

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ROGER P. JACKSON
Patent Owner

Patent No. 10,548,641
Filing Date: April 27, 2018
Issue Date: February 4, 2020
Title: MEDICAL IMPLANT RECEIVERS HAVING DUAL LEAD IN
CLOSURE MATING THREAD FORMS

Inter Partes Review No. IPR 2023-01431

**PETITION FOR *INTER PARTES* REVIEW
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *ET SEQ.***

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Exhibit 1003:	Declaration of Dr. Carl McMillin
Exhibit 1004:	Dr. Carl McMillin Curriculum Vitae
Exhibit 1005:	U.S. Patent Application Publication No. 2005/0267477 (“the ‘477 Publication”)
Exhibit 1006:	U.S. Patent No. 7,857,834 (“Boschert”)
Exhibit 1007:	U.S. Patent Application Publication No. 2011/0152947 (“Kirschman”)
Exhibit 1008:	U.S. Patent Application Pub. No. 2007/0088357 (“Johnson”)
Exhibit 1009:	U.S. Patent No. 8,911,479 (“’479 Patent”)
Exhibit 1010:	U.S. Patent No. 10,898,233 (“’233 Patent”)
Exhibit 1011:	U.S. Patent No. 11,129,646 (“’646 Patent”)
Exhibit 1012:	U.S. Patent No. 7,160,300 (“Jackson ’300”)
Exhibit 1013:	U.S. Patent No. 6,726,689 (“Jackson ’689”)
Exhibit 1014:	MACHINERY’S HANDBOOK 28 (28th Ed., 2008) (“Machinery’s Handbook”) (<i>Excerpt</i>)
Exhibit 1015:	U.S. Patent No. 447,775 (“Higbee”)
Exhibit 1016:	U.S. Patent No. 6,296,642 (“Morrison”)
Exhibit 1017:	U.S. Patent No. 6,302,888 (“Mellinger”)

Exhibit 1018	German Patent No. 29810798
Exhibit 1019	U.S. Patent No. 7,250,052 (“Landry”)
Exhibit 1020	U.S. Patent Application Publication No. 2004/0167526
Exhibit 1021	U.S. Patent Application Publication No. 2004/0162560 (“Raynor”)
Exhibit 1022	U.S. Patent Application Publication No. 2011/0106179 (“Prevost”)
Exhibit 1023	U.S. Patent Application Publication No. 2006/0058794 (“Jackson ’794”)
Exhibit 1024	U.S. Department of Commerce’s 1969 Handbook H28 (“Handbook H28”)
Exhibit 1025	U.S. Patent No. 4,707,001 (“Johnson ’001”)
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Exhibit 1029	American Heritage Dictionary, Fifth Edition (2011)
Exhibit 1030	U.S. Patent Application Publication No. 2006/0069391 (“the ’391 Publication”)
Exhibit 1031	American Society of Mechanical Engineering Standard B1.7-2006 (“ASME B1.7-2006”) (<i>Excerpt</i>)
Exhibit 1032	U.S. Patent No. 4,545,374 to Jacobson (“Jacobson”)
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Exhibit 1034	U.S. Patent Application Publication No. 2005/0286984
Exhibit 1035	U.S. Patent Application Publication No. 2010/0137918 ("Wilcox")
Exhibit 1036	U.S. Patent Application Publication No. 2010/0312287
Exhibit 1037	Stipulation Regarding Invalidity Contentions ("Sotera Stipulation")
Exhibit 1038	June 21, 2022 Memorandum regarding Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation ("Sotera Memo")
Exhibit 1039	U.S. Patent No. 6,488,681
Exhibit 1040	U.S. Patent No. 6,280,442
Exhibit 1041	U.S. Patent No. 6,074,391
Exhibit 1042	File History U.S. Patent No. 10,898,233
Exhibit 1043	File History U.S. Patent No. 11,129,646
Exhibit 1044	File History of U.S. Patent Application No. 15/397,959 ("the '959 Application") (<i>Excerpt</i>)

ZimVie, Inc. and Zimmer Biomet Spine, Inc. (“Petitioners”) respectfully request *inter partes* review (“IPR”) of claims 1-28 (“the Challenged Claims”) of U.S. Patent No. 10,548,641 (“the ’641 Patent”) (EX1001) owned by Dr. Roger Jackson.

I. MANDATORY NOTICES (37 C.F.R. § 42.8)

A. Real Party-in-Interest

Petitioners are the real parties-in-interest for this petition. Petitioner Zimmer Biomet Spine, Inc. is a subsidiary of Petitioner ZimVie, Inc. No parties other than Petitioners are funding, controlling, or directing this petition.

B. Related Matters

The ’641 Patent is subject to a pending lawsuit entitled *Jackson v. ZimVie Inc.*, No. 1:22-cv-00891-RGA (D. Del. Filed June 30, 2022) (the “Litigation”). In the Litigation, Patent Owner has asserted claims of infringement, and Petitioner ZimVie, Inc. is the defendant. Petitioners are filing three additional petitions seeking IPR of related U.S. Patent Nos. 8,911,479; 10,898,233; and 11,129,646 (the “’479 Patent” (EX1009), “’233 Patent” (EX1010), and “’646 Patent” (EX1011) respectively; collectively, “the Related Patents”). The Related Patents are also at issue in the Litigation.

C. Counsel

Pursuant to 37 C.F.R. §§ 42.8(b)(3) and 42.10(a), Petitioners hereby identify their lead and backup counsel as follows:

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Please address all correspondence to the lead and back-up counsels at the addresses shown above. Petitioners also consent to electronic service to all of the email addresses shown above.

II. STANDING AND FEES

A. Certification of Grounds for Standing (37 C.F.R. § 42.104(a))

Petitioners certify that the '641 Patent is available for IPR and that Petitioners are not barred or estopped from requesting IPR of the Challenged Claims on the grounds identified in this Petition.

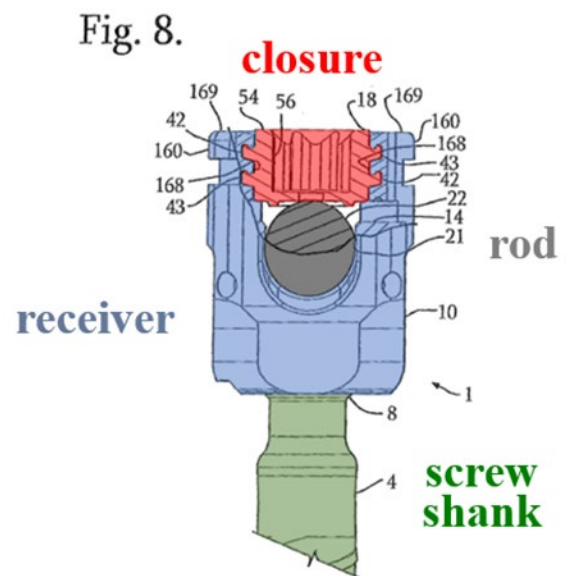
B. Fees (37 C.F.R. § 42.103)

Petitioners authorize the Director to charge the request and post-institution fees, and any additional required fees, to Deposit Account No. DA060029.

III. THE '641 PATENT

A. Overview

The '641 Patent is directed to threaded closures (also called “setscrews” or “closure tops”) used to capture a rod in the U-shaped receiver of a spinal pedicle screw as was known in the prior art. The specification admits that “*open-ended bone anchors are known*,”¹ EX1001, 1:35-42, and, as shown in annotated Figure 8 below, generally include known components such as “a threaded shank with a head or *receiver*



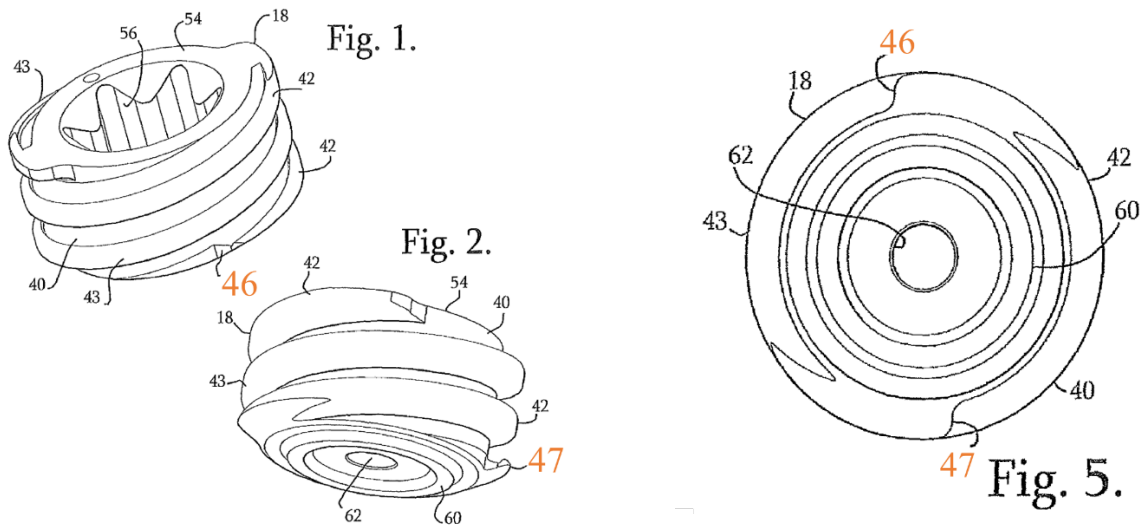
¹ Emphases and text coloring added unless specified throughout.

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., 1:51-55. As taught in the prior art, this U-shaped channel is “closed by a closure member after the rod or other longitudinal connecting member is placed in the channel.” *Id.*, 1:60-62. These known components are highlighted and annotated in Fig. 8. The specification also states that “[k]nown closures include...a variety of single start *helically wound guide and advancement structures* including, for example, thread forms having *v-thread, reverse angle buttress or square thread forms*, to name a few, as well as other non-threadlike helically wound forms.” *Id.*, 1:62-2:1.

The specification identifies the problem addressed as follows: “when the closure is a cylindrical plug having a single start helically wound guide and advancement structure, such structure must be aligned with mating structure on one of the implant arms and then rotated until a portion of the structure is captured by mating guide and advancement structure on both arms of the implant, all the while the closure is being pressed down on the rod while other forces are pushing and pulling the rod back out of the implant.” *Id.*, 2:17-23. The specification purports to address these issues by using a “double-start closure ... having two helically wound forms thereon, each form having a start structure for simultaneously engaging a

mating helical form on a respective open implant arm.” *Id.*, 2:44-47. The “start structures 46 and 47” are identified in annotated Figures 1, 2, and 5 below.



During prosecution, Dr. Jackson’s patentability argument based on double-start threads fell flat when it was discovered that U.S. Patent No. 6,010,602 (“Bagby”) (EX1026) previously taught double-start threads. As a result, he pivoted to claiming other conventional elements of his preferred embodiments—primarily a curvate leading face on each thread. This feature was known in the prior art, with U.S. Patent Publication Application No. 2005/0267477 (“the ’477 Publication”) (EX1005) disclosing the same curvate leading face. The ’477 Publication was not considered before the claims were allowed, however.

The ’641 Patent includes three independent claims—Claims 1, 21, and 26. These claims substantially overlap, with slight variations in the claims’ descriptions

of the leading face's curvate surface. The dependent claims recite additional conventional components of closures and the receivers they thread into, including a guide tool (Claim 2), additional characteristics of known threads (Claims 3-4, 6, 24-25), additional characteristics of known thread starts (Claims 5, 7-19, 27-28), breakoff extensions on the receiver arms (Claim 20), and additional characteristics of known closures (Claims 22-23).

Petitioners provide as an Appendix to the Petition a claim listing of all Challenged Claims. Because many limitations are common, each of these limitations has been assigned a unique identifier. This claim listing, and the assignment of a unique identifier for each limitation, are intended for ease of reference. The Petition addresses every limitation of the Challenged Claims.

B. Priority Date

The '641 Patent claims priority to January 10, 2012 ("Priority Date"). EX1001. Although Petitioners do not concede that the '641 Patent is entitled to this priority date, Petitioners assume this date for purposes of this Petition.

IV. Level of Ordinary Skill in the Art

A. Qualifications of a Person of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSA") 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. EX1003, ¶42; *see also id.*, ¶¶36-41.

B. Knowledge of a POSA

Before the priority date of the '641 Patent, a POSA would have been well familiar with open spinal pedicle screws for receiving a rod and various closures that could be used to close the open receiver. EX1003, ¶¶43-50. Further, a POSA would have been aware of a number of options when designing such a system, including multi-start threads, *id.*, ¶¶51-63; truncated threads with curvate leading faces, *id.*, ¶¶64-74; thread manufacturing processes, *id.*, ¶¶75-79; various thread types, *id.*, ¶¶80-85; flat bottoms, *id.*, ¶¶87-90; breakoff arm extensions, *id.*, ¶¶92-97; and attachable/detachable guide tools, *id.*, ¶¶98-108.

V. IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(b))

A. Claims and Statutory Grounds (37 C.F.R. § 42.104(b)(1)-(2))

Petitioners respectfully request cancellation of the Challenged Claims as obvious under 35 U.S.C. § 103 on the following grounds:

Ground	Claims	Basis
1	1, 3-19, and 21-28	Obvious in view of the '477 Publication (EX1005) and Boschert (EX1006)
2	2	Obvious in view of the '477 Publication (EX1005) in combination with Boschert (EX1006) and the '391 Publication (EX1030)
3	20	Obvious in view of the '477 Publication (EX1005) in combination with Boschert (EX1006) and Johnson (EX1008)

B. Claim Construction (37 C.F.R. § 42.104(b)(3))

The Challenged Claims are construed under the same standard used in federal district court. 37 C.F.R. § 42.100(b). This Petition requests construction of the following terms:

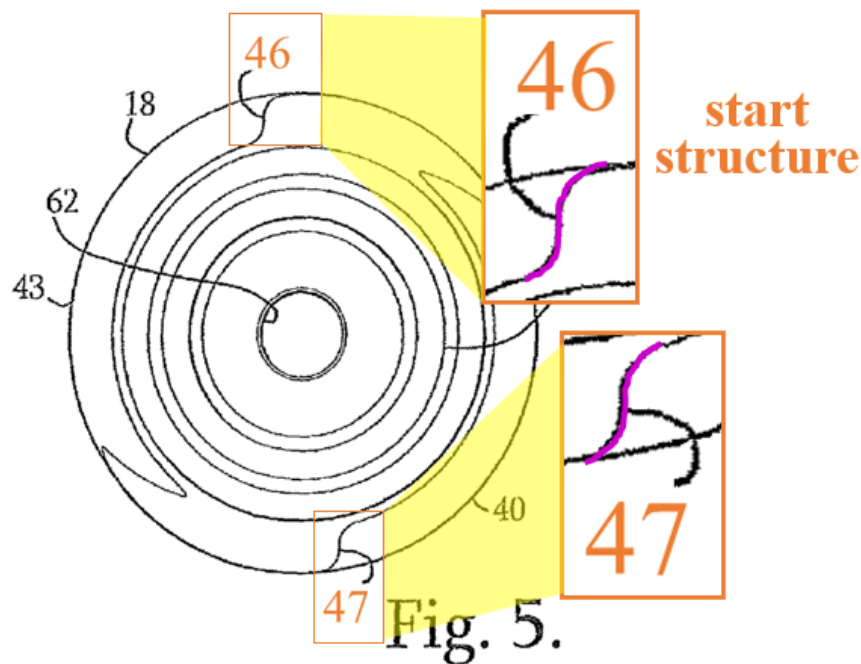
1. **“a first start structure with a leading face surface extending below a first upper loading surface disposed between a root and a crest of the first continuously helically wound thread form”/“a second start structure with a leading face surface extending below a second upper loading surface disposed between a root and a crest of the second continuously helically wound thread form” (Claims 1 and 26)/“each of the first start structure and the second start structure having a leading face surface” (Claim 21)**

The claimed “leading face” is never specifically identified in the ’641 Patent.

The entirety of the written description on this feature states:

Each 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.

EX1001, 7:51-55. Start structures 46 and 47 are shown in Figure 5, annotated/enlarged below, which is the only figure that shows the described concave and convex surfaces on the leading face.



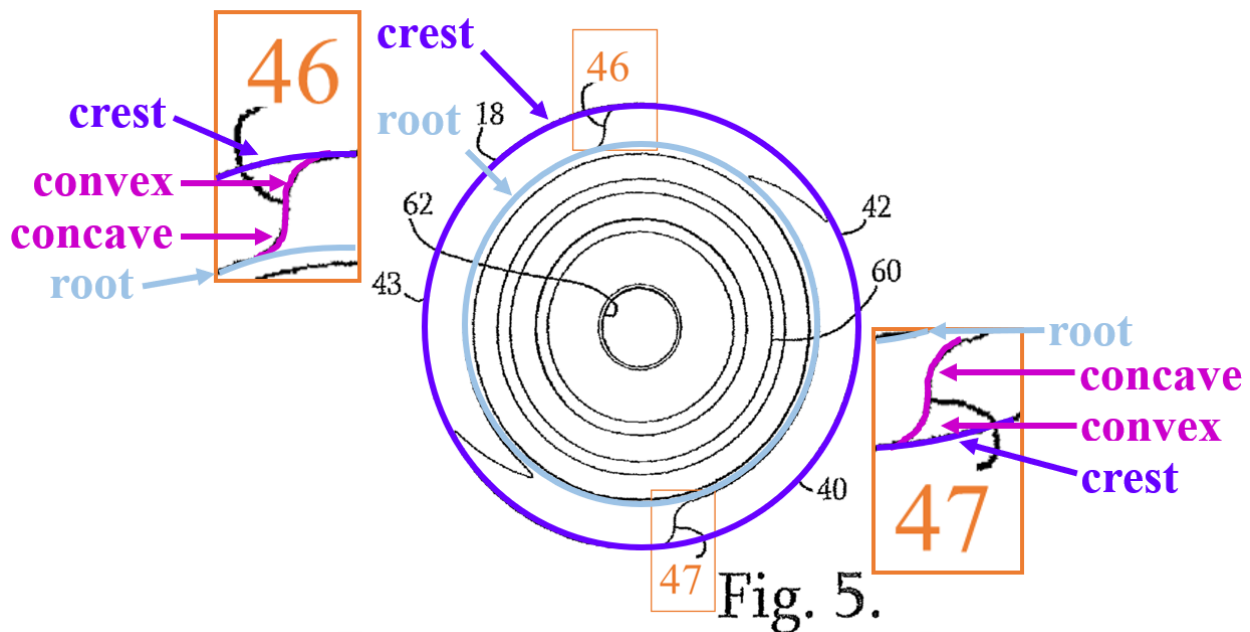
From this disclosure, and consistent with the plain meaning, a POSA would have understood that a “start structure” is the beginning of a thread and the “leading face” is the forward most surface of the thread in the direction the thread is to be rotated. EX1003, ¶¶151-52.

2. “wherein the concave surface is adjacent the root and the convex surface is adjacent the crest” (Claims 11 and 27)

The claimed “concave surface” that is “adjacent the root” and “convex surface” that is “adjacent the crest” is never specifically identified by reference number in the ’641 Patent. EX1003, ¶153. Figure 5 is the only figure that shows the described concave and convex surfaces on the leading face. EX1003, ¶153.

A “thread” is a ridge in the form of a helix on the external or internal surface of a cylinder. EX1003, ¶154. The “crest” of the thread is the surface that joins the

flanks and is farthest from the cylindrical body from which the thread projects. *Id.* 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. *Id.* Therefore, a POSA would have understood that, 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. *Id.*, ¶155. The approximate location of the root and crest are illustrated below with reference to Figure 5.

