

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner,

v.

MOSKOWITZ FAMILY LLC,
Patent Owner.

IPR2020-01305
Patent 10,478,319 B2

Before MEREDITH C. PETRAVICK, NEIL T. POWELL, and
JAMES J. MAYBERRY, *Administrative Patent Judges*.

MAYBERRY, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background and Summary

Globus Medical, Inc. (“Petitioner”) filed a Petition (“Pet.”) requesting *inter partes* review of claims 1–5, 7–9, 11, 12, 14, 15, and 18–21 (the “Challenged Claims”) of U.S. Patent No. 10,478,319 B2 (Ex. 1001, “the

'319 patent”). Paper 1. Moskowitz Family LLC (“Patent Owner”) filed a Preliminary Response (“Prelim. Resp.”) to the Petition. Paper 6.

We have authority under 35 U.S.C. § 314 to determine whether to institute review. *See also* 37 C.F.R. § 42.4(a) (permitting the Board to institute trial on behalf of the Director). To institute an *inter partes* review, we must determine that the information presented in the Petition shows “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). For the reasons set forth below, upon considering the Petition, Preliminary Response, and evidence of record, we deny the Petition and do not institute an *inter partes* review.

B. Real Parties in Interest

Petitioner identifies itself as the real party-in-interest. Pet. 1. Petitioner states that “[n]o other party had access to the Petition, and no other party had any control over, or contributed to any funding of, the preparation or filing of the Petition.” *Id.* at 1–2. Patent Owner identifies itself as the sole real party-in-interest. Paper 4, 2.

C. Related Matters

The parties identify *Moskowitz Family LLC v. Globus Medical Inc.*, Case No. 2:20-cv-03271 (E.D. Pa.), as a matter related to the '319 patent. Pet. 2; Paper 4, 2 (“Pending Litigation”). This case was transferred from the District Court for the Western District of Texas on July 6, 2020. *Id.*

Petitioner indicates that it filed *inter partes* review proceedings challenging five other patents asserted in the Pending Litigation. Pet. 2–3 (identifying U.S. Pat. Nos. 8,353,913; 9,889,022; 10,028,740; 10,251,643; and 10,307,268). Petitioner states that it filed, concurrent with the present Petition, a second petition challenging the same Challenged Claims of the

'319 patent. *Id.* at 3; *see* Paper 4, 2 (identifying IPR2020-01306 as the second proceeding).¹

D. The '319 Patent

The '319 patent, titled “System with Tool Assembly and Expandable Spinal Implant,” issued November 19, 2019, from an application filed February 20, 2019. Ex. 1001, codes (54), (45), (22). The '319 patent's earliest priority claim is to a provisional application (U.S. provisional no. 60/670,231), filed April 12, 2005. *Id.* at 1:4–13.

The '319 patent “relates to . . . bi-directional fixating transvertebral (BDFT) screws which can be used as a stand-alone intervertebral device which combines the dual functions of an intervertebral spacer which can be filled with bone fusion material(s), as well as a transvertebral bone fusion screw apparatus.” *Id.* at 1:18–25. We reproduce Figures 1B and 1D from the '319 patent, below.

¹ Petitioner ranks the current Petition as the first of the two petitions we should consider. Pet. 4.

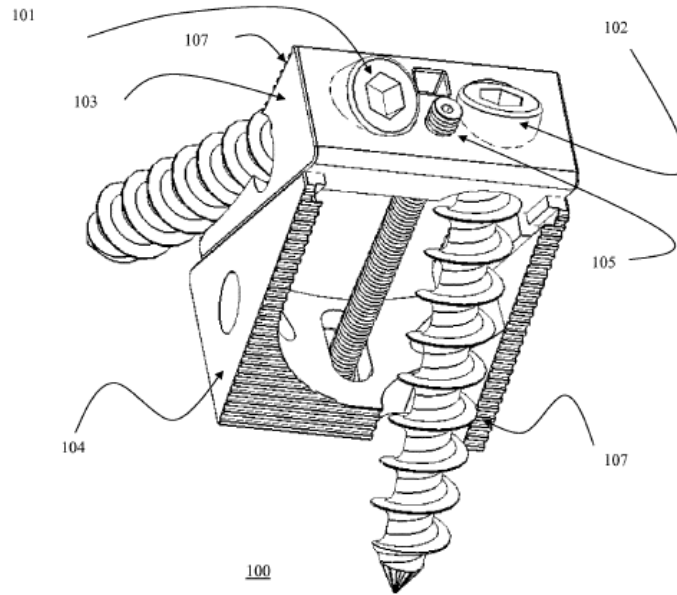


Fig. 1B

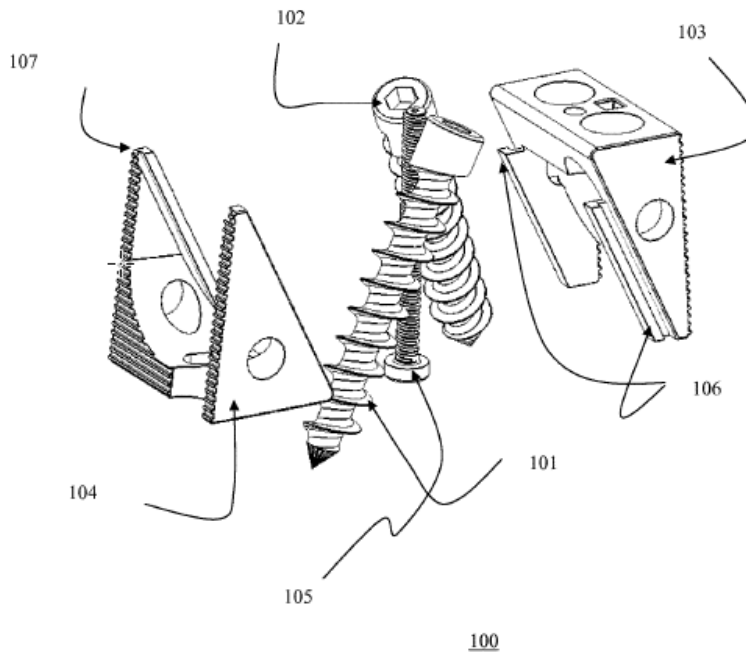


Fig. 1D

Figure 1B provides a superior perspective view of an expandable screw box and Figure 1D provides an exploded view of the same screw box. Ex. 1001,

6:31–35. Expandable box 100 includes two BDFT screws 101, 102, triangular sliding bases 103, 104, and adjustment screw 105. *Id.* at 7:42–53. The surfaces of triangular sliding bases 103, 104 that contact vertebral body surfaces include ridges 107 to facilitate fusion of the screw box with the vertebral bodies. *Id.* at 7:66–8:5. Triangular sliding bases 103, 104 are hollow and include holes to allow bone filling. *Id.* at 8:3–6.

