

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ZIMVIE, INC. AND ZIMMER BIOMET SPINE, INC.,
Petitioner,

v.

ROGER P. JACKSON,
Patent Owner.

IPR2023-01431
Patent 10,548,641 B2

Before ULRIKE W. JENKS, SHERIDAN K. SNEDDEN, and
ZHENYU YANG, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*.

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

I. INTRODUCTION

ZimVie, Inc. and Zimmer Biomet Spine, Inc. (“Petitioner”) filed a Petition (Paper 2 (“Pet.”)), seeking an *inter partes* review of claims 1–28 of U.S. Patent No. 10,548,641 B2 (Ex. 1001, “the ’641 patent”). Dr. Roger P. Jackson (“Patent Owner”) filed a Patent Owner Preliminary Response. Paper 6 (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a).

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Accordingly, we institute an *inter partes* review of all challenged claims based on all grounds raised in the Petition. *See* 37 C.F.R. § 42.108(a) (“When instituting . . . review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.”); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1359–60 (Fed. Cir. 2018) (interpreting the relevant statutory provisions to require “a simple yes or no institution choice respecting a petition, embracing all challenges included in the petition”).

A. Related Matters

According to Petitioner, the ’641 patent is asserted against Petitioner in *Jackson v. ZimVie Inc.*, Case No. 1:22-cv-00891-RGA (D. Del.). Pet. 1. Petitioner also identifies three additional petitions seeking *inter partes* review of related U.S. Patent Nos. 8,911,479 (Ex. 1009); 10,898,233 (Ex. 1010); and 11,129,646 (Ex. 1011) as related proceedings. *Id.* Those

proceedings are IPR2023-01430,¹ IPR2023-01432, and IPR2023-01433, respectively.

Patent Owner states that “[o]ther than the related matters provided in Petitioner’s mandatory notices, Patent Owner is not aware of any other judicial or administrative matters that might affect, or be affected by, a decision in this proceeding.” Paper 5, 1.

B. The ’641 Patent and Related Background

The ’641 patent relates to medical receivers having dual lead in closure mating thread forms. Ex. 1001, code (54). The ’641 patent “is directed to structure[s] for joining together parts of a medical implant, in particular to closure mechanisms for use with open bone anchors in spinal surgery, and in some embodiments thereof, for use with spinal bone anchors such as polyaxial screws.” *Id.* at 1:23–27.

The ’641 patent explains that “[b]one anchors, such as bone screws and hooks are utilized in many types of spinal surgery in order to secure various implants to vertebrae along the spinal column for the purpose of stabilizing and/or adjusting spinal alignment.” Ex. 1001, 1:28–32. According to the ’641 patent, open-ended bone screws typically “include a threaded shank with a head or receiver having a pair of parallel projecting branches or arms which form a yoke with a U-shaped slot or channel to receive a rod or other longitudinal connecting member.” *Id.* at 1:51–55. The invention described in the ’641 patent is a medical implant assembly with a closure structure for insertion between spaced arms of an open medical implant where each closure structure simultaneously engages and is captured by

¹ Patent Owner in the related IPR2023-01430 filed a statutory disclaimer disclaiming all of the claims of U.S. Patent No. 8,911,479 (Ex. 1009).

spaced arms of the open implant upon initial rotation of the closure structure with respect to the open implant arms. *Id.* at 2:35–43.

An embodiment of a medical implant assembly according to the '641 patent is shown below in Figure 8.

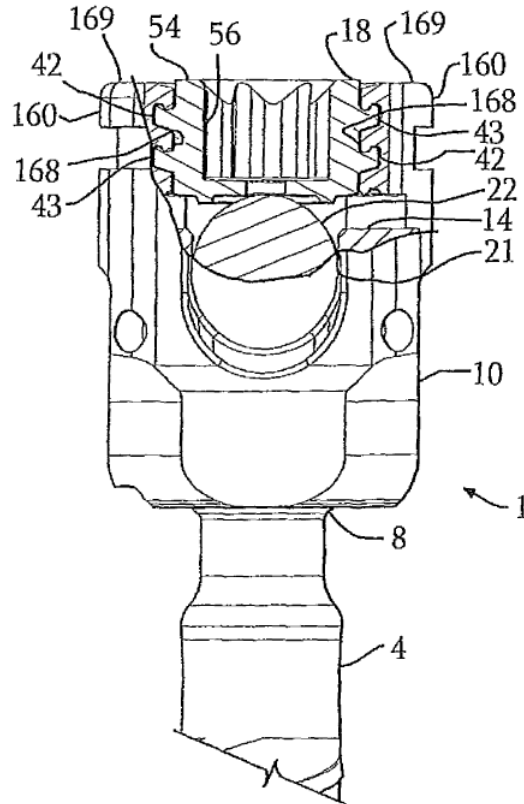


Figure 8 of the '641 patent depicts a partial front elevational view of an open bone screw assembly, with portions broken away to show the detail thereof, including a receiver, a shank, and a compression insert, which are shown in engagement with the closure structure and a longitudinal connecting member in the form of a hard rod. Ex. 1001, 3:58–63. The open implant 1 includes a polyaxial bone screw apparatus or assembly that cooperates with an illustrated closure structure 18. *Id.* at 5:39–41. Closure structures may be used with “open implants requiring a plug or closure mechanism to fix a rod or other implant member to a vertebra or other bone.” *Id.* at 5:53–55.

[T]he illustrated assembly 1 includes a shank 4 with an upwardly extending upper portion or capture structure 8; an open receiver 10; a retaining structure or retainer (not shown) that pivots with the shank 4, a compression or pressure insert 14 and the multi-start closure structure or plug 18 in the form of a cylindrical plug having a double-start helically wound flange-form. The closure structure 18 presses against and captures a longitudinal connecting member, for example, a rod 21 which in turn engages the compression insert 14 that presses against the shank upper portion 8 that is attached to the retaining structure that in turn presses against an inner surface of the receiver 10, so as to capture and fix the longitudinal connecting member 21 within the receiver 10 and thus fix the member 21 relative to a vertebra (not shown).

Ex. 1001, 5:58–6:4.

C. Illustrative Claims

Among the challenged claims, claims 1, 21, and 26 are independent.

Claim 1 is illustrative of the claimed subject matter and is reproduced below.

1. [1.P] A medical implant assembly comprising:

[1.A] a receiver having a first arm and a second arm spaced apart from each other by a channel, the first arm and the second arm each having a top surface and an inner surface having a first thread on the first arm and a second thread on the second arm comprising discontinuously helically wound threads being symmetrically and diametrically opposed to each other and extending up to the top surface on each arm, the opposed discontinuously helically wound threads forming a dual lead in closure starting arrangement for the receiver;

[1.B] a closure having a longitudinal axis with an outer surface having a first continuously helically wound thread form and a second continuously helically wound thread form, the first continuously helically wound thread form having a first start structure with a leading face surface extending below a first upper loading surface disposed between a root and a crest of the first continuously helically wound thread form, the second continuously helically wound thread form

having a second start structure with a leading face surface extending below a second upper loading surface disposed between a root and a crest of the second continuously helically wound thread form,

[1.B1] the leading face surface on each of the first start structure and the second start structure including *at least one curvate surface*;

[1.A1] the channel positioned between the first arm and the second arm and opening onto the top surface, the channel adapted to receive a longitudinal connecting member, the channel closeable with the closure having an axis of rotation;

[1.A2] the first discontinuously helically wound thread form on the inner surface of the first arm having a first lower loading surface, the first start structure being rotatably advanceable under the first discontinuously helically wound thread form and the first lower loading surface being mateable with the first upper loading surface; and

[1.A3] the second discontinuously helically wound thread form on the inner surface of the second arm having a second lower loading surface, the second start structure being rotatably advanceable under the second discontinuously helically wound thread form and the second lower loading surface being mateable with the second upper loading surface,

[1.B2] a rotation of the closure about the axis of rotation between the first arm and the second arm causing a simultaneous advancement of the first start structure under the first discontinuously helically wound thread form and the second start structure under the second discontinuously helically wound thread form and a mating of the first and second lower loading surface with the first and second upper loading surface, respectively,

[1.C] the closure rotationally advanceable within the channel until the closure locks the longitudinal connecting member within the channel.

Ex. 1001, 11:55–12:41 (emphasis added) (formatting, brackets, and numbering added for reference convenience)².

Claim 21 is also directed to a medical device having many overlapping features with the device of claim 1. The closure recited in claim 21 differs from the closure recited in claim 1. Specifically, the closure in claim 21 further recites “each of the first start structure and the second start structure having a leading face surface extending below each closure loading surface and including at *least a partial concave surface*.” *Id.* at 14:37–41 (emphasis added).

Claim 26 is also directed to a medical device having many overlapping features with the device of claim 1. The closure recited in claim 26 differs from the closure recited in claim 1. Specifically, the closure in claim 26 further recites “each of the first start structure and the second start structure having a leading face extending below their respective upper loading surfaces, each leading face *including at least a partial concave surface and a partial convex surface*.” *Id.* at 15:36–16:3 (emphasis added).

² We adopt and apply below Petitioner’s designations for the elements of the challenged claims. *See* Pet. 25–40.

D. Asserted Challenges to Patentability

Petitioner asserts the following challenges to patentability:

Claim(s) Challenged	35 U.S.C. §	References
1, 3–19, 21–28	103 ³	'477 Publication, ⁴ Boschert ⁵
2	103	'477 Publication, Boschert, '391 Publication ⁶
20	103	'477 Publication, Boschert, Johnson ⁷

Petitioner relies on the declaration of Dr. Carl McMillin as support for its Petition. Ex. 1003 (“the McMillin declaration”).

II. ANALYSIS

A. Principles of Law

“In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to

³ We apply pre-AIA §§ 102 and 103(a) to this proceeding. *See* Pet. 6 (“The ’641 Patent claims priority to January 10, 2012 (‘Priority Date’). EX1001. . . . Petitioners assume this date for purposes of this Petition.”); Prelim. Resp. 4.

⁴ Jackson, US Patent Application Publication No. 2005/0267477 A1, published December 1, 2005 (Ex. 1005, “the ’477 Publication” or “’477 Publication”).

⁵ Boschert, US Patent No. 7,857,834 B2, issued December 28, 2010 (Ex. 1006, “Boschert”).

⁶ Jackson, US Patent Application Publication No. US 2006/0069391 A1, published March 30, 2006 (Ex. 1030, “the ’391 Publication” or “’391 Publication”).

⁷ Johnson et al., US Patent Application Publication No. 2007/0088357 A1, published April 19, 2007 (Ex. 1008, “Johnson”).

each claim”)). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

If an *inter partes* review is instituted, Petitioner must demonstrate by a preponderance of the evidence⁸ that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). A claim is unpatentable 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 of the invention to a person having ordinary skill in the art. *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 “the scope and content of the prior art”; “differences between the prior art and the claims at issue”; “the level of ordinary skill in the art;” and “objective evidence of non-obviousness.” *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art “to combine . . . known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a

⁸ The burden of showing something by a preponderance of the evidence requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before the trier of fact may find in favor of the party who carries the burden. *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr. for S. Cal.*, 508 U.S. 602, 622 (1993).

reason for combining the elements in the manner claimed.” *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotations and citations omitted).

