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571-272-7822

Paper 7
Entered: January 27, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner,

v.

MOSKOWITZ FAMILY LLC,
Patent Owner.

IPR2020-01304
Patent 10,307,268 B2

Before NEIL T. POWELL, JAMES A. TARTAL, and JAMES J. MAYBERRY, *Administrative Patent Judges*.

POWELL, *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 (Paper 1, "Pet.") requesting an *inter partes* review of claims 1, 3, 5, 7–11, and 21–26 ("the Challenged Claims") of U.S. Patent No. 10,307,268 B2 (Ex. 1001, "the '268 patent"). Mosowitz Family LLC ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.") to the Petition.

An *inter partes* review may not be instituted unless "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). We determine that Petitioner does not demonstrate a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the '268 patent is unpatentable. Accordingly, the Petition is denied, and no trial is instituted.

B. Real Parties in Interest

Petitioner identifies itself, Globus Medical, Inc., as the real party in interest. Pet. 1. Patent Owner identifies itself as the real party in interest. Paper 4, 2.

C. Related Matters

The parties indicate that the '268 patent is the subject of the following district court case: *Moskowitz Family LLC v. Globus Medical, Inc.*, Civil Action No. 2:20-cv-03271 (E.D. Pa.). Pet. 1–2; Paper 4, 2. The parties indicate that this district court case was transferred from the following prior district court case: *Moskowitz Family LLC v. Globus Medical, Inc.*, Civil Action No. 6:19-cv-672 (W.D. Tex.). Pet. 1–2; Paper 4, 2. Patent Owner

notes that the ’268 patent has also been challenged by Petitioner in IPR2020-01303. Paper 4, 2.

D. The ’268 Patent

The ’268 patent discloses inserting screw box constructs that have bi-directional fixating transvertebral (BDFT) screws into a denuded intervertebral disc space. Ex. 1001, 7:41–44. The ’268 patent discusses one embodiment of a screw box in connection with Figures 1A–1E. Figure 1B is reproduced below.

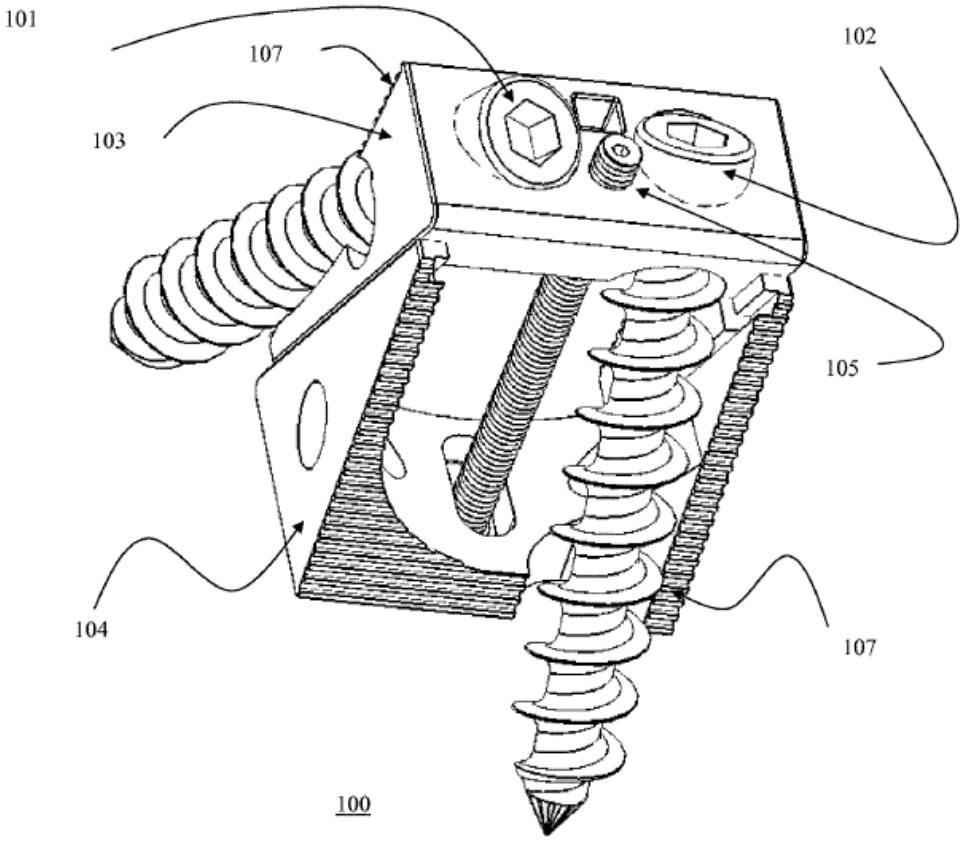

Fig. 1B

Figure 1B shows screw box 100, which includes BDFT screws 101, 102, triangular sliding bases 103, 104, and height/depth adjusting screw 105. *Id.* at 7:45–56.

Screw box 100 has provisions for adjusting its depth and height. *Id.* at 7:56–64. Triangular base 103 has sliding rails 106. *Id.* at 7:58–59. Triangular base 104 has corresponding rail inserts 107, on which rails 106 slide when adjusting screw 105 is turned. *Id.* at 7:56–60. When rails 106 slide on rail inserts 107, the height and depth of screw box 100 changes. *Id.* at 7:56–62. This allows customizing screw box 100 to the disc space. *Id.* at 7:60–64.

Each triangular base has ridges 107. *Id.* at 8:1–4. Ridges 107 contact adjacent vertebrae. *Id.* at 8:2–4. This helps screw box 100 fuse with and incorporate into those vertebrae. *Id.* at 8:4–6.

Screw box 100 serves as both a bi-directional transvertebral screw fusion device and an intervertebral bone fusion spacer. *Id.* at 8:6–12. Toward this end, screw box 100 allows bone placement intended for fusion by including holes 108, which perforate triangular base 103 and triangular base 104. *Id.* at 8:6–8. Additionally, to enable bone filling, screw box 100 is hollow. *Id.* at 8:8–10.

The ’268 patent also discloses external drill/screw guide-box expander 500. *Id.* at 8:58–62. External drill/screw guide-box expander 500 appears in Figures 5A–5C. *Id.* Figure 5A is reproduced below.

