non-threaded longitudinal through bore extending from the first end to the second end of the driving ramp." *See, e.g.*, Pet. 37–38; Prelim. Resp. 91–95.

Petitioner contends that Chung discloses a driving ramp (opposing wedge 40) that includes "a non-threaded longitudinal through bore ('penetrating hole (41)') extending from a first end to the second end." Pet. 37–38 (citing Ex. 1005, 6); *see also id.* at 30 (citing Ex. 1005, 4), 31 (citing Ex. 1005, Figs. 1–4). In support of its contention that the longitudinal through bore is non-threaded and extends from the first end to the second end of the driving ramp, Petitioner relies on an annotated version of Chung Figure 3, which we reproduce below:



Pet. 37. Petitioner's annotated version of Chung's Figure 3, reproduced above, depicts Chung's lumbar holder. Petitioner annotates the "[f]irst end" of the "driving ramp" in green, the "[s]econd end" of the "driving ramp" by a red arrow, and the "non-threaded longitudinal through bore" by a red arrow. *See id.* Petitioner acknowledges that a portion of Chung's bore hole "shows some threads," but contends that those threads are "situated *within* 

the first end itself and are not related to the operation of the groove fastening screw." *Id.* at 38 (emphasis added). Petitioner also contends that "the threads facilitate attachment of a structure Chung identifies as a 'wrapper (3),' which the surgeon uses to maintain control and positioning of the device." *Id.* (citing Ex. 1005, 6). Petitioner contends that an ordinarily skilled artisan "would have been well aware of other methods and configurations for maintain[ing] control and positioning of the device," and thus, "it would have been an obvious modification to simply omit these particular threads from the outer portion of Chung's bore hole, thereby providing an entirely unthreaded bore hole." *Id.* (citing Ex. 1002 ¶ 139).

Patent Owner responds that Petitioner has admitted that Chung's bore hole "shows some threads," and argues that "a through bore having threads is not a 'non-threaded' through bore as required by the claims." Prelim. Resp. 92 (citing Ex. 2001 ¶¶ 172–173). Patent Owner also argues that Petitioner's annotation of the entire right half of the driving ramp (in green) as the "first end" is arbitrary and shows that the non-threaded portion of Chung's through bore does not extend "from the first end to the second end of the driving ramp" as required by the claim. *Id.* at 93–94 (citing Ex. 2001 ¶ 175). Finally, Patent Owner argues that Petitioner's obvious analysis is conclusory and legally deficient. *Id.* at 94–95.

On this record, Petitioner has not persuaded us that Chung teaches or suggests a non-threaded longitudinal through bore extending from the first end to the second end of the driving ramp. By the plain language of claim 1, the non-threaded longitudinal through bore must extend from the first end to the second end of the driving ramp. Ex. 1001, 23:34–37. Petitioner does not appear to explain or provide sufficient evidence as to why an ordinarily

skilled artisan would have considered the entire portion Petitioner annotates in green to be the "first end" of wedge 40. Instead, as Patent Owner points out, it appears that Petitioner arbitrarily drew the "first end" to coincidentally correspond to only the threaded portion of Chung's bore hole.

We also agree with Patent Owner that Petitioner's obviousness analysis appears to be conclusory. "In an [inter partes review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." Harmonic Inc. v. Avid Tech., Inc., 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring inter partes review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). Here, in two sentences, Petitioner contends that "[a] POSITA would have been well aware of other methods and configurations for maintain[ing] control and positioning of [Chung's] device," and thus, "it would have been an obvious modification to simply omit these particular threads from the outer portion of Chung's bore hole, thereby providing an entirely unthreaded bore hole." Pet. 38 (citing Ex. 1002 ¶ 139).

Petitioner's explanation appears to lack, for example, clarity and detail regarding why an ordinarily skilled artisan to would have modified Chung's penetrating hole 41 with a non-threaded longitudinal through bore that extends from the first end to the second end of wedge 40 based on the teachings of Chung. Petitioner states only in a conclusory manner that it would have been obvious. Pet. 38. For example, although Petitioner mentions "other methods and configurations," the Petition does not appear to explain with particularity what those "other methods and configurations" were, and why the ordinarily skilled artisan would have had a reasonable

