

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. 11,129,646

Filing Date: December 16, 2020

Issue Date: September 28, 2021

Title: MEDICAL IMPLANT THREADED PLUG HAVING A START
STRUCTURE WITH SYMMETRICALLY SHAPED CONCAVE AND
CONVEX LEADING SURFACES

Inter Partes Review No. IPR 2023-01433

**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 1001:	U.S. Patent No. 11,129,646 (“the ’646 Patent”)
Exhibit 1002:	File History U.S. Patent No. 11,129,646
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 Publication No. 2007/0088357 (“Johnson”)
Exhibit 1009:	U.S. Patent No. 8,911,479 (“’479 Patent”)
Exhibit 1010:	U.S. Patent No. 10,548,641 (“’641 Patent”)
Exhibit 1011:	U.S. Patent No. 10,898,233 (“’233 Patent”)
Exhibit 1012:	U.S. Patent Application Publication No. 2010/0137918 (“Wilcox”)
Exhibit 1013:	U.S. Patent Application Publication No. 2005/0286984
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
Exhibit 1018	German Patent No. 29810798 (“Schafer”)

Exhibit 1019	U.S. Patent No. 7,250,052 (“Landry”)
Exhibit 1020	U.S. Patent Application Publication No. 2004/0167526 (“the ‘526 Publication”)
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”)
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Exhibit 1026	U.S. Patent No. 6,010,502 (“Bagby”)
Exhibit 1027	U.S. Patent No. 5,697,929 (“Mellinger ’929”)
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Exhibit 1029	American Heritage Dictionary, Fifth Edition (2011)
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Exhibit 1031	American Society of Mechanical Engineering Standard B1.7-2006 (“ASME B1.7-2006”) (<i>Excerpt</i>)
Exhibit 1032	U.S. Patent Application Pub. No. 2010/0312287
Exhibit 1033	Stipulation Regarding Invalidity Contentions (“Sotera Stipulation”)
Exhibit 1034	June 21, 2022 Memorandum regarding Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (“Sotera Memo”)
Exhibit 1035	File History U.S. Patent No. 8,911,479

Petition for *Inter Partes* Review of U.S. Patent No. 11,129,646
Filed September 22, 2023

Exhibit 1036 File History of U.S. Patent Application No. 15/397,959 (“the
 ‘959 Application”) (*Excerpt*)

ZimVie, Inc. and Zimmer Biomet Spine, Inc. (“Petitioners”) respectfully request *inter partes* review (“IPR”) of Claims 1-20 (“the Challenged Claims”) of U.S. Patent No. 11,129,646 (“the ’646 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 ’646 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 *inter partes* review of related U.S. Patent Nos. 8,911,479 (EX1009); 10,548,641 (EX1010); and 10,898,233 (EX1011) (the “’479,” “’641,” and “’233 Patent,” respectively; collectively, “the Related Patents”), to be filed concurrently herewith. The Related Patents are also at issue in the Litigation. The ’646 Patent is a continuation of the Related Patents.

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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II. STANDING AND FEES

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

Petitioners certify that the '646 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.

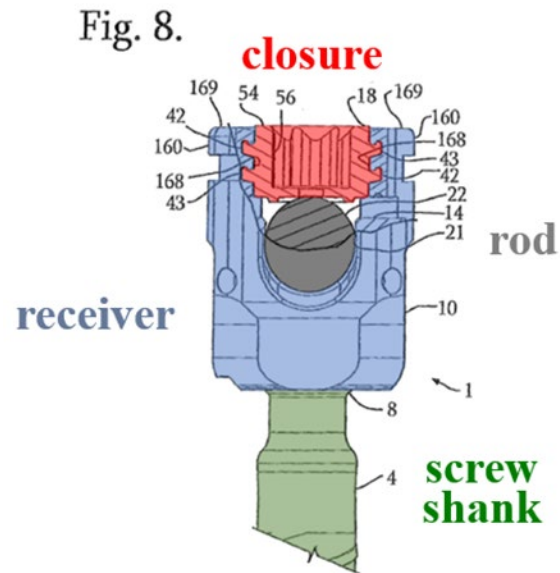
B. Fees (37 C.F.R. § 42.103)

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

III. THE '646 PATENT

A. Overview

The '646 Patent is directed to threaded closure plugs (also called “closure tops” or “setscrews”) 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, 1:39-40, and, as shown right in annotated Figure 8,