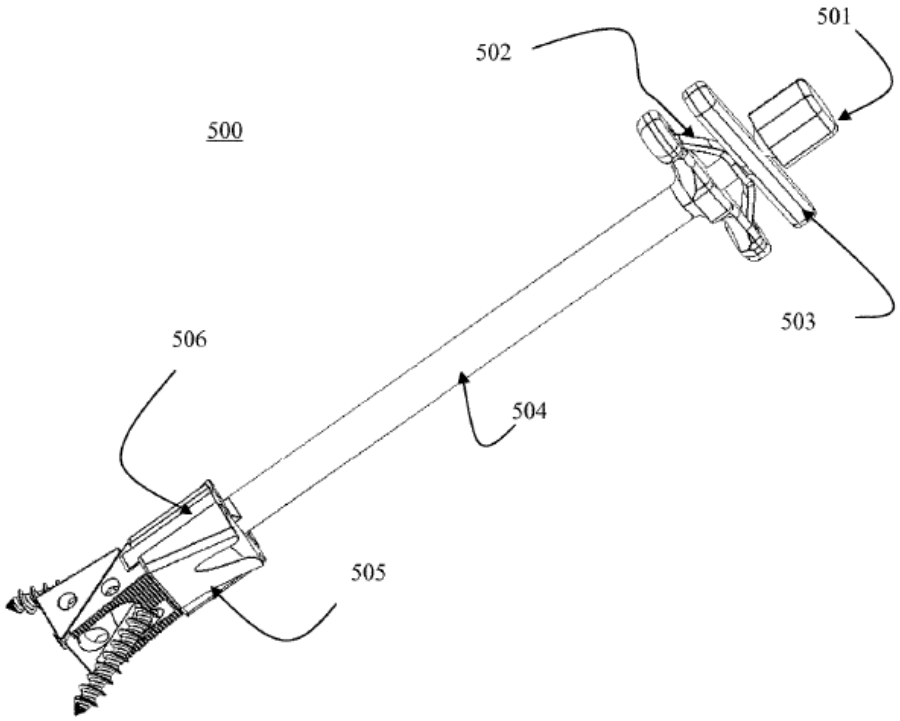

Fig. 5A

Figure 5A shows external drill/screw guide-box expander 500, which includes Allen key 501, spring 502, handle 503, griper 504, and screw guide 505. *Id.* at 8:58–65.

Griper 504 includes griper prongs 506. *Id.* at 9:1–2. Screw guide 505 has grooves into which griper prongs 506 insert. *Id.* at 9:2–3. Additionally, griper prongs 506 are inserted into a screw box. *Id.* This perfectly aligns them. *Id.* at 9:3–4.

The '268 patent explains the process of assembling external drill/screw guide-box expander 500. *Id.* at 9:9–15. Allen key 501 is inserted into handle 503. *Id.* at 9:11–12. Handle 503 is inserted through spring 502 and griper 504. *Id.* at 9:13–14. Griper 504 is inserted into screw guide 505. *Id.* at 9:14–15.

External drill/screw guide-box expander 500 can be used to adjust the width and depth of a screw box. *Id.* at 8:65–9:1. This is done by turning Allen key 501 to rotate the screw adjuster, "which in turn regulates top and bottom triangular screw box base sliding." *Id.*

E. Illustrative Claim

Of the challenged claims, claims 1 and 21 are independent. Claim 1 is reproduced below with certain reformatting.[1]

1. [1.1] A system comprising:

an intervertebral expandable implant having a first vertebral body engagement surface for engaging a first vertebral body and a second vertebral body engagement surface for engaging a second vertebral body, wherein the second vertebral body engagement surface is positioned opposite of the first vertebral body engagement surface, the intervertebral expandable implant comprising:

[1.2] a first implant structure defining the first vertebral body engagement surface and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail between the first inwardly-facing rail and the first

[1] We have added carriage returns and numbered the claim limitations with the same numbers used by the Petition to identify claim 1's limitations.

vertebral body engagement surface, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the first vertebral body engagement surface,

[1.3] wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the first vertebral body engagement surface, wherein the first implant structure defines an end gap between the first and second opposing side surfaces at a first end of the first vertebral body engagement surface,

[1.4] wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein at least some of the ridges are positioned on the first vertebral body engagement surface on opposite sides of the end gap;

[1.5] a second implant structure defining a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first

inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure,

[1.6] wherein the second implant structure defines third and fourth opposing side surfaces positioned on opposite sides of the second vertebral body engagement surface,

[1.7] wherein the second implant defines first and second tool engagement indentations on the third and fourth opposing side surfaces, respectively, wherein the first and second tool engagement indentations are positioned proximate a proximate end of the second implant structure, and

[1.8] wherein the second implant structure defines an adjusting screw hole sized for receiving an adjusting screw at a proximal portion of the second implant structure between the third and fourth side surfaces; and

[1.9] an adjusting screw positioned in the adjusting screw hole;

[1.10] a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first distal end, wherein the first and second engagement prongs are sized and positioned to extend into the first and second tool engagement indentations of the second implant structure so as to allow the first tool to engage the intervertebral expandable implant; and

[1.11] a second adjusting tool having a second proximal end and a second distal end with a handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the handle to the

> screw engagement portion, wherein the screw engagement portion is sized and configured for engaging and turning the adjusting screw when the screw engagement portion is engaged with the adjusting screw, 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 to engage and turn the adjusting screw of the intervertebral expandable implant to expand the intervertebral expandable implant when the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the intervertebral expandable implant.

Ex. 1001, 13:2–14:36.

F. Evidence

Petitioner submits the following evidence:

Evidence	Exhibit No.
Declaration of Dr. Jorge A. Ochoa ("Ochoa Declaration")	1003
McLuen, US 2006/0253201 A1, published Nov. 9, 2006 ("McLuen")	1030
Allen, US 5,658,335, issued Aug. 19, 1997 ("Allen")	1031
Sutcliffe, US 2002/0143399 A1, published Oct. 3, 2002 ("Sutcliffe")	1032
Chung et al., KR 20-0290058, issued Sept. 10, 2002 ("Chung")	1033

G. Asserted Grounds

Petitioner asserts that the challenged claims are unpatentable on the following grounds:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1, 3, 5, 7–10	103	Chung, McLuen, Allen
11, 21–26	103	Chung, McLuen, Allen, Sutcliffe

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Regarding the level of skill in the art, Petitioner asserts that

> [a]s established in the Declaration of Dr. Ochoa, (EX1003, at ¶¶ 26-30; EX1004) a person having ordinary skill in the art (PHOSITA) of the '268 patent would have a Bachelor's or equivalent degree in Mechanical Engineering or a related discipline (e.g. biomechanics or biomedical engineering), and at least five years of experience. The 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. Alternatively, a PHOSITA could have an advanced degree in the technical disciplines noted above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above.