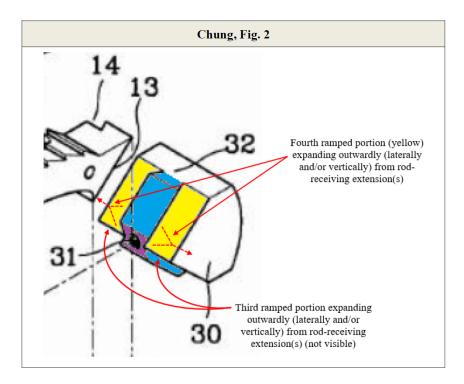
expectation of success in "simply omit[ting]" Chung's "particular threads." *Id.* Moreover, neither Petitioner nor Mr. Drewry appear to acknowledge or explain why—if the entire portion in green is the "first end" as Petitioner contends—an ordinarily skilled artisan would have had a reason to extend a non-threaded bore hole beyond the "first end." *Id.*; *see also* Ex. 1002 ¶ 139.

For these reasons, we determine that Petitioner has failed to establish sufficiently for institution that the Chung discloses or renders obvious limitation 1[n].

b. Limitation 1[u]: wherein the third ramped portion and the fourth ramped portions extend outwardly from a rod receiving extension of the central ramp

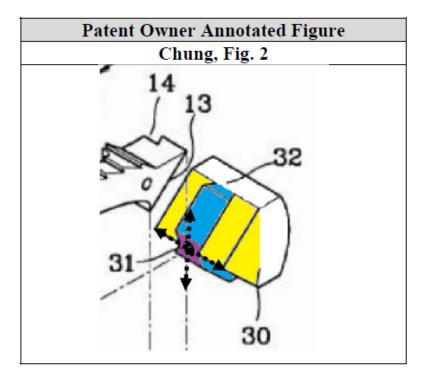
The parties dispute whether Chung teaches limitation 1[u], which recites that "the third ramped portion and the fourth ramped portions extend outwardly from a rod receiving extension of the central ramp." *See*, *e.g.*, Pet. 45–47; Prelim. Resp. 45–60. Relevant to this Decision, the parties dispute in particular whether Chung teaches the "rod receiving extension."

Petitioner first maps Chung's "lead wedge (30)" to the claimed "central ramp" and Chung's "dovetail (32)" to the claimed "rod receiving extension." Pet. 45. Petitioner contends that the "dovetail 32 'extends' from the surface of lead wedge (30) and houses bore hole 31," and thus, "serv[es] as *one embodiment* of a 'rod receiving extension." *Id.* (citing Ex. 1005, 6, Figs. 3–5) (emphasis added). To illustrate, we reproduce below Petitioner's annotated excerpt of Chung's Figure 2:



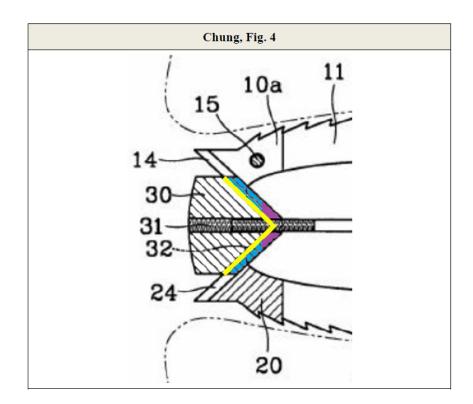
Pet. 46. Petitioner's annotated excerpt of Chung's Figure 2, reproduced above, shows Chung's lead wedge (30). Petitioner highlighted dovetail (32) (which Petitioner maps to the claimed "rod receiving extension") in blue. *Id.* at 45–46.

On this record, Petitioner's argument is not persuasive. Under Petitioner's construction of "rod receiving extension"—which we adopt for this Decision—the "rod receiving extension" must be a longitudinal protrusion on the central ramp/lead wedge (30). *Supra* § II.D.; *see also* Prelim. Reply 2. And, on this record, we find that the annotated excerpt of Chung's Figure 2 is inconclusive as to whether dovetail (32) (blue) extends in a longitudinal direction from the lead wedge (30). Based on the excerpt of Chung's Figure 2, it is equally likely that the structure colored blue terminates in the same plane as alleged third and fourth ramped portions colored yellow, as shown in Patent Owner's further annotated excerpt of Chung's Figure 2, reproduced below:



Prelim. Resp. 48. In Patent Owner's further annotated excerpt of Chung's Figure 2 reproduced above, Patent Owner demonstrates that Chung's dovetail (blue) does not appear to extend in a longitudinal direction past the plane where the expanded portions of the central ramp (yellow) terminate. *See id.* On this record, we find Patent Owner's interpretation of Chung Figure 2 more plausible than Petitioner's.