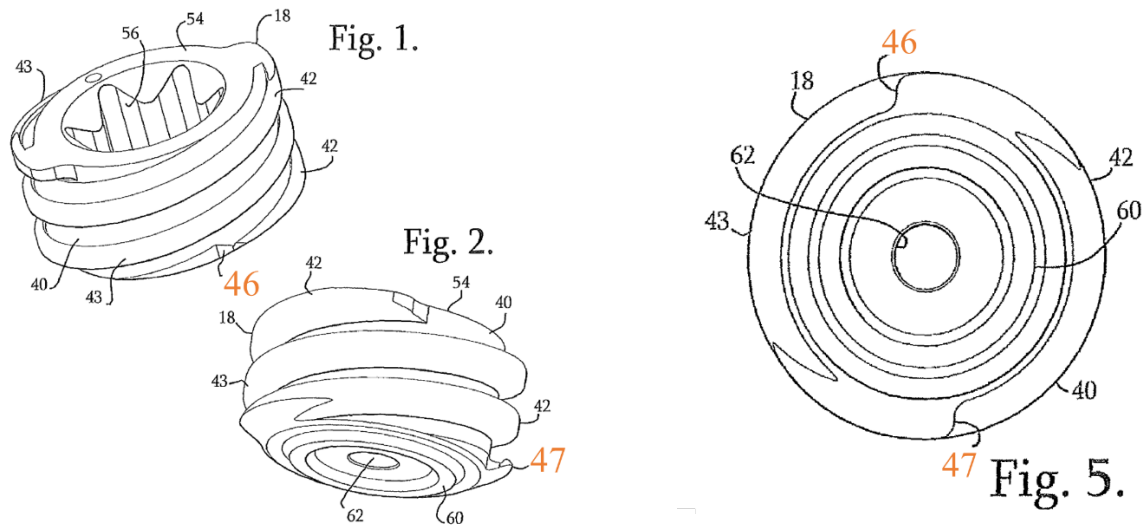


¹ Emphases and text coloring added unless specified throughout.

generally include known components such as “a threaded shank with a head or *receiver having a pair of parallel projecting* branches or *arms* which form a yoke with a *U-shaped slot or channel to receive a* rod or other *longitudinal connecting member.*” *Id.*, 1:54-58. 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.*, 1:61-65. 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.*, 1:65-2:4.

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.*, 2:17-27. 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.*, 2:47-51. 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. 7,857,834 (“Boschert”) (EX1006) previously taught double-start closure tops. As a result, he pivoted to claiming other conventional elements of his preferred embodiments that were mentioned in the specification without any disclosed benefit, including a curvate leading face on each thread and a substantially flat bottom surface of the closure top that includes an annular outer edge spaced apart from the thread starts. Both of these features were known in the prior art, with U.S. Patent Publication Application No. 2005/0267477 (“the ’477 Publication”) (EX1005) disclosing the same curvate leading face, and both the ’477 Publication and U.S. Patent Application

Publication No. 2011/0152947 (“Kirschman”) disclosing the same closure top bottom.

The ’646 Patent includes only two independent claims—Claims 1 and 12. These claims substantially overlap, but Claim 1 does not specify the number of thread starts, whereas Claim 12 requires double-start threads. The dependent claims recite additional conventional components of closure plugs and the receivers they thread into, including additional characteristics of known threads (Claims 2-7, 13-16, and 20), a breakoff drive mechanism for the closure top (Claims 8 and 17), additional characteristics of conventional receivers (Claim 9), and breakoff extensions on the receiver arms (Claims 10-11 and 19).

Petitioners provide as an Appendix to the Petition a claim listing of all Challenged Claims and their assigned unique identifiers. This claim listing is intended for ease of reference. The Petition addresses every limitation of the Challenged Claims.

B. Priority Date

The ’646 Patent claims priority to January 10, 2012 (“Priority Date”). EX1001. Although Petitioners do not concede that the ’646 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, ¶43; *see also id.*, ¶¶37-42 (analyzing factors for determining the level of skill in the art).

B. Knowledge of a POSA

Before the priority date of the ’646 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, ¶¶44-48. Further, a POSA would have been aware of a number of options when designing such a system, including multi-start threads, *id.*, ¶¶52-64, truncated threads with curvate leading faces, *id.*, ¶¶65-76, thread manufacturing techniques, *id.*, ¶¶77-81, various thread types, *id.*, ¶¶82-87, substantially flat bottoms with an annular outer edge spaced below the thread starts, *id.*, ¶¶89-96, breakoff closure tops, *id.*, ¶¶97-102, and breakoff arm extensions, *id.*, ¶¶103-09.

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 anticipated under pre-AIA 35 U.S.C. § 102 or obvious under 35 U.S.C. § 103 on the following grounds:

Ground	Claims	Basis
1	1-2 and 4-9	Anticipated or obvious in view of the '477 Publication (EX1005)
2	1-2 and 4-9	Obvious in view of the '477 Publication (EX1005) in combination with Kirschman (EX1007)
3	10 and 11	Obvious in view of the '477 Publication (EX1005), alone or in combination with Kirschman (EX1007), in combination with Johnson (EX1008)
4	3, 12-18, and 20	Obvious in view of the '477 Publication (EX1005) in combination with Boschert (EX1006)
5	3, 12-18, and 20	Obvious in view of the '477 Publication (EX1005) in combination with Boschert (EX1006) and Kirschman (EX1007)
6	19	Obvious in view of the '477 Publication (EX1005) in combination with Boschert (EX1006), alone or further in combination with Kirschman (EX1007), in combination with Johnson (EX1008)