The superior and inferior segments of the height/depth adjusting screw 105 are integrated and connected to the two separate top and bottom triangular bases 103, 104, respectively. By turning this adjusting screw 105 back and forth i.e. clock-wise, and counter clockwise, the sliding rails 106 of the top triangular base 103 (FIG. 1D) slide up and down the rail inserts 107 on the bottom triangular base 104 (FIG. 1D). This action will simultaneously alter the intervertebral height and depth of the screw box 100 allowing individualized custom fitting of the screw box 100 conforming to the dimensions of the disc space.

Ex. 1001, 7:50–57.

We reproduce Figures 5A and 5C from the '319 patent, below.

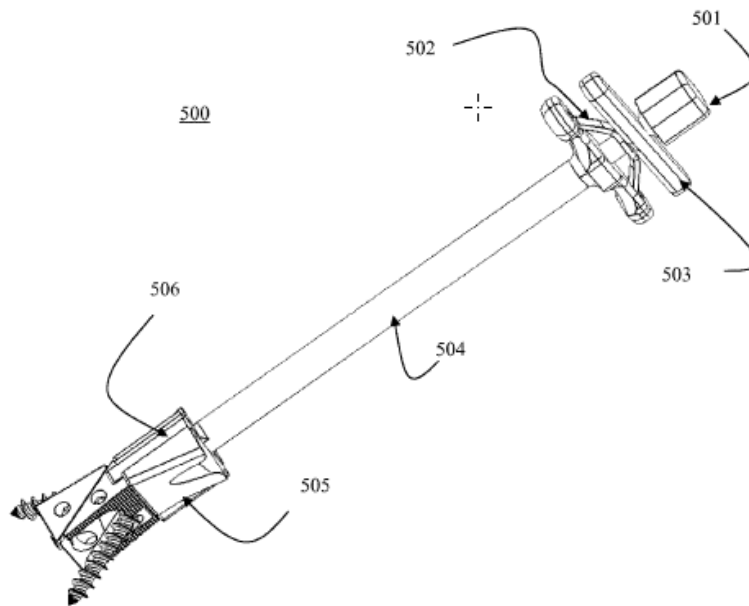


Fig. 5A

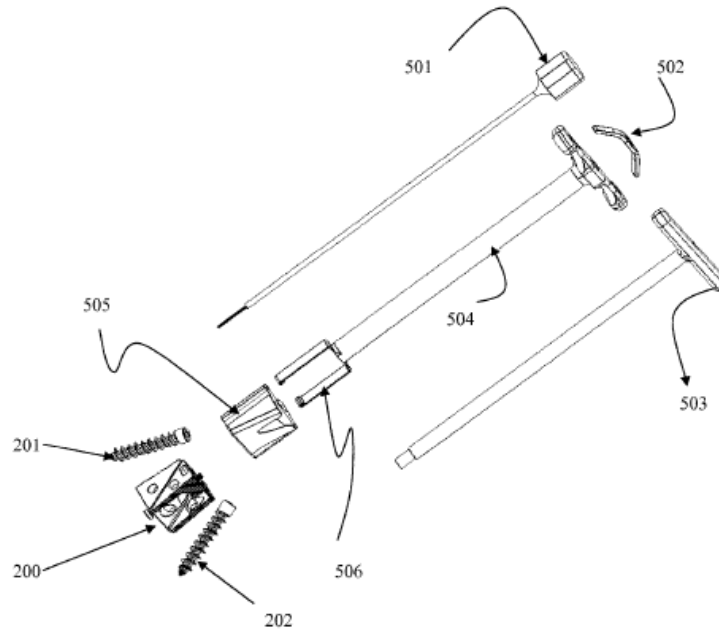


Fig. 5C

Figures 5A and 5C depict a positioning tool in oblique perspective and exploded views, respectively. Ex. 1001, 6:54–56. Tool 500 includes Allen key 501, handle 503, and gripper 504. *Id.* at 8:62–63. Gripper 504 includes a hollow passageway, into which Allen key 501 is inserted. *Id.* at 8:64–65.

Gripper 504 includes gripper prongs 506, which insert into grooves or indentations of a screw box to align Allen key 501 with the head of adjustment screw 105. Ex. 1001, 8:67–9:3. The surgeon uses the knob at one end of Allen key 501 to adjust the relative positioning of triangular sliding bases 103, 104 by turning adjustment screw 105. *Id.* at 8:64–67.

E. Illustrative Claims

Of the Challenged Claims, claims 1, 9, and 20 are independent. We reproduce claim 1, which is representative, below.

1. A system comprising:
a tool assembly which comprises:
a first tool having a first proximal end and a first distal end with a first handle and a gripper,

the gripper being positioned at the first distal end, cooperating with the first handle, and having first and second engagement prongs positioned at the first distal end,
wherein the first tool defines an adjusting tool passage through the first tool; and
a second adjusting tool having a second proximal end and a second distal end with a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion,
wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and
an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, a second expandable spinal implant structure, and an adjusting screw having a screw head and a threaded portion,
wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw,
wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool,
wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

Ex. 1001, 12:64–13:36.

F. Prior Art and Asserted Grounds

Petitioner asserts that the Challenged Claims are unpatentable based on two grounds:

| Claims Challenged | 35 U.S.C. § | References/Basis |
|---------------------------------|--------------------|---|
| 1–4, 7–9, 11, 12, 14, 15, 18–20 | 103(a) | Allen, ² Baynham, ³ McLuen ⁴ |
| 5, 21 ⁵ | 103(a) | Allen, Baynham, McLuen, Sutcliffe ⁶ |

Petitioner relies on declaration testimony of Dr. Jorge A. Ochoa (Ex. 1003) in support of these grounds.