Petitioner also contends that "part of dovetail 32 further extends longitudinally from lead wedge (30) toward opposing wedge (40), having bore hole 31," and thus, "represents *a second embodiment* of the claimed 'rod receiving extension." Pet. 45 (citing Ex. 1005, 6, Figs. 3–5) (emphasis added). For this argument, Petitioner relies on an annotated excerpt of Chung's Figure 4, which we reproduce below:



Pet. 47. Petitioner's annotated excerpt of Chung's Figure 4, reproduced above, shows Chung's lead wedge (30). Petitioner highlighted a portion of the dovetail (32) (which Petitioner also maps to the claimed "rod receiving extension") in purple extending past two yellow lines added by Petitioner. *Id.* at 45.

Patent Owner argues that Petitioner's annotations to this figure are misleading. Prelim. Resp. 49. Patent Owner explains that "Chung teaches that 'Figure 4 is a cross-sectional diagram' (Ex-1005, 3) which means it is depicting the lead wedge 30 cut in half and viewed directly from the side, resulting in only the central layer of material in the lead wedge 30 being visible." *Id.* at 50 (citing Ex. 2001 (Culbert Decl.) ¶ 183). Patent Owner argues that in a cross-section view, the yellow structure would be hidden behind the exposed central layer, making it impossible for Figure 4 to depict

any portion of the dovetail (32) (blue or purple) extending beyond the yellow structure, as shown in Petitioner's annotations. *Id.* at 51–52.

On this record, we agree with Patent Owner that Petitioner has inaccurately annotated Chung's Figure 4. As Patent Owner explains, given that Chung's Figure 4 is "a cross-sectional diagram" (Ex. 1005, 3), the yellow structures marked by Petitioner would not be visible for the reasons Patent Owner explains on pages 50–54 of the Preliminary Response. In other words, properly annotated, the yellow portions of lead wedge 30 (which Petitioner highlighted in Chung Figure 2) are hidden behind the central layer material of the lead wedge 30 in Chung's Figure 4. *See* Prelim. Resp. 50–54. Accordingly, on this record we find that Chung's Figure 4 does not support Petitioner's contention that a portion of dovetail (32) constitutes the "rod receiving element" as claimed.

For these reasons, we determine that Petitioner has failed to establish sufficiently for institution that the Chung teaches limitation 1[u]. We note that Petitioner makes no argument that the "rod receiving element" would have been obvious over Chung. *See* Pet. 45–47.

### c. Conclusion on Claim 1

On this record, we determine that Petitioner has not shown a reasonable likelihood that claim 1 is anticipated by, or obvious over, Chung because Petitioner has not shown a reasonable likelihood (or made the argument) that Chung teaches or suggests limitations 1[n] and 1[u] of claim 1.

# 2. Dependent Claims 3 and 4

Claims 2 and 3 depend directly from claim 1, and thus include all the limitations of claim 1. Petitioner's arguments for dependent claims 2 and 3

do not overcome the deficiencies discussed above with respect to independent claim 1. *Supra* § II.F.1. Accordingly, for at least the same reasons discussed above for claim 1, on this record we determine that Petitioner has not shown a reasonable likelihood that Chung anticipates or renders obvious claims 2 and 3.

# 3. Independent Claim 10

Petitioner states that "[c]laim 10 consists solely of limitations already addressed previously," and refers to its previous analysis of claim 1. *See* Pet. 50–53. Claim 10, like claim 1, recites a "rod receiving extension." Ex. 1001, 24:62–63. Petitioner's arguments for claim 10 do not overcome the deficiencies discussed above with respect to independent claim 1's "rod receiving extension." *Supra* § II.F.1.b. Accordingly, for at least the same reasons discussed above for claim 1, on this record we determine that Petitioner has not shown a reasonable likelihood that Chung anticipates or renders obvious claim 10.

# 4. Summary for Ground 1

In sum, based on the record before us, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing that Chung anticipates or renders obvious claims 1, 2, 3, and 10.

Nevertheless, the Board, in a decision to institute under 35 U.S.C. § 314(b), may not institute review on fewer than all claims challenged in the petition.