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the “type of problems encountered in the art, [the] prior art solutions to those problems, [the] rapidity with which innovations are made, [the] sophistication of the technology, and [the] educational level of active workers in the field.” *Custom Accessories, Inc. v. Jeffrey-Allan Indus. Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner asserts that a person of ordinary skill in the art would have had “(1) a degree in Mechanical Engineering or equivalent technical background and (2) at least two years experience designing or implanting spinal implants with threaded connections. More education could substitute for less experience, and vice versa.” Pet. 6–7 (citing Ex. 1003 ¶¶ 36–42). Patent Owner does not dispute Petitioner’s definition of the person of ordinary skill. *See generally* Prelim. Resp. Because Petitioner’s proposed definition is unopposed and appears consistent with the Specification and art of record, we apply it here.

C. Claim Construction

In an *inter partes* review, we construe a claim term “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 that standard, the words of a claim “are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Claim 1⁹ recites a “leading face surface on each of the first start structure and the second start structure including at least one curvate surface.” Petitioner argues that “‘leading face’ is never specifically identified in the ’641 Patent.” Pet. 8. Petitioner argues that based on the disclosure of the ’641 patent, “and consistent with the plain meaning, a [person of ordinary skill in the art (POSA)] would have understood that a ‘start structure’ is the beginning of a thread and the ‘leading face’ is the forward most surface of the thread in the direction the thread is to be rotated.” *Id.* at 9 (citing Ex. 1003 ¶¶ 151–152; Ex. 1001, 7:51–55, Figure 5).

Petitioner argues that a person of ordinary skill in the art would have understood that a “curvate surface includes at least one radius of curvature.” Pet. 8; Ex. 1001, 7:51–55. Petitioner argues that the limitation “wherein the

⁹ Independent claims 21 and 26 similarly recite a “leading face” but the shape of the face differs from claim 1. Specifically, claim 21 recites “a leading face surface extending below each closure loading surface and including at least a partial concave surface.” Ex. 1001, 14:39–41. Claim 26 recites “each leading face including at least a partial concave surface and a partial convex surface.” *Id.* at 16:1–3.

concave surface is adjacent the root and the convex surface is adjacent the crest” would have been understood to mean “when the closure is viewed from the bottom, the root has a smaller circumference and is located adjacent the concave (inwardly curving) portion of the leading face, while the crest has a larger circumference and is located at the perimeter of the thread near the convex (outwardly curving) portion of the leading face.” Pet. 10 (citing Ex. 1003 ¶ 155).

Petitioner argues that “[t]he ‘crest’ of the thread is the surface that joins the flanks and is farthest from the cylindrical body from which the thread projects.” Pet. 9–10 (citing Ex. 1003 ¶ 154); Ex. 1024, 10; Ex. 1014, 4 (“Crest: This is that surface of a thread which joins the flanks of the thread and is farthest from the cylinder or cone from which the thread projects.”). “The ‘root’ is the surface that joins the flanks of the adjacent threads and is immediately adjacent to the cylindrical body from which the thread projects.” Pet. 10 (citing Ex. 1003 ¶ 154); Ex. 1014, 6 (“Root: That surface of the thread which joins the flanks of adjacent thread forms and is immediately adjacent to the cylinder or cone from which the thread projects.”). According to Petitioner, a “beveled surface” is a sloping surface. *See* Pet. 12–13.

Petitioner argues that a person of ordinary skill in the art would understand “[b]ottom’ means the underside or lowermost part of something and ‘closed’ to mean enclosed.” Pet. 15 (citing Ex. 1003 ¶ 164); Ex. 1029, 4. Therefore, a “bottom surface that is closed” in the context of the claims would be understood [by a POSA] to be a surface that lacks a cannulation. *Id.* (citing Ex. 1003 ¶ 165); Ex. 1029, 5.

Petitioner argues that a person of ordinary skill in the art would also understand that “[p]artial’ means relating to a part rather than a whole, and ‘planar’ means flat.” Pet. 14 (citing Ex. 1003 ¶ 161); Ex. 1029, 6, 7. A “partially planar surface,” therefore, refers to a surface that contains some flat parts. Pet. 14 (“[T]he approximate point where the curve changes from convex to concave is the ‘partial planar surface.’”).

Finally, Petitioner argues that a person of ordinary skill in the art would understand that “simultaneous mating” refers to the way the “first and second continuously helically wound thread forms engaged the first and second discontinuously helically wound thread forms at the same time.” Pet. 15–16 (citing Ex. 1003 ¶ 168).

Patent Owner contends “there are no express constructions for the Board to consider or the Patent Owner to address” because “Petitioner doesn’t provide any constructions, but rather alleges that the ‘plain meaning’ of the limitations encompass certain embodiments in the ’641 Patent or are taught by certain features of the asserted prior art.” Prelim. Resp. 5.

We disagree with Patent Owner’s allegation because Petitioner sufficiently explains the plain meaning of the terms. *See* Pet. 8–16. On this record, and for purposes of this Decision, we adopt Petitioner’s proposed constructions of these terms and apply them to our analysis below.

Claim terms need only be construed “to the extent necessary to resolve the controversy.” *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011). On this record, and for purposes of this Decision, we see no need to address the construction of any other claim term.

D. Alleged Obviousness over the '477 Publication and Boschert

Petitioner asserts that claims 1, 3–19, and 21–28 of the '641 patent would have been obvious over the '477 Publication in view of Boschert. Pet. 16–69. Based on this record, and for at least the following reasons, we determine Petitioner has established a reasonable likelihood that it would prevail in its assertion with respect to claims 1, 3–8, 14, 15, 17–19, and 21–25, but not with respect to claims 9–13, 16, or 26–28.

1. Prior Art Disclosures

a. The '477 Publication

The '477 Publication relates to “[a] closure for use in conjunction with an open receiver of a medical implant for capturing and locking a rod member in the implant.” Ex. 1005, code (57).

Specifically, the '477 Publication teaches a bone screw closure for use in a spinal implant system for correcting degenerative conditions, deformities, injuries, or defects to the spinal column of a patient, which is illustrated in Figure 6, reproduced below. *Id.* ¶¶ 14, 18–19, 25.

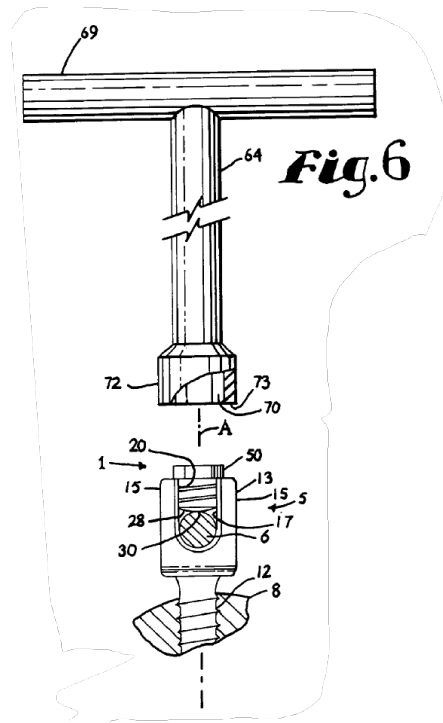


Figure 6 is a reduced and fragmentary side elevational view of a bone screw closure without the break-off portion and further showing a removal tool with a portion broken away to show the detail thereof. Ex. 1005 ¶ 19. Figure 6 depicts a closure 1 used to close a top of a polyaxial medical implant bone screw 5 to capture an elongate member or rod 6. *Id.* ¶ 25.

The polyaxial bone screw 5 is inserted into a vertebra 8 and includes a threaded shank 12 that is pivotally attached to an open receiver or head 13 with a pair of spaced arms 15 that are generally parallel, include interior surfaces 20, and form an open U-shaped channel 17 therebetween. Ex. 1005 ¶¶ 25–26. The closure 1 has a body with a convex shaped region or dome 28 with an apex 30 that covers the entire bottom end of the closure 1. *Id.* ¶ 29. The body of the closure 1 includes a guide and advancement structure (e.g., a helically wound reverse angle thread form) that mates with the interior surfaces 20 of the arms 15 and allows the closure 1 to be inserted and rotated

relative to the receiver 13 to guide the closure 1 towards or away from the rod 6. *Id.* ¶ 30.

An installation/removal tool 64 with a handle 69 is used to install or remove the closure 1 by rotating it in the receiver 13. Ex. 1005 ¶¶ 35–37. The tool 64 has a lower portion 72 with a bottom surface 73 and a socket 70 that is shaped and sized to receive a driving head and a removal head 50 so it can be used for both installation and removal. *Id.*

b. Boschert

Boschert describes “[a]n orthopedic fixation device for securing a rod to a bone” (Ex. 1006, code (57)), or more specifically, “intervertebral connection systems suited for stabilization of the spine” (*id.* at 1:5–7).

Figure 3, reproduced below, shows Boschert’s orthopedic fixation device with a rod in a locked position within a receiver of the device.

FIG.3

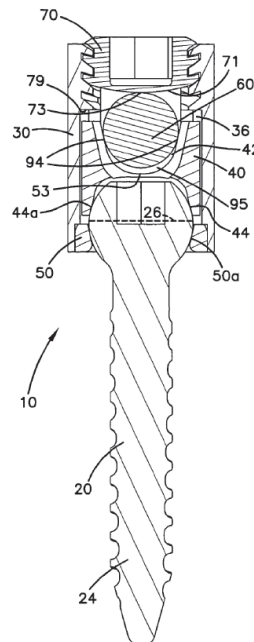


Figure 3 is a cross-sectional view of an orthopedic fixation device taken along a vertical cross-sectional plane that bisects the device. Ex. 1006,

2:58–3:2. The orthopedic fixation device 10 includes a receiver 30, a seat structure 40, a retainer 50, a screw 20, and a setscrew 70. *Id.* at 4:13–28. The receiver 30 includes a keying feature (e.g., opposing internal slots) 36 for aligning the seat structure 40 in the correct rotational orientation relative to the receiver 30. *Id.* at 6:34–41. The seat structure 40 has a non-contact area 95, two contact locations 94 for a rod 60, a top seat 42, and a bottom seat 44 with an annular seating surface 44a. *Id.* at 5:12–32, 5:62–65. The retainer 50 includes an annular seating surface 50a that generally complements the shape of the exterior of the screw 20 head. *Id.* at 6:60–63. The screw 20 includes a major diameter 26 and a bone engaging end 24 with external threads that allow the screw 20 to be inserted into bone material. *Id.* at 4:65–5:5. The setscrew 70 includes a curved bottom surface 71. *Id.* at 7:16–17.