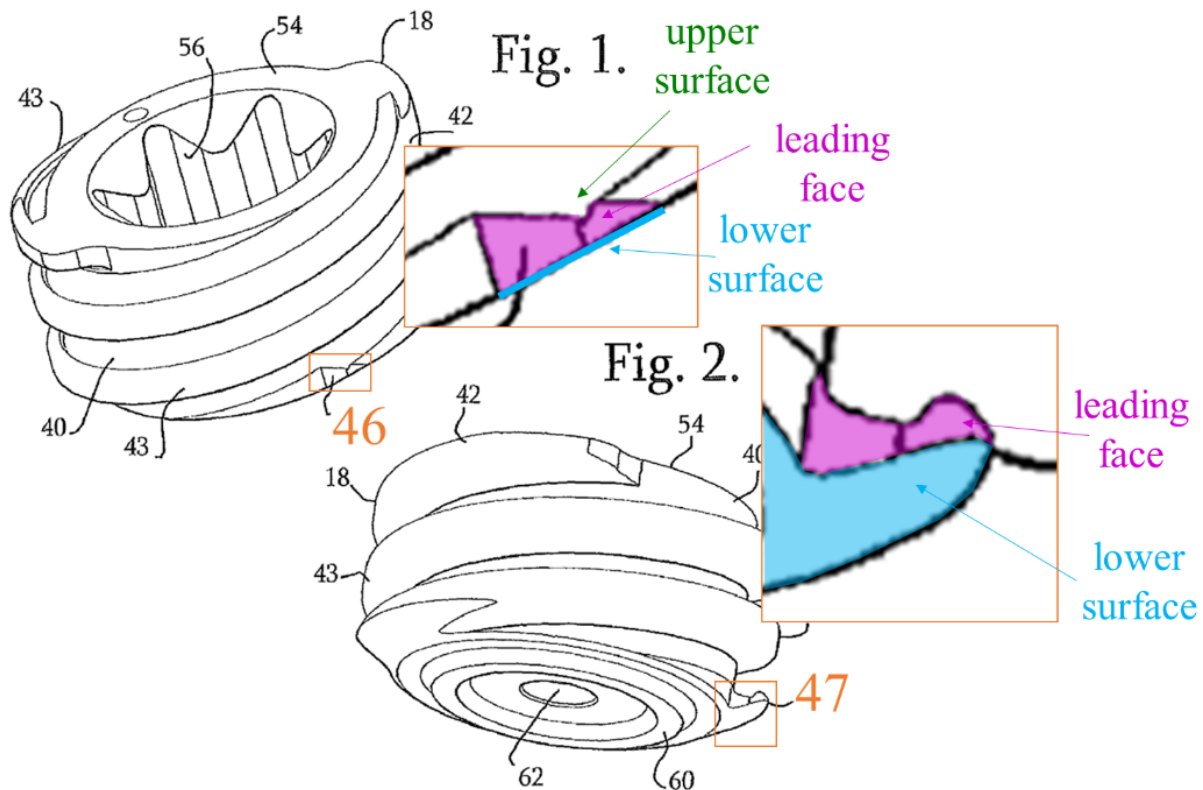


Id.

3. “each of the first start structure and the second start structure includes a bottom beveled surface” (Claim 13)

The specification does not contain any textual description of a bottom-beveled surface of the first start structure or the second start structure. Nevertheless, a POSA would have understood this phrase according to its plain meaning. EX1003, ¶156. “Beveled” means a line or surface that meets another line or surface with an angle or inclination other than 90 degrees. *Id.*, ¶157.

95. The claim language identifies the “bottom beveled surface” as part of the start structure. EX1001, cl. 13. Claim 1, from which claim 13 depends, identifies 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” and 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.” *Id.*, cl. 1. This is shown below in annotated/enlarged Figures 1 and 2.



EX1001, Figs. 1, 2; EX1003, ¶158. A POSA would have understood that the figures of the '641 Patent are consistent with the plain meaning of this phrase and show the sloped angle of the lower surface of the start structure. EX1003, ¶159. Unlike the normal thread profile, in Figure 5 the leading face the lower outside corner of the thread has been removed, resulting in a beveled (i.e., sloping) lower surface of the leading face. A cropped/annotated Figure 3 (below left) shows the beveled lower surface of the leading face in comparison to the normal thread profile shown in Figure 10 (below right). *Id.*

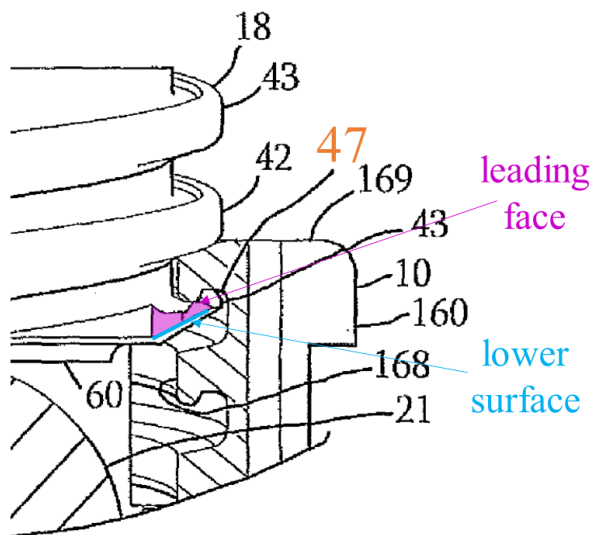


Figure 3

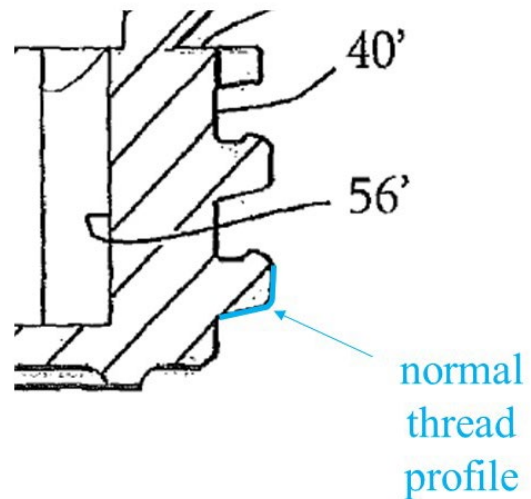
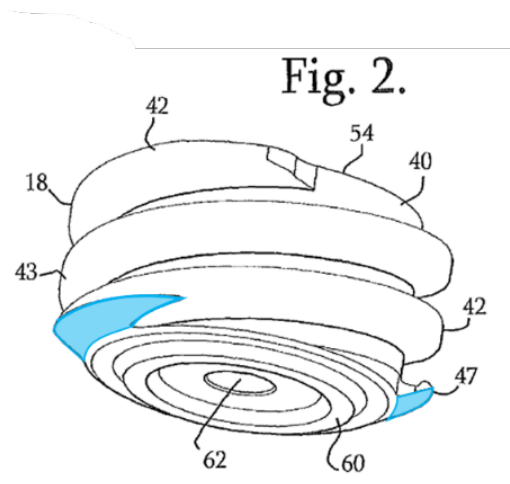
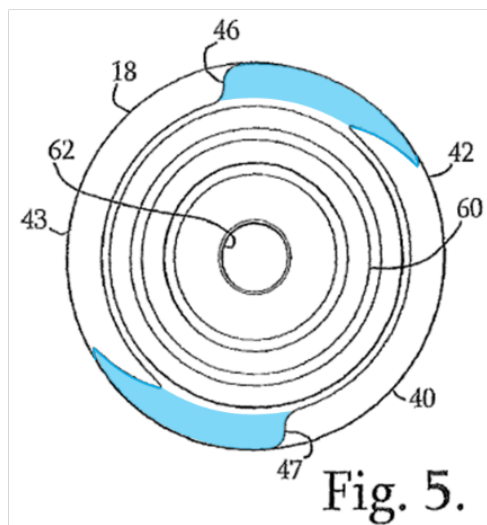


Figure 10

EX1001, Figs. 3, 5. Figures 2 and 5 also show the point at which the thread reaches its full profile, with the length of the beveled segment highlighted blue.

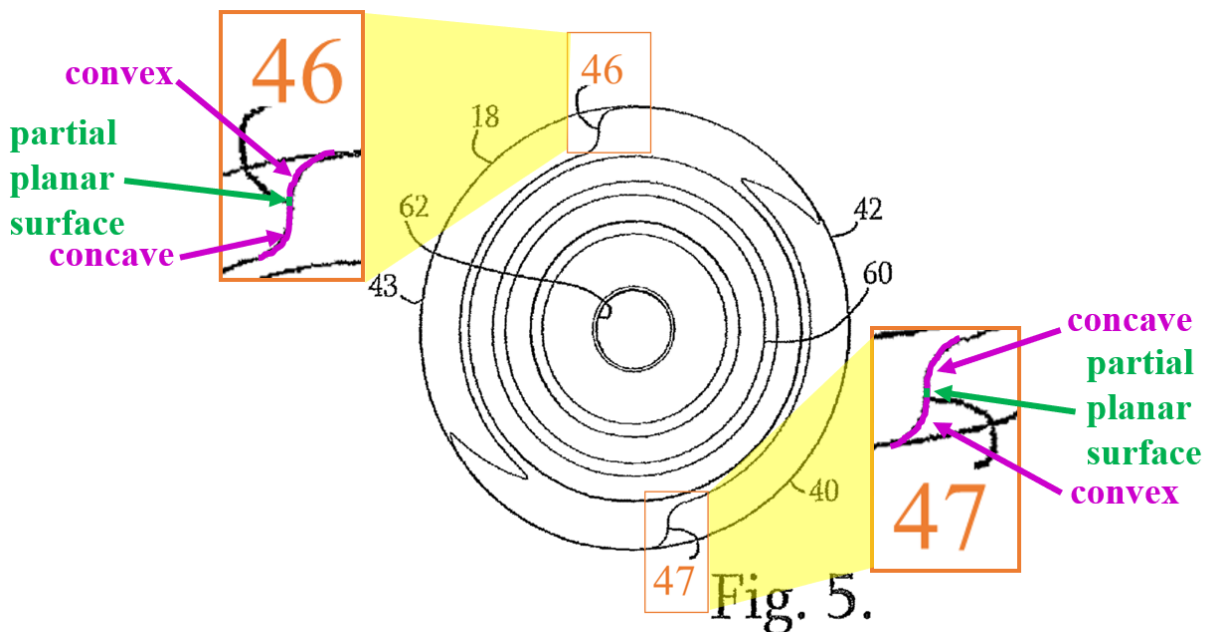


EX1001, Figs. 2, 5.

4. **“the first and second start structure leading face surfaces are at least partially planar surfaces parallel with respect to each other” (Claim 14)/“each of the leading face surfaces of the first start structure and the second start structure include at least a partial planar surface” (Claim 19)**

The specification’s text never identifies “partially planar surface[s]” that are part of the leading face of a thread. Nevertheless, a POSA would have understood this phrase according to its plain meaning. EX1003, ¶160. “Partial” means relating to a part rather than a whole, and “planar” means flat. *Id.*, ¶161.

Claims 14 and 19 refer to the leading faces of the start structure. As illustrated in reference to enlarged/annotated Figure 5 below, the approximate point where the curve changes from convex to concave is the “partial planar surface.” At this location, the leading face is approximately flat in all directions. At all other locations, the leading face is curved in at least one direction. *Id.*, ¶162.



EX1001, Fig. 5.

5. “the closure has a bottom surface that is closed” (Claim 22)

The specification never identifies a “bottom surface that is closed.” Nevertheless, a POSA would have understood this phrase according to its plain meaning. EX1003, ¶163. “Bottom” means the underside or lowermost part of something and “closed” to mean enclosed. *Id.*, ¶164. The ’641 Patent describes only a bottom surfaces that is “planar and further includes a rim 60” and a “cannulation through bore 62.” EX1001, 7:19-25, Figs. 1-14. Nevertheless, a POSA would have understood that a “closed” bottom surface lacks a cannulation. EX1003, ¶165.

6. “simultaneous mating” (Claim 26)

The specification never uses the term “simultaneous mating.” Nevertheless, a POSA would have understood this phrase according to its plain meaning. EX1003, ¶166. The ’641 Patent discloses a closure top that includes one or more helically wound guide and advancement features each having a start surface that simultaneously engage the arms of the open implant. EX1001, 2:35-43, 3:7-12, 8:33-40, Figs. 3, 8, 9, 11-15, 17; EX1003, ¶167. In view of the ’641 Patent’s specification and the context of Claim 26, a POSA would have understood that “simultaneous mating” meant that the first and second continuously helically wound

thread forms engaged the first and second discontinuously helically wound thread forms at the same time. EX1003, ¶168.

C. Challenge and Support (37 C.F.R. § 42.104(b)(4)-(5))

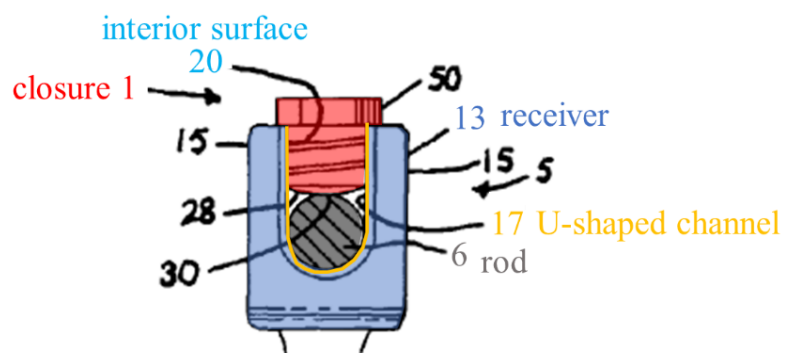
The grounds set forth in Sections VI-VIII below, as supported by the Declaration of Dr. Carl McMillin (EX1003), demonstrate that the Challenged Claims are unpatentable.

VI. GROUND 1: CLAIMS 1, 3-19, AND 21-28 ARE UNPATENTABLE OVER THE '477 PUBLICATION IN VIEW OF BOSCHERT

A. Overview of the '477 Publication

The '477 Publication published on December 1, 2005, and is prior art to the '641 Patent under Section 102(b). As described further below, because the '477 Publication discloses a closure used to capture and lock a rod in a spinal implant, it is in the same field of endeavor as, and analogous art to, the '641 Patent. *Compare* EX1005, ¶[0007], *with* EX1001, 1:27-31; *see also* EX1005, ¶¶[0026]-[0029],[0039]-[0041].

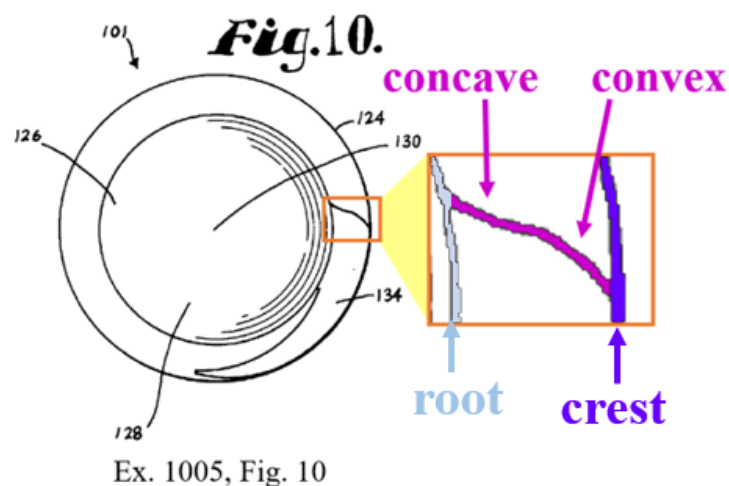
As shown in annotated Figure 6, the '477 Publication discloses a polyaxial screw that includes a receiver 13 with



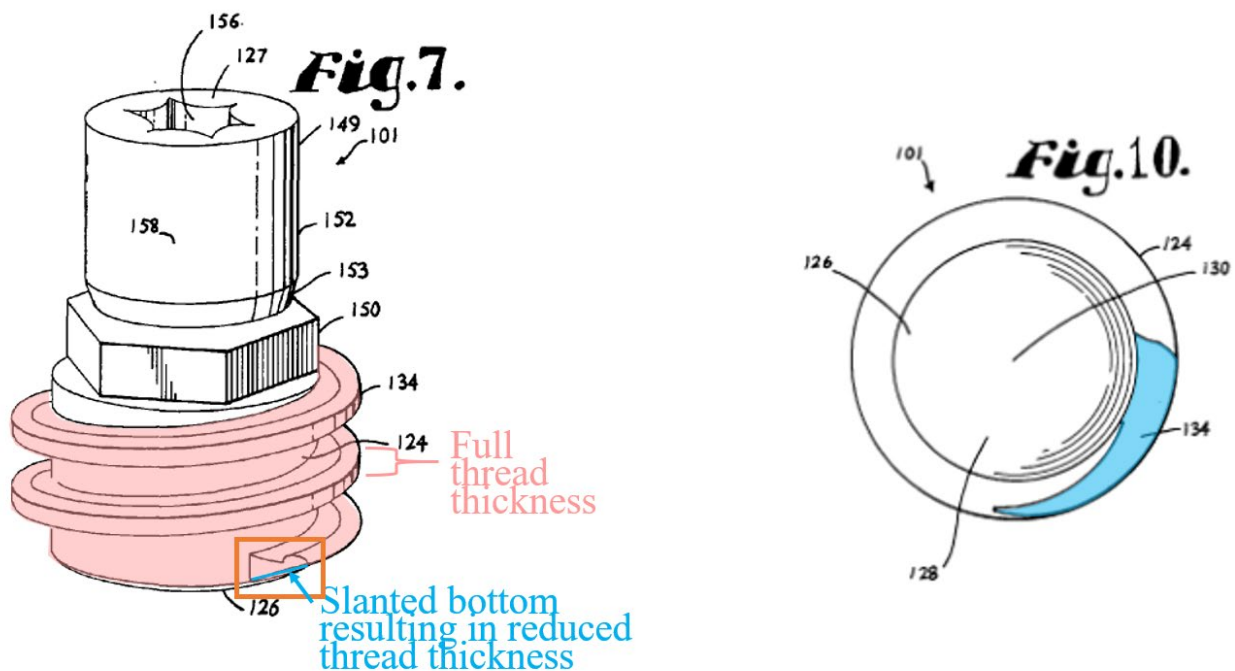
Ex. 1005, Fig. 6

a pair of upstanding arms 15 forming a U-shaped channel 17 for receiving a rod 6. EX1005, ¶¶[0007],[0034]-[0045], Figs. 5-10. The inner surface 20 of each arm has a thread that mates with a similar structure on closure 1 when the closure is rotated. *Id.*, ¶¶[0026],[0030], [0039], Fig. 6. The thread could be one of a variety of different types, including a reverse angle thread. *Id.*, ¶[0030].

The '477 Publication discloses two embodiments of the closure. *See id.*, ¶[0039]. The primary difference between the embodiments is the shape of the break-off head. *Id.*, ¶[0033] (hexagonal), ¶[0043] (cylindrical); *compare id.*, Fig. 1, with *id.*, Fig. 7. Focusing on the second embodiment, the '477 Publication discloses a start structure with a leading face that is truncated and that is formed in an s-curve, with a partial concave surface adjacent the root and a partial convex surface adjacent the crest. *Id.*, Fig. 10; EX1003, ¶¶72, 174.



Figs. 7 and 10 show that the start structure has a sloped bottom surface that reduces the thickness of the thread, and therefore teaches a bottom beveled surface at the thread start. EX1005, Figs. 7 & 10.



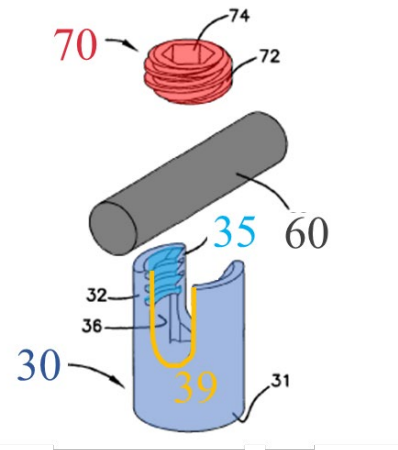
The '477 Publication shows the second embodiment as having a domed bottom, *id.*, Figs. 7, 8, 10, but also discloses that the bottom surface may be substantially flat and may have a central point and a lateral rim, *id.*, ¶[0040].

B. Overview of Boschert

Boschert published on December 15, 2005, and is prior art to the '641 Patent under Section 102(b). As described further below, because Boschert discloses a closure used to capture and lock a rod in a spinal implant, Boschert is in the same

field of endeavor as, and analogous art to, the '641 Patent. *Compare* EX1006, Abstract, 4:26-28, *with* EX1001, 1:27-31.

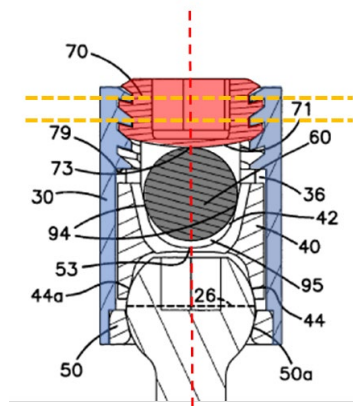
Boschert is directed to an orthopedic fixation device for securing a rod to a bone for stabilization of the spine. EX1006, Abstract, 1:5-7; EX1003, ¶¶176-77. Boschert discloses a “receiver 30” with “two upwardly extending legs” defining a U-shaped “saddle 39... for receiving the rod 60”. EX1006, 6:20-24, Fig.