SAS Inst. Inc. v. Iancu, 138 S. Ct. 1348, 1355–56 (2018). In addition, per Board practice, if the Board institutes trial, it will "institute on all grounds in the petition." Consolidated TPG, 5–6; see also PGS Geophysical AS v. Iancu, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to

require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition").

For the reasons explained below, we determine that Petitioner has met its burden under 35 U.S.C. § 314(a) as to its challenge of at least one claim of the '001 patent on other grounds. Thus, we institute *inter partes* review as to all claims challenged in the Petition, and on all grounds presented, pursuant to *SAS* and the Consolidated TPG.

G. Ground 2 – Alleged Obviousness Over Chung With Knowledge of a POSITA or Olmos

For Ground 2, Petitioner asserts that claims 2, 5–9, and 11 are unpatentable as obvious over Chung in view of the knowledge of an ordinarily skilled artisan or Olmos. Pet. 54–66. Claims 2, 5–9, and 11 depend directly or indirectly from claim 1, and thus include all the limitations of claim 1. Petitioner's arguments under this Ground are directed solely to the additional limitations of claims 2, 5–9, and 11, and do not address or overcome the deficiencies discussed above with respect to independent claim 1. *Supra* § II.F.1. Accordingly, for at least the same reasons discussed above for claim 1, on this record we determine that Petitioner has not shown a reasonable likelihood that claims 2, 5–9, and 11 are unpatentable as obvious over Chung in view of the knowledge of an ordinarily skilled artisan or Olmos.

H. Ground 3 – Alleged Obviousness Over Chung With Baynham or Baynham and Olmos

For Ground 3, Petitioner asserts that claims 1, 3, 4, 10 are unpatentable as obvious over Chung in view of Baynham, and that claims 2, 5–9, and 11 are unpatentable as obvious over Chung in view of Olmos and Baynham. Pet. 66–75.

In brief, for claims 1, 3, 4, and 10, Petitioner asserts that "should Patent Owner argue that Chung fails to disclose the required access path, rod-receiving extension, and bone graft material elements, these claims are alternatively obvious under 35 U.S.C. §103 over Chung in view of Baynham." *Id.* at 66 (citing Ex. 1002 ¶¶ 254–285). For claims 2, 5–9, and 11, Petitioner asserts that "these claims are alternatively obvious under 35 U.S.C. § 103 over Chung in view of Olmos and Baynham." *Id.* At this stage of the proceeding, Patent Owner disputes only Petitioner's contentions regarding limitation 1[n] (relating to a "non-threaded longitudinal through bore extending from the first end to the second end of the driving ramp") and limitations 1[u] and 10[o] (relating to a "rod receiving extension"). *See* Prelim. Resp. 29–94.

# 1. Independent Claim 1

Although Petitioner relies on references other than Chung to teach certain limitations of claim 1 (i.e., access path, rod-receiving extension, and bone graft material elements), Petitioner relies only on Chung for limitation 1[n] (relating to a "non-threaded longitudinal through bore extending from the first end to the second end of the driving ramp"). Pet. 66 (stating that "Chung discloses all elements of claims 1 and 10"). We refer back to our analysis above in determining that Petitioner has not sufficiently shown for institution that Chung teaches the claimed "non-threaded longitudinal through bore extending from the first end to the second end of the driving ramp." *Supra* § II.F.1.a. Accordingly, for at least the same reasons discussed above for claim 1, on this record we determine that Petitioner has not shown a reasonable likelihood that claim 1 is unpatentable as obvious over Chung in view of Baynham.

# 2. Dependent Claims 3, 4

Claims 3 and 4 depend directly or indirectly from claim 1. Petitioner's arguments for these claims do not address or overcome the deficiencies discussed immediately above with respect to independent claim 1. *See* Pet. 71 (arguing only that "Chung discloses all elements added by" dependent claims 3 and 4). Accordingly, for at least the same reasons discussed above, on this record we determine that Petitioner has not shown a reasonable likelihood that claims 3 and 4 are unpatentable as obvious over Chung in view of Baynham.