The seat structure 40 and the head of the screw 20 are loaded into the bottom portion of the receiver 30 and then captured in the receiver 30 by the retainer 50. Ex. 1006, 4:13–28. A stop structure 79 prevents the seat structure 40 from being pushed upwardly through the top end of the receiver 30. *Id.* at 6:30–33. A rod 60 fits in the receiver 30 and is held in place by the setscrew 70 at a single point of contact 73 by threading the setscrew 70 into the receiver 30 and tightening it. *Id.* at 4:13–28, 4:47–56, 7:17–18. Continued tightening of the setscrew 70 forces the seat structure 40 downwardly in the receiver 30 and clamps the head of the bone screw 20 between the bottom of the seat structure 40 and the retainer 50, and clamps the rod 60 between the setscrew 70 and the top of the seat structure 40. *Id.*

2. Analysis

We focus our analysis on claim 1. Petitioner contends that the '477 Publication in combination with Boschert teaches each limitation of claim 1. Pet. 25–40. Petitioner accounts for each limitation in detail. *Id.*

Patent Owner challenges, arguing that Petitioner fails to show the prior art teaches a “leading face of the start structure that includes at least one curvate surface[/a partial concave surface/a partial concave surface and a partial convex surface].” Prelim. Resp. at 5–6. Patent Owner further argues that Petitioner’s declarant never explains why Figure 10 of the '477 Publication should be interpreted to include a leading surface having a partial concave and partial convex surface. *Id.* at 11–12 (“Absent any supporting evidence or technical reasoning provided by Dr. McMillin’s declaration to support the conclusions in the Petition, Petitioner has no evidence that the unidentified line in Figure 10 of the '477 Publication suggests the flat leading face surface of Figure 7 should be considered to have concave and convex surfaces.”).

Based on the current record, and as explained below, we find Petitioner’s argument more persuasive with respect to at least claim 1.

a. Independent Claim 1

The '641 patent is directed to a medical implant device, in particular to closure mechanisms for use with open bone anchors in spinal surgery, such as polyaxial screws. Ex. 1001, 1:23–27. Claim 1 recites an implant that comprises a receiver, a closure, and a channel for receiving a longitudinally connecting member. *See id.* at 11:55–12:41. The closure contains “the leading face surface on each of the first start structure and the second start structure including at least one curvate surface.” *Id.* at 12:11–13.

i. Claim 1 Elements

(1) Element 1.P

Element 1.P recites “[a] medical implant assembly comprising:” Ex. 1001, 11:55. Petitioner states that “[i]f the preamble is limiting, the ’477 Publication/Boschert combination discloses this limitation.” Pet. 25 (citing Ex. 1003 ¶ 220; Ex. 1005 ¶ 2; Ex. 1006, 1:34–37). Patent Owner does not present arguments for this element. To the extent element 1.P is limiting, we determine, based on the current record, that Petitioner provides an adequate showing for purposes of institution that the ’477 Publication and Boschert meet this claim limitation.

(2) Element 1.A

Element 1.A recites:

a receiver having a first arm and a second arm spaced apart from each other by a channel, the first arm and the second arm each having a top surface and an inner surface having a first thread on the first arm and a second thread on the second arm comprising discontinuously helically wound threads being symmetrically and diametrically opposed to each other and extending up to the top surface on each arm, the opposed discontinuously helically wound threads forming a dual lead in closure starting arrangement for the receiver.

Ex. 1001, 11:56–65.

Petitioner states that the combination of the ’477 Publication and Boschert teaches this claim limitation. Pet. 26 (citing Ex. 1003 ¶¶ 221–213). Specifically, Petitioner asserts that “Boschert discloses a U-shaped receiver with symmetrical and diametrically opposed discontinuous helically wound threads on the interior surface of each arm forming a starting arrangement for a double-start closure.” *Id.* Petitioner provides an annotated version of an excerpt of Figure 1 from Boschert:

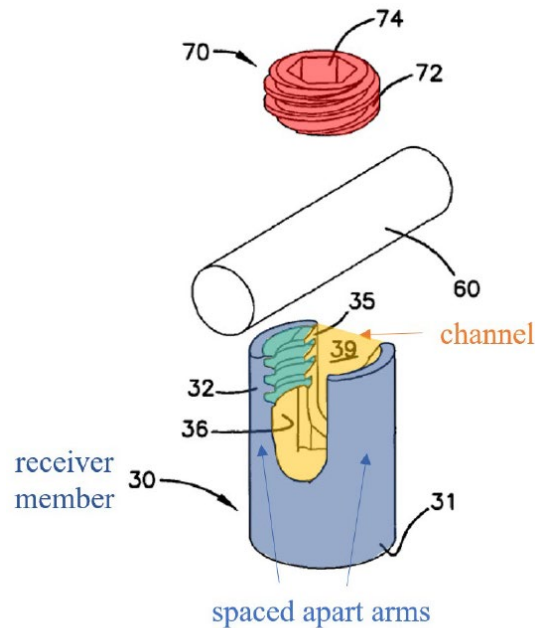


Fig. 1 (excerpt)

The figure above shows a receiver member containing spaced apart arms (blue) and containing interior threads (green), a channel for receiving a rod (yellow), a threaded closure (red). Pet. 26 (citing Figure 1, Ex. 1006, 6:25–28); Ex. 1006, 4:16–19 (“a receiver 30 having a top portion 32 defining a saddle 39 (i.e., a pocket) for receiving a rod 60, and a bottom portion 31 adapted for receiving a head” of a bone fastener such as a bone screw.). Petitioner additionally cites Figures 3 and 15 (not shown) of Boschert to support the position “that the threads on either side of the receiver extend to the top of the receiver and are symmetrically and diametrically opposed to one another across the longitudinal axis.” Pet. 27.

The record evidence, summarized above, supports Petitioner’s position as to this limitation. Patent Owner does not dispute that Boschert teaches the subject matter of this limitation. We determine, based on the current record, that Petitioner provides an adequate showing for purposes of institution that the combination of the ’477 Publication and Boschert meets this claim limitation.

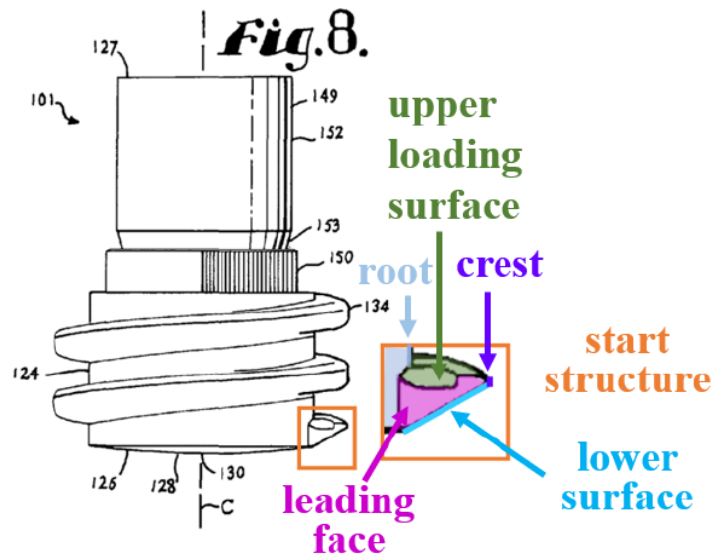
(3) Element 1.B

Element 1.B recites:

a closure having a longitudinal axis with an outer surface having a first continuously helically wound thread form and a second continuously helically wound thread form, the first continuously helically wound thread form having a first start structure with a leading face surface extending below a first upper loading surface disposed between a root and a crest of the first continuously helically wound thread form, the second continuously helically wound thread form having a second start structure with a leading face surface extending below a second upper loading surface disposed between a root and a crest of the second continuously helically wound thread form.

Ex. 1001, 11:66–12:11.

Petitioner states that the combination of the '477 Publication and Boschert teaches this claim limitation. Pet. 28 (citing Ex. 1003 ¶¶ 224–229). Petitioner asserts that “[t]he '477 Publication discloses a ‘closure for use in conjunction with an open receiver of a medical implant for capturing and locking a rod in the implant.’” *Id.* (citing Ex. 1005 ¶¶ 2, 7, 29, 30, 40, 41 and Figures 1, 2, 5, 6). According to Petitioner, “[t]he '477 Publication discloses that its thread ‘is a helical interlocking form.’” *Id.* (citing Ex. 1005 ¶ 41). Petitioner provides an annotated version of Figure 8 from the '477 Publication:



The figure shows an expanded view of the start structure (orange) of Figure 8 of the '477 Publication and highlights the leading face (pink), lower surface (blue), thread crest (purple), thread root (grey) and upper loading surface of the thread (green). Pet. 28 (citing Ex. 1005, Figure 8). Petitioner acknowledges that the '477 Publication discloses a single thread but argues that “Boschert teaches that a double thread ‘allow[s] the setscrew 70 to start more easily than with a single lead.’” *Id.* at 29 (citing Ex. 1006, 7:21–23). Petitioner concludes that a person of ordinary skill in the art at the time the invention was made “would have been motivated to combine the '477 Publication and Boschert to include two continuously helically wound threads with two start structures on a closure.” *Id.*

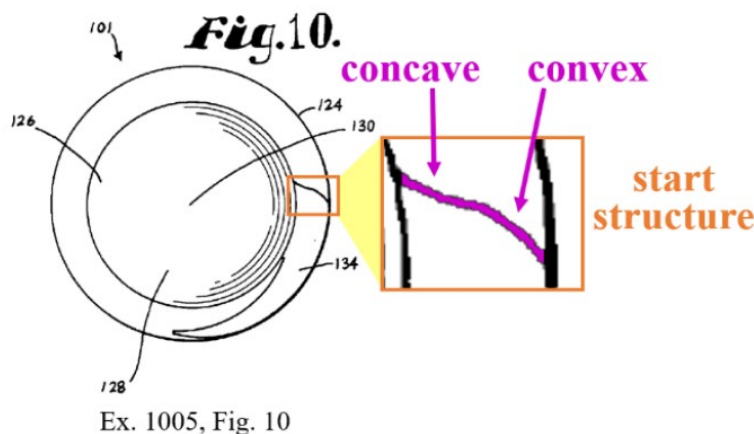
The record evidence, summarized above, supports Petitioner’s position as to this limitation. Patent Owner does not dispute that the combination of the '477 Publication and Boschert teaches the subject matter of this limitation. We determine, based on the current record, that Petitioner provides an adequate showing for purposes of institution that the

combination of the '477 Publication and Boschert meets this claim limitation.

(4) Element 1.B1

Element 1.B1 recites “the leading face surface on each of the first start structure and the second start structure including *at least one curvate surface*.” Ex. 1001, 12:11–13 (emphasis added).