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

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

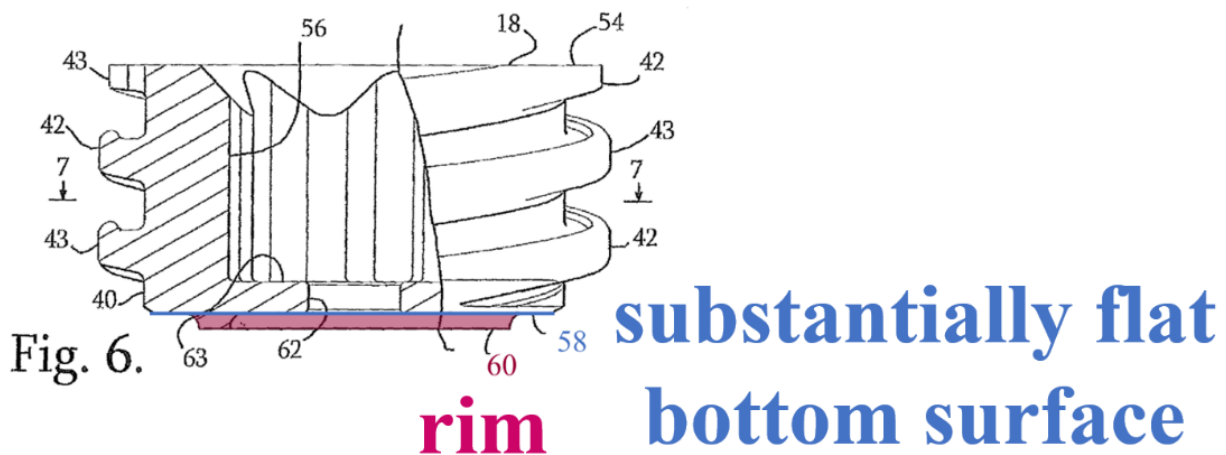
- 1. “a substantially flat bottom surface with an annular outer edge, the substantially flat bottom surface configured to engage the rod” (Claim 1) and “a substantially flat bottom surface with an annular outer edge” (Claim 12)**

The specification never identifies an “annular outer edge” on any “substantially flat bottom surface,” but a POSA would have understood this phrase to refer to the embodiment in the specification disclosing a closure top with a planar bottom surface and a downwardly projecting rim. EX1003, ¶144. This is consistent with the plain meaning of the phrase, with “substantially” meaning for the most part (or essentially), “bottom” meaning either the underside of something or lowermost, “annular” meaning ring-shaped, “outer” meaning farther from the center, and “edge” meaning either a thin, sharpened side or a line that is the intersection of two surfaces. *Id.*, ¶145.

The '646 Patent describes only two closure top bottoms, one that “is planar and further includes a rim 60 for engagement and penetration into the surface 22 of the rod 21,” EX1001, 9:4-7, Figs. 1-14, and another “that has a domed portion 66’ with a central nub 68’ in lieu of the flat and rimmed surfaces,” *id.*, 9:58-62, Fig. 50.

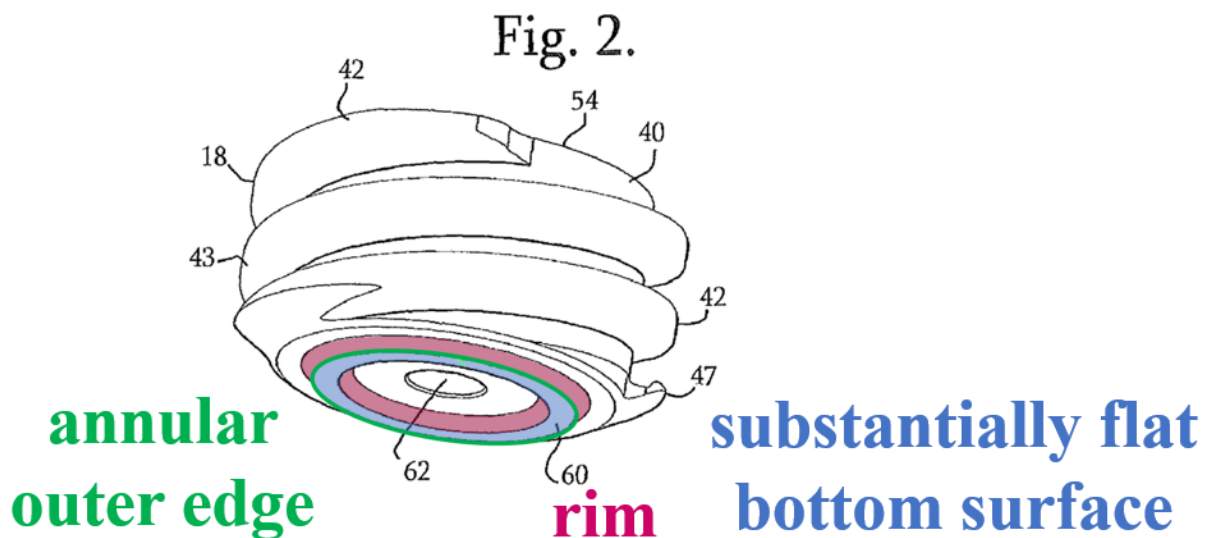
A POSA would have understood the claims to include the first set of embodiments (rimmed), but not the second (domed), at least because a domed bottom is not flat. EX1003, ¶146.