# 3. Dependent Claims 2, 5–9, and 11

Claims 2, 5–9, and 11 depend directly or indirectly from claim 1. For these claims, Petitioner asserts that "all elements added by these claims are disclosed by a combination of Chung and Olmos (and/or the knowledge of a POSITA)" and "are likewise obvious for the reasons provided for these claims in Ground 2 and here." Pet. 71 (citing Ex. 1002 ¶ 285). Petitioner's arguments for dependent claims 2, 5–9, and 11, however, do not overcome the deficiencies discussed above with respect to independent claim 1. *Supra* § II.H.1. Accordingly, for at least the same reasons discussed above for claim 1, on this record we determine that Petitioner has not shown a

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<sup>&</sup>lt;sup>8</sup> On page 66 of the Petition, Petitioner asserts that claims 2, 5–9, and 11 "are alternatively obvious under 35 U.S.C. § 103 over Chung in view of Olmos and Baynham," whereas on page 71 of the Petition, Petitioner asserts that these claims would have been obvious over "Chung and Olmos (and/or the knowledge of a POSITA)." *Compare* Pet. 66, *with id.* at 71. We assume the latter characterization of this alleged Ground of unpatentability constitutes a typographical error. Our decision would be the same under either combination of prior art.

reasonable likelihood that claims 2, 5–9, and 11 are unpatentable as obvious over Chung in view of Olmos and Baynham.

### 4. Independent Claim 10

Claim 10, like claim 1, recites a "rod receiving extension." Ex. 1001, 24:62–63. But, unlike claim 1, claim 10 does not recite a "non-threaded longitudinal through bore extending from the first end to the second end of the driving ramp" (i.e., limitation 1[n]). Thus, the dispute over claim 10 centers on whether the cited prior art teaches or suggests the "rod-receiving extension" of claim 10, referred to as limitation 10[o]. Pet. 67.

Petitioner argues that it "would have been obvious to add a further rod-receiving extension to Chung's central ramp to further engage the actuation member 40, as taught by Baynham." Pet. 67. In particular, Petitioner describes Baynham's spinal fusion implant as including a threaded tube that engages a screw/actuation member. *See id.* at 67–69. Petitioner maps Baynham's threaded tube to the claimed "rod receiving extension" (i.e., limitation 10[o]). *See id.* at 68–69.

Petitioner argues that a person of ordinary skill in the art "would have been motivated to modify the structure surrounding Chung's screw hole (31) . . . to lengthen it longitudinally toward the bore in Chung's driving ramp, as exemplified by Baynham's tube 27." *Id.* at 72. Petitioner argues that this modification would have provided advantages such as "improving the strength of the connection" and "allow[ing] use of a shorter screw." *Id.* at 73 (citing Ex. 1002 (Drewry Decl.) ¶¶ 270–71). Petitioner further argues that a person of ordinary skill in the art would have had a reasonable expectation of success in combining Baynham's tube with Chung, including because it is a "simple substitution of known mechanical features with each

performing their known and expected function." *Id.* at 74 (citing Ex. 1002 (Drewry Decl.)  $\P$  273–74).

Patent Owner responds that Petitioner's proffered motivations to combine Chung and Baynham are based on hindsight and ignore the purpose of Baynham's extension. Prelim. Resp. 60–71. In brief, Patent Owner argues that "Chung has no use for an extension because the implant already has sufficient threaded engagment [sic] that (1) provides enough structural integrity and (2) allows for full expansion of the device without the screw protruding from the distal end of the lead wedge." *Id.* at 62 (citing Ex. 2001 (Culbert Decl.) ¶ 99). Patent Owner also argues that Petitioner has not demonstrated a reasonable expectation of success in adding Baynham's extension to Chung. *Id.* at 71–73.

After considering the arguments and evidence of record, we determine that Petitioner has shown a reasonable likelihood of establishing that claim 10 would have been obvious over Chung and Baynham. Nevertheless, we recognize that the issues in dispute are highly fact-intensive and implicate genuine issues of fact more appropriately resolved on a fully developed record. At this early stage, we offer the following observations on Patent Owner's arguments.

Patent Owner contends that "[n]otably absent is any evidence that a POSITA would have recognized or identified any of these issues with Chung's connection such that a threaded extension would be desired or needed." Prelim. Resp. 64. To the extent Patent Owner maintains this argument post-institution, Patent Owner may want to address why such evidence is needed, given the Federal Circuit's statement that "a challenger need not prove that there was a known problem with the prior art in order to

demonstrate that there was a motivation to combine prior art references." *Arctic Cat Inc. v. Polaris Indus., Inc.*, 795 F. App'x 827, 833 (Fed. Cir. 2019); *see also Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1002–03 (Fed. Cir. 2016) (finding that patent challenger need not establish "a known problem with the prior art system in order to articulate the required rational underpinning for the proposed combination").