Pet. 14. Patent Owner does not dispute this characterization of the level of skill in the art. *See generally,* Prelim. Resp. For purposes of deciding whether to institute *inter partes* review, we adopt Petitioner's proposed level of skill in the art.

B. Legal Principles

A claim is unpatentable for obviousness 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." *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 skill in the art; and (4) when in evidence, objective indicia of nonobviousness, i.e., secondary considerations.[2] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Additionally, the obviousness inquiry typically requires an analysis of "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")); *see In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1333 (Fed. Cir. 2016) (citing *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006)).

C. Claim Construction

In an *inter partes* review proceeding, a claim of a patent is construed using the same standard used in federal district court, including construing the claim in accordance with the ordinary and customary meaning of the claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. 37 C.F.R. § 42.100(b) (2019). According to the applicable standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art in

[2] At this time, the parties do not address objective indicia of nonobviousness, which accordingly do not form part of our analysis.

question at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317. Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. America Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999)).

Arguing that most terms in the challenged claims "should be given their ordinary and customary meaning," Petitioner asserts that certain claim terms "should be construed in accordance with the intrinsic evidence and Petitioner offered the same constructions in the pending litigation." Pet. 12–13. Petitioner then offers proposed constructions for the claim language "first implant structure," "second implant structure," "adjusting screw positioned in the adjusting screw hole," "an adjusting tool passage extending through the first tool from the first proximal end to the first distal end," and "an indentation adjacent to the screw hole." *Id.* at 13.

Patent Owner argues that Petitioner does not meet our requirements for construing claim language. Prelim. Resp. 9–17. Noting that Petitioner offers no construction for claim 3, Patent Owner argues that this omission violates 37 C.F.R. § 42.104(b)(3). *Id.* at 9–14. Patent Owner argues that

"there is no dispute that" 35 U.S.C. § 112, ¶ 6 "controls" claim 3's recitation of "means to facilitate incorporation into and fusion with the superior and inferior vertebral bodies." *Id.* at 11. In support of this, Patent Owner notes that Petitioner identified this claim language as a means-plus-function term in the related district court proceeding. *Id.* Patent Owner also argues that Petitioner did not explain adequately its bases for the claim constructions that the Petition does propose. *Id.* at 15–17.

We find it necessary to discuss only one claim-construction issue. Specifically, we address the Petition's omission of any construction for claim 3's language "means to facilitate incorporation into and fusion with the superior and inferior vertebral bodies." We require that the Petition "set forth . . . [h]ow the challenged claim is to be construed," and "[w]here the claim to be construed contains a means-plus-function or step-plus-function limitation . . . , the construction of the claim must identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function." 37 C.F.R. § 42.104(b)(3). Additionally, where, as here, the claim language contains the word "means," we presume that the language is means-plus-function claim language. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (citing *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed. Cir. 1998)).

Petitioner has not argued that this presumption is rebutted, nor has Petitioner cited any evidence to rebut this presumption. *See generally,* Pet. Petitioner also has not identified the specific portions of the Specification that describe the structure, material, or acts corresponding to the function recited in claim 3. *See id.* Given our requirements and the presumption that

claim 3 contains means-plus-function language, Petitioner's silence regarding the meaning of claim 3 supports denial of the Petition. To the extent the Petition does not violate Rule 42.104(b)(3) by omitting any discussion of claim 3's meaning, this omission creates burdensome issues for Patent Owner and the Board. In combination with certain deficiencies discussed in detail below, the Petition's silence regarding the meaning of claim 3 contributes to our decision to deny the Petition.

D. Alleged Obviousness of Claims 1, 3, 5, and 7–10 over Chung, McLuen, and Allen

1. Overview of Chung

Chung discloses a lumbar holder. Ex. 1033, 5. Chung's lumbar holder appears in Figure 1. *Id.* at 2. Figure 1 of Chung is reproduced below.

Figure 1

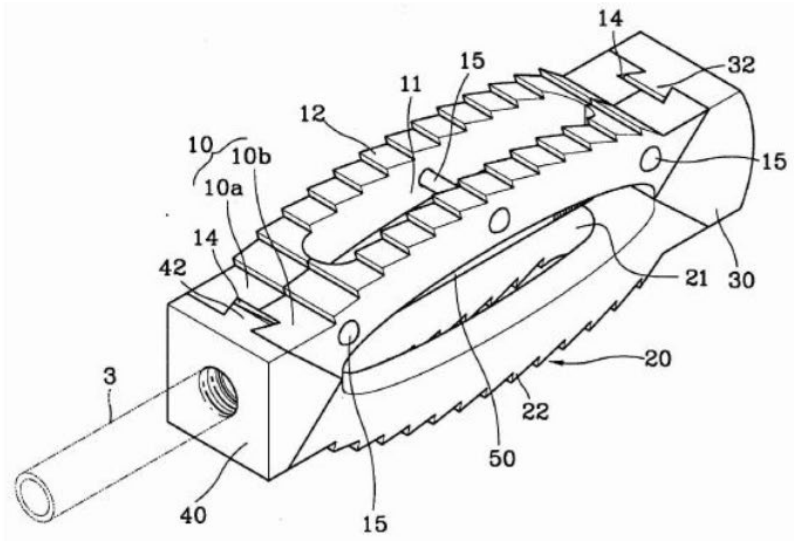

Figure 1 shows Chung's lumbar holder, which includes holder body (10), opposing holder body (20), lead wedge (30), and opposing wedge (40). *Id.* at 5.

Holder bodies (10), (20) have an arch shape. *Id.* Saw tooth (12) is on an outer surface of holder body (10). *Id.* Saw tooth (22) is on an outer surface of holder body (20). *Id.*

Figure 2 of Chung is reproduced below.

Figure 2

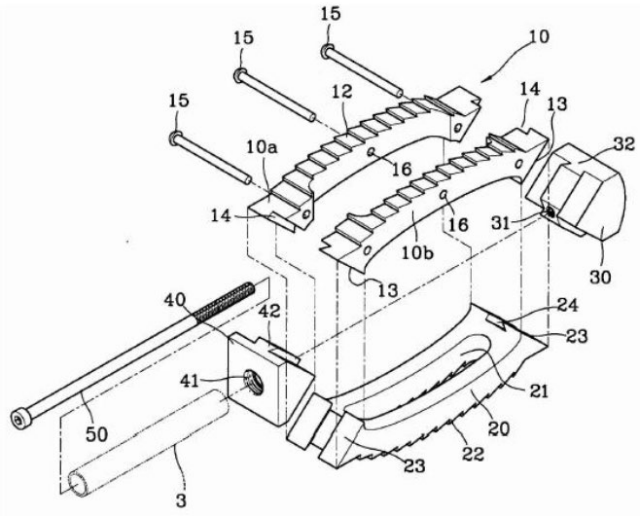

Figure 2 shows Chung's holder body in a disassembled state. *Id.* at 2.