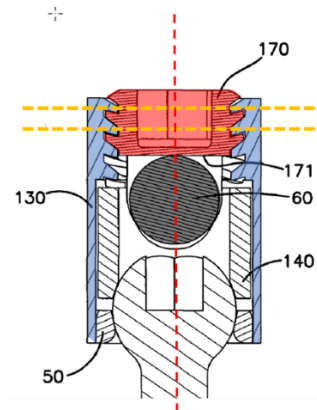
Ex. 1006, Fig. 1

1. The legs have “interior threads 35 that mate with corresponding exterior threads 72 [on] the setscrew 70,” such that the setscrew can be threaded into the saddle to lock the rod in place. *Id.*, 6:24-48, 7:12-15. Boschert discloses that it would be advantageous to design the set screw’s threads to have a “*double lead to allow the setscrew 70 to start more easily than with a single lead.*” *Id.*, 7:21-23.

Boschert discloses closure start structures that simultaneously advance into and mate with the receiver’s interior threads. EX1003, ¶¶178-82. As shown in annotated Figures 3 and 15 below, Boschert discloses that interior threads on the receiver are mirrored along a longitudinal axis (**red**) thereby providing for simultaneously receiving the double leads of the closure. EX1006, Figs. 3, 15; EX1003, ¶¶178-79.



EX1006, Fig. 3



EX1006, Fig. 15

As discussed in more detail below (*see* §§VI.D.1.b,h), the double threads of Boschert's closure are also symmetrical and diametrically opposed, and therefore simultaneously mate into the symmetrical threads of the receiver. *See* EX1003, ¶¶180-82; EX1006, Figs. 3, 7, 15; EX1014 at 3; EX1026 at 13:35-41.

Finally, Boschert discloses various possible bottom surfaces of the closure, including a domed bottom, EX1006, 7:15-16, Fig. 4, and a flat bottom, *id.*, 7:40-42, Fig. 15. Both disclosed bottoms provide a locking force on the rod, *id.*, 7:7-8, 7:40-43, and both bottoms are closed, *see id.*, Figs. 4, 15.

C. Motivation to Combine the '477 Publication with Boschert

It would have been obvious to a POSA to combine the closure of the '477 Publication and the receiver of Boschert before the priority date of the '641 Patent. EX1003, ¶¶197-209.

The '477 Publication and Boschert are in the same field as each other and the '641 Patent. *Supra* §VI.A-B. 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.” EX1005, ¶[0007]; *see also id.*, Abstract, ¶¶[0025], [0027]. The generic “medical implant” shown for use with the claimed closure is a polyaxial bone screw with a U-shaped receiver. *Supra* §VI.A. Boschert also teaches a polyaxial pedicle screw including a U-shaped receiver for capturing a rod once its opening has been closed with a setscrew. *Supra* §VI.B. Boschert discloses that it would be advantageous to design closures with a double lead in order “to start more easily than with a single lead.” EX1006, 7:21-23. Boschert also expressly contemplates potential modifications to its disclosed closure, stating that “[t]he embodiments of the locking arrangements disclosed herein (e.g., the set screw 70[]) are merely examples of types of locking arrangements that can be used.” *Id.*, 7:58-60.

Based on the express teachings of the references and their complementary disclosures, a POSA would have been motivated to combine the closure of the '477 Publication and the receiver of Boschert. EX1003, ¶201. A POSA implementing the '477 Publication would have looked to Boschert's teachings of the advantages of double-start leads and symmetrical threads disposed on the receiver. *Id.* A POSA

would have been motivated to use the dual-start threads of Boschert in combination with any of the various thread types discussed in the '477 Publication, each with a curvate leading face. *Id.* Further, in making this combination, it would have been obvious to a POSA that the closure bottom surface could be designed to have any known shape, as there were a limited number of known bottom shape options all of which had been successfully used to lock a rod into place. *Id.*

1. Motivation to Use Known Dual Threads

The '477 Publication teaches that closures should include threading (of various types) for mating with the arms of the receiver, a leading thread face that includes a concave surface near the root and a convex surface near the crest, a bottom beveled surface at the thread start, and a bottom surface of the closure top that is closed. EX1003, ¶¶202-04. Boschert teaches that it would be advantageous to design a closure with simultaneous mating double lead threads to allow the closure “to start more easily than with a single lead.” EX1006., 7:21-23. A POSA would have been motivated to modify the closure of the '477 Publication with the double lead thread disclosed in Boschert given the POSA’s understanding that such a change would result in more reliable threading of the fastener into the receiver, as was expressly taught by Boschert. EX1003, ¶¶202-04. A POSA would also have been motivated to so modify the '477 Publication to take advantage of known benefits of double-lead threads, including balancing insertion forces and increasing

insertion speed. *Id.* In 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. *Id.* The resulting closure would thus have dual-lead threads, each with a curvate leading face, that simultaneously mate with matching threads on the receiver. *Id.*

Such a combination of familiar elements using known methods would yield predictable and successful results, as it was well known to a POSA before the priority date of the '641 Patent that double-lead threads provided these advantages and could be successfully used in closures and because the techniques for machining double lead threads were well known and already in use. *Id.*, ¶204.

2. Motivation to Use a Flat Closure Top Bottom

In combining the disclosures of the '477 Publication and Boschert it also would have been obvious to use any of the closure bottom surface shapes taught in either the '477 Publication or Boschert, all of which are disclosed as successfully engaging and locking the rod. EX1003, ¶¶205-09. Closure bottom shape was a design choice from among a limited number of options (e.g., domed, flat, rimmed) each with a reasonable expectation of success. *Id.*

The '477 Publication shows domed bottoms, EX1005, ¶¶[0029], [0040] Figs. 2, 4, 8, 10, but also states that a domed bottom is optional and instead “may be flat

and may have a central point and lateral rim,” *id.*, ¶¶[0029], [0040]. Boschert also discloses a domed, EX1006, 7:15-16, Fig. 4, as well as a flat embodiment, *id.*, 7:40-43, Fig. 15. From these teachings, a POSA would have understood that the bottom surface shape is not critical so long as it engages and locks the rod. EX1003, ¶206.

As the ’477 Publication and Boschert reflect, a POSA would have understood that when designing a closure there were a limited number of options for the shape of the bottom surface, including a domed surface, a flat surface, and a rimmed surface. *Id.*, ¶208. Each of these shapes had been successfully used to engage and lock a rod into a receiver. *Id.* Therefore, a POSA would have known that closure bottom shape was a design choice from among a limited number of options each with a reasonable expectation of success, and thus it would have been obvious to try a flat bottom surface when combining the disclosures of the ’477 Publication and Boschert. *Id.*

Using a flat bottom closure surface would yield predictable and successful results, because it was well known before the priority date of the ’641 Patent that a closure with a flat bottom would successfully lock a rod in place and the techniques for machining a flat bottom were well known and already in use. *Id.*, ¶209.

D. Claim Analysis.

1. Claim 1

a. 1[Preamble]: “A medical implant assembly comprising:”

If the preamble is limiting, the '477 Publication/Boschert combination discloses this limitation. EX1003, ¶220. The '477 Publication discloses “a closure and/or locking member for use in conjunction with medical implants.” EX1005, ¶[0002]. Boschert discloses “surgical implants [] used for fusing together and/or mechanically immobilizing vertebrae of the spine.” EX1006, 1:34-37.

b. 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”

The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶221-23. 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.

“[R]eceiver 30 ... includes *two upwardly extending legs* 38 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.” EX1006, 6:25-28.

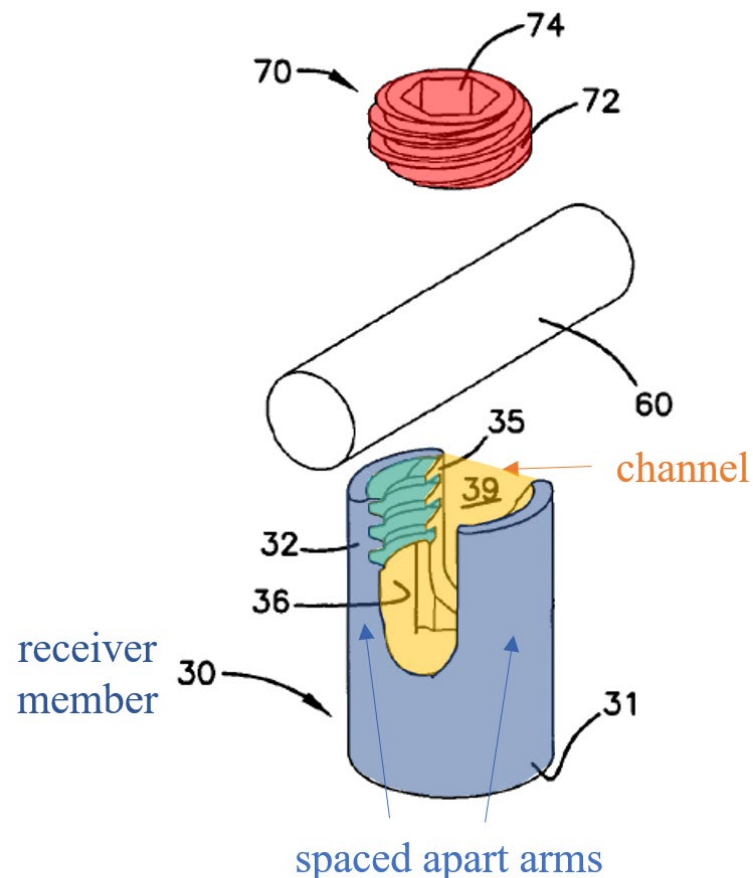
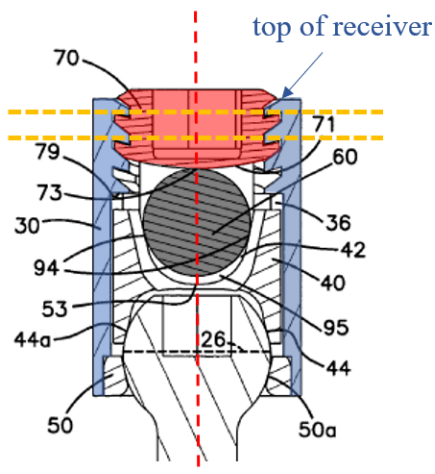
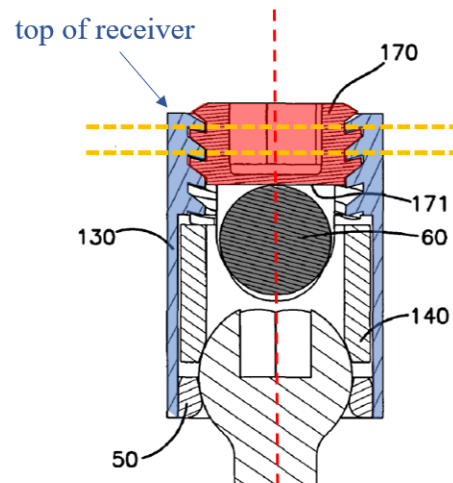


Fig. 1 (excerpt)

Figures 3 and 15 show 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. *Id.*, Figs. 3, 15; *see also id.*, Fig. 14.



Ex. 1006, Fig. 3



Ex. 1006, Fig. 15

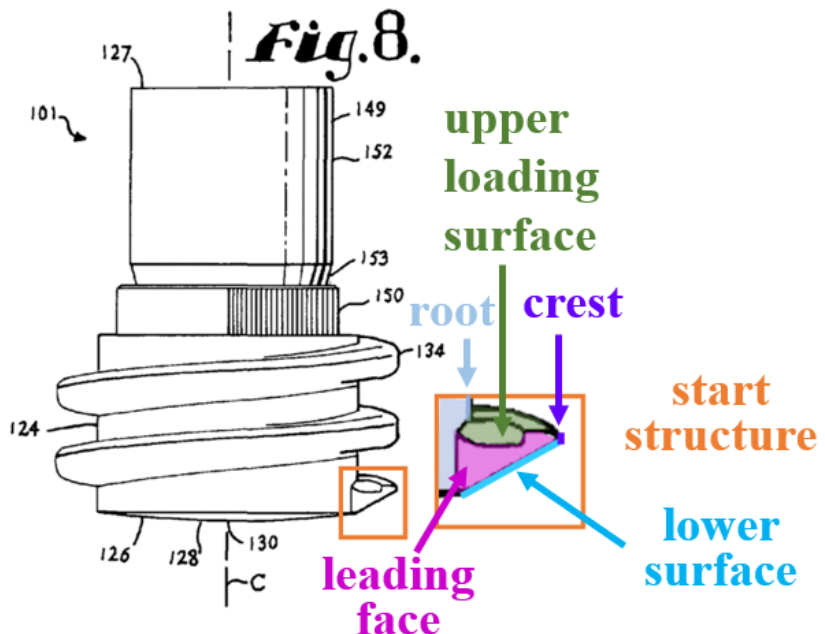
Boschert also discloses that “[t]he threads 72 of the *setscrew 70 can also be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead.*” *Id.*, 7:21-23.

- c. **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”

The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶224-29. The '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.” EX1005, Abstract; *see also id.* ¶[0002], Fig. 6. The “**closure** 101 ... has ... **a central axis** of rotation C.” *Id.*, ¶[0040]; *see also id.*, ¶[0029]. The '477 Publication’s closures “are **externally threaded** and are screwed into mating threads on the interior surfaces of the implant arms.” *Id.*, ¶¶[0005], [0007], [0030], [0041], Figs. 1-2, 5-6.

The '477 Publication discloses that its thread “is a helical interlocking form,” *id.*, ¶[0041], that has “a **root 38 and a crest 40**. Further, the thread form 36 has a lead [lower] surface 42 and a trailing [upper] surface 44 (described relative to the position thereof during insertion of the closure 1 into the bone screw receiver 13),” *id.*, ¶[0031]. As annotated at right, the '477 Publication discloses a start structure

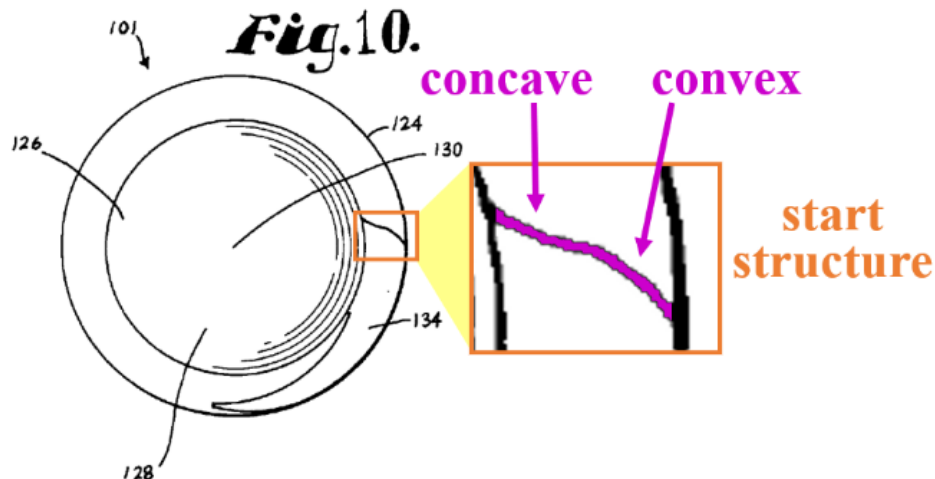


with an upper loading surface extending between a root and a crest of the continuously helically wound thread, the start structure having a leading face extending below the upper loading surface to a lower surface of the start structure. *Id.*, Figs. 7, 8.

While the '477 Publication discloses a single thread, Boschert teaches that a double thread “allow[s] the setscrew 70 to start more easily than with a single lead.” EX1006, 7:21-23. As explained above, a POSA 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. *Supra* §VI.C.1; EX1003, ¶¶227-28. In doing so, a POSA would have used the start structure and leading face disclosed in the '477 Publication on each thread. *Id.*

- d. 1[B1]: “the leading face surface on each of the first start structure and the second start structure including at least one curvate surface”

The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶230-33. As annotated below, the '477 Publication discloses a leading face of the start structure that includes at least one curvate surface. EX1005, Fig. 10; EX1003, ¶230.



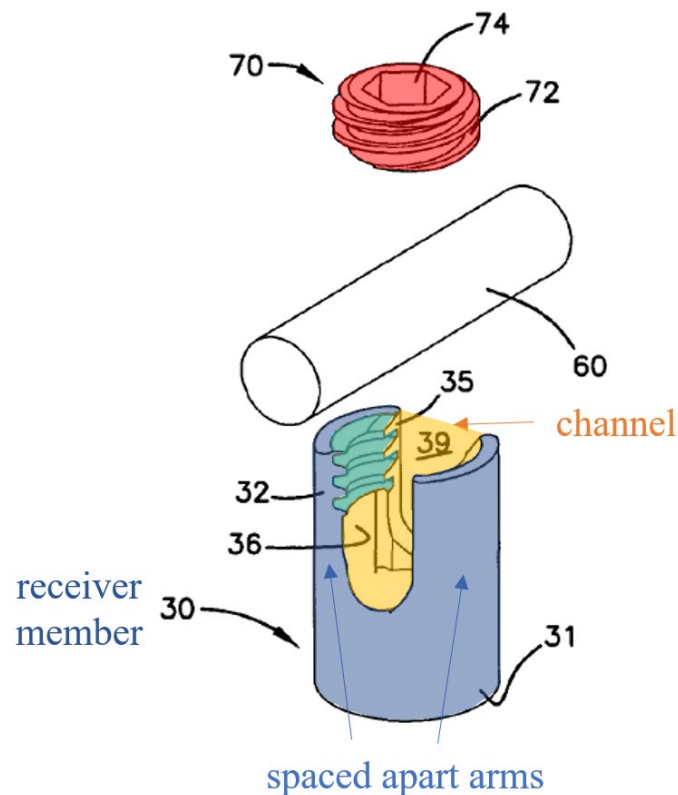
Ex. 1005, Fig. 10

As explained above, *supra* §VI.C.1, when combining the '477 Publication and Boschert, a POSA would have kept the '477 Publication's leading face, including its at least one curvate surface, on each of the dual threads of Boschert. EX1003, ¶¶231-33.

- e. 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;”

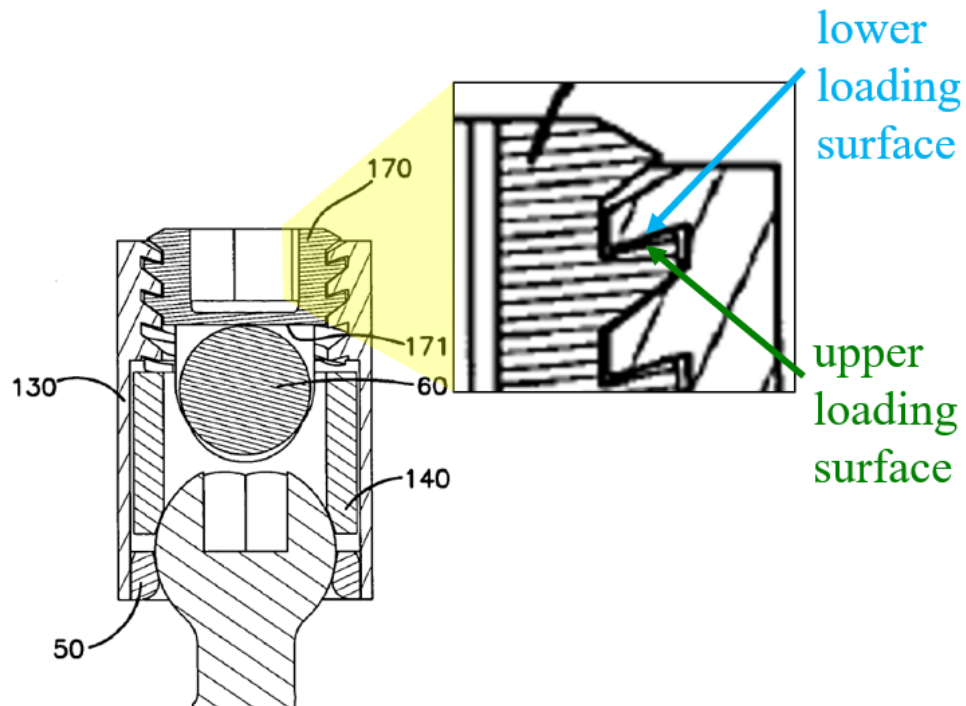
The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶234-35. Boschert discloses a receiver that “includes two upwardly extending legs 38 [i.e., arms] between which the saddle 39 of the receiver 30 is defined. The saddle 39 of the receiver 30 provides an open region or pocket 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.” EX1006, 6:11-28. As shown below, the saddle opens onto the top surface and is closable by rotating the closure around its axis of rotation. *E.g., id.*, Figs. 1, 3.