Patent Owner also argues that a person of ordinary skill in the art would have understood "the importance of leaving available space within the implant to facilitate natural integration of the expandable implant between the vertebral bodies as the body heals." Prelim. Resp. 69 (citing Ex. 2001 (Culbert Decl.) ¶ 113; Ex. 2004 [sic, 2003] ¶ 113; Ex. 1006 ¶ 75). Patent Owner argues that a person of ordinary skill in the art "would have been motivated to avoid unnecessarily sacrificing any of this space for an extension, given that Chung already provides sufficient threading to allow for full expansion and to maintain the necessary structural integrity." *Id.* at 57 (citing Ex. 2001 (Culbert Decl.) ¶ 107).

To the extent Patent Owner pursues this argument during trial, the parties may want to more specifically address the volume of bone graft material needed to facilitate natural integration of the expandable implant, as compared to the space occupied by the proposed elongated extension. Additionally, Patent Owner may want to more specifically address how this argument is compatible with prior art that teaches embodiments that can include both bone graft material and elongated extensions. *See* Prelim. Reply 6–7 (citing, *e.g.*, Ex. 1006 ¶ 75; Pet. 102–103).

Regarding reasonable expectation of success, Patent Owner argues that "Petitioner fails to account for additional changes to Chung that would

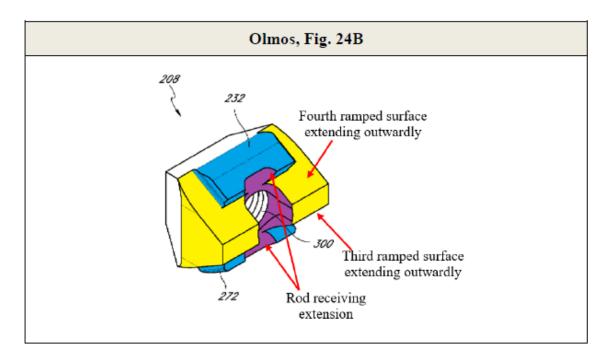
be required if an extension were added," and that "[a]llowing for additional threaded engagement without additional changes would result in an expandable implant that can easily over expand and fall apart." Prelim. Resp. 72 (citing Ex. 2001 (Culbert Decl.) ¶ 122). During the trial phase we encourage the parties to keep in mind that "[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference," *see Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1343 (Fed. Cir. 2020) (citations omitted), and to consider tailoring their arguments accordingly.

# 5. Summary for Ground 3

In sum, based on the record before us, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing that claim 10 would have been obvious over Chung in view of Baynham.

I. Ground 4 – Alleged Anticipation by, or Obviousness Over, Olmos
Petitioner asserts that claims 1–11 are unpatentable as anticipated by,
or obvious over, Olmos. Pet. 75–115. Petitioner provides a limitation-bylimitation analysis as to how Olmos allegedly teaches each and every
limitation of the challenged claims. See Pet. 75–115. As to limitations 1[u]
and 10[o] (relating to a "rod receiving extension of the central ramp"),
Petitioner provides additional analysis alleging that these limitations also
would have been obvious over Olmos. Id. at 102–106. Patent Owner
disputes Petitioner's contentions. Prelim. Resp. 29–45, 73–91.

For the claimed "rod receiving extension" (i.e., limitations 1[u] and 10[o]), Petitioner relies on an annotated version of Olmos Figure 24B showing distal wedge member 208, reproduced below:



Pet. 102. In Petitioner's annotated version of Olmos Figure 24B, reproduced above, Petitioner highlights "upper guide member 232" and "lower guide member 272" in blue, "at least a portion of members 232 and 272 [that] are configured to receive a rod" in purple, and structure flanking the guide members 232 and 272 in yellow. *See id.* at 101–102. Petitioner maps the "distal wedge member 208" to the claimed central ramp, the "upper guide member 232" and "lower guide member 272" (blue) as "extending guide members," "at least a portion of members 232 and 272" (purple) as "the rod-receiving portion," and the flanking structure (yellow) to the claimed "third ramped portion and the fourth ramped portions [that] extend outwardly from a rod receiving extension." *Id.* Petitioner argues that guide members 232/272 "extend outwardly (laterally to the sides, and vertically above and below) from the surface of distal wedge member 208 and at least partially along a longitudinal axis." *Id.* 