Petitioner states that the combination of the '477 Publication and Boschert teaches this claim limitation. Pet. 30 (citing Ex. 1003 ¶¶ 230–233). Petitioner provides an annotated version of Figure 10 from the '477 Publication:



The figure shows an exploded view of a start structure having a concave and convex surface as identified by Petitioner. Pet. 30 (citing Ex. 1005, Figure 10). Petitioner asserts that one of ordinary skill in the art at the time the invention was made “would have kept the '477 Publication’s leading face, including its at least one curvate surface, on each of the dual threads of Boschert.” *Id.* (citing Ex. 1003 ¶¶ 231–233).

Patent Owner disagrees with Petitioner’s assessment that the '477 Publication shows this limitation. *See generally* Prelim. Resp. 5–19. Patent Owner contends that “Petitioner’s argument is based entirely on an

undescribed line in Figure 10 of the '477 Publication.” Prelim. Resp. 5. Patent Owner contends that “Petitioner’s reliance on the undescribed line in Figure 10 as a concave and convex leading face surface is inconsistent with the figures of other closures in the '477 Publication and its parent application.” *Id.* at 6. “Given the '477 Publication never discusses or even identifies the line Petitioner relies on in Figure 10, the only evidence of its meaning would need to be provided by Petitioner’s expert declaration.” *Id.* at 10.

As explained below in reference to claim 26, we find Petitioner does not sufficiently persuade us that the line in Figure 10 of the '477 Publication depicts a curvate structure that is both concave and convex. *See* II.D.2.c. The leading surface in claim 1, however, only needs to have a curvate surface. Petitioner contends that because the closure is intended to be used in a surgical environment the ordinary artisan would have been motivated to eliminate any sharp edges that could pierce a surgeon’s glove. Pet. 23 (citing Ex. 1003 ¶¶ 202–204); *see also* Ex. 1003 ¶ 64 (“By truncating a thread start a POSA was able to avoid very thin portions of the tapered thread, which are sharp and could cut a surgeon’s glove, could be easily damaged, and could lead to cross threading.”). Petitioner’s declarant, Dr. McMillin asserts that one of ordinary skill in the art at the time the invention was made would have understood that in the process of eliminating sharp edges using a “sanding, grinding, or milling bit used to truncate the threads would have typically left a concave, curvate surface near the root of the thread.” Ex. 1003 ¶ 78 (citing Ex. 1034 ¶¶ 34–36). Dr. McMillin, further explains that there are limited shape options for creating blunt end thread structures that include: an oblique plane, a cut off square, or rounded end. Ex. 1003

¶ 67 (citing Ex. 1015, Figures 1–6, 2:88–94). Petitioner, therefore, does not solely rely on Figure 10 of the '477 Publication to arrive at the limitation of a leading surface containing a curvate surface as recited in claim 1. Based on the current record, Petitioner provides an adequate showing for purposes of institution that the combination of the '477 Publication and Boschert in conjunction with the knowledge of an ordinary artisan suggests the “at least one curvate surface” claim limitation.

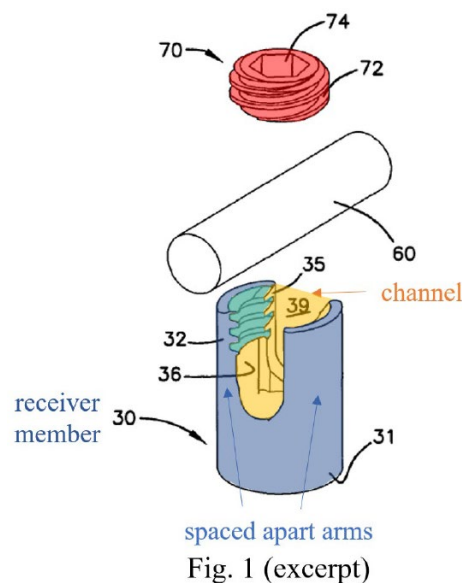
(5) Element 1.A1

Element 1.A1 recites:

the channel positioned between the first arm and the second arm and opening onto the top surface, the channel adapted to receive a longitudinal connecting member, the channel closeable with the closure having an axis of rotation.

Ex. 1001, 12:14–18.

Petitioner states that the combination of the '477 Publication and Boschert teaches this claim limitation. Pet. 31 (citing Ex. 1003 ¶¶ 234–235). Petitioner provides an annotated version of an excerpt of Figure 1 from Boschert:



The figure shows a receiver member containing spaced apart arms (blue) and containing interior threads (green), a channel for receiving a rod (yellow), a threaded closure (red). Pet. 32 (citing Ex. 1006, Figure 1). Petitioner asserts that Boschert

discloses a receiver that “includes two upwardly extending legs 38 [i.e., arms] between which the saddle 39 of the receiver 30 is defined. The saddle 39 of the receiver 30 provides an open region or pocket for receiving the rod 60 ... [T]he legs 38 are shown defining interior threads 35 that mate with corresponding exterior threads 72 of the setscrew 70 to allow the setscrew 70 to be threaded into the saddle 39 to lock the rod 60 and screw in place.

Id. at 31 (citing Ex. 1006, 6:11–28).

The record evidence, summarized above, supports Petitioner’s position as to this limitation. Patent Owner does not dispute that the combination of the ’477 Publication and Boschert teaches the subject matter of this limitation. We determine, based on the current record, that Petitioner provides an adequate showing for purposes of institution that the combination of the ’477 Publication and Boschert meets this claim limitation.

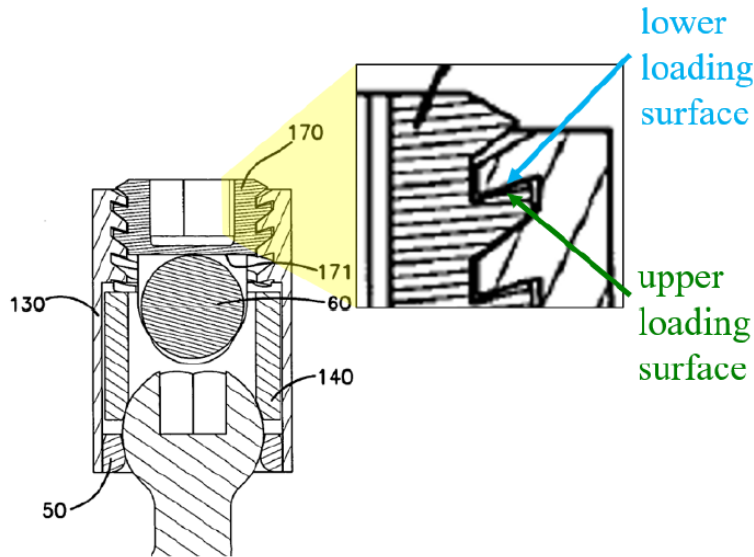
(6) Element 1.A2

Element 1.A2 recites:

the first discontinuously helically wound thread form on the inner surface of the first arm having a first lower loading surface, the first start structure being rotatably advanceable under the first discontinuously helically wound thread form and the first lower loading surface being mateable with the first upper loading surface.

Ex. 1001, 12:19–24.

Petitioner states that the combination of the '477 Publication and Boschert teaches this claim limitation. Pet. 32 (citing Ex. 1003 ¶¶ 236–237). Petitioner provides an annotated version of an excerpt of Figure 15 from Boschert:



The figure above is the reproduction of Petitioner’s annotated Figure 15 of Boschert highlighting the upper and lower loading surface. Pet. 33 (citing Ex. 1006, 6:20–28, Figure 15). Petitioner contends that based on the knowledge of one of ordinary skill in the art at the time the invention was made with respect to thread connectors, the ordinary artisan “implementing the '477 Publication/Boschert combination would have understood that the threads on the receiver must mate with the thread forms on the closure top.” *Id.* (citing Ex. 1003 ¶ 237).

The record evidence, summarized above, supports Petitioner’s position as to this limitation. Patent Owner does not dispute that the combination of the '477 Publication and Boschert teaches the subject matter of this limitation. We determine, based on the current record, that Petitioner provides an adequate showing for purposes of institution that the

combination of the '477 Publication and Boschert meets this claim limitation.

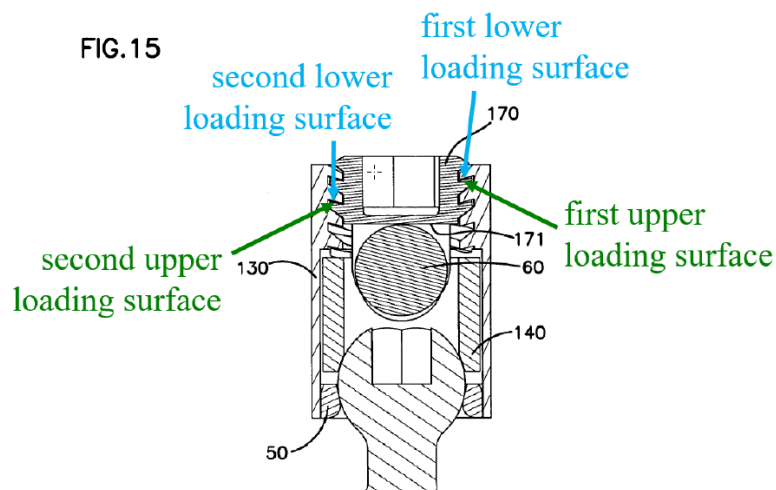
(7) Element 1.A3

Element 1.A3 recites:

the second discontinuously helically wound thread form on the inner surface of the second arm having a second lower loading surface, the second start structure being rotatably advanceable under the second discontinuously helically wound thread form and the second lower loading surface being mateable with the second upper loading surface.

Ex. 1001, 12:25–31.

Petitioner states that the combination of the '477 Publication and Boschert teaches this claim limitation. Pet. 32 (citing Ex. 1003 ¶¶ 238–239). Petitioner provides an annotated version of an excerpt of Figure 15 from Boschert:



The figure above is the reproduction of Petitioner's annotated Figure 15 of Boschert. Pet 34 (citing Ex. 1006, Figure 15). Petitioner contends that based on the knowledge of one of ordinary skill in the art at the time the invention was made with respect to thread connectors, the ordinary artisan "implementing the '477 Publication/Boschert combination would have

understood that the threads on the receiver must mate with the thread forms on the closure top.” *Id.* (citing Ex. 1003 ¶ 239).

The record evidence, summarized above, supports Petitioner’s position as to this limitation. Patent Owner does not dispute that the combination of the ’477 Publication and Boschert teaches the subject matter of this limitation. We determine, based on the current record, that Petitioner provides an adequate showing for purposes of institution that the combination of the ’477 Publication and Boschert meets this claim limitation.