- f. 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”

The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶236-37. Boschert discloses a first discontinuously helically wound thread form on the inner surface of the first arm having a first lower loading surface mateable with the first upper loading surface of the closure thread, EX1006, 6:20-28, which is shown below in annotated Figure 15. EX1003, ¶236.

FIG. 15

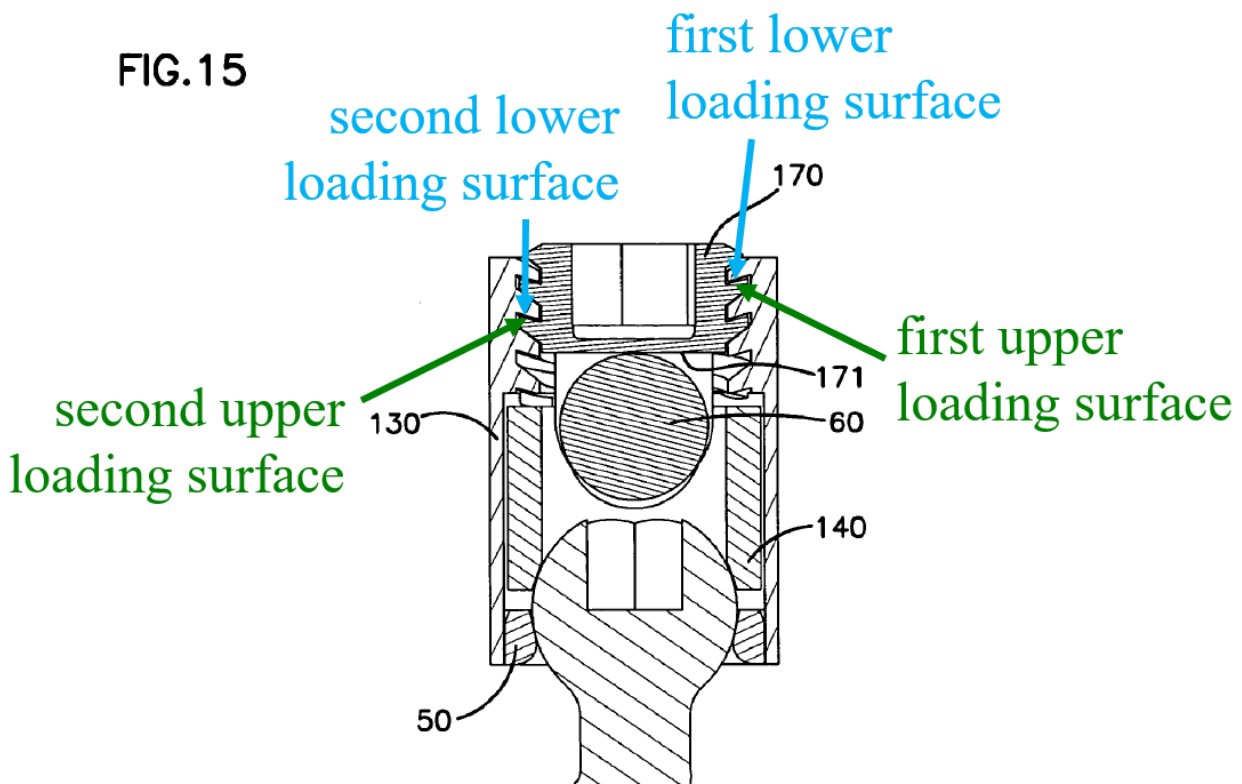


Based on the express disclosures in the '477 Publication, EX1005, ¶¶[0011], [0026], [0030], [0041], and Boschert, EX1006, 6:20-28, and a POSA's knowledge of threaded connectors, a POSA implementing the '477 Publication/Boschert combination would have understood that the threads on the receiver must mate with the thread forms on the closure top. EX1003, ¶237.

- g. 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,”

The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶238-39. Boschert discloses a dual-lead engagement. EX1006, 7:21-23;

EX1003, ¶238. As shown in annotated Figure 15, Boschert discloses a second discontinuously helically wound thread form on the inner surface of the second arm having a second lower loading surface and the second loading surface being mateable with the second upper loading surface.



EX1006, Fig. 15. As discussed above (*supra* Section VI.D.1.f), a POSA 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.

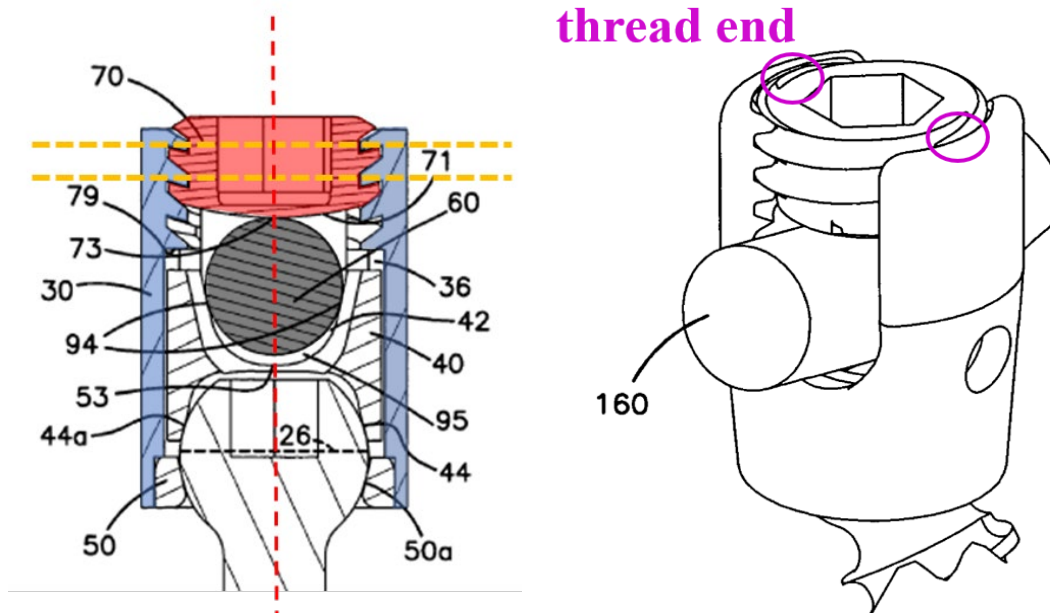
EX1003, ¶239.

- h.** 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,”

The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶240-47. The '477 Publication's closure has a “*central axis of rotation C*,” EX1005, ¶[0040], as well as threads that “act[] cooperatively” to “allow the closure” to be “inserted into and rotated relative to the bone screw receiver” and to “guide and advance the closure” along the axis of rotation as the closure is “rotated clockwise.” *Id.*, ¶[0030].

Boschert discloses that rotation of the closure about the axis of rotation between the first arm and the second arm causes 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. EX1003, ¶242. Boschert's Figure 3 (below left) shows that the threads of both the closure and receiver are symmetrically and diametrically opposed to each other across the longitudinal axis. *See also* EX1006, Fig. 15. As shown in Figure 7 (below right), Boschert also discloses that the trailing ends of the closure threads are diametrically opposed. *Id.*, Fig. 7.

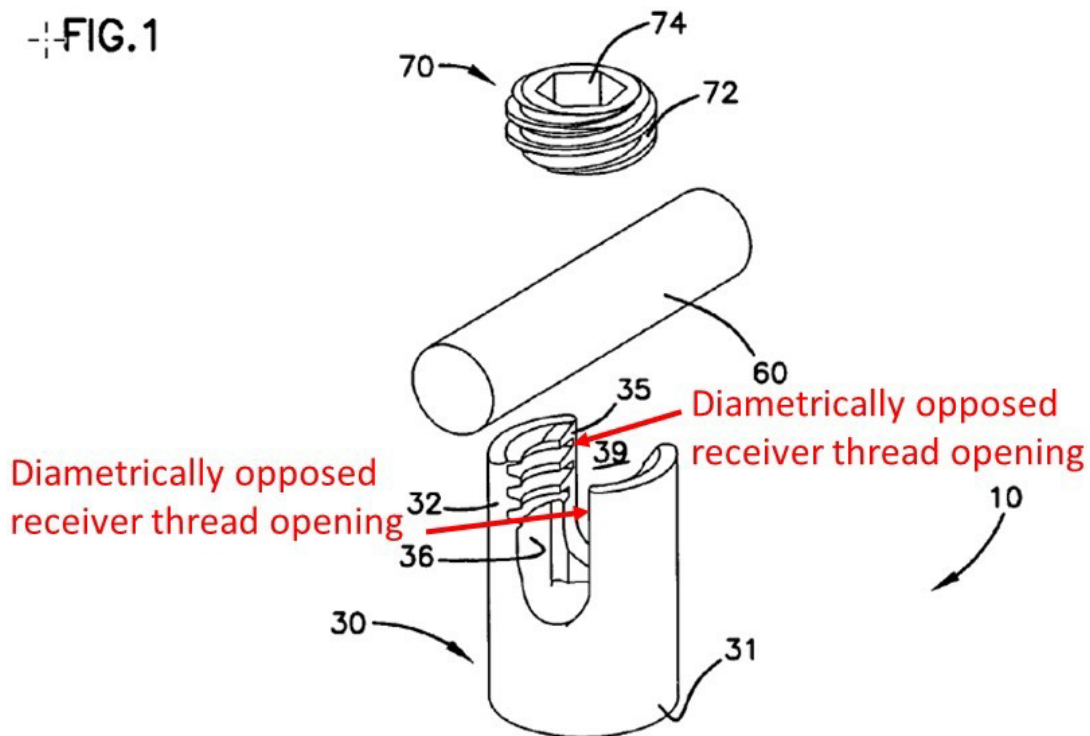


A POSA would have understood and expect that each of the double-lead threads have identical length, and therefore also have symmetrically and diametrically opposed thread starts. EX1003, ¶¶242-43.

Based on the knowledge of a POSA of the conventional manner of making double start threads before the Priority Date, a POSA would have understood Boschert to disclose diametrically opposed thread starts. *Id.*, ¶244. A POSA would have known that “each thread *has to start at an equal angle*, determined by the following calculation: Thread cylindrical spacing angle= $360/\text{Number of starts}$.” EX1014 at 3; EX1003, ¶244. Accordingly, a POSA would have understood Boschert’s disclosure as teaching two starts that have a cylindrical spacing angle of 180° (*i.e.*, $360^\circ/2$). *Id.*

In view of Boschert's disclosure of symmetrically and diametrically opposed threads, a POSA would have understood that rotation of the closure about the axis of rotation between the first and second arms causes 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. EX1003, ¶245.

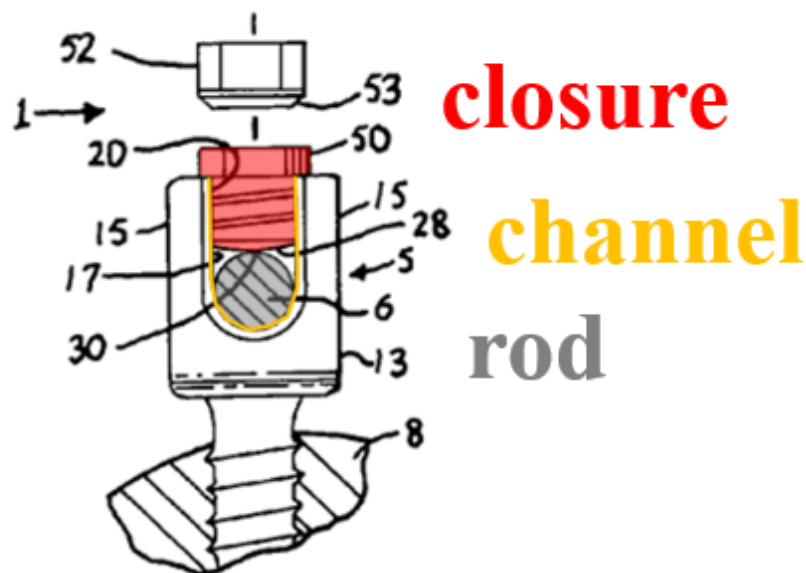
If Boschert were found not to expressly disclose this limitation, a POSA would have understood that Boschert inherently discloses it. *Id.*, ¶246. A POSA would have understood that for the double-start threads on the setscrew to engage with discontinuous and symmetrical receiver threads, and to do so more easily than a single start thread, (1) the receiver threads necessarily have to mirror each other and (2) the start structures would necessarily be spread equidistant around the closure's starting end. *Id.* A POSA would have understood that this could only be accomplished by diametrically opposing the thread starts on the closure, as illustrated in Fig. 1. Ex.1006, Fig. 1. EX1003, ¶246.



Finally, if Boschert were found to neither expressly nor inherently disclose this limitation, it would have been obvious for a POSA to use diametrically opposing the starts of dual start threads for simultaneous mating, particularly in view of Boschert's disclosures and the conventional manner of making dual-start threads, which includes using diametrically opposed thread starts. EX1014 at 3; EX1026, 13:35-41; EX1003, ¶247.

- i. 1[C]: “the closure rotationally advanceable within the channel until the closure locks the longitudinal connecting member within the channel.”

The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶248-51. The '477 Publication discloses a closure “*for capturing and locking a rod in the implant,*” EX1005, Abstract, ¶[0002], and a thread that “allow[s] the closure 1 to be inserted into and rotated relative to the bone screw receiver 13” to “guide and advance the closure 1 along the axis B as the closure 1 is rotated clockwise,” *id.*, ¶[0030]. As shown in the excerpted, annotated Figure 5, closure 1 “*lock[s] the rod 6 in position* relative to the bone screw” and within the channel. *Id.*, ¶[0037], Fig. 5; *see also id.*, ¶¶[0018]-[0019], Fig. 6.



Based on the above disclosures, the closure resulting from the obvious combination of the '477 Publication and Boschert would include a closure

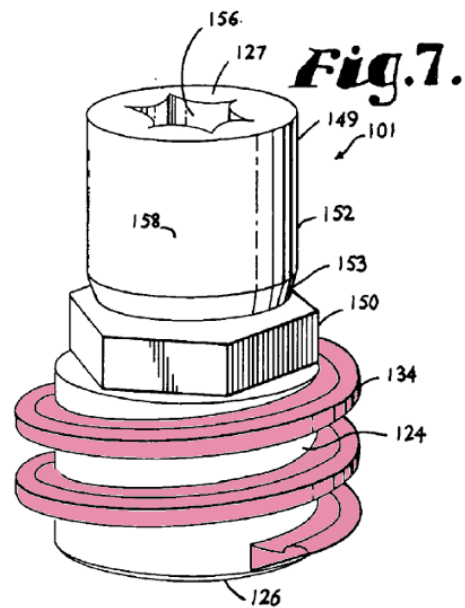
rotationally advanceable within the channel until the closure locks the longitudinal connecting member within the channel. EX1003, ¶250.

Accordingly, the '477 Publication/Boschert combination renders obvious every element of Claim 1. *Id.*, ¶251.

2. Claim 3

Claim 3 depends from Claim 1 and recites: [B3] “wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each flange forms.” EX1001, cl. 3. The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶252-57.

The '477 Publication discloses a thread that “is a helical interlocking form,” as described in Jackson '689. EX1005, ¶[0041]. As shown in annotated Figure 7 (right), the disclosed thread is a flange form. EX1005, Fig. 7. Jackson '689, incorporated by reference, further discloses a thread that “includes the external interlocking form 81 having an axially aligned shoulder or *flange-like shaped configuration*.” EX1013, 13:12-16.



While the '477 Publication only discloses a single thread, a POSA would have been motivated to combine the '477 Publication with Boschert's teachings of dual-

lead threads. EX1003, ¶255. In doing so, a POSA would have been motivated to use the flange form taught by the '477 Publication on each thread based on the '477 Publication's teaching that it “*resist[s] splaying* in the bone screw receiver 13” “during application of clockwise rotational torque.” EX1005, ¶[0030]; EX1003, ¶255. Jackson '689 cites the same splay-resisting advantages. EX1013, 13:12-24; *see also id.*, 13:28-31, 13:41-46; EX1003, ¶256. Moreover, the '477 Publication teaches that there are a finite number of thread types that could be used, including a flange form, EX1005, ¶¶[0030], [0041], and in view of the design need for a thread that resists splaying, a POSA would have had good reason to pursue known options, including a flange form, EX1003, ¶255. Using a flange form would have been well within the capabilities of a POSA and a POSA would have anticipated success in using a flange form. *Id.*

3. Claim 4

Claim 4 depends from Claim 1 and recites: [B4] “wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each one of: v-threads, square threads, reverse angle threads, or buttress threads.” EX1001, cl. 4. The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶258-63.

The '477 Publication discloses a “*helically wound reverse angle thread form* 36.” EX1005, ¶[0030]. While the '477 Publication only discloses a single thread, a

POSA would have been motivated to combine the '477 Publication with Boschert's teaching of dual-lead threads. EX1003, ¶261. In doing so, a POSA would have been motivated to use the reverse angle thread because (1) the '477 Publication teaches the splay-resisting advantages of reverse angle threads, EX1005, ¶[0030]; (2) there are a finite number of thread types that could be used, including reverse angle threads, to address the design need for a splay-resisting thread; and (3) using reverse angle threads would have been nothing more than the simple substitution of one known element (a flange form) for another, EX1003, ¶¶261-62. Using reverse angle threads would have been well within the capabilities of a POSA and a POSA would have anticipated success in using reverse angle threads. *Id.*

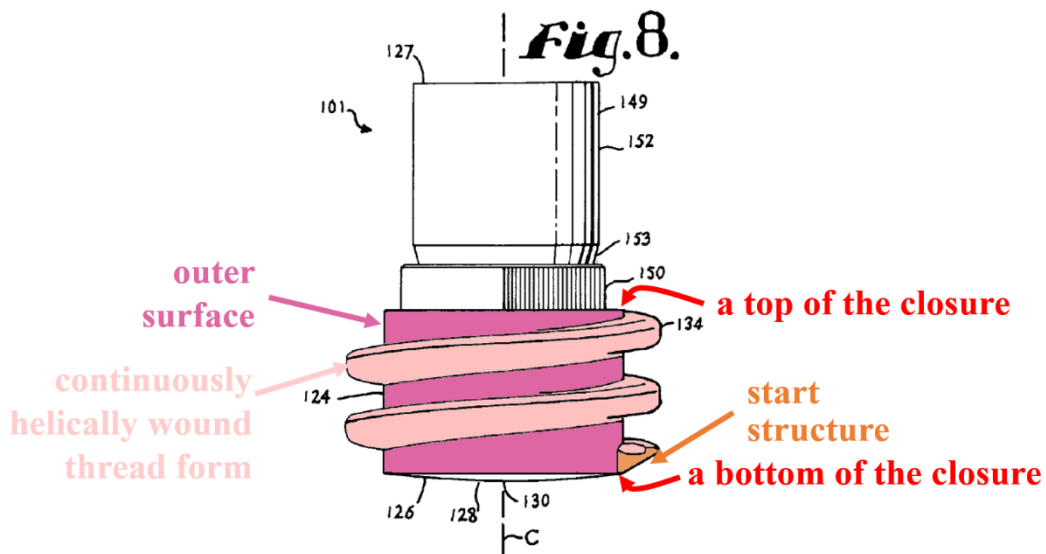
4. Claim 5

Claim 5 depends from Claim 1 and recites: **[B5]** “wherein the first start structure is disposed at a diametrically opposite location on the closure from the second start structure.” EX1001, cl. 5. The '477 Publication/Boschert combination includes this limitation. EX1003, ¶¶264-72. As discussed above in reference to limitation **1[B2]**, Boschert expressly discloses, inherently discloses, and renders obvious two start structures disposed at diametrically opposite locations on the closure such that those start structures simultaneously mate with the corresponding symmetrical threads on the receiver arms. *Supra* §VI.D.1.h.