The following subsections provide a brief description of the asserted prior art references.

1. Allen

Allen, titled “Spinal Fixator,” issued August 19, 1997. Ex. 1031, codes (54), (45). Allen is directed to “a contoured, adjustable spinal fixator for insertion between damaged or resected vertebrae.” *Id.* at 1:6–7. We reproduce Allen’s Figure 12, below.

² Allen, US 5,658,335, issued August 19, 1997 (Ex. 1031, “Allen”).

³ Baynham et al., US 2007/0270968 A1, published November 22, 2007 (Ex. 1029, “Baynham”).

⁴ McLuen, US 2006/0253201 A1, published November 9, 2006 (Ex. 1030, “McLuen”).

⁵ Petitioner includes claim 21 in its listing for and analysis of Ground 1. *See* Pet. 6, 65–67. Petitioner, however, relies on teachings from Sutcliffe in contending that claim 21 would have been obvious over the prior art. *See id.* at 66–67. So, we include claim 21 in Ground 2.

⁶ Sutcliffe, US 2002/0143399 A1, published October 3, 2002 (Ex. 1032, “Sutcliffe”).

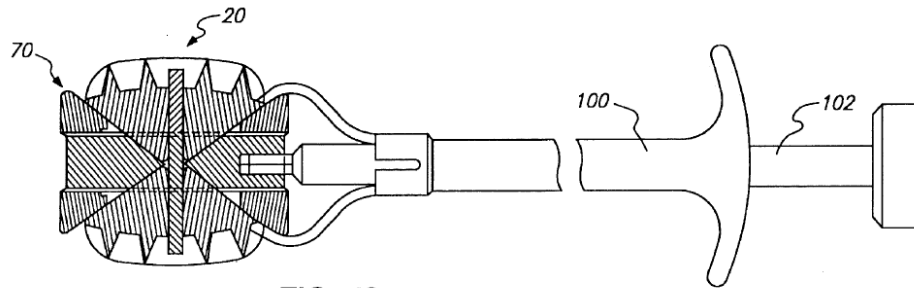


FIG. 12

Figure 12 depicts a “sectional view of [Allen’s] spinal fixator . . . shown with [an] insertion tool.” *Id.* at 3:48–50. Relevant to our Decision, hollow insertion tool 100 is used to insert spinal fixator 20 between two vertebrae. *Id.* at 5:18–20. As seen in Figure 12, two prongs on tool 100 grasp nut assembly 70. *Id.*; *id.* at Fig. 12. Tool 102, which ends in a hex configuration, is inserted through the hollow interior of tool 100 to engage aperture 60 (which is used to expand spinal fixator 20). *Id.* at 5:21–26.

2. Baynham

Baynham, titled “PLIF Opposing Wedge Ramp,” published November 22, 2007. Ex. 1029, codes (54), (43). Baynham is directed to “implants . . . placed between vertebrae in the spine.” *Id.* ¶ 3. We reproduce Baynham’s Figure 1 below.

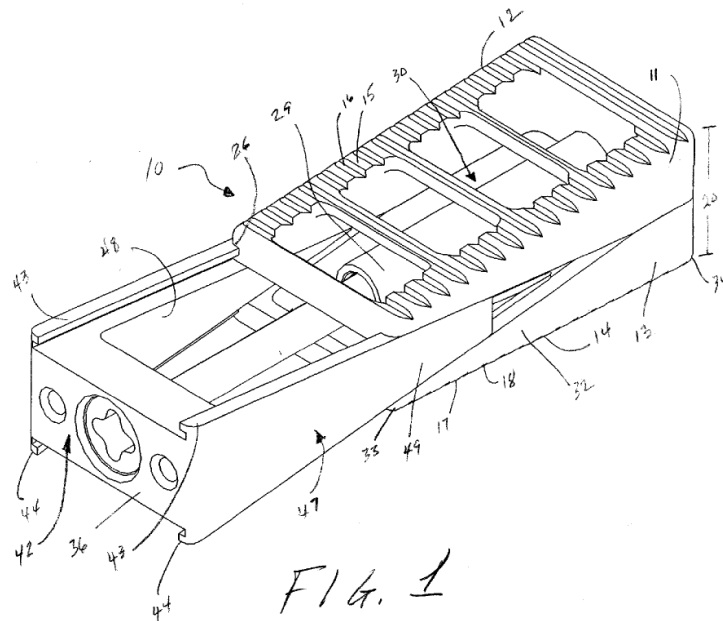


Figure 1 depicts “a perspective of the spinal fusion implant of [Baynham’s] invention.” *Id.* ¶ 16. Spinal fusion device 10 includes upper section 11, with top surface 12, and lower section 13, with bottom surface 14. *Id.* ¶ 22. Top surface 12 and bottom surface 14 include lands and grooves 15, 16, 17, 18 forming a roughened surface to contact the end plates of vertebrae. *Id.*

Ramp or distractor 42 inserts between upper section 11 and lower section 13. Ex. 1029 ¶ 28. Distractor 42 includes a slot and rail configuration on which upper section 11 and lower section 13 move relative to distractor 42. *Id.* “[J]ack screw 67 is inserted through bore 61 engaging the threads in the tube 27. As the jack screw 67 is tightened, the ramp is drawn toward the leading end of the implant and the leading ends of the upper and lower sections slide apart along flanges 65 and 66.” *Id.* at ¶ 29.

3. McLuen

McLuen, titled “Bone Fusion Device,” published November 9, 2006. Ex. 1030, codes (54), (43). McLuen is directed to “bone fusion devices . . . for fusing vertebrae of the spine.” *Id.* ¶ 2. We reproduce McLuen’s Figure 16, below.