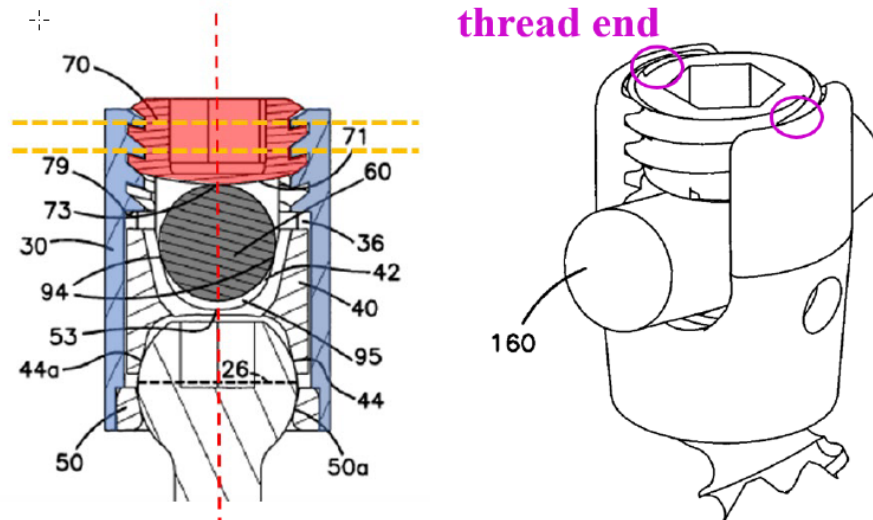
(8) Element 1.B2

Element 1.B2 recites:

a rotation of the closure about the axis of rotation between the first arm and the second arm causing a simultaneous advancement of the first start structure under the first discontinuously helically wound thread form and the second start structure under the second discontinuously helically wound thread form and a mating of the first and second lower loading surface with the first and second upper loading surface, respectively,

Ex. 1001, 12:31–39.

Petitioner states that the combination of the ’477 Publication and Boschert teaches this claim limitation. Pet. 35 (citing Ex. 1003 ¶¶ 240–247). Petitioner provides an annotated version of an excerpt of Figure 3 (below left) and an annotated version of Figure 7 (below right) from Boschert, reproduced below:



The figures above are the reproduction of Petitioner’s annotated Figure 3 (above left) and an annotated version of Figure 7 (above right) from Boschert. Pet. 36 (citing Ex. 1006, Figures 3 and 7).

Boschert’s Figure 3 . . . shows that the threads of both the closure and receiver are symmetrically and diametrically opposed to each other across the longitudinal axis. . . As shown in Figure 7 . . . Boschert also discloses that the trailing ends of the closure threads are diametrically opposed.

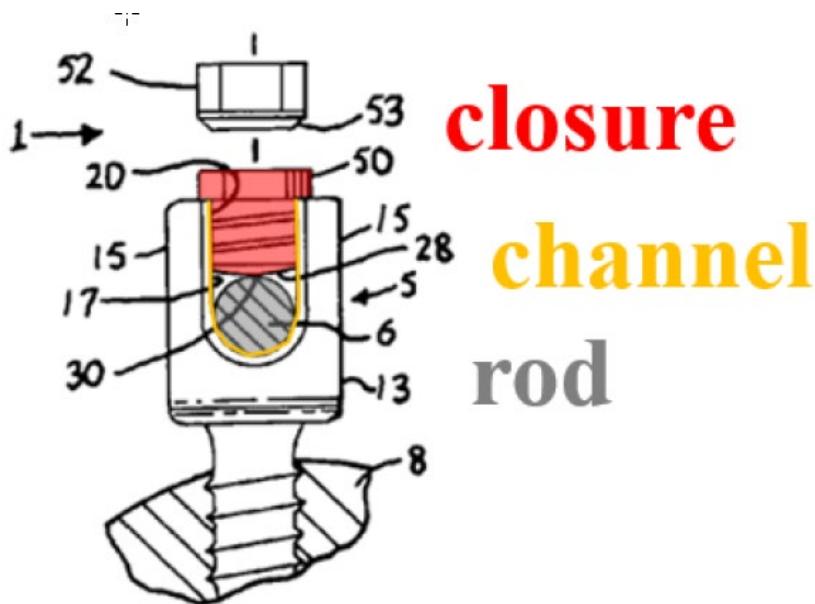
Pet. 35. Petitioner contends that based on the knowledge of one of ordinary skill in the art at the time the invention was made with respect to thread connectors, a POSA “would have understood and expect[ed] that each of the double-lead threads have identical length, and therefore also have symmetrically and diametrically opposed thread starts.” *Id.* at 36 (citing Ex. 1003 ¶¶ 242–243). Petitioner contends that based on the conventional manner of making double start threads, a person of ordinary skill in the art at the time the invention was made “would have understood Boschert to disclose diametrically opposed thread starts . . . that have a cylindrical spacing angle of 180° (i.e., 360°/2).” *Id.* (citing Ex. 1003 ¶ 244; Ex. 1014, 3).

The record evidence, summarized above, supports Petitioner's position as to this limitation. Patent Owner does not dispute that the combination of the '477 Publication and Boschert teaches the subject matter of this limitation. We determine, based on the current record, that Petitioner provides an adequate showing for purposes of institution that the combination of the '477 Publication and Boschert meets this claim limitation.

(9) Element 1.C

Element 1.C recites “the closure rotationally advanceable within the channel until the closure locks the longitudinal connecting member within the channel.” Ex. 1001, 12:39–41.

Petitioner states that the combination of the '477 Publication and Boschert teaches this claim limitation. Pet. 39 (citing Ex. 1003 ¶¶ 248–251). Petitioner provides an annotated version of an excerpt of Figure 5 from the '477 Publication:



The figure shows a closure (red), a channel (yellow) and a rod sitting inside the channel (grey). Pet. 39 (citing Ex. 1005, Figure 5). Petitioner contends

that the '477 Publication describes a closure for capturing and locking a rod in an implant by rotationally advancing the closure within the channel until the closure locks the longitudinal connecting member within the channel. *Id.* (citing Ex. 1005, code (57), ¶¶ 2, 18–19, 30, 37, Figures 5 and 6; Ex. 1003 ¶¶ 250–251).

The record evidence, summarized above, supports Petitioner's position as to this limitation. Patent Owner does not dispute that the combination of the '477 Publication and Boschert teaches the subject matter of this limitation. We determine, based on the current record, that Petitioner provides an adequate showing for purposes of institution that the combination of the '477 Publication and Boschert meets this claim limitation.

ii. The Proposed Combination of the '477 Publication and Boschert
(1) Petitioner's assertions

Petitioner asserts that there was a motivation to combine the '477 Publication and Boschert because the references are from the same field of endeavor. Petitioner asserts that the '477 Publication teaches closures that could be used with any conventional bone screw receivers, stating “[a] closure and locking member is provided for a medical implant. The implant may be a bone screw, hook, or other open or closed element.” Pet. 21 (citing Ex. 1005 ¶¶ 7, 25, 27). Petitioner asserts that Boschert similarly teaches a polyaxial pedicle screw including a U-shaped receiver for capturing a rod once its opening has been closed with a closure (i.e. setscrew). Because both the '477 Publication and Boschert are directed to medical implants we agree with Petitioner that the references are from the same field of endeavor.

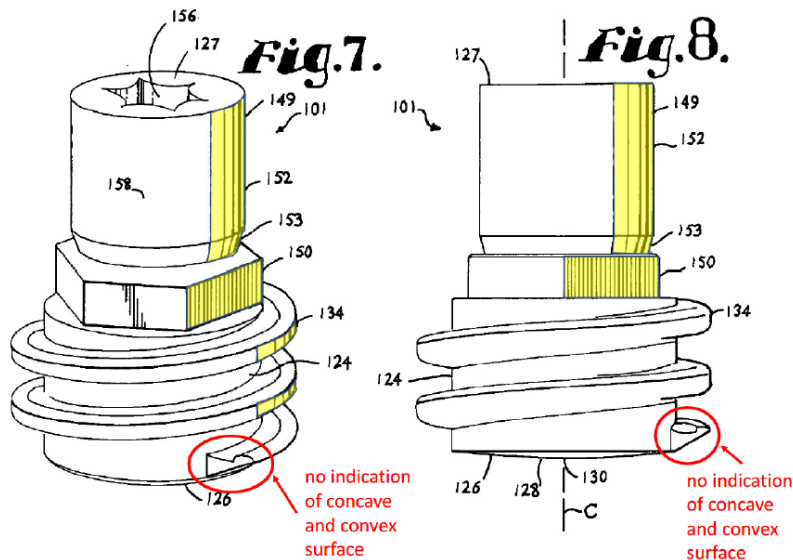
Boschert discloses that it would be advantageous to design closures for use in a medical implant with a double lead because the threading with a double lead “start[s] more easily than with a single lead.” Pet. 21 (Ex. 1006, 7:21–23 (“The threads 72 of the setscrew 70 can also be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead.”)). Petitioner concludes that based on the combined teachings of the ’477 Publication and Boschert a person of ordinary skill in the art at the time the invention was made would have been motivated to modify the ’477 Publication to take advantage of known benefits of double-lead threads, including balancing insertion forces and increasing insertion speed.” *Id.* at 22–23 (citing Ex. 1003 ¶¶ 202–204).

Specifically, Petitioner contends that “[i]n making this combination, a POSA would have retained the truncated thread starts of the ’477 Publication with their curvate leading faces to obtain their known advantages for further easing thread insertion, reduce thread deformation, and reducing sharp edges.” Pet. 23 (citing Ex. 1003 ¶¶ 202–204); *see also* Ex. 1003 ¶ 202 (“a POSA would have been familiar with truncated thread starts, such as the curvate leading face of the ’477 Publication, and their advantages for easing thread insertion, reducing thread deformation, and eliminating sharp edges.”), *see id.* ¶¶ 67 (“[t]he exact form of the thread end is not very important so long as it is blunt and substantially symmetrical with respect to the center line of the thread’ and ‘may be cut off on an oblique plane’ . . . ‘or rounded’” (citing Ex. 1015, Figs. 1–5)), 74 (“a POSA would commonly know to select a curvate leading face in order to present a less sharp surface for surgeon’s gloves on either a single or a double start closure.”).

(2) Patent Owner's assertions

Patent Owner presents arguments regarding the proposed combination of the '477 Publication and Boschert. Prelim. Resp. 5–19. Specifically, Patent Owner contends that the prior art is missing the claim elements of “a leading face with a ‘curvate surface’ (Claim 1), ‘a partial concave surface’ (Claim 21) or ‘a partial concave surface and a partial convex surface’ (Claim 26).” Prelim. Resp. 5.