Wedge (30) includes a dovetail (32), and wedge 40 includes a dovetail (42). *Id.* at 5. Corresponding dovetail grooves (14), (24) are formed on holder bodies (10), (20). *Id.* at 2, 5, Fig. 2. Holder bodies (10), (20) also have guiding surfaces (13), (23). *Id.* at 2, 5, Fig. 2.

Chung also discloses groove fastening screw (50). *Id.* at 2, 5, Fig. 2. Wedges (30), (40) have provisions for engaging groove fastening screw. *Id.* at 5. As Chung explains, "wedge (30) has a screw hole (31) of certain diameter formed at the center in order for the screw component of the aforementioned groove fastening screw (50) to be fastened." *Id.* at 6. Chung also teaches that "wedge (40) has a penetrating hole (41) with raised spot in order for the aforementioned groove fastening screw (50)'s head to be held." *Id.*

Chung also discloses wrapper (3). *Id.* at 2, 6, Fig. 2. Wedge (40) includes provisions for engaging wrapper (3). *Id.* at 6. As Chung explains,

> wedge (40)'s penetrating hole (41) has a double raised spot structure that expands to the external side, and on the inner circumference of the large diameter side of the aforementioned penetrating hole (41), a screw line is formed in the direction of the left screw so that a circular pipe wrapper (3) with which the operating person can wrap the aforementioned lumber holder can be combined.

Id.

Chung discusses how its lumbar holder is inserted between vertebrae in connection with Figure 3. *Id.* at 6. Figure 3 is reproduced below.

Figure 3

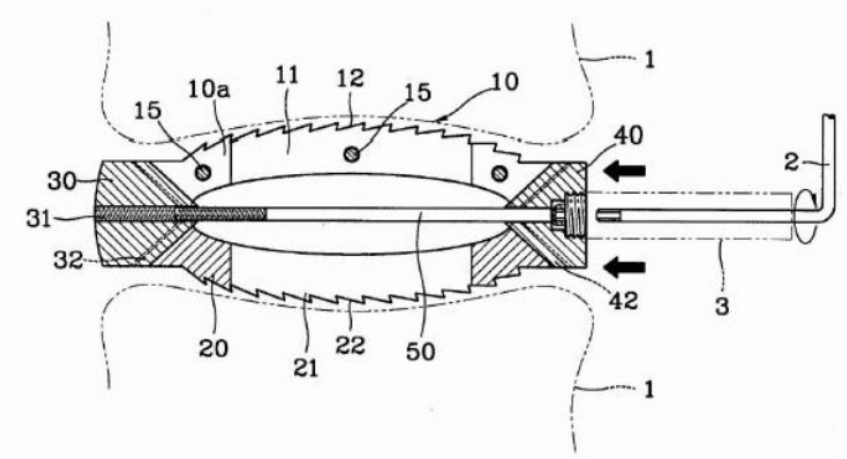

Figure 3 is a cross-sectional view of Chung's lumbar holder inserted between two vertebrae. *Id.* at 2.

> Outlining details of the insertion process, Chung explains that
>
> with the lumber holder under the present invention with the aforementioned configuration, after holding the wrapper (30) and inserting between neighboring two back bones (1), a wrench (2) is inserted into the aforementioned wrapper (3) to fasten the aforementioned groove fastening screw (50) so that the outer surfaces of the main holder bodies (10) (20) are attached to the

surfaces of the aforementioned back bones (1) to fix them robustly.

Id. at 6.

Chung discusses the effect of adjusting groove fastening screw (50) in connection with Figure 4. *Id.* Figure 4 is reproduced below.

Figure 4

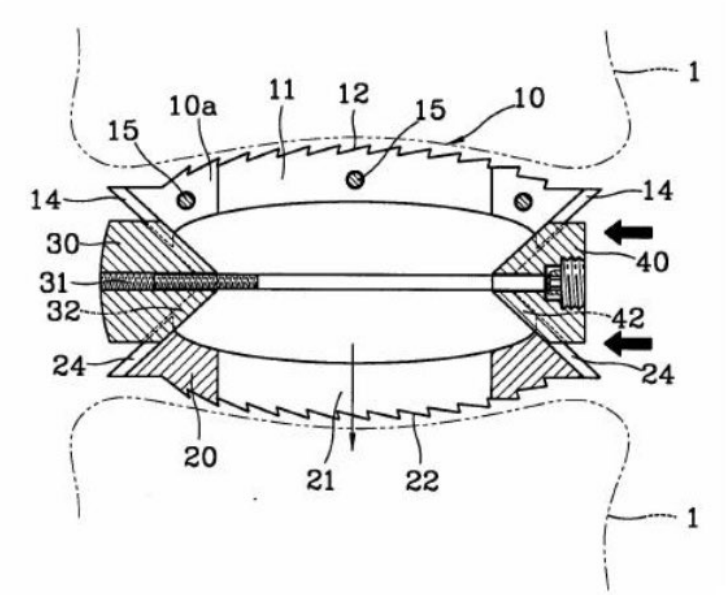

Figure 4 is a cross-sectional view of Chung's lumbar holder adjusting the space between vertebrae. *Id.* at 2.

Tightening groove fastening screw (50) draws wedges (30), (40) toward one another. *Id.* at 6. When this happens, the interaction between dovetails (32), (42) and guiding surfaces (13), (23) drives main bodies (10), (20) away from one another. *Id.*

2. Overview of McLuen

McLuen discloses a bone fusion device as shown in Figure 16. Ex. 1030 ¶ 73. Figure 16 is reproduced below.