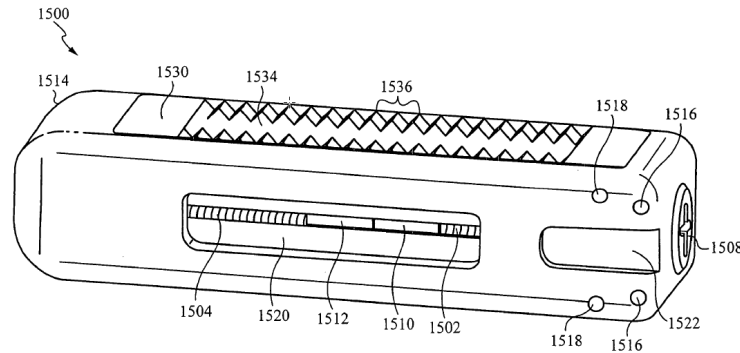


Fig. 16

Figure 16 depicts “a side perspective view of the bone fusion device in the preferred embodiment of” McLuen’s invention. *Id.* ¶ 32. Relevant to this Decision, bone fusion device 1500 is expanded by using a screwdriver to turn positioning means 1508. *Id.* ¶ 76. McLuen provides that “[s]crew drivers unfortunately have the ability to slip out of place. When performing surgery near someone’s spine, it is preferable to prevent or at least minimize the slipping ability.” *Id.* Bone fusion device 1500 includes channels 1522 on each side of the device to receive a tool, which has attachments that fit within channels 1522. *Id.* In this way, the tool is secured to bone fusion device 1500 to prevent a screwdriver from slipping and injuring the patient when interfacing positioning means 1508. *Id.* at ¶ 78.

4. *Sutcliffe*

Sutcliffe, titled “Anchorable Vertebral Implant,” published October 3, 2002. Ex. 1032, codes (54), (43). Sutcliffe is directed to “an implant used to replace . . . [a] vertebrae and/or intervertebral disk.” *Id.* ¶ 2. We reproduce Sutcliffe’s Figure 6, below.

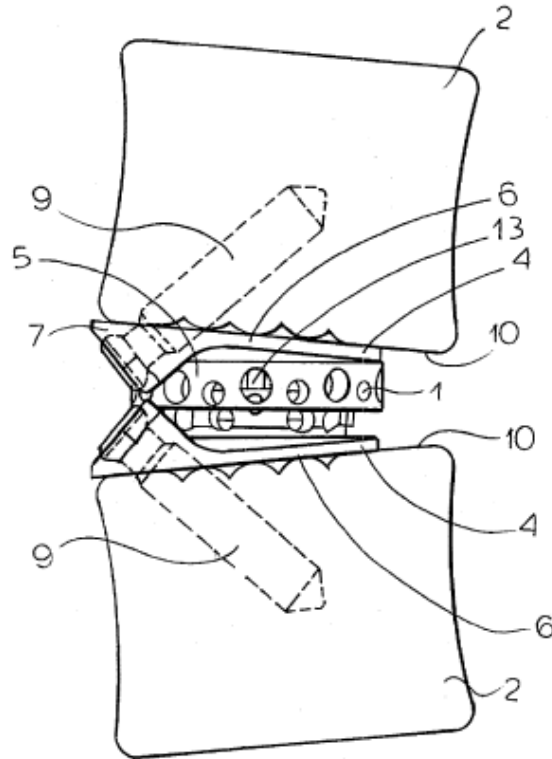


FIG. 6

Figure 6 depicts an implant. *Id.* ¶ 21. Relevant to this Decision, Sutcliffe’s implant includes through holes 13, “so that an interior [volume of the implant] can be packed with bone chips and so that bone growth through the implant 1 is possible.” *Id.* ¶ 23. Also, Figure 6 illustrates cortical screws 9 extending through angled guides. *Id.* Fig. 6.

II. UNPATENTABILITY

A. *Applicable Law*

Petitioner’s asserted grounds of unpatentability are based on obviousness under 35 U.S.C. § 103.

Section 103(a) forbids issuance of a patent when “the differences between the subject matter sought to be patented 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.”

KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of 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 available, objective evidence, such as commercial success, long felt but unsolved needs, and failure of others.⁷ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

“[O]bviousness must be determined in light of *all the facts*, and . . . a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine” teachings from multiple references. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (emphasis added); *see also PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014) (“The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact.” (quoting *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed.Cir.2006))).

B. Level of Ordinary Skill in the Art

The level of skill in the art is “a prism or lens” through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Petitioner contends that a person having ordinary skill in the art “of the ’319 patent would have a Bachelor’s or equivalent degree in Mechanical Engineering or a related discipline (e.g.

⁷ The Patent Owner does not direct us to any objective evidence of non-obviousness in the current record.

biomechanics or biomedical engineering), and at least five years of experience.” Pet. 14 (referencing Ex. 1003 ¶¶ 26–30, Ex. 1004). Petitioner adds that “[t]he experience would consist of a) designing, developing, evaluating and/or using prosthetic devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants.” *Id.* Petitioner contends, as an alternative, a person having ordinary skill in the art “could have an advanced degree in the technical disciplines provided above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above.” *Id.*

Patent Owner does not contest Petitioner’s contentions nor does Patent Owner offer its own level of ordinary skill.

Based on the current record, we adopt Petitioner’s level of ordinary skill for this Decision. We determine, on the current record, that the proposed level of ordinary skill is commensurate with the ’319 patent and prior art of record.

C. Claim Construction

In *inter partes* reviews, 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) (2020). 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.*

Petitioner contends “that the claim terms [of the Challenged Claims] require no express construction and that they should be given their ordinary and customary meaning.” Pet. 13. Petitioner then asserts that “[t]his is true for all limitations, except” the term “first expandable spinal implant

structure” / “second expandable spinal implant structure.” *Id.* at 13–14.

Petitioner contends that this term “should be construed in accordance with the intrinsic evidence and Petitioner offered the same constructions in the Pending Litigation.” *Id.* at 13.

Petitioner proposes that we construe the term “first expandable spinal implant structure” / “second expandable spinal implant structure” to mean “a [first/second] implant structure comprising the [first/second] vertebral body engagement surface.” Pet. 14. Neither Petitioner nor Dr. Ochoa identifies any supporting intrinsic or extrinsic evidence for the proposed construction. *See id.* at 13–14; *see also* Ex. 1003 ¶ 12 (stating that “I have been advised by Counsel that . . . [Petitioner] has proposed the . . . construction” presented above).