Petitioner alternatively contends that "it would have been obvious to add a further extension disclosed in Olmos Fig. 8 to the central ramp of Fig. 24B." *Id.* at 102; *see also id.* at 103–106 (discussing outer sleeve member 34 from Olmos Fig. 8). Petitioner argues that a person of ordinary skill in the art would have been motivated to make this modification including because it would allow use of a shorter actuator/screw and would make the device more robust. *Id.* at 105. Petitioner further argues that a person of ordinarily skill in the art would have had a reasonable expectation of success "because this combination amounts to nothing more than the simple substitution of known mechanical features with each performing their known and expected function." *Id.* at 106 (citing Ex. 1002 ¶ 368).

At this stage of the proceeding, Patent Owner disputes Petitioner's contentions regarding (i) whether Olmos's Figure 16–26 embodiment teaches a "rod receiving extension" and (ii) whether it would have been obvious to add an extension (or further extension) to Olmos's Figure 16–26 embodiment. *See* Prelim. Resp. 31–46, 73–91.

After considering the arguments and evidence of record, we determine that Petitioner has shown a reasonable likelihood of establishing that claims 1–11 would have been obvious over Olmos. Nevertheless, we recognize that the issues in dispute are highly fact-intensive and implicate genuine issues of fact more appropriately resolved on a fully developed record. At this early stage, we offer the following observations on Patent Owner's arguments.

1. Whether Olmos Teaches the Claimed "rod receiving extension"

Patent Owner argues that guide members 232/272 in Olmos's Figure 16–26 embodiment are not a "rod receiving extension" as claimed. *See, e.g.*,

Prelim. Resp. 31–45. Patent Owner argues that a person of ordinary skill in the art would have recognized Olmos's guide members 232/272 (colored blue in Petitioner's annotated version of Olmos's Figure 24B reproduced above) as "clearly part of the wedge's expansion portion," not the claimed "rod receiving extension," and argues that during prosecution, the Examiner never identified Olmos's guide members as the claimed "extension." *See, e.g.*, Prelim. Resp. 35–36, 37–41. Patent Owner further argues that Petitioner has failed to show that guide members 232/272 extend in a longitudinal axis. Prelim. Resp. 84. We have reservations as to whether Petitioner has sufficiently shown that Olmos's guide members 232/272 teach the claimed "rod receiving extension."

Under Petitioner's construction of "rod receiving extension"—which we adopt for this Decision—the "rod receiving extension" must be a longitudinal protrusion on the central ramp. *Supra* § II.D.; *see also* Prelim. Reply 2. Referring to Petitioner's annotated version of Olmos's Figure 24B, reproduced above, guide members 232/272 (blue) and the ramped portions (yellow) appear to terminate in the same plane on the rear side of distal wedge 208, and the guide members 232/272 (blue) appear to terminate before the ramped portions (yellow) on the front side of distal wedge 208. On this record, we determine that the Petition fails to adequately explain how the guide members 232/272 longitudinally protrude from the central ramp.

We note, however, that this issue does not undermine Petitioner's alternative argument that a person of ordinary skill in the art would have been motivated to add a further extension (namely, outer sleeve member 34) from Olmos's Figure 8 embodiment to Olmos's Figure 16–26 embodiment.

See Pet. 102–106. Petitioner contends that outer sleeve member 34 "extends longitudinally from an expansion portion of the driving ramp/proximal wedge and receives the actuator shaft 30." *Id.* at 102–103. On this record, Petitioner's contention appears to be reasonable, and Patent Owner does not presently dispute it.