5. Claim 6

Claim 6 depends from Claim 1 and recites: **[B6]** “wherein each of the continuously first and the second helically wound thread form is disposed at a top of the closure, the first helically wound thread form and the second helically wound thread form each extending along the outer surface of the closure to a bottom of the closure and ending at the first and the second start structure, respectively.” EX1001, cl. 6. The ’477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶273-76.

The ’477 Publication discloses a continuously helically wound thread form that is disposed at a top of the closure, extends along the outer surface of the closure surface to a bottom of the closure, and ends at a start structure, as shown in Figure 8 below. EX1005, Fig. 8; *see also id.*, Figs. 7, 9-10. EX1003, ¶274.

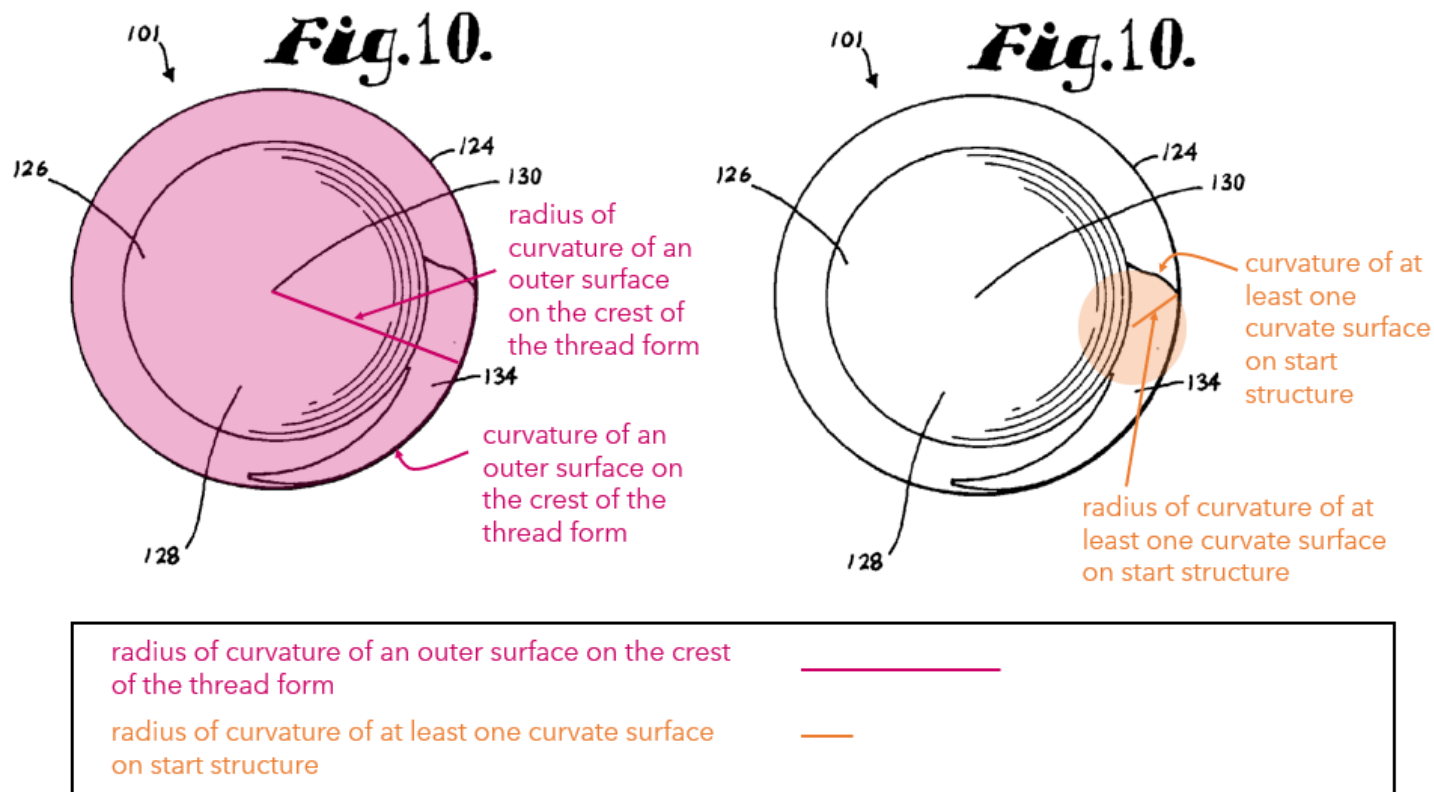


As explained above, a POSA would have been motivated to modify the closure of the '477 Publication to add dual-start threads based on the teachings of Boschert. *Supra* §VI.C.1; EX1003, ¶275. Thus, the single thread of the '477 Publication would be replaced with a dual-start thread in the same location. EX1003, ¶275.

6. Claim 7

Claim 7 depends from Claim 1 and recites: [B7] “wherein the at least one curvate surface of both the first start structure and the second start structure is defined by at least one radius of curvature, the at least one radius of curvature being less than a radius of curvature for an outer surface on the crest of the first continuously helically wound thread form.” EX1001, cl. 7. The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶277-79.

As shown below, the '477 Publication discloses a start structure wherein at least one curvate surface of the start structure is defined by a radius of curvature that is less than a radius of curvature for an outer surface on the crest of the continuously helically wound thread form. EX1005, Fig. 10; EX1003, ¶278.



As discussed above, when combining the '477 Publication and Boschert, a POSA would have used the start structure of the '477 Publication on each of the dual-lead threads. EX1003, ¶278; *see also supra* §VI.C.1.

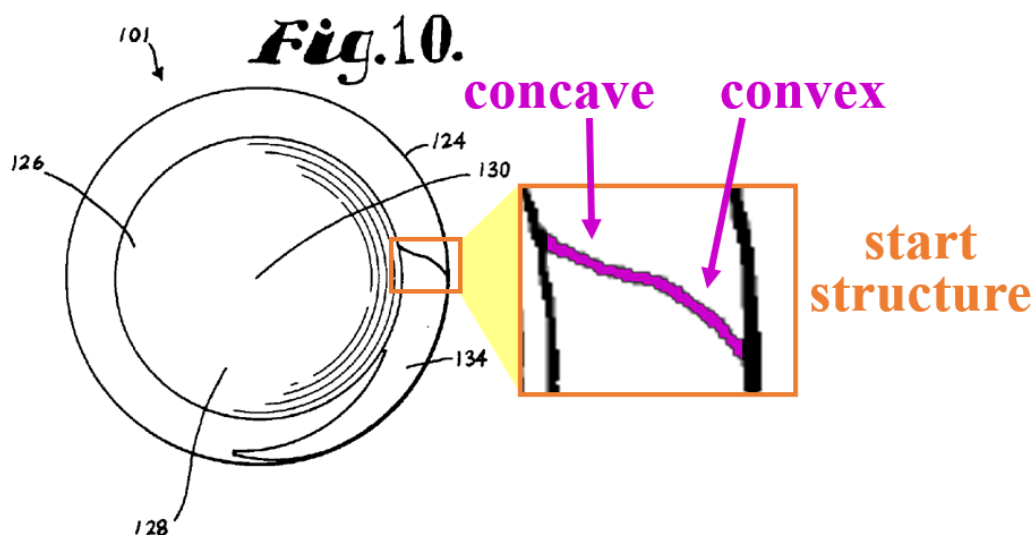
7. Claim 8

Claim 8 depends from Claim 1 and recites: [B8] “wherein the at least one curvate surface of both the first start structure and the second start structure is defined by at least one radius of curvature, the at least one radius of curvature being less than a radius of curvature for an outer surface on the crest of the second continuously helically wound thread form.” EX1001, cl. 8. The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶280-82.

As discussed above (*supra* §VI.D.6), the start structure of the '477 Publication satisfies the radius of curvature requirements of the start structure and the outer surface on the crest, and a POSA would have been motivated to use the '477 Publication's start structure with Boschert's teaching of dual-lead threads. EX1003, ¶281. This combination would have resulted in a second start structure that satisfies the radius of curvature requirements of Claim 8. *Id.*

8. Claim 9

Claim 9 depends from Claim 1 and recites: [B9] "wherein the at least one curvate surface includes both a convex surface and concave surface." EX1001, cl. 9. The '477 Publication/Boschert combination discloses this limitation, as shown in the '477 Publication below. EX1003, ¶¶283-85.

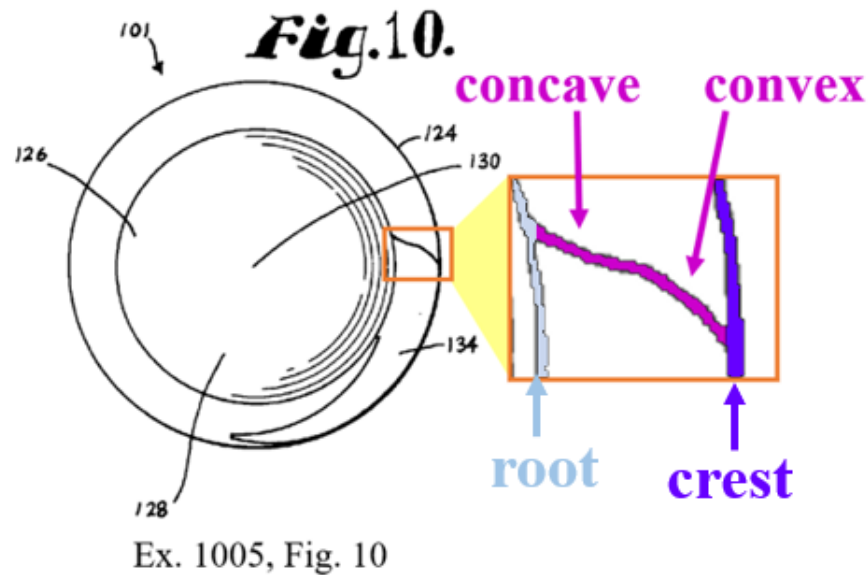


Ex. 1005, Fig. 10

As discussed above (*supra* §VI.D.6), a POSA would have been motivated to use the '477 Publication's start structure with Boschert's teaching of dual-lead threads. EX1003, ¶284. This combination would have resulted in two start structures each with a curvate surface that includes both convex and concave surfaces. *Id.*

9. Claim 10

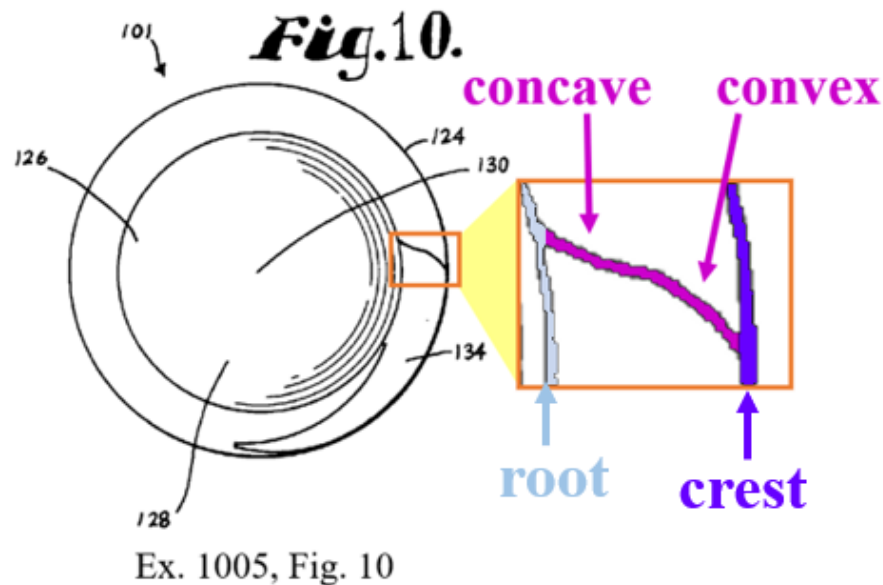
Claim 10 depends from Claim 9 and recites: **[B10]** “wherein both of the concave surface and the convex surface of the first start structure are positioned between the root and the crest of the first continuously helically wound thread form, and wherein both of the concave surface and the convex surface of the second start structure are positioned between the root and the crest of the second continuously helically wound thread form.” EX1001, cl. 10. The '477 Publication/Boschert combination discloses this limitation, as shown in annotated/enlarged Figure 10 from the '477 Publication below. EX1005, Fig. 10; EX1003, ¶¶286-92.



As discussed above (*supra* §VI.D.1.d), when combining the '477 Publication and Boschert, a POSA would have used the start structure of the '477 Publication on each of the dual-lead threads. EX1003, ¶¶286-92.

10. Claim 11

Claim 11 depends from Claim 10 and recites: **[B11]** “wherein the concave surface is adjacent the root and the convex surface is adjacent the crest of the first and second start structures for the first and second continuously helically wound thread form, respectively.” EX1001, cl. 11. The '477 Publication/Boschert combination discloses this limitation, as shown below from the '477 Publication. EX1003, ¶¶293-96.



As discussed above (*supra* § VI.D.1.d), when combining the '477 Publication and Boschert, a POSA would have used the start structure of the '477 Publication on each of the dual-lead threads. EX1003, ¶¶295-98.

11. Claim 12

Claim 12 depends from Claim 9 and recites: **[B12]** “wherein a radius of curvature of the convex surface is substantially equal to a radius of curvature of the concave surface.” EX1001, cl. 12. The '477 Publication/Boschert combination disclose this limitation, as shown below from the '477 Publication. EX1003, ¶¶297-99.

While the '477 Publication does not disclose the numeric radii of curvature of its surfaces, Claim 12 does not require any numeric radii of curvature. EX1003, ¶298. The '477 Publication's disclosure is consistent with the easiest manufacturing

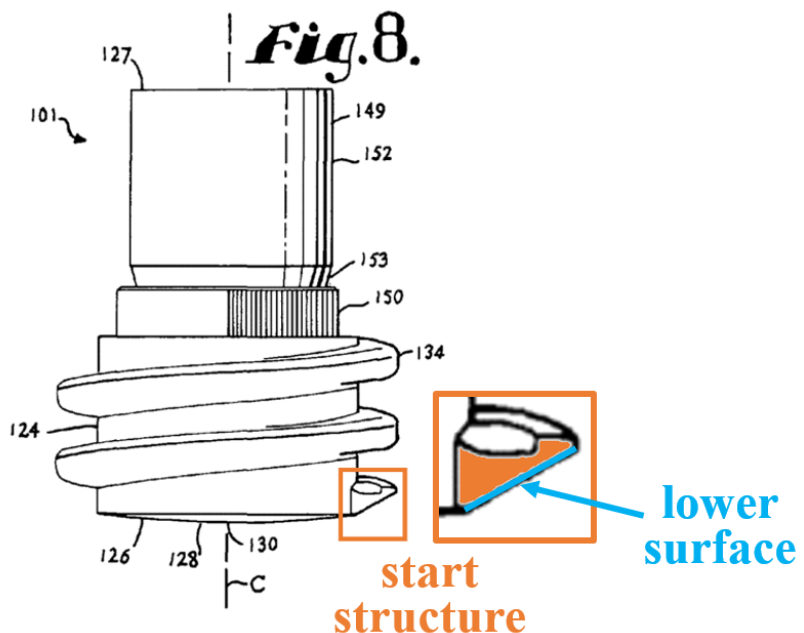
process for the leading face of a thread start and provides the same level of disclosure available in the '641 Patent itself. *Id.*

As discussed above (*supra* §VI.D.1.d), when combining the '477 Publication and Boschert, a POSA would have used the start structure of the '477 Publication on each of the dual-lead threads. EX1003, ¶299.

12. Claim 13

Claim 13 depends from Claim 9 and recites: **[B13]** “wherein each of the first start structure and the second start structure includes a bottom beveled surface.” EX1001, cl. 13. The '477 Publication/Boschert combination include this limitation. EX1003, ¶¶300-03.

The '477 Publication discloses that the lower surface of the start structure is a beveled (i.e., sloped) surface, rather than a squared one, as shown in enlarged/annotated Figure 8 (right). EX1005, Fig. 8; EX1003, ¶301. This is the same level of disclosure in the '641 Patent. *See* EX1001, Fig. 3; EX1003, ¶301.

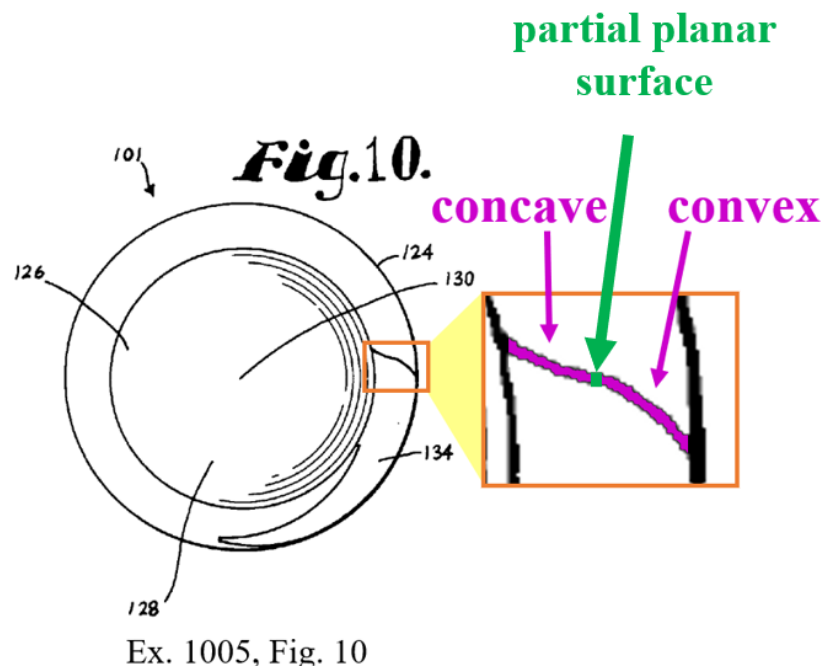


As discussed above (*supra* §VI.D.1.d), when combining the '477 Publication and Boschert, a POSA would have used the start structure of the '477 Publication on each of the dual-lead threads. EX1003, ¶302.

13. Claim 14

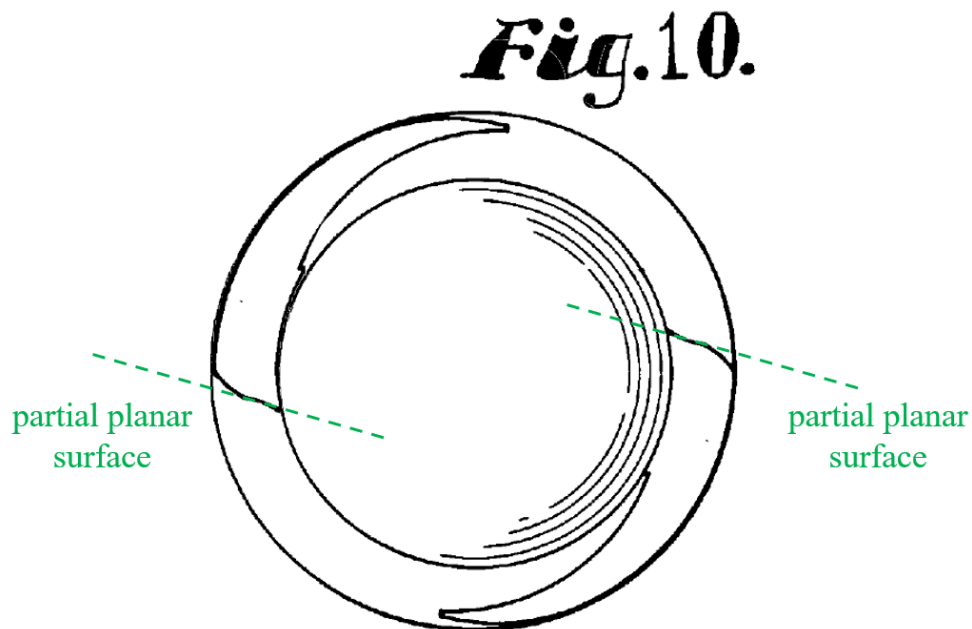
Claim 14 depends from Claim 1 and recites: [B14] “wherein the first and second start structure leading face surfaces are at least partially planar surfaces parallel with respect to each other.” EX1001, cl. 14. The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶304-08.

The '477 Publication discloses a leading face that includes a partial planar surface, at least around the point of inflection between the concave and convex surfaces, as shown below. EX1005, Fig. 10. A POSA would have understood that the leading face at this location is approximately flat. EX1003, ¶¶304-08



This is the same level of disclosure in the '641 Patent. *See* EX1001, Fig. 5; EX1003, ¶305.