Patent Owner argues that Petitioner fails to meet its claim construction burden. Prelim. Resp. 9. Patent Owner argues that the Consolidated Trial Practice Guide requires a petitioner that proposes an express construction for a claim term to identify the intrinsic and extrinsic evidence that supports the proposed construction. *Id.* (citing Consolidated Trial Practice Guide 44, available at <https://www.uspto.gov/TrialPracticeGuideConsolidated> (Nov. 2019)).

We determine that we need not expressly construe any term of the Challenged Claims to resolve the parties’ dispute. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

We are not persuaded by Petitioner’s proposed construction, as Petitioner fails to provide any supporting evidence for the construction. *See*

Consolidated Trial Practice Guide 44 (“If a petitioner believes that a claim term requires an express construction, the petitioner must include a statement identifying a proposed construction of the particular term *and where the intrinsic and/or extrinsic evidence supports that meaning.*” (emphasis added)). Accordingly, we apply the plain and ordinary meaning to the terms “first expandable spinal implant structure” and “second expandable spinal implant structure.”

In summary, no claim terms require express constructions, and we apply the plain and ordinary meaning to the terms of the Challenged Claims.

D. Ground 1: Claims 1–4, 7–9, 11, 12, 14, 15, and 18–20 as Obvious Over Allen, Baynham, and McLuen

Petitioner contends that the combination of Allen, Baynham, and McLuen renders claims 1–4, 7–9, 11, 12, 14, 15, and 18–20 obvious.⁸

1. Independent claim 1

For independent claim 1, we first analyze Petitioner’s contentions as to how the combination of Allen, Baynham, and McLuen discloses the subject matter recited in claim 1. Then we turn to Petitioner’s reasons for combining the teachings of these three references.

a) Subject matter of claim 1

(1) Tool assembly limitations

Claim 1 recites, in relevant part, a “tool assembly” that comprises “a first tool” and “a second adjusting tool.” Ex. 1001, 12:64–13:15 (the “tool assembly” limitations of claim 1). Specifically, claim 1 recites

a first tool having a first proximal end and a first distal end with a first handle and a gripper, the gripper being positioned at the

⁸ Petitioner also includes claim 21 in Ground 1. Pet. 6. We consider it in Ground 2, as Petitioner relies on Sutcliffe for certain teachings directed to that claim. *See id.* at 66.

first distal end, cooperating with the first handle, and having first and second engagement prongs positioned at the first distal end, wherein the first tool defines an adjusting tool passage through the first tool.

Id. at 12:66–13:5 (the “first tool” limitation of claim 1). Claim 1 also recites

a second adjusting tool having a second proximal end and a second distal end with a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool.

Id. at 13:6–15 (the “second adjusting tool” limitation of claim 1).

Petitioner contends that Allen discloses the “first tool” and “second adjusting tool” limitations of claim 1. Pet. 21–24 (referencing Ex. 1031, 5:19–47, Fig. 12; Ex. 1003 ¶¶ 61–64). We reproduce Allen’s Figure 12, below.

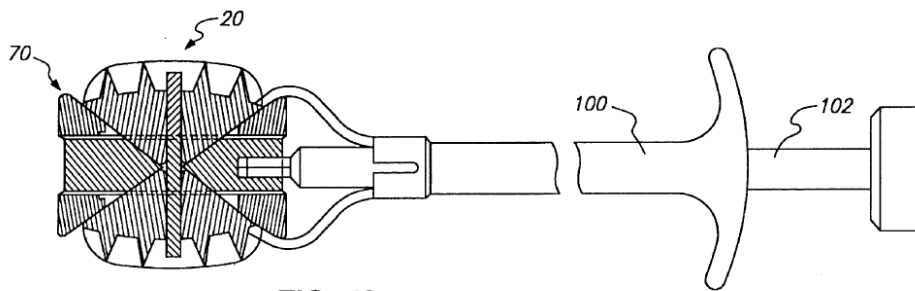


FIG. 12

Figure 12 depicts a “sectional view of [Allen’s] spinal fixator . . . shown with [an] insertion tool.” Ex. 1031, 3:48–50. Petitioner contends that insertion tool 100 corresponds to the first tool, which includes a handle at one end and a gripper having prongs at the other. Pet. 21. Petitioner contends that insertion tool 100 is hollow, defining the adjusting tool passage. *Id.* at 22; *see also* Ex. 1031, 5:18–20 (“A conventional, hollow

insertion tool 100 is used to gasp a nut assembly 70 to insert the retracted spinal fixator 20 between the two vertebrae bodies 4.”).

Petitioner contends that tool 102 corresponds to the recited second adjusting tool, with a second handle at one end and a screw engagement portion at the other and a shaft extending between the handle and screw engagement portion. Pet. 22–23; *see also* Ex. 1031, 5:21–26 (“[T]ool 102 having a terminus defining a hex configuration is inserted through the insertion tool 100 to engage in aperture 60 in the core member 50. The tool 102 is used to rotate core member 50 to extend the crowns 90 outwardly . . .”). Petitioner contends that tool 102 is sized to fit within the hollow passage of tool 100. Pet. 23–24; *see* Ex. 1031, 5:21–23.

We determine that Petitioner has made the requisite showing, at this stage of the proceeding, that Allen discloses the subject matter of the “tool assembly” limitations of claim 1. Patent Owner does not dispute these contentions at this time.

(2) First and second expandable spinal implant structures limitation

Claim 1 also recites “an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, [and] a second expandable spinal implant structure.” Ex. 1001, 13:16–19 (the “first and second expandable spinal implant structures” limitation of claim 1).

Petitioner contends that Baynham teaches an expandable spinal implant satisfying the “first and second expandable spinal implant structures” limitation of claim 1. Pet. 24–25 (referencing Ex. 1029 ¶¶ 10, 22, 25, 26, 29, 30, Figs. 1–3; Ex. 1003 ¶ 67). Specifically, Petitioner contends that Baynham’s device 10 includes upper section 11 (corresponding to the first

expandable spinal structure) and lower section 13 and distractor 42 (together corresponding to the second expandable spinal structure). *Id.* We reproduce Baynham's Figure 1 below.