Applying this construction, Figure 6, as shown below, identifies “bottom surface 58 of the closure” as “planar” (i.e., flat). EX1001, 9:4-7. This surface “further includes a rim 60 for engagement and penetration into the surface 22 of the rod 21.” *Id.* A POSA would have understood that, despite the presence of the rim, bottom surface 58 is substantially flat, because it is mostly planar. EX1003, ¶147. Moreover, a POSA would have understood that “rim 60” is the claimed “annular outer edge.” *Id.* This rim is ring shaped (i.e., annular), located near the periphery of the closure top bottom (i.e., outer), and it has a narrow shape (i.e., an edge). *Id.* This is also consistent with how the prior art refers to annular edges. EX1003, ¶¶147-48; EX1018, 9:9-12.



The bottom surface of rim 60 could therefore alternatively be understood as the “substantially flat bottom surface configured to engage the rod.” EX1003, ¶149.

Under this alternative construction, a POSA would have understood that the “**annular outer edge**” of the “substantially flat bottom surface” is the ring-shaped line where the bottom surface of rim 60 meets the outer sidewall as shown in annotated Figure 2.



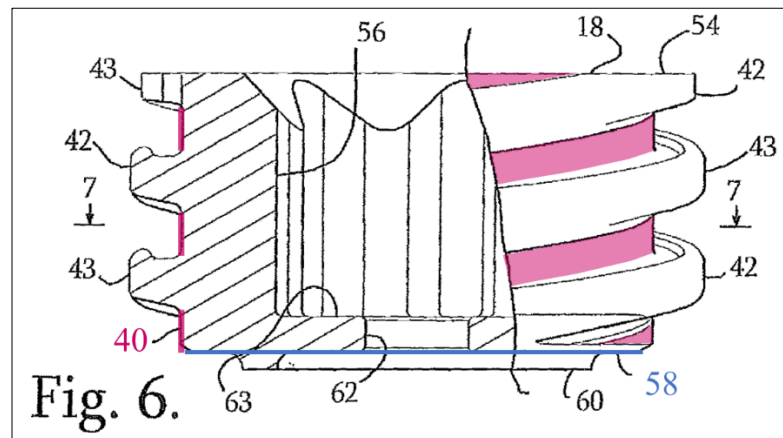
EX1001, Fig. 2; EX1003, ¶150.

2. “an outward facing surface encircling the substantially flat bottom surface” (Claim 12)

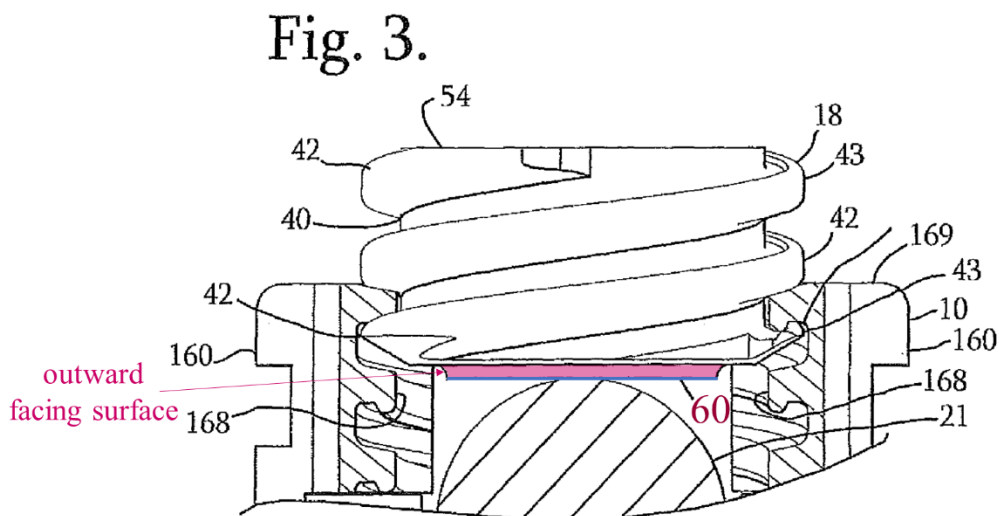
The specification never identifies an outward facing surface encircling the substantially flat bottom surface. Nevertheless, a POSA would have understood this phrase to have its plain meaning, with “outward” meaning facing toward the outside

(or away from the center) of the closure top and “encircling” meaning forming a circle around and surrounding. EX1003, ¶¶153-54.

Applying these plain meanings to the preferred embodiments, there are two surfaces that could meet this limitation. EX1003, ¶155. First, the “cylindrical **closure plug body 40**” comprises a surface that faces away from the center of the closure top (i.e., outward facing) and forms a circle around (i.e., encircles) the substantially flat **bottom surface**. EX1001, 8:22-30. Because **closure plug body 40** is cylindrical, its side surface is necessarily in the shape of a circle. And this circle formed by the **body 40** surrounds **bottom surface 58** (under the preferred construction of bottom surface as discussed above), as shown in annotated Fig. 6 below. *Id.*, Fig.1; EX1003, ¶155.