As discussed above (*supra* §VI.D.1.d), when combining the '477 Publication and Boschert, a POSA would have used the start structure of the '477 Publication on each of the dual-lead threads. EX1003, ¶306. Because, as discussed above (*supra* §VI.D.1.h), the start structures would be diametrically opposed to each other, a POSA would have understood that the partial planar surfaces would be parallel to each other, as shown in modified Figure 10 below. EX1003, ¶¶307-08.

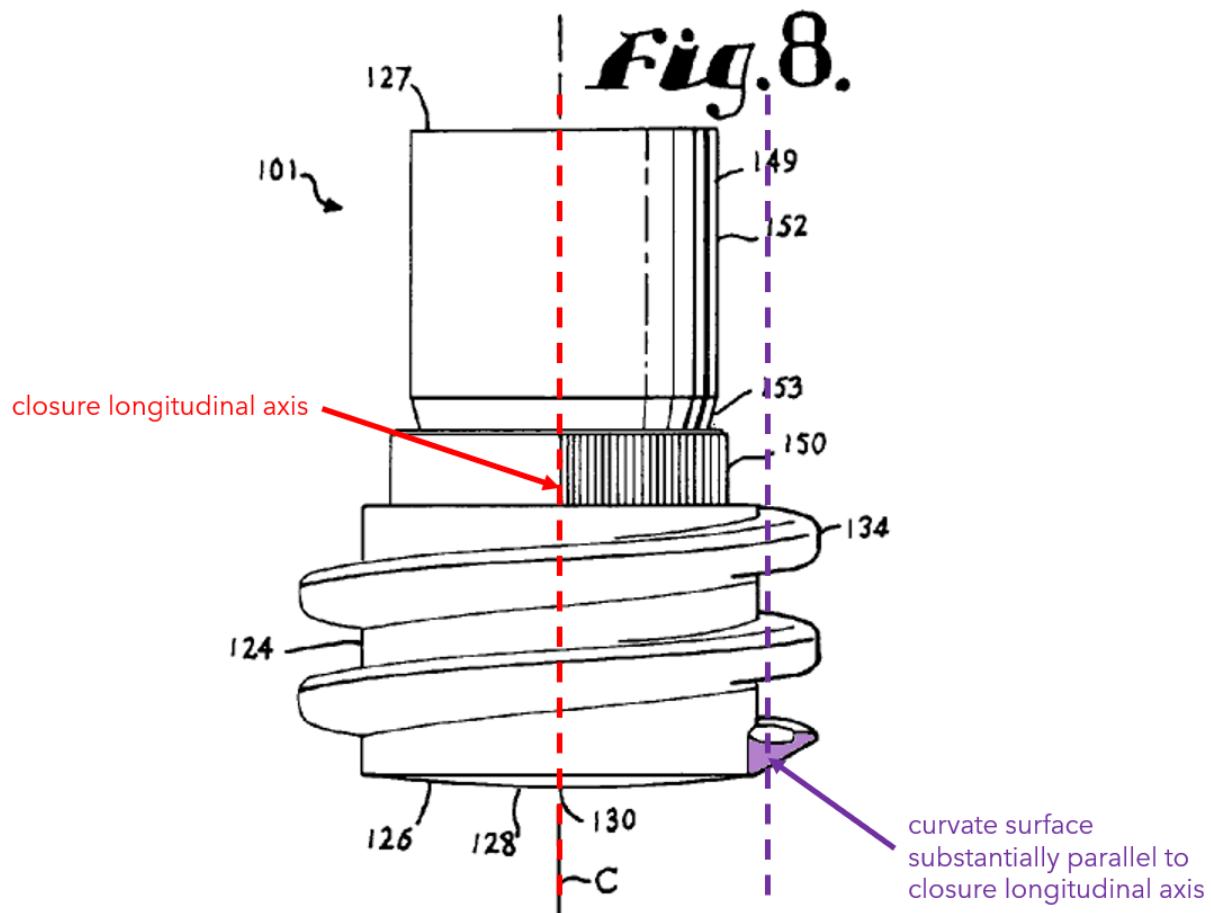


14. Claim 15

Claim 15 depends from Claim 1 and recites: **[B15]** “wherein each of the at least one curvate surfaces is substantially parallel to the closure longitudinal axis.” EX1001, cl. 15. The '477 Publication/Boschert combination discloses this

limitation, as shown in annotated/enlarged Figure 8 from the '477 Publication.

EX1005, Fig. 8; EX1003, ¶309-11.



This is the same level of disclosure as the '641 Patent. EX1001, Figs. 1-2; EX1003, ¶310.

As discussed above (*supra* §VI.D.1.d), when combining the '477 Publication and Boschert, a POSA would have used the start structure of the '477 Publication on each of the dual-lead threads. EX1003, ¶¶309-11.

15. Claim 16

Claim 16 depends from Claim 1 and recites: **[B9]** “wherein each of the at least one curvate surface includes both a convex surface and concave surface.” EX1001, cl. 16. This limitation is similar to Claim 9, except that it requires that *each* of the curvate surfaces include a convex surface and concave surface. EX1003, ¶312. The ’477 Publication/Boschert combination disclose this limitation. *Id.*, ¶¶312-15.

As discussed above (*supra* §VI.D.8), the ’477 Publication discloses a start structure with a curvate surface that includes both convex and concave surfaces. EX1003, ¶313; EX1005, Fig. 10; EX1001, Fig. 5. As discussed above (*supra* §VI.D.1.d), when combining the ’477 Publication and Boschert, a POSA would have used the start structure of the ’477 Publication on each of the dual-lead threads. EX1003, ¶¶314-15.

16. Claim 17

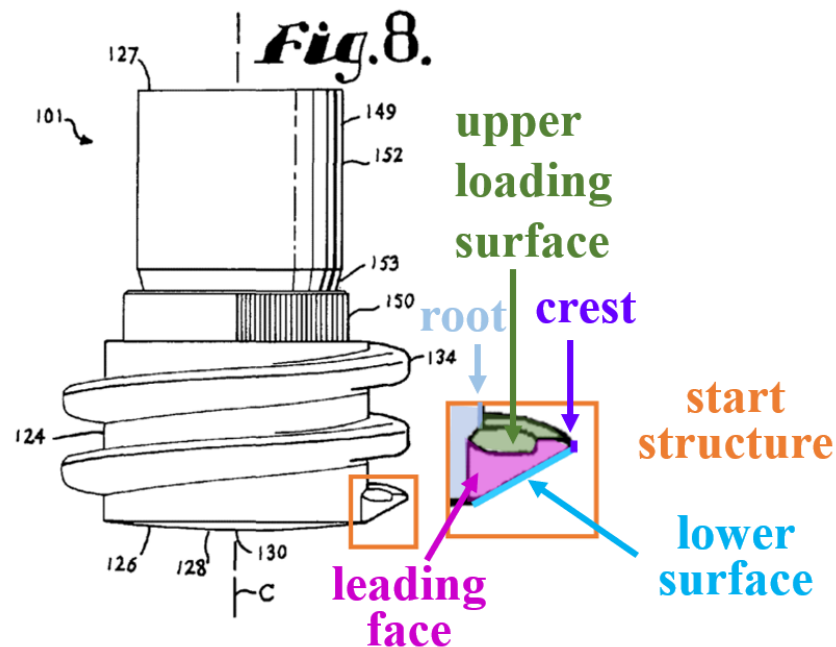
Claim 17 depends from Claim 1 and recites: **[B9]** “wherein each of the at least one curvate surfaces is a concave surface.” EX1001, cl. 17. This limitation is similar to Claim 16, except that it requires that each of the curvate surfaces is a concave surface. EX1003, ¶316. The ’477 Publication/Boschert combination discloses this limitation. *Id.*, ¶¶316-19.

As discussed above (*supra* §VI.D.8), the ’477 Publication discloses a start structure that has a curvate surface that is concave. EX1003, ¶317; EX1005, Fig.

10; EX1001, Fig. 5. As discussed above (*supra* §VI.D.1.d), when combining the '477 Publication and Boschert, a POSA would have used the start structure of the '477 Publication on each of the dual-lead threads. EX1003, ¶¶316-19.

17. Claim 18

Claim 18 depends from Claim 1 and recites: **[B16]** “wherein the closure first continuously helically wound thread form includes a first lower surface disposed between the root and the crest and the closure second continuously helically wound thread form includes a second lower surface disposed between the root and the crest, and wherein the leading face surface of the first start structure extends between the first upper surface and the first lower surface and the leading face surface of the second start structure extends between the second upper surface and the second lower surface.” EX1001, cl. 18. The '477 Publication/Boschert combination discloses this limitation in the excerpt below from the '477 Publication. EX1005, Fig. 8; *see also id.*, Fig. 7; EX1003, ¶¶320-23.



As discussed above (*supra* §VI.D.1.d), when combining the '477 Publication and Boschert, a POSA would have used the start structure of the '477 Publication on each of the dual-lead threads. EX1003, ¶¶322-23.

18. Claim 19

Claim 19 depends from Claim 18 and recites: [B14] “wherein each of the leading face surfaces of the first start structure and the second start structure include at least a partial planar surface.” EX1001, cl. 19. This limitation is similar to Claim 14, except that Claim 19 does not require that the leading face structures are parallel. EX1003, ¶324. The '477 Publication/Boschert combination discloses this limitation for the reasons set forth above (*supra* §VI.D.13). EX1003, ¶¶324-27.

19. Claim 21

- a. **21[Preamble]:** “A medical implant assembly comprising:”

The '477 Publication/Boschert combination discloses this limitation for the same reasons set forth above with reference to Limitation 1[Preamble]. EX1003, ¶328; *supra* §VI.D.1.a.

- b. **21[A]:** “a receiver having a first arm and a second arm spaced apart from each other by a rod-receiving 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 first and second discontinuously helically wound threads, respectively, 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;”

This limitation, while worded slightly differently, includes the same requirements as Limitation 1[A]. EX1003, ¶329. The '477 Publication/Boschert combination discloses this limitation for the reasons set forth above. *Id.*; *supra* §VI.D.1.b.

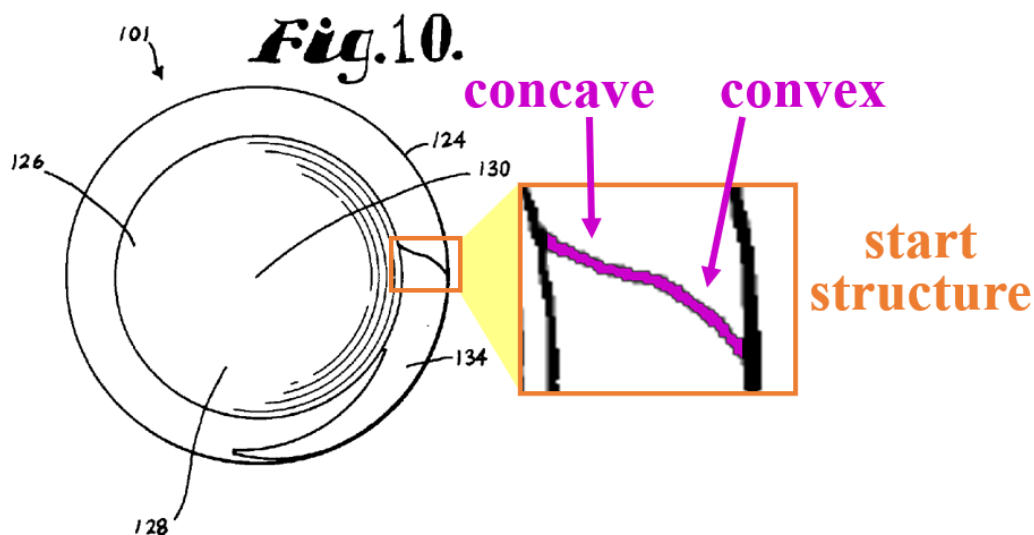
- c. **21[B]:** “a closure having a first continuously helically wound thread form and a second continuously helically wound thread form, the first continuously helically wound thread form having a first start structure and a first loading surface extending between a root and a crest of the first continuously helically wound thread form, the second continuously helically wound thread form having a second start structure and a second loading surface

extending between a root and a crest of the second continuously helically wound thread form,”

This limitation, while worded slightly differently, includes the same requirements as Limitation 1[B], except that Limitation 21[B] does not require that the closure include a longitudinal axis or that the start structures include leading faces. EX1003, ¶330. The '477 Publication/Boschert combination discloses this limitation for the reasons set forth above. EX1003, ¶330; *supra* §VI.D.1.c.

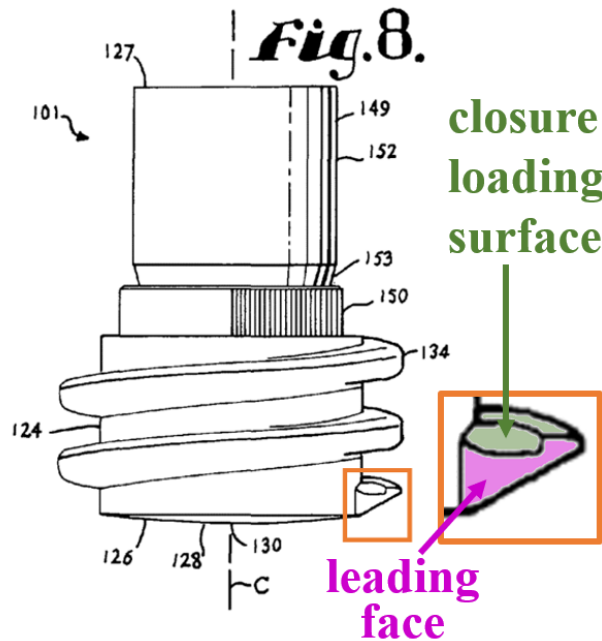
- d. **21[C]:** “each of the first start structure and the second start structure having a leading face surface extending below each closure loading surface and including at least a partial concave surface;”

The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶331-35. As shown below, the '477 Publication discloses a leading face that includes at least a partial concave surface. EX1005, Fig. 10; EX1003, ¶331.



Ex. 1005, Fig. 10

As shown in Figure 8, the leading face surface extends below the closure loading surface. EX1005, Fig. 8; *see also id.*, Fig. 7; EX1003, ¶332.



As discussed above (*supra* §VI.D.1.c), a POSA would have been motivated to combine the '477 Publication with Boschert's teaching of double-lead threads while retaining the '477 Publication's leading face. EX1003, ¶¶333-34. This combination would have resulted in a first and second start structure that satisfy the requirements of Limitation 21[C]. *Id.*, ¶335.

- e. **21[A1]:** “the channel being formed by the first arm and the second arm, the channel closeable with the closure having an axis of rotation;”

This limitation, while worded slightly differently, includes the same requirements as Limitation 1[A1], except that Limitation 21[A1] does not require

that the channel be configured to receive a longitudinal connecting member. EX1003, ¶336. The '477 Publication/Boschert combination discloses this limitation for the reasons set forth above. *Id.*; *supra* §VI.D.1.e.

- f. **21[A2]:** “the first discontinuously helically wound thread form on the inner surface of the first arm having a first discontinuous loading surface, the first start structure rotatable under the first discontinuously helically wound thread form and the first discontinuous loading surface mateable with the closure first loading surface; and,”

This limitation, while worded slightly differently, includes the same requirements as Limitation 1[A2], except that Limitation 21[A2] does not require “upper” or “lower” loading surfaces. EX1003, ¶337. The '477 Publication/Boschert combination discloses this limitation for the reasons set forth above. *Id.*; *supra* §VI.D.1.f.

- g. **21[A3]:** “the second discontinuously helically wound thread form on the inner surface of the second arm having a second discontinuous loading surface, the second start structure rotatable under the second discontinuously helically wound thread form and the second discontinuous loading surface mateable with the closure second loading surface,”

This limitation, while worded slightly differently, includes the same requirements as Limitation 1[A3], except that Limitation 21[A3] does not require “upper” or “lower” loading surfaces. EX1003, ¶338. The '477 Publication/Boschert

combination discloses this limitation for the reasons set forth above. *Id.*; *supra* §VI.D.1.g.

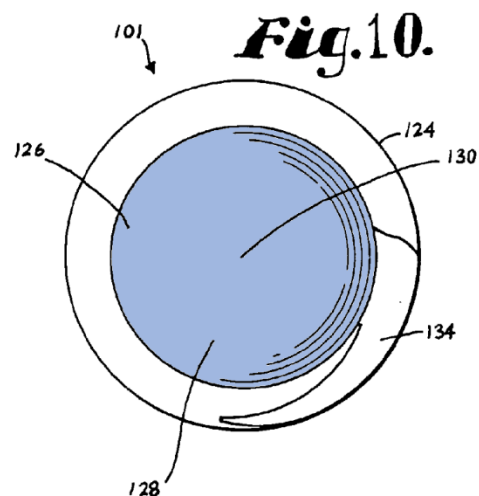
- h. 21[B2]:** “a rotation of the closure about the axis of rotation between the first arm and the second arm causing the first start and the second start structures to simultaneously rotatably advance under the first discontinuously helically wound thread form and the second discontinuously helically wound thread form, respectively, the closure rotationally advanceable within the channel until a rod positioned within the channel is locked therein”

This limitation, while worded slightly differently, includes the same requirements as Limitations 1[A3] and 1[B2]. EX1003, ¶¶339-40. The '477 Publication/Boschert combination discloses this limitation for the reasons set forth above. *Id.*; *supra* §VI.D.1.g-h.

20. Claim 22

Claim 22 depends from Claim 21 and recites: [B17] “wherein the closure has a bottom surface that is closed.” EX1001, cl. 22.

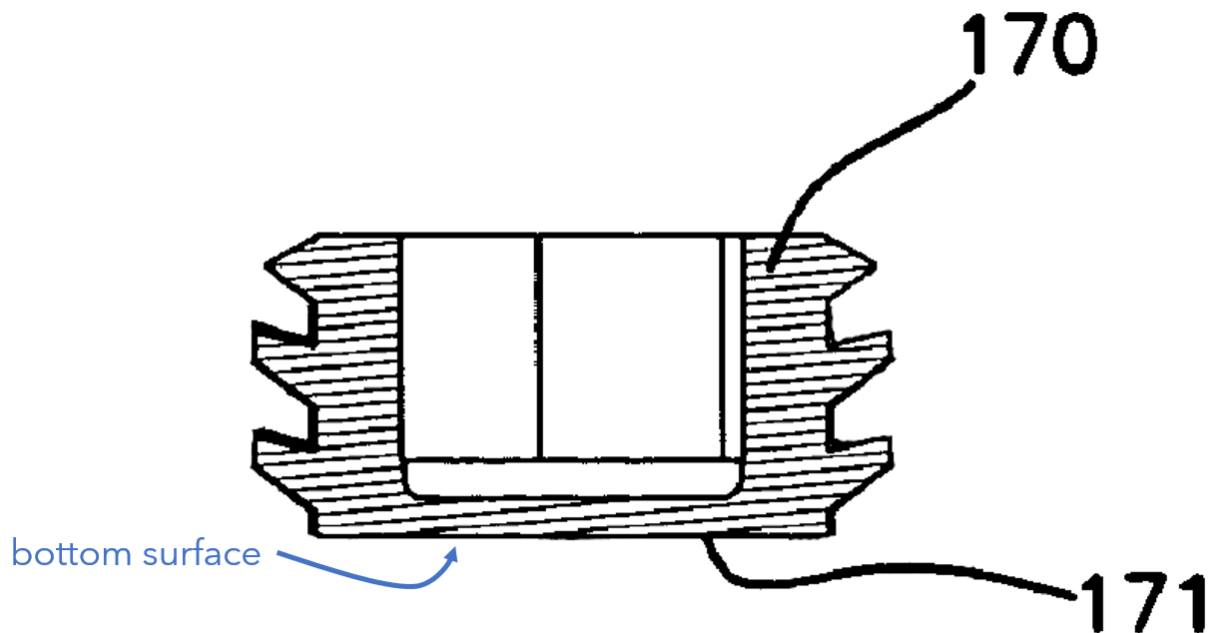
The '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶341-43. As shown in Figure 10, the '477 Publication discloses a closure bottom surface that is closed. EX1005, Fig. 10; *see also id.*, Fig. 4; EX1003, ¶342.



21. Claim 23

Claim 23 depends from Claim 22 and recites: **[B18]** “wherein the bottom surface is flat.” EX1001, cl. 23. The ’477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶344-49.