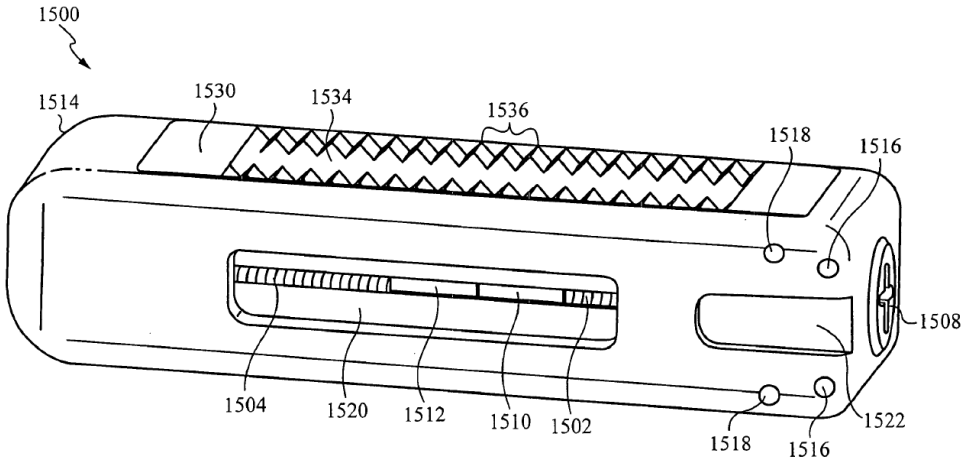

Fig. 16

Figure 16 shows bone fusion device 1500, which includes first screw 1502, second screw 1504, positioning means 1508, first extending block 1510, second extending block 1512, frame 1514, channels 1522, and tabs 1530. *Id.* ¶¶ 74, 76.

Bone fusion device 1500 functions as follows. Positioning means 1508 can be rotated to drive extending blocks 1510, 1512 closer to screws 1502, 1504. *Id.* ¶ 75. As this happens, tabs 1530 are pushed outward by blocks 1510, 1512. *Id.* This drives tabs 1530 against surrounding bones, thereby anchoring bone fusion device 1500 in place. *Id.* McLuen further explains 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.

Id. ¶ 76.

3. Overview of Allen

Allen discloses an embodiment of a spinal fixator in connection with Figures 1–13. Ex. 1031, 3:21–52. Figure 3 is reproduced below.

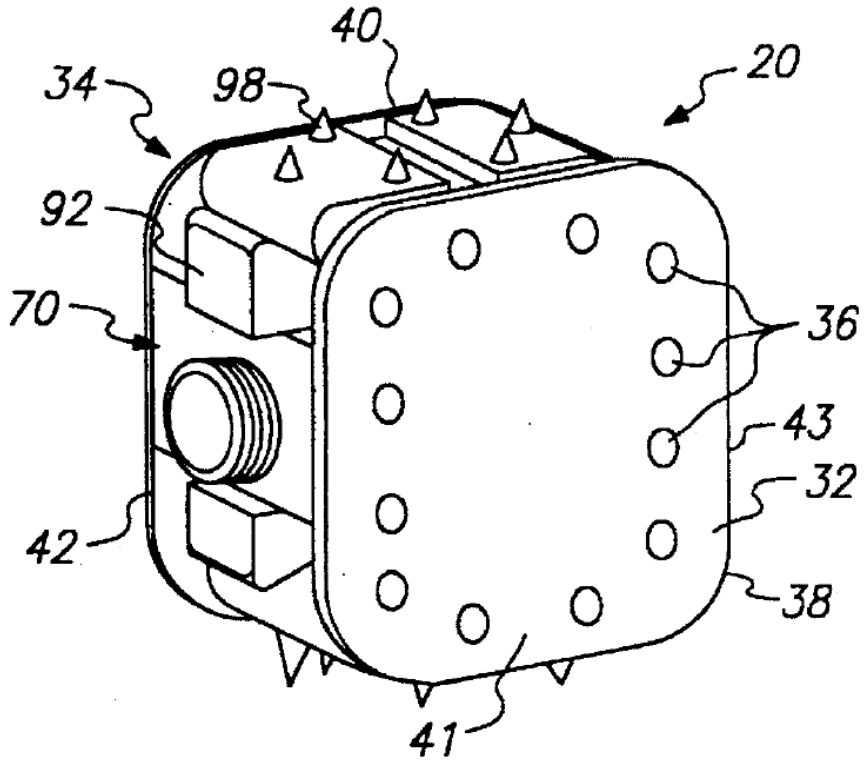

FIG. 3

Figure 3 is a perspective illustration of spinal fixator 20, which includes front cover 32, back cover 34, nut assemblies 70, and crown members 90 (not labeled in Figure 3). *Id.* at 3:29–30. "Each crown member defines a curved flange 92." *Id.* at 4:51–52. Conical teeth 98 project from crown members 90. *Id.* at 4:62–63.

Allen discusses inserting spinal fixator 20 between vertebrae as shown in Figure 12. *Id.* at 5:5–20. Figure 12 is reproduced below.

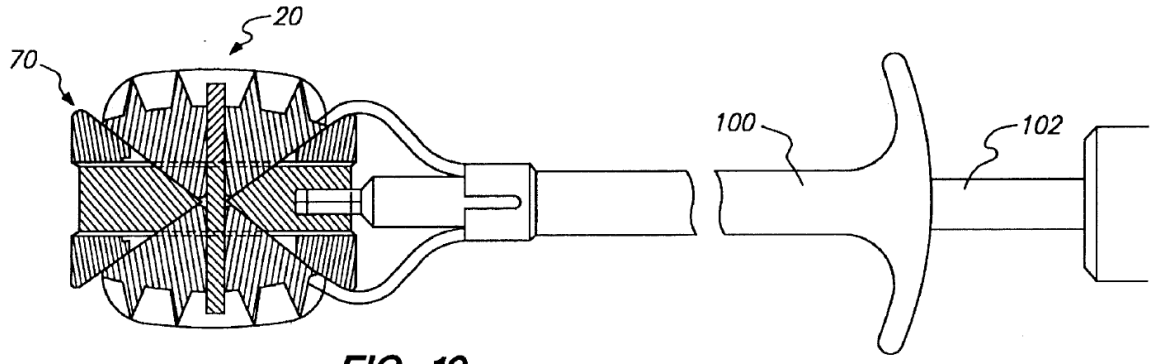

FIG. 12

Figure 12 shows spinal fixator 20 with hollow insertion tool 100 and tool 102. *Id.* at 3:48–50, 5:15–20.

Allen explains that "[a] conventional, hollow insertion tool 100 is used to gasp a nut assembly 70 to insert the retracted spinal fixator 20 between" vertebrae. *Id.* at 5:18–20. Subsequently, tool 102 is passed through hollow insertion tool 100 to engage within aperture 60 (not labeled in Figure 12) of core member 50 (not labeled in Figure 12). *Id.* at 5:21–23. Then, using tool 102, core member 50 is rotated, driving crowns 90 (not labeled in Figure 12) outward, pushing teeth 98 (not labeled in Figure 12) into adjacent vertebrae (not shown in Figure 12). *Id.* at 5:23–26. Tool 102 has "a terminus defining a hex configuration." *Id.* at 5:21–22.