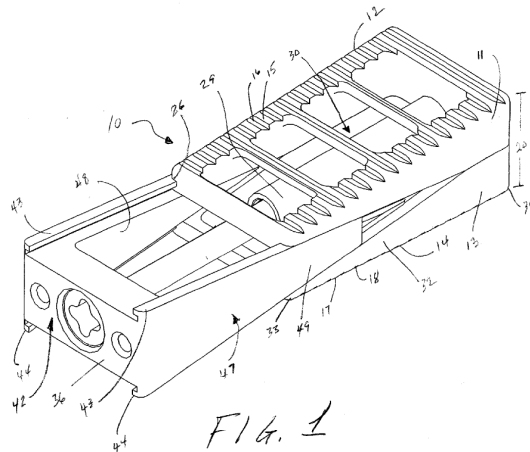


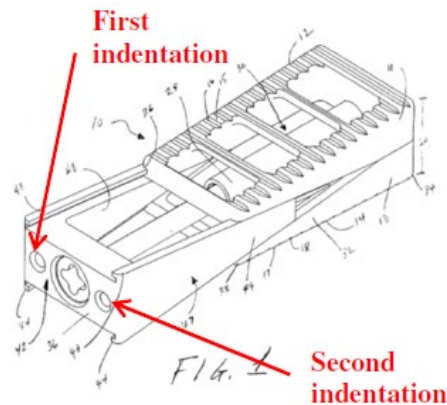
Figure 1 depicts “a perspective of the spinal fusion implant of [Baynham’s] invention,” showing upper section 11, lower section 13, and distractor 42. Ex. 1029 ¶¶ 16, 22, 23.

We determine that Petitioner has made the requisite showing, at this stage of the proceeding, that Baynham discloses the subject matter of the “first and second expandable spinal implant structures” limitation of claim 1. Patent Owner does not dispute these contentions directed to the subject matter of this limitation at this time.

(3) Tool engagement indentations limitation

Claim 1 also requires “the expandable spinal implant [to] define[] first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool.” Ex. 1001, 13:25–28 (the “tool engagement indentations” limitation of claim 1). Petitioner contends that Baynham discloses an implant with first and second tool indentations. Pet. 26. Specifically, Petitioner contends that Baynham discloses holes in end wall 36 of distractor 42 positioned on either side of

countersink 63. *Id.* We reproduce Petitioner’s annotated version of Baynham’s Figure 1, below.



Pet. 27. This annotated figure identifies the structures Petitioner contends corresponds to the recited first and second tool engagement indentations. Petitioner acknowledges that Baynham does not expressly disclose the function of these structures, but contends that a person having ordinary skill in the art “would have understood that these indentations *could* function as tool engagement indentations.” *Id.* (emphasis added) (referencing Ex. 1003 ¶ 69) (emphasis added).

Petitioner also contends that a person having ordinary skill in the art “would have understood that [Allen’s tool] . . . *could* be used to insert and expand” Baynham’s implant. Pet. 27 (emphasis added).

Petitioner contends that, to the extent that Allen’s tool must interface with the outside surface of an implant, a person having ordinary skill in the art “would have understood that [Baynham’s] implant *could* be modified as a matter of simple substitution to move the indentations from the end (36) to opposing side surfaces of the implant so that the first and second tool engagement indentations would be positioned at the proximal end of the implant.” Pet. 27 (referencing Ex. 1003 ¶ 70). Petitioner restates its position as “placement and positioning of indentations for insertion tool

engagement at the proximal or trailing end of the implant is a predictable substitution that does not affect its function.” *Id.*

Petitioner contends that McLuen discloses spinal implant 1500 having indentations 1522 on either side of the implant near an adjustment screw head. Pet. 27–28. We reproduce McLuen’s Figure 16, below.

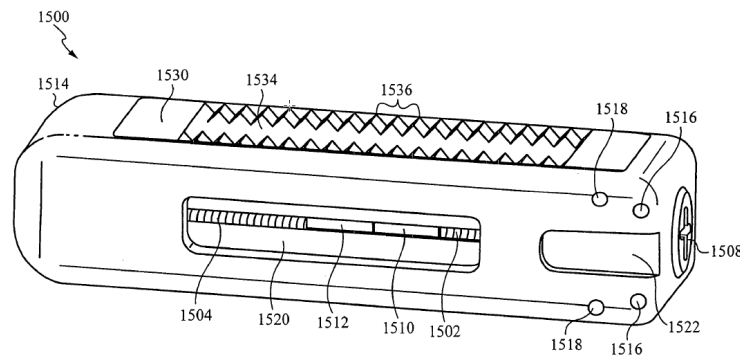


Fig. 16

Figure 16 depicts “a side perspective view of the bone fusion device in the preferred embodiment of” McLuen’s invention. Ex. 1030 ¶ 32. Petitioner contends that McLuen teaches that, because of the risk of a screwdriver slipping when driving screw 1508 and injuring a patient, its implant includes channels 1522 on opposing sides of the implant to receive a tool. Pet. 28 (referencing Ex. 1030 ¶¶ 76, 77, Fig. 16; Ex. 1003 ¶ 71). Petitioner contends that:

It would therefore have been obvious to a [person having ordinary skill in the art] to combine the teachings of Baynham with McLuen to substitute the indentations disclosed in Baynham for the indentations in McLuen, moving the indentations from either side of the countersink (63) to opposing sides at the proximal end of the implant to provide the disclosed advantage of prevention or minimization of screw driver slippage.

Id. Petitioner adds that “[t]his substitution would represent a design choice which would yield a predictable result with a reasonable expectation of success.” *Id.* at 28–29 (referencing Ex. 1003 ¶ 72).

We understand Petitioner’s position to be that it would have been obvious to modify Baynham’s implant by including McLuen’s indentations on the side of body 47 of distractor 42 rather than the indentations adjacent to countersink 63.

We determine that Petitioner has made the requisite showing, at this stage of the proceeding, that Baynham, as modified by McLuen, discloses the subject matter of the “tool engagement indentations” limitation of claim 1. Patent Owner does not dispute the contentions directed to the subject matter of this limitation at this time.