Second, under the alternative construction above, the “substantially flat bottom surface” is the flat bottom surface of the rim, and a POSA would have understood “an outward facing surface encircling the substantially flat bottom



3. “a start structure with an upper surface extending between a root and a crest ... having a leading face extending below the upper surface to a lower surface of the start structure, the leading face including a partial concave surface adjacent the

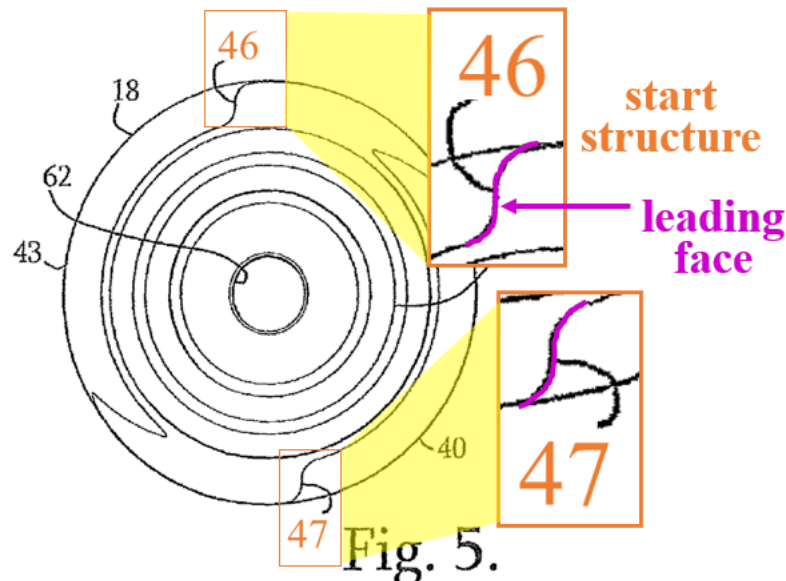
root and a partial convex surface adjacent the crest” (Claims 1 and 12 (modified to claim “first” and “second” start structures))

The claimed “leading face” is never specifically identified in the ’646 Patent.

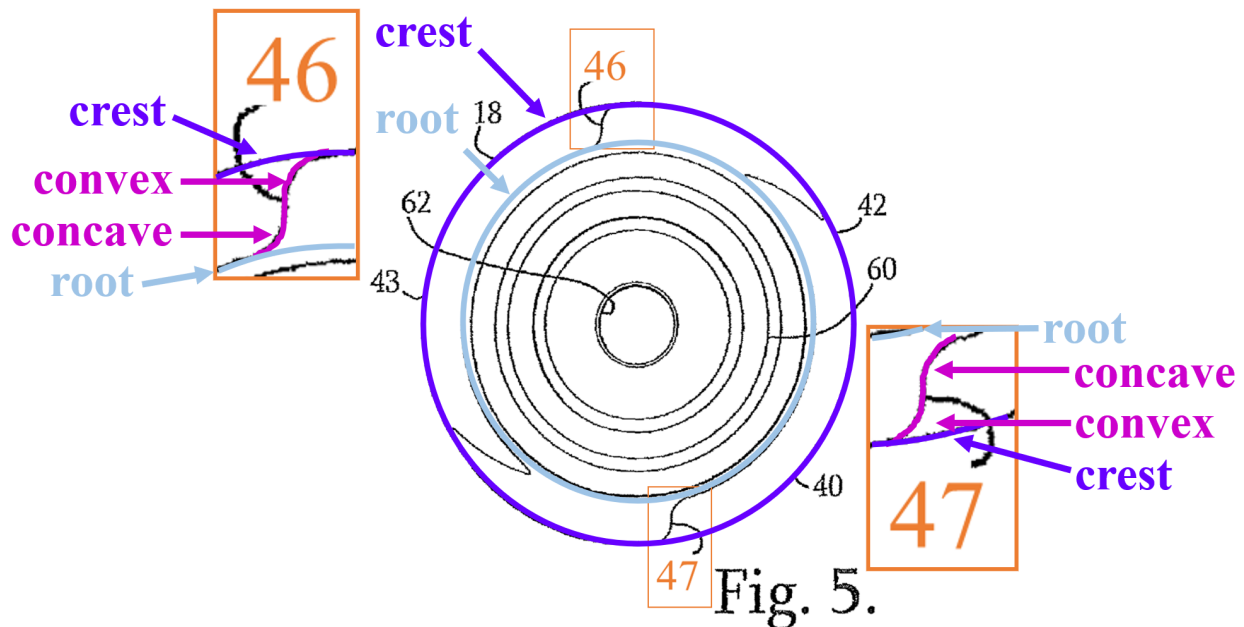
The entirety of the written description on this feature states:

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, 9:38-42. 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.