4. Discussion

Petitioner asserts that it would have been obvious to modify and combine certain teachings of Chung, McLuen, and Allen in ways that meet the limitations of claims 1, 3, 5, and 7–10. Pet. 20–45. Asserting that Chung's apparatus has tool engagement indentations, the Petition asserts that it would have been obvious to move those tool engagement indentations to side surfaces of the apparatus. *Id.* at 30–33. Petitioner also argues that it would have been obvious to use Allen's tools 100, 102 with Chung's apparatus. *Id.* at 34–38. Additionally, Petitioner asserts that it would have

been obvious to the combination of the references' teachings in certain ways required by method claims 9 and 10. *Id.* at 41–45.

Patent Owner argues that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertions of obviousness. Prelim. Resp. 1–2, 9–27. Patent Owner argues that Petitioner has not supported sufficiently its assertions that it would have been obvious to make certain modifications to Chung's apparatus. *E.g., id.*, at 22–27.

We agree with Patent Owner that Petitioner has not carried its burden to demonstrate a reasonable likelihood of prevailing on even one Challenged Claim. In the following sections, we address in detail at least some of the Petition's shortcomings.

a. *Claim Limitation 1.7*

Claim limitation 1.7 requires "wherein the second implant defines first and second tool engagement indentations on the second and third opposing side surfaces, respectively, wherein the first and second tool engagement indentations are positioned proximate a proximate end of the second implant structure." Ex. 1001, 13:62–67. Addressing this claim limitation, Petitioner asserts that "Chung discloses the second implant [structure] (40 and 20) defines tool engagement indentations for engagement of tool (3)." Pet. 30. Petitioner elaborates that

> [a person having ordinary skill in the art] would have understood that Chung discloses that the opposing wedge (40) has a penetrating hole (41) with a counter bore ("double raised spot structure") that expands to the external side, and on the inner circumference of the large diameter side of the penetrating hole (41), a screw thread ("line") is formed so that a circular pipe tool ("wrapper") (3) can be used by the surgeon to hold and position the implant.

Id. at 31. Petitioner adds that

> [t]o the extent that Chung does not explicitly disclose first and second tool engagement indentations on the third and fourth opposing side surfaces of the second implant (40 and 20), it would have been obvious to [person having ordinary skill in the art] as a matter of simple substitution to modify the implant disclosed to move the indentation from the hole (41) to the third and fourth opposing sides of the second implant structure (40 and 20), so that the first and second tool engagement indentations are positioned proximate a proximate end of the second implant structure. Stated another way, placement and positioning of indentations for insertion tool engagement at the proximate end of the second implant structure is a predictable substitution that does not affect the function of the implant.

Id. at 31–32.

In support of its assertion that it would have been obvious to modify Chung's lumbar holder to have indentations as recited in claim limitation 1.7, Petitioner also cites McLuen. *Id.* at 32. Petitioner argues that McLuen "discloses channels or indentations (1522) on opposing sides of the implant to receive a tool" to minimize or prevent a screwdriver from slipping out of place when using a screwdriver to turn screw 1508. *Id.* Petitioner and Dr. Ochoa conclude that

> [i]t would therefore have been obvious to a [person having ordinary skill in the art] to combine the teachings of Chung with McLuen to modify the indentation disclosed in Chung as disclosed in McLuen, moving the indentation from the counter bored structure of penetrating hole (41) to a position proximate a proximate end of the second implant structure to provide the disclosed advantages of prevention or minimization of screw driver slippage.

Id. at 32–33; Ex. 1003 ¶ 121.

We do not find that Petitioner has provided sufficient rational underpinning for its contention that it would have been obvious to modify Chung's structure to have "first and second tool engagement indentations on

the second and third opposing side surfaces," as required by claim limitation 1.7. Petitioner's arguments regarding McLuen do not provide rational underpinning for Petitioner's obviousness assertion. Petitioner indicates that a person having ordinary skill in the art would add McLuen's indentations to Chung's system in order to prevent or minimize slippage of a screwdriver. Pet. 32. Petitioner fails, however, to present persuasive explanation or evidence that McLuen's concerns about screwdriver slippage would apply to Chung's system. In Chung's system, "a wrench (2) is inserted into the aforementioned wrapper (3) to fasten the aforementioned groove fastening screw (50) so that the outer surfaces of the main holder bodies (10) (20) are attached to the surfaces of the aforementioned back bones (1) to fix them robustly." Ex. 1033 6. Petitioner does not present persuasive evidence that Chung's system uses a screwdriver that could slip. Nor does Petitioner present persuasive evidence that a person having ordinary skill in the art would have had any concerns about tool slippage with wrench (2) inserted into wrapper (3). Therefore, Petitioner does not persuade us sufficiently that a person having ordinary skill in the art would have had reason based on McLuen to modify Chung's system.

Like its arguments regarding McLuen, Petitioner's other allegations in support of obviousness also fail to provide sufficient rational underpinning. For example, Petitioner does not provide persuasive evidence of its assertion that "placement and positioning of indentations for insertion tool engagement at the proximate end of the second implant structure is a predictable substitution that does not affect the function of the implant." Pet. 31–32. Dr. Ochoa's testimony matches Petitioner's assertion, but Dr. Ochoa cites no supporting evidence for this opinion. *See* Ex. 1003 ¶ 121.

Therefore, we find Dr. Ochoa's testimony provides little persuasive support for the suggestion that the proposed modification amounts to no more than a predictable substitution. *See* 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."). Petitioner's and Dr. Ochoa's other assertions regarding how easily the modification could have been made suffer from the same lack of persuasive supporting evidence. *See* Pet. 31–32; Ex. 1003 ¶ 121.

Moreover, even if we accepted as accurate the Petition's assertions regarding how easily a person having ordinary skill in the art could have modified Chung's system, these assertions do not provide rational underpinning for the assertion of obviousness, as Petitioner does not provide sufficiently persuasive reasoning or evidence of why a person having ordinary skill in the art would have modified Chung in the proposed manner. "[O]bviousness 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) (emphases added).

For these reasons, the Petition does not provide sufficiently persuasive evidence that it would have been obvious to modify Chung's apparatus in a manner that it would meet claim limitation 1.7. Accordingly, the Petition does not demonstrate a reasonable likelihood of prevailing on its assertion that independent claim 1 would have been obvious over Chung, McLuen, and Allen. Additionally, the Petition's discussion of dependent claims 3, 5, and 7–10 fails to sure the deficiency in the discussion of independent claim 1.