(4) Adjusting screw limitations

Claim 1 also recites “an adjusting screw having a screw head and a threaded portion.” Ex. 1001, 13:20–21. Claim 1 requires “the expandable spinal implant [be] configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw.” *Id.* at 13:21–25. Claim 1 also requires

the adjusting screw [be] positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

Id. at 13:29–36 (the “adjusting screw” limitations of claim 1).

Petitioner contends that Baynham discloses the subject matter of the adjusting screw limitations of claim 1, identifying Baynham’s jack screw 67. Pet 24, 25–26, 29–31 (referencing Ex. 1029 ¶¶ 28–30, Fig. 2; Ex. 1003 ¶¶ 67, 68, 73–75). Petitioner explains that “[t]he surgeon turns the jack screw (67) causing the upper and lower sections to move along the

complementary inclined plane to shorten the fusion device and increase the distance between the end plates of the adjacent vertebrae.” *Id.* at 26.

Petitioner adds that:

Allen discloses the second adjusting tool (102) can extend through the adjusting tool passage of the first tool (100) to engage the screw head of the adjusting screw (67) while the first and second engagement prongs of the first tool (100) are engaged with the first and second tool engagement indentations of the expandable spinal implant. Allen discloses that following placement of the implant, the tool (102) having a terminus defining a hex configuration is inserted through the hollow insertion tool (100) to engage an adjusting screw.

Id. at 30 (referencing Ex. 1031, 5:19–28; Ex. 1003 ¶ 75).

We determine that Petitioner has made the requisite showing, at this stage of the proceeding, that Baynham, as modified by McLuen, discloses the subject matter of the “adjusting screw” limitations of claim 1. Patent Owner does not dispute the contentions directed to the subject matter of this limitation at this time.

b) Reasons to combine the teachings of Allen, Baynham, and McLuen

First, we address Petitioner’s reasoning for combining the teachings of Allen’s tool with Baynham’s implant. Petitioner contends that a person having ordinary skill in the art would have understood that Allen’s tool “is configured to interface with any number of expandable spinal implants” and that the tool “is of a typical design.” Pet. 24. Petitioner concludes that Allen’s tool “could be combined/used with the expandable spinal implant in Baynham or in McLuen.” *Id.* (referencing Ex. 1003 ¶ 66). Petitioner adds that a person having ordinary skill in the art “would have understood that the inserter disclosed by Allen could be used to insert and expand” Baynham’s implant.

Patent Owner argues that Petitioner’s reasons to combine the teachings of Allen and Baynham rely on improper hindsight. Prelim. Resp. 12. Patent Owner argues that Petitioner’s rationale amounts to nothing more than conclusory statements. *Id.* Patent Owner also argues that Petitioner’s rationale fails to recognize that Allen already discloses an implant, so there would be no reason to modify Allen with Baynham’s implant. *Id.* at 12–13.

Patent Owner also argues that Dr. Ochoa’s testimony repeats, verbatim, the conclusory statements from the Petition and that Dr. Ochoa “fails to explain how or why a [person having ordinary skill in the art] would have ‘understood’ that Allen and Baynham could be combined.” Prelim. Resp. 13–14. Patent Owner concludes that Petitioner’s rationale to combine the teachings of Allen and Baynham, “at best, reduces to an assertion that the proposed combination *could* be made, without the requisite reasoning as to why a [person having ordinary skill in the art] *would* have been motivated to” make the proposed combination. *Id.* at 14.

We determine that Patent Owner’s argument, at least in part, is persuasive of a deficiency in the Petition. As an initial point, we are not persuaded by the argument that Petitioner fails to recognize that Allen already has an implant. We understand Petitioner’s position to be that a person having ordinary skill in the art would have employed Allen’s tool to insert Baynham’s implant (as modified by McLuen), given the typical nature of the tool. *See* Pet. 24. We do not read the Petition to propose using Baynham’s insert because of some inadequacy with Allen’s implant or otherwise as a substitute for Allen’s implant.

We determine, however, that Petitioner fails to provide sufficient reasons, with rational underpinnings, to employ Allen’s tool with Baynham’s implant. As Patent Owner argues, Petitioner’s bases its reasoning on the position that Allen’s tool *could* be used for Baynham’s implant, not that a person having ordinary skill in the art *would* have been motivated to use Allen’s tool with Baynham’s implant. *See* Prelim. Resp. 14; Pet. 24. Our reviewing court has stated that “obviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.” *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015). The information in the Petition lacks such a rationale.

Even if we assume Petitioner’s statements represent sufficient reasoning for combining Allen’s tool with Baynham’s implant, we determine that Petitioner fails to provide a rational underpinning of facts to support that reasoning. *See KSR Int’l Co.*, 550 U.S. at 418 (stating that, to facilitate the analysis of an obviousness position, the proponent should provide “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”). The only evidence Petitioner directs us to is testimony from Dr. Ochoa. *See* Pet. 24, 31. We determine, however, that this testimony is entitled to very little weight. Dr. Ochoa fails to provide any underlying support for the testimony. *See* Ex. 1003 ¶¶ 60–76 (providing analysis of claim 1 under Ground 1 and including numerous statements about what a person having ordinary skill would have known or understood without providing the basis for those statements). These unsupported statements are entitled to little or no weight. 37 C.F.R. 42.65(a)

(“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”).

We recognize that Petitioner characterizes Allen’s tool as of a “typical design.” Pet. 24. Petitioner also contends that tools such as Allen’s “were in common use at the time” of the invention of claim 1 and that “[s]imilar devices were also used in arthroscopic and endoscopic surgery.” *Id.* at 31 (referencing Ex. 1003 ¶ 76). Such general statements, without more, do not sufficiently support a finding that a person having ordinary skill in the art would have been motivated to employ Allen’s tool with Baynham’s implant. *See KSR Int’l Co.*, 550 U.S. at 418 (“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.”).