Patent Owner asserts that “Petitioner’s argument is based entirely on an undescribed line in Figure 10 of the '477 Publication, shown with no elevation, structure, or identifiable related surface, that Petitioner alleges is a leading face with concave and convex surface portions.” *Id.* Patent Owner contends that “Petitioner’s reliance on the undescribed line in Figure 10 as a concave and convex leading face surface is inconsistent with the figures of other closures in the '477 Publication and its parent application.” *Id.* at 6. Patent Owner contends that Figures 7, 8, and 10 of the '477 Publication depict the same closure embodiment from different viewpoints. *Id.* at 7. Figures 7 and 8 of the '477 Publication as annotated by Patent Owner are reproduced below:



Reproduced above are Figures 7 and 8 of the '477 Publication, as annotated by Patent Owner highlighting the start structures of the closures. Prelim Resp. 8. Patent Owner contends that “Figures 7 and 8 depict a flat continuous surface for the leading face.” *Id.* Patent Owner contends that this interpretation is consistent with Dr. McMillin’s, Petitioner’s declarant’s, understanding that the creation of a “flat continuous leading face surface was well-known at the time of the '477 Publication.” *Id.* (citing Ex. 1003 ¶¶ 64–68”).

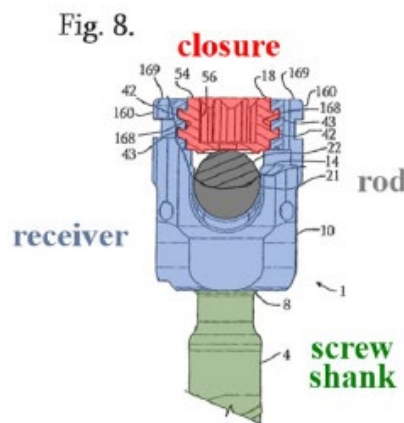
“Given [that] the '477 Publication never discusses or even identifies the line Petitioner relies on in Figure 10, the only evidence of its meaning would need to be provided by Petitioner’s expert declaration.” Prelim. Resp. 10. Patent Owner contends that “the declaration provides no explanation of why Dr. McMillin concludes the line in Figure 10 matches the shape of the leading face surface in Figures 7 or 8, when a reasonable inspection of Figures 7 and 8 indicates they do not depict a leading face with a concave and convex surface.” *Id.* “Absent any supporting evidence or technical reasoning provided by Dr. McMillin’s declaration to support the conclusions

in the Petition, Petitioner has no evidence that the unidentified line in Figure 10 of the '477 Publication suggests [that] the flat leading face surface of Figure 7 should be considered to have concave and convex surfaces.” *Id.* at 11–12.

(3) Analysis

Claim 1 of the '641 patent is directed to a medical implant assembly that comprises a receiver, a closure, and a channel for receiving a longitudinal connecting member. Ex. 1001, 11:55–12:41. The “closure ha[s] a longitudinal axis with an outer surface having a first continuously helically wound thread form and a second continuously helically wound thread form, . . . the leading face surface on each of the first start structure and the second start structure including at least one curvate surface.” *Id.* at 11:66–12:13.

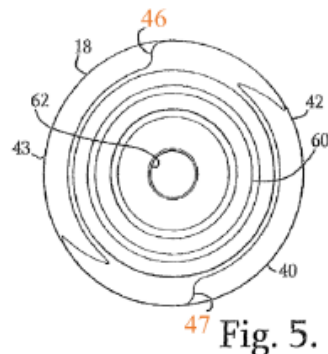
Figure 8 of the '641 patent as annotated by Petitioner is reproduced below:



The figure above is a reproduction of Petitioner’s annotated Figure 8 of the '641 patent and depicts the closure in red, the receiver in blue, and the screw shank in green, and it also depicts a rod in grey. Pet. 3. Figure 8 shows “a partial front elevational view of an open bone screw assembly, with portions broken away to show the detail thereof, including a receiver, a shank, a

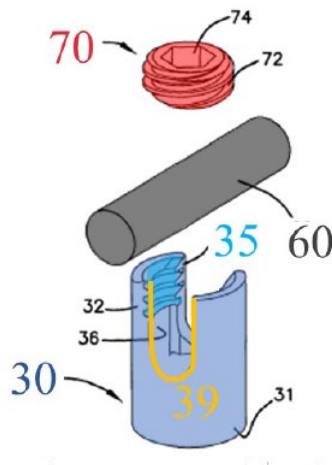
compression insert and also shown in engagement with the closure top . . . and a longitudinal connecting member in the form of a hard rod.” Ex. 1001, 3:58–63.

Figure 5 of the ’641 patent as annotated by Petitioner is reproduced below:



The figure above is a reproduction of Petitioner’s annotated Figure 5 of the ’641 patent; the figure shows a closure that identifies the “start structures 46 and 47” in orange. Pet. 5. The ’641 patent describes a closure as containing start structures, and “[e]ach of the start structures 46 and 47 includes a leading face having at least one curvate surface. The at least one curvate surface includes at least one radius of curvature. In one embodiment, the at least one curvate surface is both concave and convex.” Ex. 1001, 7:51–55.

Boschert teaches “orthopedic fixation systems for securing a rod to a bone with means for receiving curved rods.” Ex. 1006, 2:39–41. An excerpt of Boschert’s Figure 1 as annotated by Petitioner is reproduced below:



Ex. 1006, Fig. 1

The figure above is a reproduction of Petitioner's annotated Figure 1 of Boschert; the figure shows a set screw 70 (red) and a receiver 30 (blue) having a top portion 32 defining a saddle 39 (i.e., a pocket (shown in orange)) for receiving a rod 60. Pet. 19; Ex. 1006, Figure 1, 4:13–28.

Boschert explains that

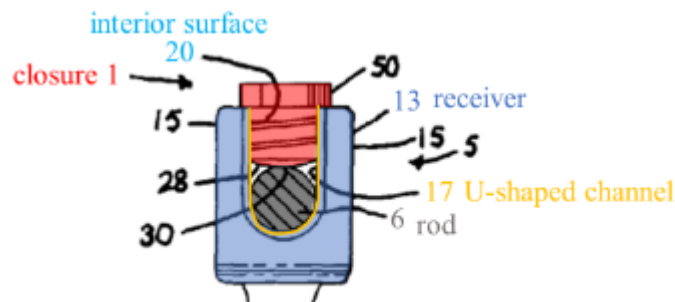
the set screw may 70 include a curved bottom surface 71. With this configuration, the setscrew 70 contacts the rod 60 at a single point of contact 73. This feature provides stability to a rod that has been bent upwardly when it is seated on the top seat 42 of the seat structure 40. *The threads 72 of the setscrew 70 can also be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead.* Torque for driving the setscrew 70 can be provided by a tool (e.g., a torque wrench) inserted into sockets 74 (e.g., hex-sockets) provided in the setscrews 70.

Ex. 1006, 7:16–26 (emphasis added). Boschert explains that the use of a double lead allows the set screw to start more easily than a set screw with a single lead. *Id.* at 7:21–23. Boschert, therefore, provides a reason to include a double lead on a set screw but does not otherwise describe the shape of the leading face.

The '477 Publication teaches a closure for use in a medical implant.

A typical implant for use with a closure . . . includes a receiver having a pair of spaced arms with an open channel located therebetween. The channel receives a rod or other elongate structure. A closure . . . is used to capture and fix the rod in the receiver subsequent to the receiver receiving the rod. In particular, internal surfaces of the arms of the receiver include a discontinuous guide and advancement structure, and the closure includes cooperating external guide and advancement structure so as to be rotated and driven into the receiver. Once the closure is matingly received in the receiver, the closure acts to capture the rod member.

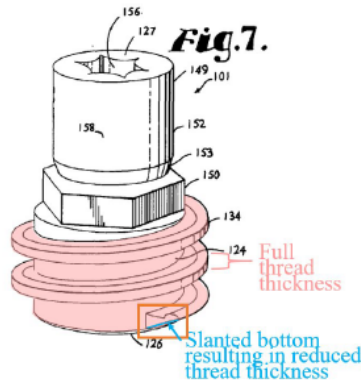
Ex. 1005 ¶ 7. An excerpt of the '477 Publication Figure 6 as annotated by Petitioner is reproduced below:



Ex. 1005, Fig. 6

The figure above is a reproduction of Petitioner's annotated Figure 6 of the '477 Publication. Pet. 16. The figure shows a "polyaxial screw that includes a receiver 13 with a pair of upstanding arms 15 forming a U-shaped channel 17 for receiving a rod 6." *Id.* at 16–17 (citing Ex. 1005 ¶¶ 7, 34–45, Figures 5–10).

Figure 7 showing a bone screw closure of the '477 Publication as annotated by Petitioner is reproduced below:



The figure above shows a full thread thickness (pink) of a closure and identifies a slanted bottom (blue) that reduces the thread thickness. Pet. 18.

The '477 Publication describes the closure in Figure 7 as follows:

The closure 101 includes a body 124 that has a generally cylindrical or plug shape with a substantially circular horizontal cross section and a central axis of rotation C. Located at a lead or bottom end 126 . . . the closure 101 is a convex shaped region or dome 128 that projects outwardly from the body 124 along the axis C . . . and has an apex 130 where the dome 128 intersects axis C.

Ex. 1005 ¶ 40.

Figure 10 of the '477 Publication is reproduced below:

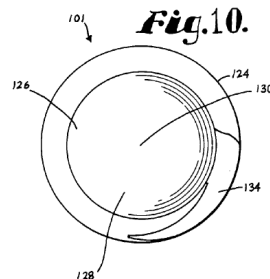
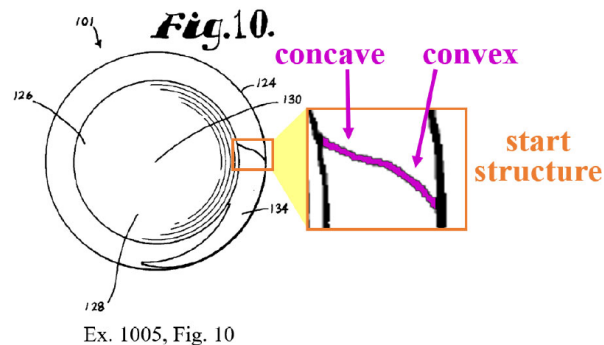


Figure 10, reproduced above, shows “an enlarged bottom plan view of the closure of FIG. 7.” Ex. 1005 ¶ 23. “Located on the cylindrical closure body 124 is a guide and advancement structure 134 mateable with a guide and advancement structure on inner surfaces of the arms of the bone screw receiver (not shown) or other implant.” *Id.* ¶ 41. Other than indicating that

Figure 10 is a bottom view of Figure 7, and that the structure 134 of Figure 10 is mateable with a guide and advancement structure on inner surfaces of the arms there is no other description of Figure 10 in the '477 Publication.

Petitioner argues that the combination of the '477 Publication and Boschert teaches each and every limitation of claim 1 (Pet. 25–40), including that the closure has a “curvate surface” (Pet. 30). In order to arrive at the leading face having a curvate surface limitation, Petitioner relies on Figure 10 of the '477 Publication in conjunction with the testimony provided by Petitioner’s declarant, Dr. McMillin. Pet. 30 (citing Ex. 1003 ¶¶ 230–233). Figure 10 of the '477 Publication as annotated by Petitioner is reproduced below:



The figure above shows an exploded view of a start structure having a concave and convex surface as identified by Petitioner. Pet. 30; Ex. 1003 ¶ 230.