Also, as discussed in detail immediately below in Section II.D.4.b, the Petition does not provide a sufficiently clear explanation of how the combination of the cited references' teachings would allegedly meet both claim limitation 1.7 and claim limitation 1.8.

b. *Claim Limitation 1.8*

Claim limitation 1.8 recites "wherein the second implant structure defines an adjusting screw hole sized for receiving an adjusting screw at a proximal portion of the second implant structure between the third and fourth side surfaces." Ex. 1001, 13:67–14:4. Addressing this claim language, the Petition vaguely cites some of the same portions of Chung's teachings that the Petition cites in addressing claim limitation 1.7's "tool indentations." In arguing that Chung teaches "tool engagement indentations," the Petition explains that "Chung discloses that the opposing wedge (40) has a penetrating hole (41) with a counter bore." Pet. 30–31. The Petition then argues that "it would have been obvious . . . to modify the implant disclosed to move the indentation from the hole (41) to the third and fourth opposing side surfaces of the second implant structure." *Id.* at 31. Subsequently, when addressing claim limitation 1.8, the Petition states that "Chung discloses the second implant structure (40 and 20) defines an adjusting hole (41) sized for receiving an adjusting screw (50) at a proximal portion of the second implant structure (40 and 20) between the third and fourth side surfaces." *Id.* at 33.

We find these vague explanations in the Petition do not explain with adequate clarity which features of Chung allegedly constitute claim limitation 1.7's "tool engagement indentations," and which allegedly constitute claim limitation 1.8's "adjusting screw hole." For example, the

Petition does not explain clearly enough how claim 1.7's "tool engagement indentations" are taught by "penetrating hole (41) with a counter bore." *See* Pet. 31. Additionally, the Petition does not explain with sufficient clarity how the same disclosed features of Chung's apparatus meet both claim limitation 1.7's "tool engagement indentations" and claim limitation 1.8's "adjusting screw hole." We find the explanation particularly confusing in view of the Petition's assertion that it would have been obvious to move the features of Chung constituting "tool engagement indentations" to third and fourth side surfaces. If a person having ordinary skill in the art would have moved the alleged "tool engagement indentations" of Chung to the third and fourth side surfaces, we find it unacceptably unclear how the Petition could rely on the same features as meeting claim 1.8's requirement for "an adjusting screw hole . . . between the third and fourth side surfaces."

The Petition's unacceptably confusing explanation of how both claim limitations 1.7 and 1.8 were taught by or obvious over Chung prevents Petitioner from demonstrating a reasonable likelihood of prevailing on its assertion that independent claim 1 would have been obvious over Chung, McLuen, and Allen. Additionally, the Petition's discussion of dependent claims 3, 5, and 7–10 does not remedy this deficiency.

c. *Claim Limitation 1.10*

Claim limitation 1.10 recites, among other things,

> a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first distal end.

Ex. 1001, 14:7–11. Addressing claim limitation 1.10, Petitioner asserts that

> [a person having ordinary skill in the art] would have understood that Chung discloses that a circular pipe tool ("wrapper") (3) can

> be used by the surgeon to hold and position the implant. EX1033 at 6 (¶ 2-3). Further, Chung discloses that the circular pipe tool (3) has an adjusting tool passage for receiving wrench (2). EX1033 at 6 (¶ 2-3); FIG. 3; EX1003 at ¶ 124.

Pet. 34. Petitioner adds that "Allen discloses a hollow first tool (100) having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and an adjusting tool passage extending through the first tool from the first proximal end to the first distal end." *Id.* Petitioner argues that

> [i]t would have been obvious to a [person having ordinary skill in the art] to use the prongs on the tool disclosed by Allen to engage the first and second tool indentations of the second implant structure disclosed by Chung in combination with McLuen to insert the implant into the disk space between adjacent vertebrae.

Id. at 35.

We do not find Petitioner has provided sufficient rational underpinning for its assertion that it would have been obvious to modify Chung's system to use Allen's tool 100. Petitioner supports its obviousness contention by asserting that a person having ordinary skill in the art would recognize Allen's tool 100 has been configured to engage Chung's apparatus with modifications based on McLuen. *Id.* at 35. Specifically, Petitioner argues that

> [a person having ordinary skill in the art] would have understood that the first and second engagement prongs of [Allen's] insertion tool (100) are sized and positioned to extend into the first and second tool engagement indentations of a structure (the second implant structure (40 and 20) of Chung in view of McLuen noted above) to allow the first tool to engage the intervertebral expandable implant.

Id. This exact assertion also appears in Dr. Ochoa's testimony, which cites

no supporting evidence for the assertion. Ex. 1003 ¶ 125. This unsupported assertion is unpersuasive and lacks a logical foundation. In particular, there is no plausible support for Petitioner's assertion that the prongs of Allen's tool 100 "are sized and positioned to extend into" indentations of "a structure . . . of Chung in view of McLuen." Petitioner presents no evidence that any structure of "Chung in view of McLuen" ever existed. Petitioner offers no rational reason that a person having ordinary skill in the art "would have understood that" Allen's tool 100 was created with prongs sized and positioned to engage indentations in a hypothetical structure that never existed. For at least this reason, Petitioner's obviousness contentions do not make sense.

Moreover, even if we accepted Petitioner's factual assertions as accurate, Petitioner does not provide sufficient rational underpinning for its assertion of obviousness. Even if accurate, Petitioner's assertions might demonstrate that a person having ordinary skill could have combined the references' teachings in the asserted manner, but they do not sufficiently support any reason that a person having ordinary skill in the art would have combined the references' teachings in the asserted manner. *See Belden*, 805 F.3d at 1073. Petitioner acknowledges that "[a person having ordinary skill in the art] would have understood that Chung discloses that circular pipe tool ('wrapper') (3) can be used by the surgeon to hold and position the implant" (Pet. 36), and Petitioner does not provide a persuasive reason that a person having ordinary skill in the art would have modified Chung's system to use Allen's tool 100 to hold and position the implant.

d. *Claim 9*

Claim 9 recites "[a] method of using the system of claim 1."

Ex. 1001, 14:66. The method of claim 9 includes, among other steps, "implanting the intervertebral expandable implant into a disc space in a lumbar spine via the first tool using a transforaminal lumbar interbody fusion (TLIF) approach." *Id.* at 15:5–8.

Petitioner's challenge of claim 9 builds on the challenge of independent claim 1 as allegedly obvious over Chung, McLuen, and Allen. *See* Pet. 41. Petitioner's challenge of claim 9 as obvious over Chung, McLuen, and Allen does not remedy the above-discussed deficiencies in the challenge of independent claim 1. For at least this reason, Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claim 9 would have been obvious over Chung, McLuen, and Allen.