2. Whether it Would Have Been Obvious to Add an Extension to Olmos's Figure 16–26 Embodiment

With respect to Petitioner's argument that a person of ordinary skill in the art would have been motivated to combine the extension in Olmos's Figure 8 with Olmos's Figure 16–26 Embodiment, Patent Owner argues that "Petitioner's proposed motivations to combine here are fundamentally flawed" because "[t]hey are premised on hindsight bias and ignore the true reason Olmos relies on an extension in Figure 8." Prelim. Resp. 73. In brief, Patent Owner argues that Olmos's "Figure 16-26 Embodiment has no use for extension 34 (or 32) and is already sufficiently robust and expands without the screw protruding from distal wedge 68, while providing sufficient structural integrity." *Id.* at 75 (citing, e.g., Ex. 2001 (Culbert Decl.) ¶ 133). Patent Owner also argues that "Petitioner fails to provide any evidence that a POSITA would recognize or identify any issue with the structural integrity of Olmos's device." Id. at 78. Patent Owner also argues that a person of ordinary skill in the art "would be discouraged from adding an unnecessary additional structure within the cavity" that takes up "valuable space" for growth material and natural healing. *Id.* at 86 (citing Ex. 2001 (Culbert Decl.) ¶¶ 158–159). Patent Owner also argues that Petitioner's proposed modification would render Olmos's implant inoperable. *Id.* at 87.

Given the similarity of arguments between Ground 3 and Ground 4, we suggest that the parties consider the guidance we provided above for Ground 3 (*see supra* § II.H.4) to be applicable to Ground 4 as well.

### 3. Summary for Ground 4

In sum, based on the record before us, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing that claims 1–11 would have been obvious over Olmos.

### *J. Ground 5 – Alleged Obviousness Over Olmos and Chung*

Petitioner asserts that claims 1–9 and 11 are unpatentable as obvious over Olmos in view of Chung. Pet. 115–118. In brief, Petitioner presents this ground "should Patent Owner argue that Olmos does not teach a non-threaded driving ramp through-bore" recited in limitation 1[n]. Patent Owner does not specifically address Ground 5 in any respect. *See generally* Prelim. Resp.

Given the fact-intensive nature of Petitioner's arguments, and in the absence of any commentary on this ground from Patent Owner, we will evaluate this ground on the record that is developed during trial.

#### III. PETITIONER'S MOTION TO SEAL

Concurrent with the Petition, Petitioner filed a Motion to File Under Seal. Paper 3 ("Motion"). Petitioner requests that we seal Exhibit 1010 (a claim chart submitted as an exhibit to Patent Owner's litigation infringement contentions). *Id.* at 1. Petitioner represents that the material it seeks to seal contains its trade secrets. *Id.* at 2–3. Petitioner filed a proposed protective order, which includes modifications to the Board's default protective order. *See* Ex. 1018; Ex. 1019.

Patent Owner filed a Response to Petitioner's Motion. Paper 8.

Patent Owner indicates that it does not oppose "the Board sealing

Petitioner's confidential information," but does oppose Petitioner's proposed protective order. *Id.* at 1 (citing Ex. 1018; Ex. 1019). However, Patent

Owner represents that "the parties have conferred and agree to the terms of the stipulated protective order filed as Exhibit 2100." *Id.*; *see also* Ex. 2101 (redline comparison of Ex. 2100 to the Board's default protective order).

We find that Petitioner has established good cause to seal its trade secret information. Accordingly, we grant Petitioner's Motion. 37 C.F.R. § 42.14. We also enter the stipulated protective order filed as Exhibit 2100.

We remind the parties that confidential information that is subject to a protective order ordinarily becomes public forty-five days after denial of a petition to institute trial or 45 days after final judgment in a trial. *See* Consolidated TPG, 21–22. There is an expectation that information will be made public where the existence of the information is referred to in a decision to grant or deny a request to institute a review. *Id.* at 22. A party seeking to maintain the confidentiality of information, however, may file a motion to expunge the information from the record prior to the information becoming public. *Id.*; 37 C.F.R. § 42.56.

#### IV. CONCLUSION

For the foregoing reasons, we determine that the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that at least one of the challenged claims of the '001 patent is unpatentable.

At this preliminary stage, we have not made a final determination with respect to the patentability of any challenged claim or any underlying factual and legal issues. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial"). Any final decision in this proceeding will be based on the full trial record.

The Board will deem forfeited any issue not raised by Patent Owner in a timely response to the Petition, or as permitted in another manner during trial, even if asserted in the Preliminary Response or discussed in this Decision.

Nothing in this Decision authorizes Petitioner, in a manner not otherwise permitted by the Board's rules, to supplement the information pertaining to any ground advanced in the Petition.

#### V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted based on all grounds asserted in the Petition;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this Decision;

FURTHER ORDERED that Petitioner's Motion to File Under Seal is *granted*; AND

FURTHER ORDERED that the Stipulated Protective Order (Ex. 2100) is entered.

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