Boschert discloses a “setscrew 170 having a flat bottom surface 171 for contacting the rod 60 when the rod is clamped within the device 110.” EX1006, 7:41-43, Fig. 15; EX1003, ¶345.



While the ’477 Publication discloses a closure that has a domed bottom surface, a POSA would have been motivated to combine the ’477 Publication with Boschert’s teaching of a flat bottom surface. EX1003, ¶345. A POSA would have been motivated to use the flat bottom taught by Boschert at least because (1) Boschert teaches that a flat bottom helps lock a rod in place, EX1006, 7:41-43; (2)

both references expressly invite modification, EX1005, ¶[0047]; EX1006, 7:58-8:2, 8:44-49; (3) both references teach that there are a finite number of bottom surface shapes meant to engage with a rod, including a flat bottom surface, EX1005, ¶¶[0029], [0040], cls. 10, 24; EX1006, 7:16-17, 7:41-43, and a POSA would have had good reason to pursue the known options, including a flat bottom surface, in view of the design need for a closure bottom that engages the rod; and (4) such a combination would have been nothing more than the simple substitution of one known element (a domed bottom surface) for another (the flat bottom surface in Boschert). EX1003, ¶¶346-48. Indeed, Boschert teaches that various closure bottom configurations, including a flat bottom, are interchangeable. EX1006, 7:16-43; EX1003, ¶348. A POSA would have expected success with this combination because a flat bottom surface, and techniques for manufacturing such a surface, were well known and within the technical capabilities of a POSA. EX1003, ¶¶344-49.

22. Claim 24

Claim 14 depends from Claim 21 and recites: **[B4]** “wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each one of: v-threads, square threads, reverse angle threads, or buttress threads.” EX1001, cl. 24. This limitation is identical to the limitation in Claim 4. EX1003, ¶350. For the same reasons discussed above (*supra* §VI.D.3),

the '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶350-51.

23. Claim 25

Claim 25 depends from Claim 21 and recites: [B3] “wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each flange forms.” EX1001, cl. 25. This limitation is identical to the limitation in Claim 3. EX1003, ¶352. For the same reasons discussed above (*supra* §VI.D.2), the '477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶352-53.

24. Claim 26

a. **26[Preamble]:** “A medical implant assembly comprising:”

This limitation recites the same requirements as Limitation 1[Preamble]. EX1003, ¶354. The '477 Publication/Boschert combination discloses this limitation for the reasons set forth above. *Id.*; *supra* §VI.D.1.a.

b. **26[A]:** “a receiver having a first arm and a second arm spaced apart from each other by a rod-receiving 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 first and second discontinuously helically wound threads, respectively, 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;”

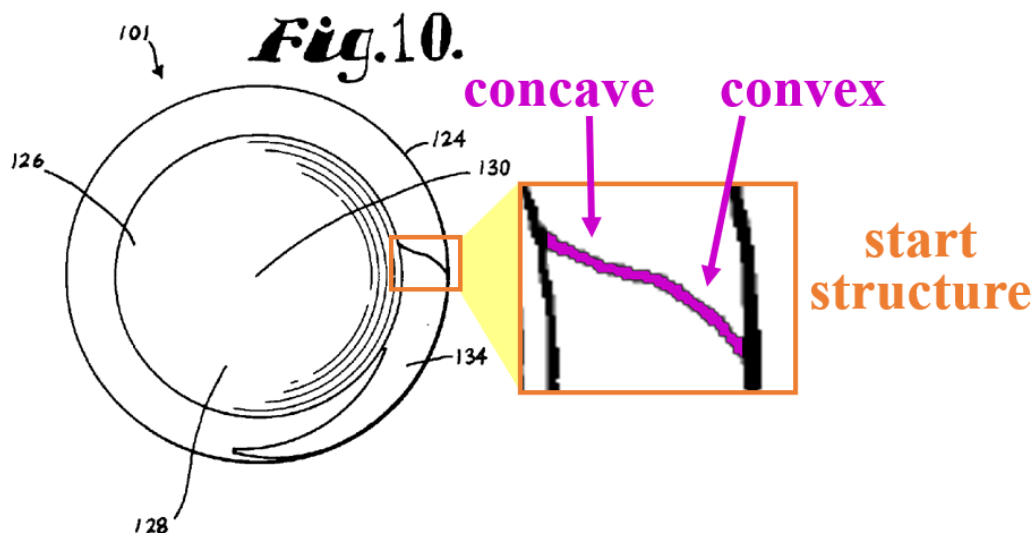
This limitation, while worded slightly differently, includes the same requirements as Limitation 1[A]. EX1003, ¶355. The ’477 Publication/Boschert combination discloses this limitation for the reasons set forth above. *Id.*; *supra* §VI.D.1.b.

- c. **26[B]:** “a closure having a first continuously helically wound thread form and a second continuously helically wound thread form, each of the first continuously helically wound thread form and the second continuously helically wound thread form being a reverse angle thread, the first continuously helically wound thread form having a first start structure and a first upper loading surface extending 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 and a second upper loading surface extending between a root and a crest of the second continuously helically wound thread form,”

This limitation, while worded slightly differently, includes the same requirements as Limitation 1[B], except that Limitation 26[B] requires reverse angle thread forms. EX1003, ¶356. As discussed above (*supra* §VI.D.3), the ’477 Publication discloses reverse angle threads, and Boschert also discloses reverse angle threads. EX1003, ¶¶356-60. Thus, the ’477 Publication/Boschert combination discloses this limitation for the reasons set forth above. *Id.*, ¶361; *supra* §§VI.D.1.c, VI.D.3.

- d. **26[C]:** “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;”

This limitation, while worded slightly differently, includes the same requirements as Limitation 21[C], except that Limitation 26[C] requires a leading face with both a partial concave surface and a partial convex surface. EX1003, ¶362. The '477 Publication/Boschert combination discloses this limitation. *Id.*, ¶¶362-64. As shown in Figure 10, the '477 Publication discloses a leading face that includes at least a partial concave surface and a partial convex surface. EX1005, Fig. 10; EX1003, ¶364.



Ex. 1005, Fig. 10

As discussed above (*supra* §VI.D.1.c), a POSA would have been motivated to combine the '477 Publication with Boschert's teaching of double-lead threads

while retaining the '477 Publication's leading face structure. EX1003, ¶363. This combination results in first and second start structures that satisfy the requirements of Limitation 26[C]. EX1003, ¶364.

- e. **26[A1]:** “the channel being formed by the first arm and the second arm opening onto the top surface, the channel adapted to receive a rod, the channel closeable with the closure having an axis of rotation;”

This limitation, while worded slightly differently, includes the same requirements as Limitation 1[A1]. EX1003, ¶365. The '477 Publication/Boschert combination discloses this limitation for the reasons set forth above. *Id.*; *supra* §VI.D.1.e.

- f. **26[A2]:** “the first discontinuously helically wound thread form on the inner surface of the first arm being a reverse angle thread having a first lower loading surface, the first start structure rotatable under the first discontinuously helically wound thread form and the first lower loading surface threadably engageable to the first upper loading surface; and”

This limitation, while worded slightly differently, includes the same requirements as Limitation 1[A2], except that Limitation 26[A2] require the threads on the receiver arms to be reverse angle threads. EX1003, ¶366. As discussed above (*supra* §VI.D.3), '477 Publication discloses reverse angle threads, and Boschert also discloses reverse angle threads. EX1003, ¶¶367-69. Thus, the '477

Publication/Boschert combination discloses this limitation for the reasons set forth above. EX1003, ¶369; *supra* §§VI.D.1.f, VI.D.3.

- g. 26[A3]:** “the second discontinuously helically wound thread form on the inner surface of the second arm being a reverse angle thread having a second lower loading surface, the second start structure rotatable under the second discontinuously helically wound thread form and the second lower loading surface threadably engageable to the second upper loading surface,”

This limitation, while worded slightly differently, includes the same requirements as Limitation 1[A3], except that Limitation 26[A3] requires the threads on the receiver arms to be reverse angle threads. EX1003, ¶370. As discussed above (*supra* §§VI.D.3, VI.D.1.g), both the '477 Publication and Boschert disclose reverse angle threads. EX1003, ¶370. Thus, the '477 Publication/Boschert combination discloses this limitation for the reasons set forth above. EX1003, ¶371; *supra* §§VI.D.1.f, VI.D.3, VI.D.24f.

- h. 26[B2]:** “a rotation of the closure about the axis of rotation between the first arm and the second arm causing a simultaneous mating of the first continuously helically wound thread form with the first discontinuously helically wound thread form and the second continuously helically wound thread form with the second discontinuously helically wound thread form, the closure rotationally advanceable within the channel until the closure locks the rod received within the channel”

This limitation, while worded slightly differently, includes the same requirements as Limitation 1[B2]. EX1003, ¶¶372-73. The '477

Publication/Boschert combination discloses this limitation for the reasons set forth above. *Id.*; *supra* §VI.D.1.h.

25. Claim 27

Claim 27 depends from Claim 26 and recites: [B11] “wherein the concave surface is adjacent the root and the convex surface is adjacent the crest for each of the first and second continuously helically wound thread forms.” EX1001, cl. 27. This limitation is identical to the limitation in Claim 11. EX1003, ¶374. For the same reasons discussed above (*supra* §VI.D.10), the ’477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶374-75.

26. Claim 28

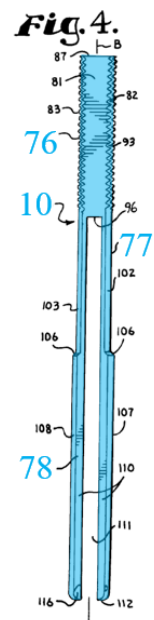
Claim 28 depends from Claim 26 and recites: [B5] “wherein the first start structure is disposed at a diametrically opposite location on the closure from the second start structure.” EX1001, cl. 28. This limitation is identical to the limitation in Claim 5. EX1003, ¶376. For the same reasons discussed above (*supra* §VI.D.4), the ’477 Publication/Boschert combination discloses this limitation. EX1003, ¶¶376-77.

VII. GROUND 2: CLAIM 2 IS UNPATENTABLE OVER THE '477 PUBLICATION IN VIEW OF BOSCHERT AND '391 PUBLICATION.

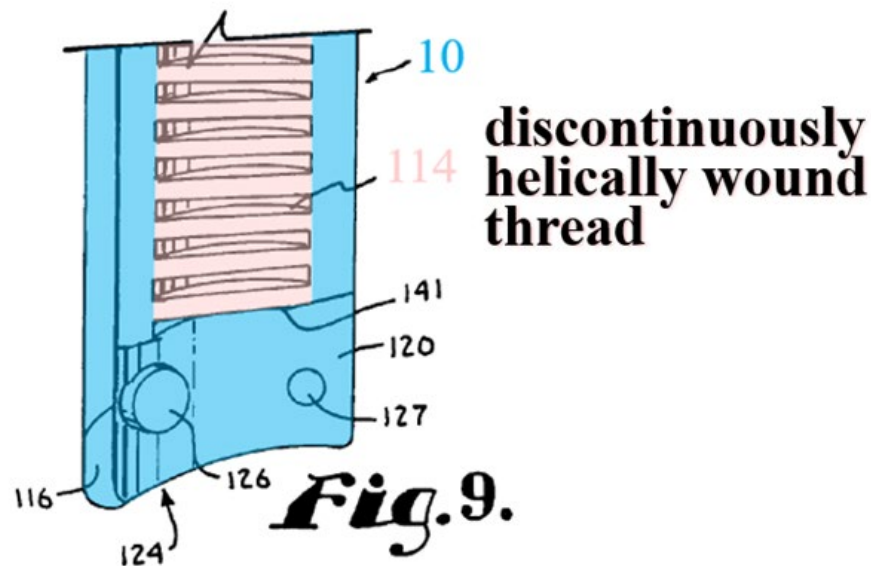
A. Overview of the '391 Publication

The '391 Publication was published on March 30, 2006, and is prior art to the '641 Patent under 35 U.S.C. § 102(b). As described further below, the '391 Publication discloses a tool set for use with U-shaped receivers of bone screws and is in the same field of endeavor as, and analogous art to, the '641 Patent. *Compare* EX1030, Abstract, ¶[0002], *with* EX1001, 1:27-31.

As shown in Figure 4 to the right, '391 Publication discloses a “tool embodiment assembly 1” that “includes an intermediate guide tool 10”. EX1030, ¶[0082]. The intermediate guide tool 10 has “an overall elongate body 74 with an upper handle portion 76, and intermediate portion 77 and a lower implant engaging portion 78 which includes opposed implant engaging members for securing one of the implants there between.” *Id.*, ¶[0096].



As shown in Figure 9 below, the bottom 112 of the intermediate tool guide 10 includes “a helically wound but discontinuous square thread 114” that “cooperates with the closure top 62,” although “other types of guide and advancement structure may be utilized such as helically wound flange forms, reverse angle threads, buttress threads, etc.” *Id.*, ¶[0103].



The bottom of the tool, shown in Figure 10, below, also includes a “radially inward facing attachment structure, generally 124.” *Id.*, ¶[0104]. The attachment structure 124 has “a first projection, stop or pin 126 in a spaced relation with a second smaller projection, stop or pin 127, both pins being disposed on the surface 120.” *Id.*, ¶[0105]. A “cooperating third projection, stop or pin 130” and “a fourth smaller projection, stop or pin 131” are disposed on the opposite leg of the intermediate tool guide 10. *Id.* “The pins 126, 127, 130 and 131 cooperate and mate with the bone screw 4, at a receiver portion, generally identified by reference numeral 145, of a head 146 thereof.” *Id.*, ¶[0110]. “[T]o attach the bone screw head 146 to the guide tool 10, the guide tool 10 is rotated about its axis B such that the legs 102 and 103 are lowered into place,” *id.*, ¶[0114], and, to “disengage” the guide tool 10 from the

discloses that the benefit of its attachable/detachable guide tool is to “allow for the insertion of bone screws, the insertion and reduction of a rod into the bone screws and the securing of the rod to the bone screws with significantly less invasion into the body of the patient and with minimal surgical incision of the skin over the operational site.” EX1030, ¶[0006]. Moreover, the ’391 Publication discloses that the threads on the guide tool “allow the closure top 62 to be rotated and the surgeon to develop mechanical advantage to urge or drive the rod 8, while still outside or partially outside the bone screw 4, toward and into the bone screw 146.” *Id.*, ¶[0120]. The ’391 Publication further discloses that alignment of the tool guide’s threads with the receiver arms’ threads “allow[s] the closure top 62 to continue to rotate and to continuously apply force to the rod 8, so as to aid in seating the rod 8 in the bone screw head 146.” *Id.*

Boschert already contemplates the use of various instruments with its disclosed receiver, and therefore discloses “grasping features” that could “accommodate instrumentation to facilitate grasping, holding or manipulating of the receiver 30” during implantation. EX1006, 6:15-19; *see also id.*, 1:55-60; EX1003, ¶186; EX1039, Figs. 4, 8; EX1040, Figs. 3A, 3B; EX1041, Fig. 7. But Boschert does not disclose the details of the tools and instruments to be used with its receiver, and thereby invites a POSA to look to tools already known in the art. EX1003, ¶¶186, 212. A POSA implementing the ’477 Publication/Boschert combination

would have naturally looked to the '391 Publication because it also discloses a closure and receiver and expressly teaches the advantages of using its guide tool with a closure and receiver. *Id.* ¶212.

A POSA would have expected success with this combination because it merely involves the combination of familiar elements using known methods to yield predictable results, and because the techniques for machining guide tools were well known. *Id.*, ¶213.

In addition, a POSA would have been motivated to combine the teachings of the '391 Publication with the '477 Publication/Boschert combination based on the demands known to the medical device design community for devices that would allow minimally invasive surgery. *Id.*, ¶214.

C. Claim Analysis.

As set forth above, the '477 Publication/Boschert combination already renders obvious every limitation of Claims 1, 3-19, and 21-28. The addition of the '391 Publication further renders obvious Claim 2. EX1003, ¶¶378-84.

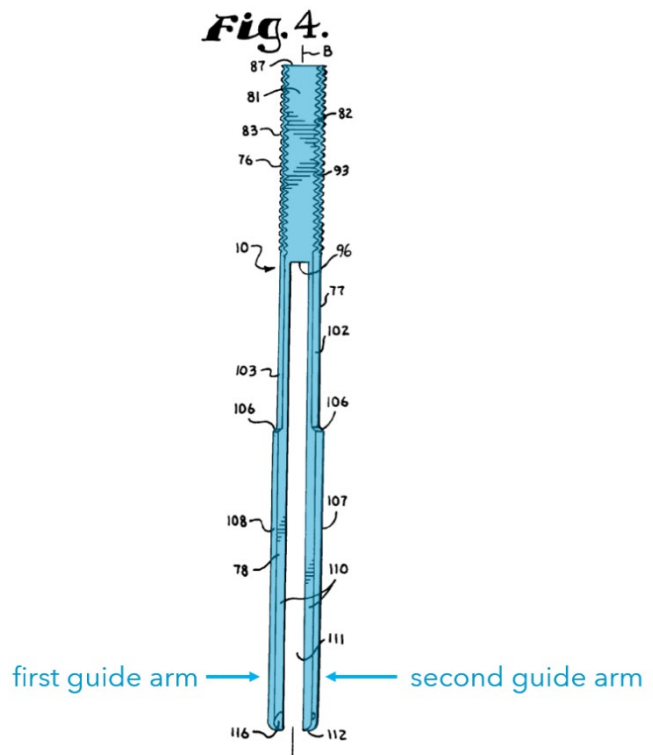
1. Claim 2

Claim 2 depends from Claim 1 and recites the following additional limitations:

- a. 2[D]: “ a guide tool having a first guide arm and a second guide arm detachably attached to the receiver”

The '477 Publication/Boschert/'391 Publication combination discloses this limitation. EX1003, ¶¶385-91. The '391 Publication discloses a “tool embodiment assembly 1” that “includes an intermediate guide tool 10.” EX1030, ¶[0082]. “[T]o

attach the bone screw head 146 to the guide tool 10, the guide tool 10 is rotated about its axis B such that legs 102 and 103 are lowered into place,” *id.*, ¶[0114], and, to “disengage” the guide tool 10 from the bone screw 4, the guide tool 10 is “rotated counterclockwise from an attaching configuration,” *id.*, ¶[0115]. See also *id.*, ¶[0017]; Fig. 4

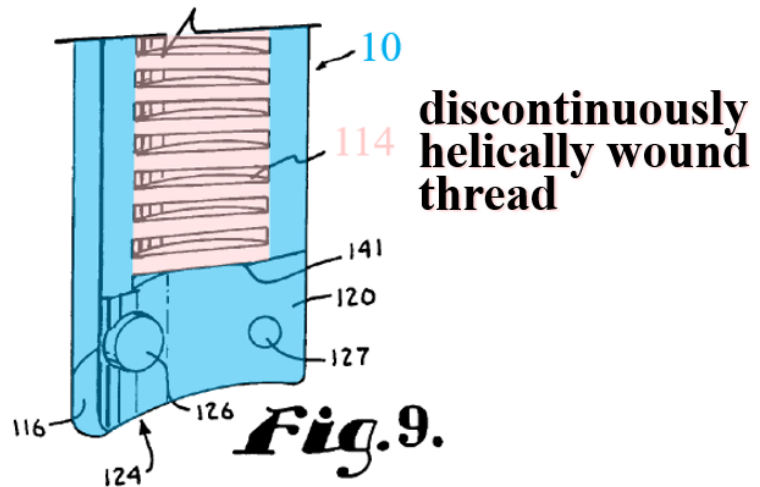


As discussed above (*supra* §VII.B), a POSA would have been motivated to combine the '391 Publication's teachings of a guide tool with the '477 Publication/Boschert combination.

- b. 2[D1]: “a third discontinuously helically wound thread form on the first guide arm; and a fourth discontinuously helically wound thread form on the second guide arm,”

The '477 Publication/Boschert/'391 Publication combination discloses this limitation. EX1003, ¶¶392-93. The '391 Publication discloses “a helically wound but discontinuous square thread 114” at the bottom 112 of the intermediate tool guide 10 that “cooperates with the closure top 62,” although “other type of guide and advancement structure may be utilized such as helically wound flange forms, reverse angle threads, buttress threads,

etc.” EX1030, ¶[0103]. As shown below, each of the guide arms includes a discontinuously helically wound thread form on the guide arm. *Id.*, Fig. 9; EX1003, ¶392.