Moreover, Petitioner's challenge of claim 9 suffers from its own, unique shortcomings. In particular, Petitioner's assertion that it would have been obvious to use Chung's system in accordance with the steps of claim 9 rests primarily on testimony of Dr. Ochoa, which we find has limited persuasive weight. Addressing claim 9's requirement for employing Chung's system "using a transforaminal lumbar interbody fusion (TLIF) approach," Dr. Ochoa testifies that

> [a person having ordinary skill in the art] would have understood that during the transforaminal approach, the surgical window is created through the removal of a facet joint to provide access to the disk space. A [person having ordinary skill in the art] would further have understood that this narrow surgical window requires an appropriately shaped cage. To the extent that Chung does not expressly disclose a use in a TLIF approach, a [person having ordinary skill in the art] would have further understood that the narrow, low profile geometry of the cage disclosed by Chung would be appropriate for use in a TLIF procedure. Further modifications for use in this application would be a matter of additional optimization of the geometry that would not

> affect the function of the invention and would therefore be an obvious design choice.

Ex. 1003 ¶ 138. In his testimony, Dr. Ochoa cites no supporting evidence for his opinions regarding the use and/or modification of Chung's system in a TLIF procedure. For example, he cites no supporting evidence of facts on which he bases his opinion that a person having ordinary skill in the art would have understood that Chung's implant "would be appropriate for use in a TLIF procedure." Nor does he cite any supporting evidence for his opinion that it "[f]urther modifications for use in [a TLIF] application would be a matter of additional optimization of the geometry that would not affect the function of the invention and would therefore be an obvious design choice." *Id.* Due to its lack of supporting evidence, we find Dr. Ochoa's testimony has little persuasive weight. *See* 37 C.F.R. § 42.65(a). This constitutes another reason that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claim 9 would have been obvious over Chung, McLuen, and Allen.

e. *Claim 10*

Claim 10 recites "[a] method of using the system of claim 1." Ex. 1001, 15:15. The method of claim 10 includes, among other steps, "implanting the intervertebral expandable implant into a disc space in a lumbar spine via the first tool using a posterior lumbar interbody fusion (PLIF) approach." *Id.* at 15:21–23.

Petitioner's challenge of claim 10 builds on the challenge of independent claim 1 as allegedly obvious over Chung, McLuen, and Allen. *See* Pet. 44. Petitioner's challenge of claim 10 as obvious over Chung, McLuen, and Allen does not remedy the above-discussed deficiencies in the challenge of independent claim 1. For at least this reason, Petitioner has not

demonstrated a reasonable likelihood of prevailing on its assertion that claim 10 would have been obvious over Chung, McLuen, and Allen.

Moreover, Petitioner's challenge of claim 10 suffers from its own, unique shortcomings. In particular, Petitioner's assertion that it would have been obvious to use Chung's system in accordance with the steps of claim 10 rests primarily on testimony of Dr. Ochoa, which we find has limited persuasive weight. Addressing claim 10's requirement for employing Chung's system "using a transforaminal lumbar interbody fusion (TLIF) approach," Dr. Ochoa testifies that

> [t]o the extent that Chung does not expressly disclose a posterior lumbar interbody fusion (PLIF) approach, a [person having ordinary skill in the art] would have understood the Chung device is of a low-profile and narrow geometry typical for posterior devices. Further, a [person having ordinary skill in the art] would have understood that the lumbar spine is almost exclusively the location in which interbody cages are implanted using a posterior approach. Therefore, it would have been obvious that the implant disclosed by Chung would be appropriate for use in a PLIF procedure.

Ex. 1003 ¶ 141. In his testimony, Dr. Ochoa cites no supporting evidence for the alleged facts on which he bases his opinion that it would have been obvious that Chung's implant "would be appropriate for use in a PLIF procedure." Due to its lack of supporting evidence, we find Dr. Ochoa's testimony has little persuasive weight. *See* 37 C.F.R. § 42.65(a). This constitutes another reason that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claim 10 would have been obvious over Chung, McLuen, and Allen.

E. Alleged Obviousness of Claims 11 and 21–26 over Chung, McLuen, Allen, and Sutcliffe

a. *Overview of Sutcliffe*

Sutcliffe discloses an implant for insertion between vertebrae. Ex. 1032 ¶ 22. One embodiment of Sutcliffe's implant appears in Figure 6. *Id.* ¶ 21. Figure 6 is reproduced below.

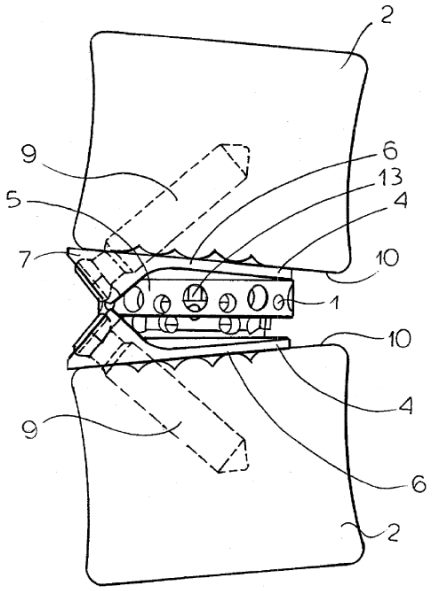

FIG.6

Figure 6 shows implant 1 disposed between vertebrae 2. *Id.* ¶¶ 21–22.

Implant 1 includes lower end part 3, upper end part 4, and center part 5. *Id.* ¶ 22. Each of lower end part 3, upper end part 4, and center part 5 has threads. *Id.* These threads connect lower end part 3, upper end part 4, and center part 5 in a manner that allows spreading apart or pulling together upper end part 4 by rotating center part 5 in one direction or another. *Id.*

Lower part 3 has two eyes 6 with collars 7 forming holes or passages 8. *Id.* ¶ 24. To secure lower part 3 to a lower vertebra 2, cortical

screws pass through eyes 6 and penetrate the lower vertebra 2. *Id.* Figure 6 shows upper end part 4 with a similar pair of eyes 6. *Id.*

b. *Discussion*

Petitioner's challenge of claims 11 and 21–26 builds from its challenge of independent claim 1 as allegedly obvious over Chung, McLuen, and Allen. *See, e.g.*, Pet. 45–53. Petitioner's challenge of claims 11 and 21–26 does not remedy the deficiencies in its challenge of independent claim 1. Accordingly, Petitioner has not demonstrated a reasonable likelihood of prevailing on its challenge of claims 11 and 21–26.

III. CONCLUSION

Petitioner does not demonstrate a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the '268 patent is unpatentable.

IV. ORDER

It is hereby

ORDERED that the Petition is denied, and no trial is instituted.

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