We have reviewed the '477 Publication and agree with Patent Owner that there is nothing in the '477 Publication that describes the unidentified line in Figure 10. *See generally* Prelim. Resp. For the reasons discussed in greater detail below with respect to claim 26 (see II.D.2.c), we agree with Patent Owner that Petitioner has not provided a sufficient factual basis based on Figure 10 of the '477 Publication from which to conclude that it would

have been obvious to arrive at a “leading face including at least a partial concave surface and a partial convex surface.”

Claim 1, however, does not recite a leading face having both a concave and convex surface. The leading surface in claim 1 only needs to have a curvate surface. Based on the current record, Petitioner has provided a sufficient rationale why one of ordinary skill in the art would have arrived at a structure containing a leading face that has a curvate surface based on the combination of the '477 Publication and Boschert. Specifically, Petitioner contends that because the closure is intended to be used in a surgical environment the ordinary artisan would have been motivated to eliminate any sharp edges that could pierce a surgeon's glove. Pet. 23 (citing Ex. 1003 ¶¶ 202–204); *see also* Ex. 1003 ¶ 64 (“By truncating a thread start a POSA was able to avoid very thin portions of the tapered thread, which are sharp and could cut a surgeon's glove, could be easily damaged, and could lead to cross threading.”).

Petitioner's declarant, Dr. McMillin, asserts that “a POSA would have had an expectation of success with this combination, at least because multi-start threads and curvate^[10] leading faces, and techniques for manufacturing them, were well known in the art.” Pet. 22; *see* Ex. 1003 ¶ 232 (citing ¶¶ 48–79 of the McMillin declaration). In addition, Petitioner asserts that “a

¹⁰ The '641 patent recites that “[e]ach of the start structures . . . includes a leading face having at least one radius of curvature. In one embodiment, the at least on one curvate surface is both concave and convex.” Ex. 1001, 7:51–55. We interpret “curvate” leading face to be either a concave or convex structure unless the language of the claim specifies that the structure contains both, such as for example recited in claims 9–13 and 26. *Id.* at 13:24–42, 16:1–3.

combination of familiar elements using known methods would yield predictable and successful results.” Pet. 23 (citing Ex. 1003 ¶ 204). Specifically, Petitioner contends that the “benefits of double-lead threads, including balancing insertion forces and increasing insertion speed” were known. Pet. 22–23 (citing Ex. 1003 ¶¶ 202–204). The use of truncated thread starts was also known for further easing thread insertion, reducing thread deformation, and reducing sharp edges. Pet. 23 (citing Ex. 1003 ¶¶ 202–204).

Dr. McMillin explains that one of ordinary skill in the art at the time the invention was made would have understood that “[b]y truncating a thread start a POSA was able to avoid very thin portions of the tapered thread, which are sharp and could cut a surgeon’s glove, could be easily damaged, and could lead to cross threading.” Ex. 1003 ¶ 64. A person of ordinary skill in the art would have understood that “[t]he Higbee cut, which is also known as a blunt start or blunt end thread . . . [requires] the removal of the incomplete thread at the end of the thread.” Ex. 1003 ¶ 68 (citing Ex. 1024, 13). In addition, Dr. McMillin asserts that by

terminating the thread below the face-level of the cylinder or annulus on or in which it is formed, and forming the extreme end so that it will have a broad blunt face lying symmetrically on each side of the center line of the thread. By this construction the ends of the threads are made strong, stout, and of substantially the same cross-section . . . so that there is the least possible risk of jamming or breaking into the thread.

Ex. 1003 ¶ 65 (citing Ex. 1015). Dr. McMillin further asserts that there are limited shape options for the blunt end structures: an oblique plane, a cut off square, or rounded. Ex. 1002 ¶ 67 (citing Ex. 1015, Figures 1–6, 2:88–94).

Dr. McMillin also asserts that one of ordinary skill in the art at the time the invention was made would have understood that in the process of truncating the thread a “sanding, grinding, or milling bit used to truncate the threads would have typically left a concave, curvate surface near the root of the thread.” Ex. 1003 ¶ 78 (citing Ex. 1034 ¶¶ 34–36); *see also* Ex. 1034 ¶ 34 (“at the completion of the cutting of screw thread 50, the starting end 50a of screw thread 50 immediately adjacent to pilot portion 64 will inherently have a scalloped or concave blunt end surface which is of substantially full screw thread form.”), *see id.* ¶ 15 (“a blunted or scalloped starting or first thread on a threaded part or work piece provides a much more robust, damage resistant, and cross threading resistant part.”).

Based on the current record, Petitioner has sufficiently shown for purposes of institution that there are benefits for using a truncated thread. As explained below, the ’477 Publication (*see* II.D.2.a.ii.3) shows a truncated thread having a leading face that is flat. Petitioner’s declarant, Dr. McMillin, however, explains that there are limited shape options for creating blunt end thread structures that include: an oblique plane, a cut off square, or rounded end. Ex. 1003 ¶ 67 (citing Ex. 1015, Figures 1–6, 2:88–94 (“The exact form of the thread end is not very important so long as it is blunt and substantially symmetrical with respect to the center line of the thread. It maybe cutoff on an oblique plane, . . . or cut off square, . . . or rounded.”), *see also id.* ¶¶ 64, 74 (“a POSA would commonly know to select a curvate leading face in order to present a less sharp surface for surgeon’s gloves on either a single or a double start closure.”), 78. Based on these disclosures, we determine that Petitioner has sufficiently established for purposes of institution that a truncated thread structure is more robust, damage resistant, and cross

threading resistant providing a reason to truncate a screw thread. Pet. 22–23. We also agree with Petitioner’s declarant that in a surgical environment it is important to avoid sharp edges that could cut a surgeon’s glove providing an additional reason to truncate the thread and round off the edges. Ex. 1003 ¶ 64. Picking one of a finite number of known solutions to a known problem is obvious. *KSR*, 550 U.S. at 421.

iii. Summary as to Independent Claim 1

In sum, based on the current record, Petitioner has sufficiently shown, for institution purposes, that the combination of the ’477 Publication and Boschert teaches each limitation of claim 1. Petitioner has also made a sufficient showing that there is a reason to combine the teachings to arrive at the all the limitations of claim 1.

b. Independent Claim 21

Claim 21 recites an implant that comprises a receiver, a closure, and a channel for receiving a longitudinally connecting member. *See id.* at 14:16–65. The closure comprises a “closure loading surface and includ[es] at least a partial concave surface.” *Id.* at 12:40–41.

Petitioner states that the combination of the ’477 Publication and Boschert teaches the claim limitation of a “closure loading surface and including at least a partial concave surface.” Pet. 58–59 (citing Ex. 1003 ¶¶ 331–334).

Petitioner’s declarant, Dr. McMillin, asserts that “[a] POSA, from their knowledge of truncated threads generally, would have understood that a truncated thread facilitates alignment and starting of threading. . . . A POSA also would have understood that a truncated thread [also] provides structural stability during assembly.” Ex. 1003 ¶ 334 (citing Ex. 1007 ¶¶ 6,

8, 43, 49; Ex. 1022 ¶ 31; Ex. 1015, 1:40–52, 2:88–94). Dr. McMillin further asserts that the process of creating a truncated thread would result in a concave curvate surface. Ex. 1003 ¶ 78 (“a sanding, grinding, or milling bit used to truncate the threads would have typically left a concave, curvate surface near the root of the thread.” (citing Ex. 1034 ¶¶ 34–36)).

Based on these disclosures, we determine that Petitioner has sufficiently established for purposes of institution that a person of ordinary skill in the art would have avoided sharp portions of a thread that could cut a surgeon’s glove by creating a blunt end. Ex. 1003 ¶ 334 (citing Ex. 1024, 13 (“‘Blunt start’ or ‘blunt end’ designates the removal of the incomplete thread at the end of the thread. This is a feature of threaded parts that are repeatedly assembled by hand, such as hose couplings and thread plug gages, to prevent cutting of hands and crossing of threads, and which was formerly known as a *Higbee cut*.”)). Petitioner has also made a sufficient showing that there is a reason to combine the teachings to arrive at the all the limitations of claim 21.

c. Independent Claim 26

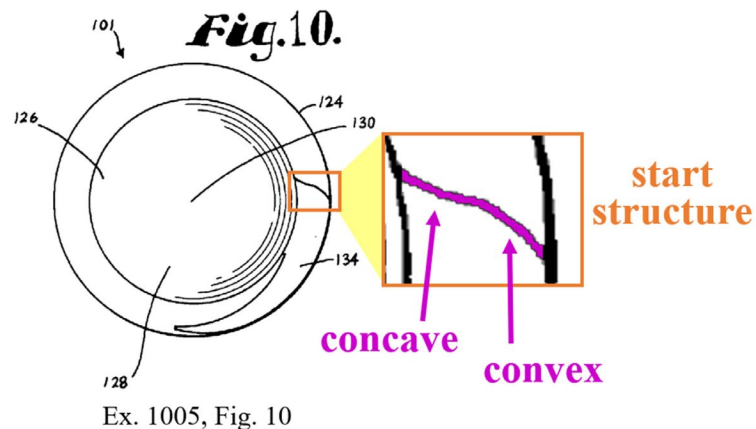
Claim 26 recites an implant that comprises a receiver, a closure, and a channel for receiving a longitudinally connecting member. Ex. 1001, 15:12–16:29. The closure contains a “leading face including at least a partial concave surface and a partial convex surface.” *Id.* at 16:1–3.

Petitioner argues that an ordinarily skilled artisan would have been motivated to use the closure having a leading face of the ’477 Publication with the double lead thread of Boschert. Pet. 66–67 (citing Ex. 1005, Fig. 10; Ex. 1003 ¶¶ 363–363).

Patent Owner counters that Petitioner fails to show the prior art teaches a “leading face including at least a partial concave surface and a partial convex surface.” Prelim. Resp. 5–19. Based on the current record, and as explained below, we find Patent Owner’s argument more persuasive.

Petitioner relies on the ’477 Publication for teaching the disputed limitation. Pet. 66–67 (citing Ex. 1005, Fig. 10; Ex. 1003 ¶¶ 363–364). Petitioner argues that the ’477 Publication teaches “a leading face that includes at least a partial concave surface and a partial convex surface.” *Id.* at 66 (citing Ex. 1003 ¶ 364; Ex. 1005, Fig. 10).