As discussed above (*supra* §VII.B), a POSA would have been motivated to combine '391 Publication's teachings of a guide tool with the '477 Publication/Boschert combination.

- c. 2[D2]: “the first start structure threadably engageable with the third discontinuously helically wound thread form simultaneously with the second start structure threadably engageable with the fourth discontinuously helically wound thread form when the closure is rotated

between the first guide arm and the second guide arm, the third discontinuously helically wound thread form and the fourth discontinuously helically wound thread form adapted to transfer the closure between the guide tool and the receiver”

The ’477 Publication/Boschert/’391 Publication combination discloses this limitation. EX1003, ¶¶394-98. As discussed above (*supra* §VI.D.1.h), the ’477 Publication/Boschert combination already discloses a closure with a first start structure and a second start structure and wherein rotation of the closure about the axis of rotation between the first arm and the second arm of the receiver causes a simultaneous advancement of the first start structure and second start structure under the first discontinuously helically wound thread form and the second discontinuously helically wound thread form.

The ’391 Publication discloses that the guide tool threads are “located and positioned to align” with threads on the “insides of the bone screw arms 150 and 151” and “*pass the closure top 62 therebetween* while allowing the closure top 62 to continue to rotate and to continually apply force to the rod 8, so as to aid in seating the rod 8 in the bone screw head 146.” EX1030, 15:49-56. Thus, a POSA would have understood that the ’391 Publication discloses that the helically wound thread forms on the closure threadably engage the discontinuously helically wound thread forms on the arms of the guide tool in the same way that they engage the discontinuously helically wound thread forms on the receiver arms. EX1003, ¶396.

Accordingly, the '477 Publication/Boschert/'391 Publication combination renders obvious every element of Claim 2. EX1003, ¶398.

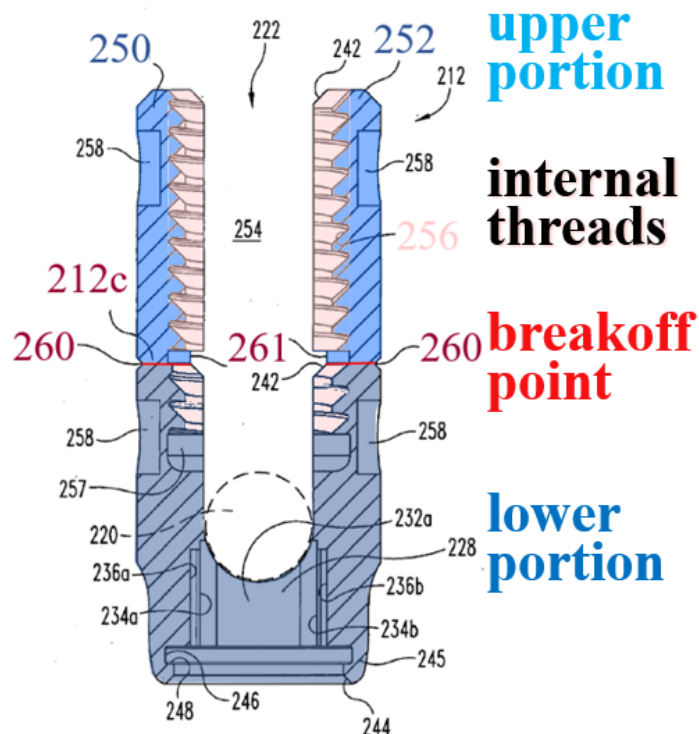
VIII. GROUND 3: CLAIM 20 IS UNPATENTABLE OVER THE '477 PUBLICATION IN VIEW OF BOSCHERT AND JOHNSON

A. Overview of Johnson

Johnson published on April 19, 2007, and is prior art to the '641 Patent under Section 102(b). As described further below, because Johnson discloses a bone screw with a U-shaped receiver that uses a closure to capture and lock a rod, Johnson is in the same field of endeavor as, and analogous art to, the '641 Patent. *Compare* EX1008, ¶[0031], *with* EX1001, 1:27-31.

Johnson discloses a receiver that “has a *lower portion 212a* and an *upper portion 212b*.” EX1008,

¶[0051], Fig. 10. “[I]n *internal threads 256* are formed in branches 250, 252 through substantially the entire length of upper portion 212b and into lower portion 212a.” *Id.*, ¶[0052]. “Threads 256 may [be] configured so that they are



essentially continuous from upper portion 212*b* to lower portion 212*a*” so that a compression member “can be inserted into upper portion 212*b* and moved down to lower portion 212*a*.” *Id.*, ¶[0053]. “Once the compression member is tightened against elongated member 220 to lock the assembly to the surgeon’s satisfaction, *[the] upper portion 212b may be cut or sheared off* or otherwise removed from lower portion 212*a*.” *Id.*, ¶[0056]. “Once separated, upper portion 212*b* may be removed from the surgical site and discarded.” *Id.*

B. Motivation to Combine Johnson with the ’477 Publication and Boschert

A POSA would have been motivated to apply Johnson’s teachings of break-off extension arms to the closure and receiver system taught by the ’477 Publication and Boschert before the priority date of the ’641 Patent. EX1003, ¶¶215-19. Johnson is in the exact same field as the ’477 Publication and Boschert in that all three references disclose bone screws with an open U-shaped receiver for locking a rod with a closure. *Id.*, ¶216. A POSA would have been motivated to add break-off extension arms to an existing system at least based on the benefits of break-off extensions as taught by Johnson. *Id.*

Johnson discloses that, “[w]hen the surgeon wishes to insert an elongated member 220 into receiver member 212, he or she *need not bend it or use a special reducing tool* to insert it into the lower end of a receiving channel. Rather, he or she

places a portion of the elongated member 220 into channel 254 in upper portion 212*b* of receiver member 212.” EX1008, ¶[0055]; *see also* EX1003, ¶196. A compression member is then threaded into threads 256 of receiver 212, forcing elongated member all the way down. *Id.* Upper portion 212*b* can then be removed from lower portion 212*a*. *Id.*, ¶[0056]. Based on these teachings, a POSA would have recognized the benefits of including break-off extension arms in an existing device, including easier delivery of a rod while maintaining a low-profile device, and would have been motivated to use this feature in the ’477 Publication/Boschert combination. EX1003, ¶217.

A POSA would have expected success with this combination because it merely involves the combination of familiar elements using known methods to yield predictable results, and because the techniques for machining break-off extension arms were well known. *Id.*, ¶218.

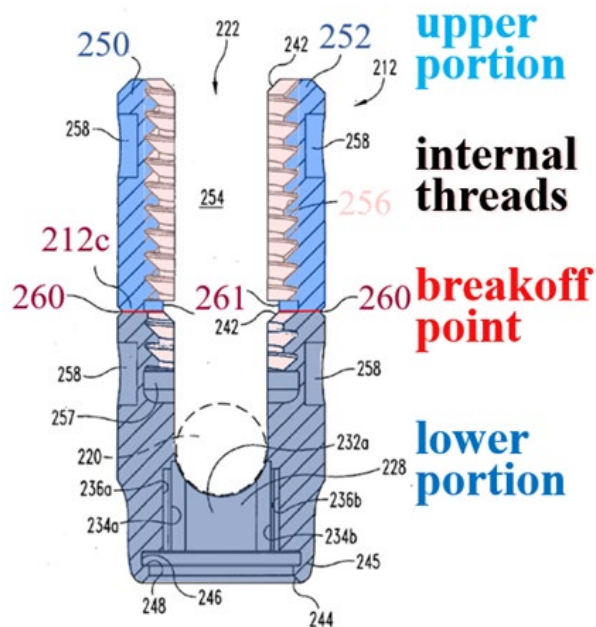
C. Claim Analysis

1. Claim 20

Claim 20 depends from Claim 1 and recites: [E]“wherein the receiver first arm and the second arm top surface each include a breakoff extension with an inner surface having a discontinuously helically wound thread form, the first arm breakoff extension thread form being continuous with the first discontinuously helically wound thread form on the inner surface of the first arm and the second arm breakoff

extension thread form being continuous with the second discontinuously helically wound thread form on the inner surface of the second arm.” EX1001, cl. 20. The ’477 Publication/Boschert/Johnson combination discloses this limitation. EX1003, ¶¶404-13.

Johnson discloses receiver member 212 that “has a lower portion 212a and an upper portion 212b separated by a thinned section 212c.” EX1008, ¶[0051], Fig. 10. As shown in Figure 12 at right, Johnson discloses that “*internal threads 256 are formed in branches 250, 252 through substantially the entire length of upper portion 212b and into lower portion 212a.*”



Id. ¶[0052]; Fig. 12. Johnson further discloses that the “[t]hreads 256 may [be] configured so that they are *essentially continuous* from upper portion 212b to lower portion 212a” so that a compression member “can be inserted into upper portion 212b and moved down to lower portion 212a.” *Id.*, ¶¶[0053], [0055], Fig. 12.

As explained above, a POSA would have been motivated by the teachings of Johnson to include these features in implementing the ’477 Publication/Boschert combination. *Supra* §VIII.B.

IX. SECONDARY CONSIDERATIONS

Petitioners are not aware of any evidence of secondary considerations in support of non-obviousness. EX1003, ¶¶414-19. To the extent Patent Owner argues that there are secondary considerations, this argument fails because the relevant evidence, if anything, underscores the obviousness of the Challenged Claims. *Id.*

X. DISCRETIONARY DENIAL IS NOT APPROPRIATE

A. 35 U.S.C. §325(d)

Denial under 35 U.S.C. §325(d) is inappropriate under the test set forth in *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*: (1) whether the same or substantially the same prior art or arguments were previously presented to the Office; and (2) whether Petitioners demonstrated that the Office materially erred. IPR2019-01469, Paper 6 at 8-9 (PTAB Feb. 13, 2020) (precedential); *see also Becton, Dickinson & Co. v. B. Braun Melsungen*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential).

None of the '477 Publication, Boschert, the '391 Publication, or Johnson were the basis for any rejection. Neither the '477 Publication nor the '391 Publication were before the Examiner. Boschert was submitted, but the Examiner appears not to have discovered Boschert's teachings of dual-start threads until the prosecution of subsequent family members. EX1003, ¶119. Therefore, part one of the *Advanced Bionics* test favors institution, as the Grounds set forth herein were not before the

Examiner during prosecution. *Thorne Res., Inc. v. Trs. of Dartmouth Coll.*, IPR2021-00491, Paper 18 at 8 (PTAB Aug. 12, 2021).

Under part two of the *Advanced Bionics* test, even if the Examiner considered the specific combinations of art and arguments presented in this Petition, the Examiner clearly erred in allowing the claims of the '641 Patent over these disclosures. As set forth above, the '477 Publication/Boschert combination, in further combination with the '391 Publication or Johnson, renders obvious each and every limitation of the Challenged Claims. *Supra* §§VI-VIII.

B. Fintiv

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 at 6 (PTAB Mar. 20, 2020) (precedential) does not apply because this Petition presents compelling evidence of unpatentability and, per PTO interim guidance, Petitioners stipulate that, unless the Board denies or vacates institution of this Petition, Petitioners will not seek resolution in the district court litigation of invalidity based on the grounds in this Petition, or any grounds that could have reasonably been raised in this Petition. EX1037; EX1038 at 2, 4-5; *Sotera Wireless, Inc. v. Masimo Corp.*, No. IPR2020-01019, Paper 12 at 17 (PTAB Dec. 1, 2020) (precedential).

XI. CONCLUSION

Petitioners respectfully request that IPR of the '641 Patent be instituted and that Claims 1-28 be cancelled.

FAEGRE DRINKER BIDDLE & REATH
LLP

Dated: September 22, 2023

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TYPE-VOLUME CERTIFICATION

Pursuant to 37 C.F.R. § 42.24(d), Petitioners hereby certify that this Petition for *Inter Partes* Review complies with the type-volume limitation of 37 C.F.R. § 42.24(a). This Petition contains 13,790 words, excluding the parts of the Petition exempted by 37 C.F.R. § 42.24(a), as calculated by Microsoft Office 2016, the word processing system used in its preparation, and including the word count in images calculated by hand.

Dated: September 22, 2023

By: / Victor P. Jonas/
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. ¶ 42.105, I hereby certify that on September 22, 2023, I caused a true and correct copy of the Petition for *Inter Partes* Review in connection with U.S. Patent No. 10,548,641 and Exhibits 1001 – 1044 to be served via:

Priority Mail Express on the following:

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APPENDIX – CLAIM LISTING (37 C.F.R. § 42.24)

I. Challenged Claims 1-28

Identifier	Element
1[Preamble]	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.
2[Preamble]	The medical implant assembly of claim 1,

Identifier	Element
2[D]	a guide tool having a first guide arm and a second guide arm detachably attached to the receiver;
2[D1]	a third discontinuously helically wound thread form on the first guide arm; and a fourth discontinuously helically wound thread form on the second guide arm;
2[D2]	the first start structure threadably engageable with the third discontinuously helically wound thread form simultaneously with the second start structure threadably engageable with the fourth discontinuously helically wound thread form when the closure is rotated between the first guide arm and the second guide arm, the third discontinuously helically wound thread form and the fourth discontinuously helically wound thread form adapted to transfer the closure between the guide tool and the receiver.
3[Preamble]	The medical implant assembly of claim 1,
3[B3]	wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each flange forms.
4[Preamble]	The medical implant assembly of claim 1,
4[B4]	wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each one of: v-threads, square threads, reverse angle threads, or buttress threads.
5[Preamble]	The medical implant assembly of claim 1,
5[B5]	wherein the first start structure is disposed at a diametrically opposite location on the closure from the second start structure.
6[Preamble]	The medical implant assembly of claim 1,
6[B6]	wherein each of the continuously first and the second helically wound thread form is disposed at a top of the closure, the first helically wound thread form and the second helically wound thread form each extending along the outer surface of the closure to a bottom of the closure and ending at the first and the second start structure, respectively.
7[Preamble]	The medical implant assembly of claim 6,
7[B7]	wherein the at least one curvate surface of both the first start structure and the second start structure is defined by at least one radius of curvature, the at least one radius of curvature being less than a radius of curvature for an outer surface on the crest of the first continuously helically wound thread form.
8[Preamble]	The medical implant assembly of claim 1,
8[B8]	wherein the at least one curvate surface of both the first start structure and the second start structure is defined by at least one radius of curvature, the at least one radius of curvature being less than a radius of curvature for an outer surface on the crest of the second continuously helically wound thread form.
9[Preamble]	The medical implant assembly of claim 1,
9[B9]	wherein the at least one curvate surface includes both a convex surface and concave surface.
10[Preamble]	The medical implant assembly of claim 9,
10[B10]	wherein both of the concave surface and the convex surface of the first start structure are positioned between the root and the crest of the first continuously helically wound thread form, and wherein both of the concave

Identifier	Element
	surface and the convex surface of the second start structure are positioned between the root and the crest of the second continuously helically wound thread form.
11[Preamble]	The medical implant assembly of claim 10,
11[B11]	wherein the concave surface is adjacent the root and the convex surface is adjacent the crest of the first and second start structures for the first and second continuously helically wound thread form, respectively.
12[Preamble]	The medical implant assembly of claim 9,
12[B12]	wherein a radius of curvature of the convex surface is substantially equal to a radius of curvature of the concave surface.
13[Preamble]	The medical implant assembly of claim 9,
13[B13]	wherein each of the first start structure and the second start structure includes a bottom beveled surface.
14[Preamble]	The medical implant assembly of claim 1,
14[B14]	wherein the first and second start structure leading face surfaces are at least partially planar surfaces parallel with respect to each other.
15[Preamble]	The medical implant assembly of claim 1,
15[B15]	wherein each of the at least one curvate surfaces is substantially parallel to the closure longitudinal axis.
16[Preamble]	The medical implant assembly of claim 1,
16[B9]	wherein each of the at least one curvate surface includes both a convex surface and concave surface.
17[Preamble]	The medical implant assembly of claim 1,
17[B9]	wherein each of the at least one curvate surfaces is a concave surface.
18[Preamble]	The medical implant assembly of claim 1,
18[B16]	wherein the closure first continuously helically wound thread form includes a first lower surface disposed between the root and the crest and the closure second continuously helically wound thread form includes a second lower surface disposed between the root and the crest, and wherein the leading face surface of the first start structure extends between the first upper surface and the first lower surface and the leading face surface of the second start structure extends between the second upper surface and the second lower surface.
19[Preamble]	The medical implant assembly of claim 18,
19[B14]	wherein each of the leading face surfaces of the first start structure and the second start structure include at least a partial planar surface.
20[Preamble]	The medical implant assembly of claim 1,
20[E]	wherein the receiver first arm and the second arm top surface each include a breakoff extension with an inner surface having a discontinuously helically wound thread form, the first arm breakoff extension thread form being continuous with the first discontinuously helically wound thread form on the inner surface of the first arm and the second arm breakoff extension thread form being continuous with the second discontinuously helically wound thread form on the inner surface of the second arm.
21[Preamble]	The medical implant assembly of claim 1,

Identifier	Element
21[A]	a receiver having a first arm and a second arm spaced apart from each other by a rod-receiving 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 first and second discontinuously helically wound threads, respectively, 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;
21[B]	a closure 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 and a first loading surface extending 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 and a second loading surface extending between a root and a crest of the second continuously helically wound thread form,
21[C]	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;
21[A1]	the channel being formed by the first arm and the second arm, the channel closeable with the closure having an axis of rotation;
21[A2]	the first discontinuously helically wound thread form on the inner surface of the first arm having a first discontinuous loading surface, the first start structure rotatable under the first discontinuously helically wound thread form and the first discontinuous loading surface mateable with the closure first loading surface; and
21[A3]	the second discontinuously helically wound thread form on the inner surface of the second arm having a second discontinuous loading surface, the second start structure rotatable under the second discontinuously helically wound thread form and the second discontinuous loading surface mateable with the closure second loading surface,
21[B2]	a rotation of the closure about the axis of rotation between the first arm and the second arm causing the first start and the second start structures to simultaneously rotatably advance under the first discontinuously helically wound thread form and the second discontinuously helically wound thread form, respectively, the closure rotationally advanceable within the channel until a rod positioned within the channel is locked therein.
22[Preamble]	The medical implant assembly of claim 21,
22[B17]	wherein the closure has a bottom surface that is closed.
23[Preamble]	The medical implant assembly of claim 22,
23[B18]	wherein the bottom surface is flat.
24[Preamble]	The medical implant assembly of claim 21,
24[B4]	wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each one of: v-threads, square threads, reverse angle threads, or buttress threads.

Identifier	Element
25[Preamble]	The medical implant assembly of claim 21,
25[B3]	wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each flange forms.
26[Preamble]	A medical implant assembly comprising:
26[A]	a receiver having a first arm and a second arm spaced apart from each other by a rod-receiving 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 first and second discontinuously helically wound threads, respectively, 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;
26[B]	a closure having a first continuously helically wound thread form and a second continuously helically wound thread form, each of the first continuously helically wound thread form and the second continuously helically wound thread form being a reverse angle thread, the first continuously helically wound thread form having a first start structure and a first upper loading surface extending 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 and a second upper loading surface extending between a root and a crest of the second continuously helically wound thread form,
26[C]	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;
26[A1]	the channel being formed by the first arm and the second arm opening onto the top surface, the channel adapted to receive a rod, the channel closeable with the closure having an axis of rotation;
26[A2]	the first discontinuously helically wound thread form on the inner surface of the first arm being a reverse angle thread having a first lower loading surface, the first start structure rotatable under the first discontinuously helically wound thread form and the first lower loading surface threadably engageable to the first upper loading surface; and
26[A3]	the second discontinuously helically wound thread form on the inner surface of the second arm being a reverse angle thread having a second lower loading surface, the second start structure rotatable under the second discontinuously helically wound thread form and the second lower loading surface threadably engageable to the second upper loading surface,
26[B2]	a rotation of the closure about the axis of rotation between the first arm and the second arm causing a simultaneous mating of the first continuously helically wound thread form with the first discontinuously helically wound thread form and the second continuously helically wound thread form with the second discontinuously helically wound thread form, the closure rotationally advanceable within the channel until the closure locks the rod received within the channel.

Identifier	Element
27[Preamble]	The medical implant assembly of claim 26,
27[B11]	wherein the concave surface is adjacent the root and the convex surface is adjacent the crest for each of the first and second continuously helically wound thread forms.
28[Preamble]	The medical implant assembly of claim 26,
28[B5]	wherein the first start structure is disposed at a diametrically opposite location on the closure from the second start structure.