EX1003, ¶158. 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. *Id.*, ¶159. A “thread” is a ridge in the form of a helix on the external or internal surface of a cylinder. *Id.*, ¶160. The “crest” of the thread is the surface of the thread which joins the flanks of the thread and is farthest from the cylindrical body from which the thread projects. *Id.* The “root” is the surface of a thread which joins the flanks of the adjacent thread forms and is immediately adjacent to the cylindrical body from which the thread projects. *Id.* Therefore, a POSA would have understood that, when the closure top 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.*, ¶161. The approximate location of the **root** and **crest** are illustrated below with reference to Fig. 5.



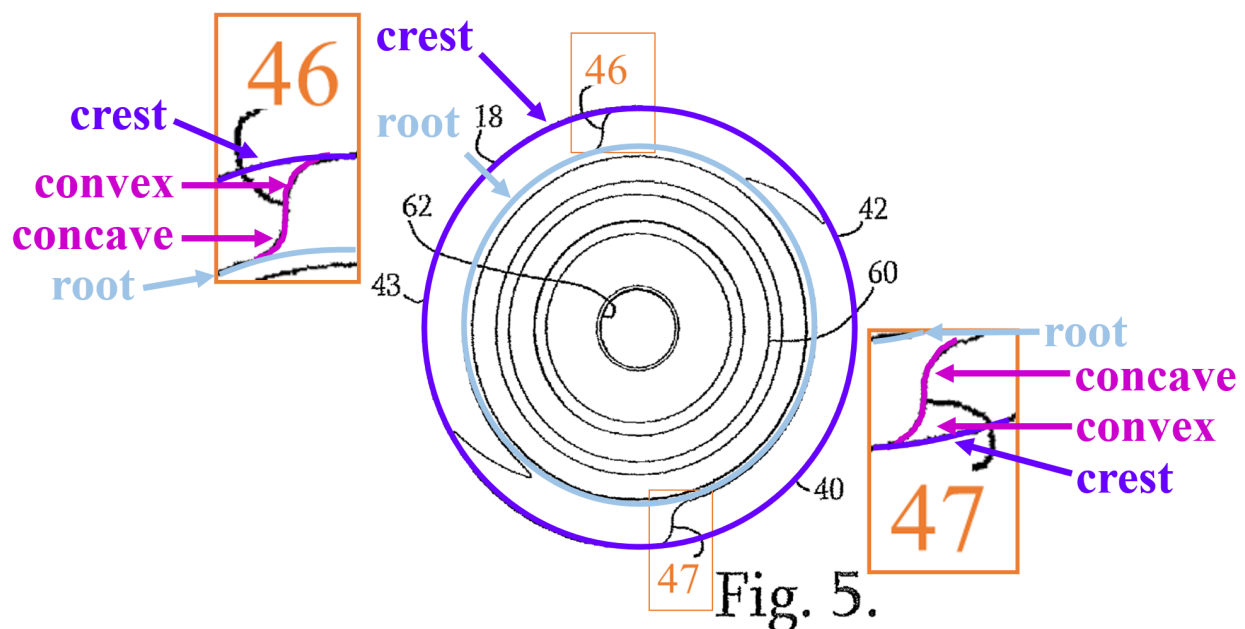
EX1001, Fig. 5; EX1003, ¶161.

4. “the partial concave surface tangentially blends with the partial convex surface” (Claim 2)

The specification never describes or identifies a partial concave surface that tangentially blends with a partial convex surface. Nevertheless, a POSA would have understood this phrase according to its plain meaning. EX1003, ¶162. “Tangent” means a line that touches a curve or curved surface at a point, but if extended does not cross it at that point, and “blend” means to combine or mix so that constituent parts are indistinguishable from one another. *Id.*, ¶163. Together, a POSA would have understood this phrase to describe a concave surface that touches a convex surface at a point such that the two curved surfaces are merged together at that point.

Id.

In the context of the claims, a POSA would have understood this phrase to relate to the “leading face” of the thread form start structures. *Id.*, ¶164. Claim 2 refers to “the partial concave surface” and “the partial convex surface.” “The” indicates an antecedent basis. The antecedent basis for these phrases is provided in Claim 1, which requires a “start structure having a leading face ... the leading face including a partial concave surface adjacent the root and a partial convex surface adjacent the crest.” As Figure 5 shows, these convex and concave surfaces touch each other at a single point near the middle of the leading face and are smoothly blended (i.e., merged) together. EX1003, ¶¶164-65.