Petitioner next refers to an annotated Figure 10 of the ’477 Publication, reproduced below:

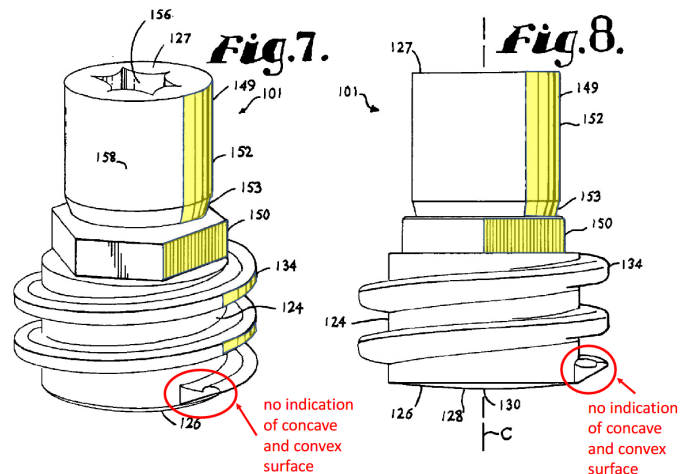


The figure above shows an exploded view of a start structure having a concave and convex surface as identified by Petitioner. Pet. 66. Petitioner asserts that an ordinarily skilled artisan would recognize the line in the orange box in annotated Figure 10 to be “a leading face that includes at least a partial concave surface and a partial convex surface.” *Id.* at 66 (citing Ex. 1003 ¶ 364). We are not persuaded.

First, we find Dr. McMillin’s testimony insufficient to support Petitioner’s argument on this point. As Patent Owner correctly points out,

the '477 Publication does not describe, or even identify, the line in Figure 10 that Petitioner relies on as the leading face. Prelim. Resp. 1, 5, 6. Thus, the only evidence that purportedly supports Petitioner's argument that the unidentified and undescribed line is the leading surface is Dr. McMillin's testimony. *See* Ex. 1003 ¶¶ 230, 362. Dr. McMillin's testimony, however, does not provide any explanation or other evidentiary support. *See id.* As a result, we accord limited weight to Dr. McMillin's testimony on this issue. *See Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (PTAB Aug. 24, 2022) (precedential).

Second, Petitioner's argument that the unidentified and undescribed line in Figure 10 shows a curved leading face is inconsistent with the disclosures in Figures 7 and 8, showing a flat leading face for the same embodiment. Indeed, Figures 7, 8, and 10 show the same bone screw closure from different viewpoints. Ex. 1005 ¶¶ 20, 21, 23 (stating Figure 7 shows the "perspective view," Figure 8 shows the "front elevational view of the closure of FIG. 7," and Figure 10 shows the "bottom plan view of the closure of FIG. 7"). Patent Owner contends that Figures 7 and 8 do not show any curved surface in the leading face. Prelim. Resp. 7. Patent Owner annotates Figures 7 and 8 as follows:

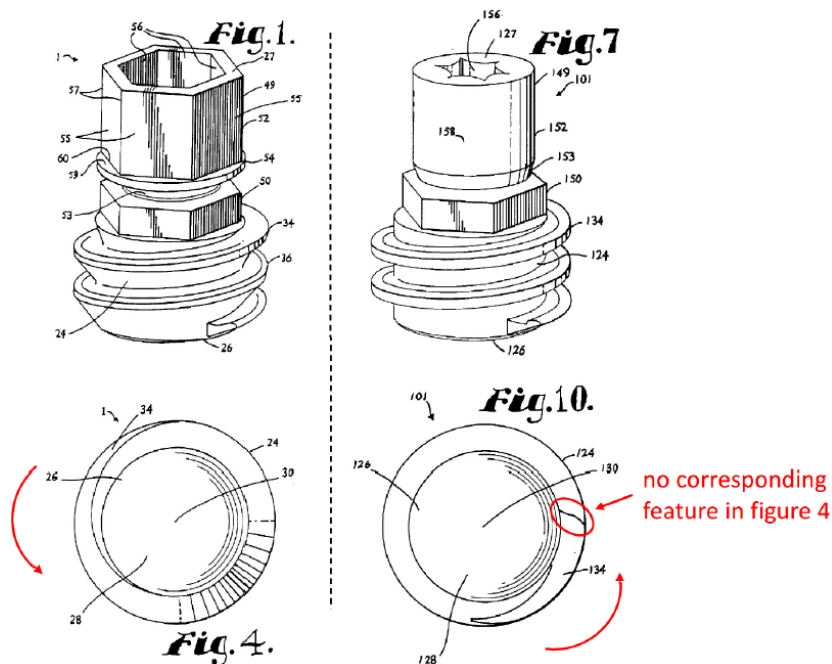


The figures above are the reproduction of Patent Owner’s annotated Figures 7 and 8 of the ’477 Publication highlighting the start structure of the thread. *Id.* at 8. We agree with Patent Owner that Figures 7 and 8 appear to depict a flat surface for the leading face, rather than a partial concave surface and a partial convex surface, as required in claim 26. *Id.* at 7–8.

We are also persuaded by Patent Owner’s showing that, in the challenged ’641 patent, the partially concave and partially convex surface is “visible across all views.” *Id.* at 8–9 (citing Ex. 1001, Figs. 1, 2, 5); *see also* Ex. 1001, 3:38–41 (explaining each of Figures 1 and 2 is a perspective view of the same closure), 3:51–52 (explaining Figure 5 is a bottom plan view of the same closure). In other words, if the ’477 Publication taught the disputed limitation, the partially concave and partially convex leading face would have been visible not only in Figure 10 (the bottom plan view), but also in Figure 7 (the perspective view). Yet, the leading face shown in Figure 7, which is the same leading face as shown in Figure 10, appears flat.

Third, Petitioner’s argument that the unidentified and undescribed line in Figure 10 shows a leading face is also inconsistent with the disclosure for another embodiment in the ’477 Publication. The ’477 Publication teaches two embodiments of bone screw closure, one shown in Figures 1–4, the other in Figures 7–10. Ex. 1005 ¶¶ 14–17, 20–23. According to Dr. McMillin, “[t]he primary difference between the embodiments is the shape of the closure break-off head.” Ex. 1003 ¶ 72 (citing Ex. 1005 ¶¶ 33, 43, Figs. 1, 7). Thus, we agree with Patent Owner that an ordinarily skilled artisan “would understand the leading face between the two embodiments is substantially the same.” Prelim. Resp. 12.

Patent Owner annotates Figures 1, 4, 7, and 10, which we reproduce below:



The figures above are the reproduction of Patent Owner's annotated Figures 1, 4, 7, and 10 of the '477 Publication. Prelim. Resp. 13. Figures 1 and 4 depict the same first embodiment of a closure from the perspective view and bottom plan view, respectively. Ex. 1005 ¶¶ 14, 17. Similarly, Figures 7 and 10 depict the same second embodiment of a closure from the perspective view and bottom plan view, respectively. Ex. 1005 ¶¶ 20, 23.

Patent Owner argues that

Given the similarity in their leading faces, one would expect the same depiction of the leading faces across all embodiments. However, the bottom view of Figure 1 (as shown in Figure 4) does not contain the same line depicted in the bottom view of Figure 7 (as shown in Figure 10) that Petitioner relies on[.]

Prelim. Resp. 12–13.

On the current record, we find Patent Owner’s argument persuasive. Indeed, from the perspective view, closure 1 shown in Figure 1 and closure 101 shown in Figure 7 appear to have substantially the same leading faces. Yet, from the bottom plan view, Figure 4 (closure 1) does not appear to have a curved line similar to the one shown in Figure 10 (closure 101), which Petitioner alleges as representing a leading face with a concave surface portion and a convex surface portion. *See* Pet. 53–54. Petitioner does not explain this discrepancy.

For the foregoing reasons, Petitioner does not persuade us that the unidentified and undescribed line in Figure 10 of the ’477 Publication represents a leading surface as required in the disputed limitation.¹¹ Petitioner does not rely on any other prior art teaching or knowledge of an ordinarily skilled artisan for the disputed limitation. *See* Pet. 66–67. In other words, Petitioner does not show the combination of the ’477 Publication and Boschert teaches or suggests “a leading face with a concave surface portion and a convex surface portion.” As a result, on this record, Petitioner has not established a reasonable likelihood that it would prevail in its obviousness challenge of claim 26 over the asserted prior art.¹²

¹¹ We also express doubt on whether Petitioner adequately shows the line in Figure 10 is partially concave and partially convex, as required in the disputed limitation. Petitioner’s argument on this point is predicated on an enlarged section of a small drawing, showing a single unidentified and undescribed line that was not apparently intended to demonstrate the direction of any curvature. *See* Pet. 66. Ultimately, we do not need to address this issue, because Petitioner does not sufficiently persuade us that the line depicts the leading face recited in the disputed limitation.

¹² Claims 9–13 and 16 depend either directly or indirectly from claim 1 and recite a “curvate surface” containing both a convex and a concave portion of the lead face structure similar to the limitation recited in claim 26. For the

3. Summary

In sum, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that claims 1 and 21 would have been obvious over the '477 Publication and Boschert.

Patent Owner does not make separate arguments to address dependent claims 3–8, 14, 15, 17–19, and 21–25. Prelim. Resp. 20. Based on the current record, we determine Petitioner has made a sufficient showing regarding these claims too. Thus, we institute an *inter partes* review as to all challenges raised in the Petition. *See* Patent Trial and Appeal Board Consolidated Trial Practice Guide 64 (Nov. 2019)¹³ (“The Board will not institute on fewer than all claims or all challenges in a petition.”); *see also* *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition”).

E. Other Combinations

Petitioner asserts that claim 2 would have been obvious over the combination of the '477 Publication, Boschert, and the '391 Publication. Pet. 70–78. Petitioner also contends that claim 20 would have been obvious over the '477 Publication, Boschert, and Johnson. *Id.* at 77–81.

Patent Owner does not make separate arguments to address these claims. Prelim. Resp. 20. Based on the current record, we determine

same reasons outlined for claim 26 we find that the combination as articulated by Petitioner does not sufficiently support the conclusion that the limitations recited in claims 9–13 and 16 would have been obvious.

¹³ Available at <https://www.uspto.gov/sites/default/files/documents/tpgnovpdf>.

Petitioner has made a sufficient showing regarding these claims too. Thus, we institute an *inter partes* review as to all challenges raised in the Petition.

III. CONCLUSION

Based on the current record, and for the reasons explained above, we find Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition. We, thus, institute an *inter partes* review of all challenged claims on all asserted grounds.

At this stage of the proceeding, the Board has not made a final determination as to the construction of any claim term or the patentability of any challenged claim. Our view with regard to any conclusion reached in the foregoing could change upon further development of the record during trial.

Any argument not raised in a timely Patent Owner Response to the Petition, or as permitted in another manner during trial, shall be deemed waived even if asserted in the Preliminary Response. In addition, nothing in this Decision authorizes Petitioner to supplement information advanced in the Petition in a manner not permitted by the Board's Rules.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted on all challenged claims of the '641 patent based on all the asserted grounds set forth in the Petition; and

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

IPR2023-01431
Patent 10,548,641 B2

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