We also recognize that Petitioner directs us to statements in McLuen that a surgeon would generally use a tool to insert a spinal implant. Pet. 28. McLuen discloses that:

To secure the bone fusion device 1500 in place, a user generally utilizes an implement such as a screw driver to turn the positioning means 1508. Screw drivers unfortunately have the ability to slip out of place. When performing surgery near someone’s spine, it is preferable to prevent or at least minimize the slipping ability. To do so, channels 1522 are implemented to receive a tool (not shown). The tool (not shown) has attachments that fit within the channels 1522 to secure the tool (not shown) in place.

Ex. 1030 ¶ 76. However, we do not read the Petition to rely on this teaching to support employing Allen’s tool with Baynham’s implant, but instead, the Petition relies on this teaching to support a modification directed to tool engagement indentations. *See* Pet. 27–29. Petitioner is the master of the Petition, and typically, the Board will not rely on a position not articulated in

a petition or otherwise fill gaps in a petition. *Cf. In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (“[T]he Board must base its decision on arguments that were advanced by a party, and to which the opposing party was given a chance to respond.”).

Accordingly, Petitioner fails sufficiently to support its reasons to combine Allen’s tool with Baynham’s implant.

Now turning to reasons to modify Baynham with McLuen, we determine that the Petition suffers from the same problem as we discuss above. We acknowledge that McLuen expressly discloses the benefits of using a tool to prevent a screwdriver from slipping, as Petitioner contends. *See* Pet. 28. We determine, however, that, absent hindsight, Petitioner fails to provide sufficient reasoning as to why a person having ordinary skill in the art would have moved Baynham’s indentations from end wall 36 to the sides of body 47 of distractor 42. For example, Petitioner fails to explain adequately why a tool (either a tool different from the one in Allen or a modified version of Allen’s tool) could not have been used to interface the indentations on end wall 36, without having to modify Baynham’s implant with McLuen’s channels 1522.

Also, Petitioner’s assertion that its proposed modification “represent[s] a design choice” fails to provide a sufficient reason, on the current record. Pet. 28–29. Petitioner does not adequately explain why the placement of Baynham’s indentations on end wall 36 solves no stated problem or is not critical to implanting Baynham’s device, such that moving the location is merely a matter of design choice. *See Ex Parte Spangler*, Appeal No. 2018-00300 (PTAB Feb. 20, 2019) (informative); *see also Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 n4. (Fed. Cir. 2018) (“The Board failed to consider that ‘[m]erely stating that a particular

placement of an element is a design choice does not make it obvious.’ Instead, the [Petitioner] must explain why a person of ordinary skill in the art ‘would have selected these components for combination in the manner claimed.’” (citations omitted); *cf. In re Kuhle*, 526 F.2d 553, 555 (CCPA 1975) (“Use of such a means of electrical connection in lieu of those used in the references solves *no stated problem* and would be an obvious matter of design choice within the skill in the art.” (emphasis added)). Said another way, we find no persuasive argument or credible supporting evidence to explain that the location of Baynham’s indentations are not critical to how its device is implanted into the spine, such that their locations could be moved as a matter of design choice or why such a modification would have been motivated.

Finally, an underlying basis for Petitioner’s position regarding modifying Baynham with McLuen’s teachings of side indentations is that the two openings adjacent to countersink 63 on end wall 36 of Baynham’s distractor 42 are tool indentations. *See* Pet. 26–27. Petitioner fails to provide any credible evidence that these openings are indeed tool indentations. *See id.*

c) Conclusion as to claim 1

For the reasons discussed above, we determine, on the current record, that Petitioner fails to provide the requisite reasoning, with rational underpinnings, for combining the teachings of Allen, Baynham, and McLuen. Accordingly, we determine that the information in the Petition does not demonstrate a reasonable likelihood that claim 1 is obvious over the combination of Allen, Baynham, and McLuen.

2. *Independent claims 9 and 20*

In contending that independent claims 9 and 20 are obvious over the combination of Allen, Baynham, and McLuen, Petitioner makes similar contentions, with respect to combining the teachings of Allen, Baynham, and McLuen, to the contentions we analyzed above for claim 1. *Compare* Pet. 41–46, 56–65 *with* Pet. 21–25. For the reasons discussed above in our analysis of claim 1, we determine, on the current record, that Petitioner fails to provide the requisite reasoning, with rational underpinnings, for combining the teachings of Allen, Baynham, and McLuen. Accordingly, we determine that the information in the Petition does not demonstrate a reasonable likelihood that claims 9 and 20 are obvious over the combination of Allen, Baynham, and McLuen.

3. *Dependent claims 2–4, 7, 8, 11, 12, 14, 15, 18, and 19*

We have reviewed Petitioner’s contentions with respect to dependent claims 2–4, 7, 8, 11, 12, 14, 15, 18, and 19. *See* Pet. 31–41, 46–55. We discern nothing in the Petition directed to these claims that remedies the deficiencies we identify above with respect to independent claims 1 and 9, from which these claims depend. Accordingly, we determine that the information in the Petition does not demonstrate a reasonable likelihood that dependent claims 2–4, 7, 8, 11, 12, 14, 15, 18, and 19 are obvious over the combination of Allen, Baynham, and McLuen.

E. Ground 2: Claims 5 and 21 as Obvious Over Allen, Baynham, McLuen, and Sutcliffe

Petitioner contends that the combination of teachings from Allen, Baynham, McLuen, and Sutcliffe renders dependent claims 5 and 21 obvious. *See* Pet. 6 (providing Petitioner’s asserted grounds), 65–67 (providing Petitioner’s analysis of claim 21 and relying on Sutcliffe’s

disclosure of side openings); 67–71 (providing Petitioner’s analysis of claim 5).

We have reviewed Petitioner’s contentions with respect to dependent claims 5 and 21. We discern nothing in the Petition directed to these claims that remedies the deficiencies we identify above with respect to independent claims 1 and 20, from which claims 5 and 21, respectfully, depend.

Accordingly, we determine that the information in the Petition does not demonstrate a reasonable likelihood that dependent claims 5 and 21 are obvious over the combination of Allen, Baynham, McLuen, and Sutcliffe.

III. CONCLUSION

After considering all the evidence and arguments presently before us, we determine that the information in the Petition fails to show a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition. Accordingly, we do not institute an *inter partes* review.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), the Petition is *denied*.

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Patent 10,478,319 B2

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