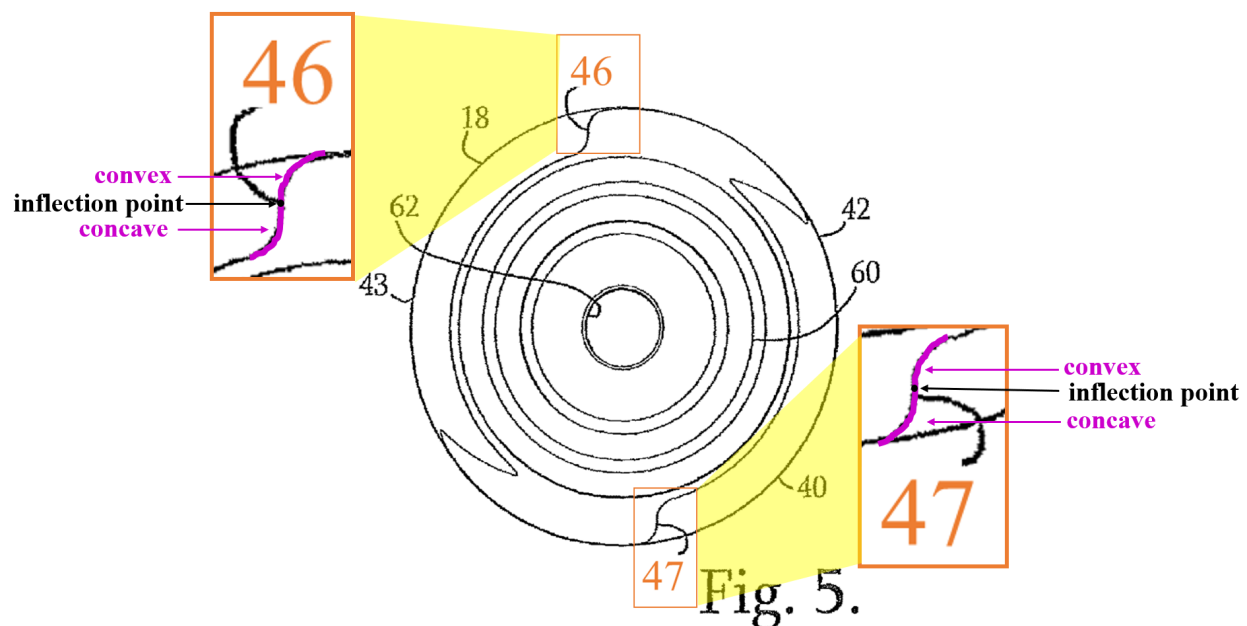


EX1001, Fig. 5.

5. “the [first/second] leading face includes a [first/second] inflection point between the partial concave surface and the

**partial convex surface of the [first/second] leading face”
(Claim 14)**

The specification never identifies an “inflection point” on any leading face of a thread. Nevertheless, a POSA would have understood this phrase according to its plain meaning. EX1003, ¶166. In particular, a POSA would have understood “inflection point” to mean a point of a curve at which a change in the direction of curvature occurs. *Id.*, ¶167. Claim 14 refers to the leading faces of the start structure, as illustrated in reference to Figure 5. In the annotated version of Figure 5 below, the approximate point where the curve changes from convex to concave is identified. A POSA would have understood this transition point to be the inflection point in the disclosed embodiment. *Id.*, ¶168.

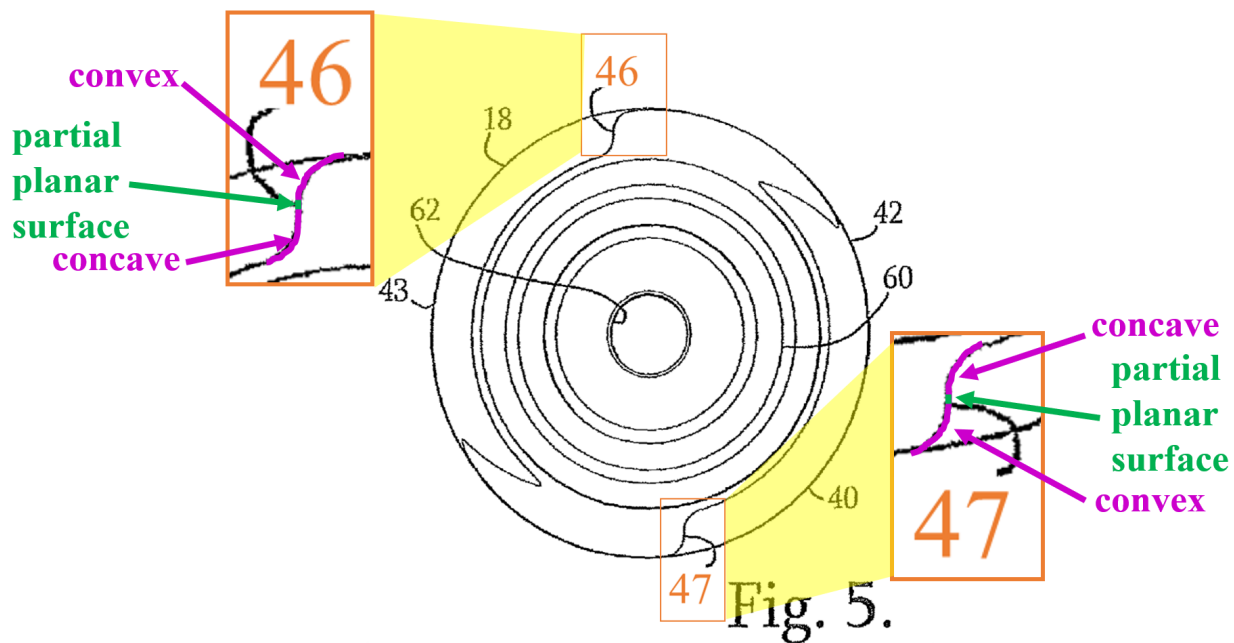


EX1001, Fig. 5.

6. “the leading face of the start structure includes at least a partial planar surface” (Claims 4 and 15)

The specification never identifies a “partial planar surface” that is part of the leading face of a thread. Nevertheless, a POSA would have understood this phrase according to its plain meaning. EX1003, ¶169. “Partial” means relating to a part rather than a whole, and “planar” means flat. *Id.*, ¶170.

Claims 4 and 15 refer to the leading faces of the start structure, as illustrated in reference to Figure 5. In the annotated Figure 5 below, the approximate point where the curve changes from convex to concave is identified as the “partial planar surface.” At this location, the surface of the leading face is approximately flat in all directions. At all other locations along the leading face, the surface is curved in at least one direction. Therefore, POSA would have understood the area around the inflection point to be a partial planar surface. *Id.*, ¶171.



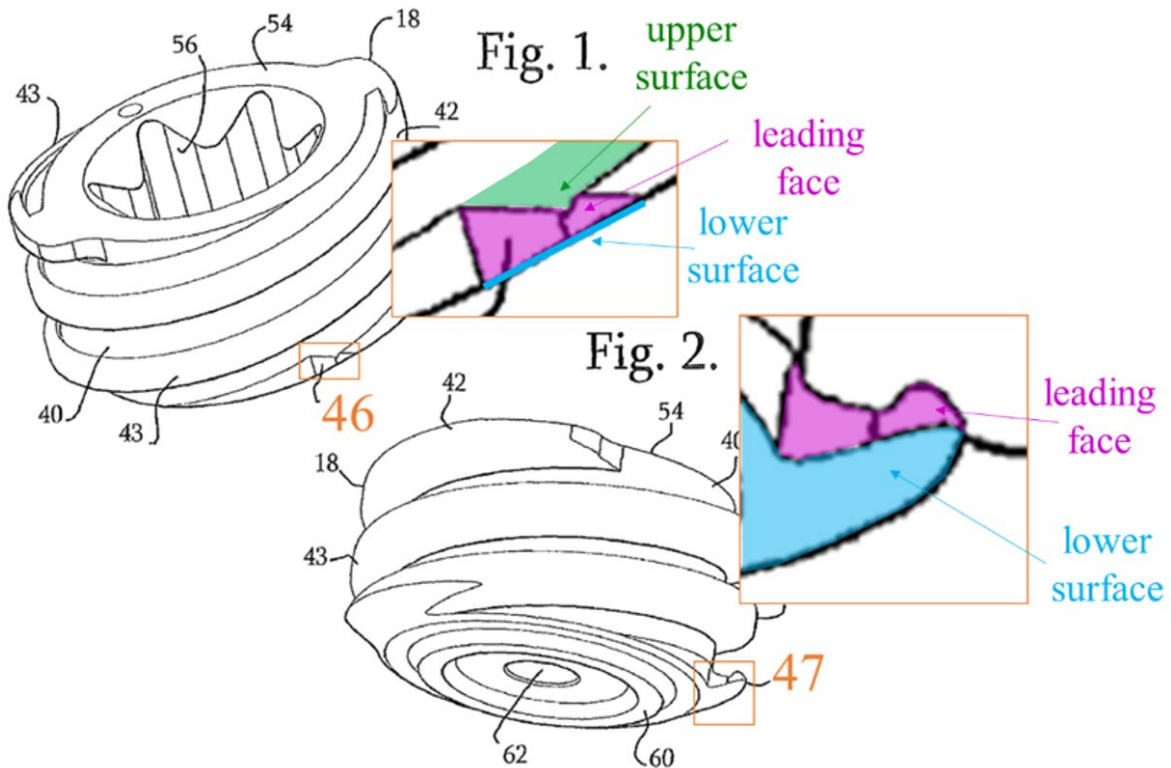
EX1001, Fig. 5.

7. “the lower surface of the start structure includes a bottom beveled surface” (Claim 5) and “the [first/second] lower surface includes a [first/second] bottom beveled surface” (Claim 16)

The specification does not contain any textual description of a bottom-beveled surface of a lower surface of the thread start structure. Nevertheless, a POSA would have understood these phrases according to their plain meaning. EX1003, ¶172. “Beveled” means a line or surface that meets another line or surface with an angle or inclination other than 90 degrees. *Id.*, ¶173.

The claim language identifies the “lower surface” as part of the start structure: “the continuously helically wound thread form having a start structure with an upper surface extending between a root and a crest of the [] thread form, the start structure

having a leading face extending below the upper surface to a lower surface of the start structure” EX1001, Claims 1, 12. This is shown below in annotated and enlarged Figures 1 and 2.



EX1001, Figs. 1, 2. A POSA would have understood that the figures of the '646 Patent are consistent with the plain meaning of this phrase and show the sloped angle of the lower surface of the start structure. EX1003, ¶175. Unlike the normal thread profile, as shown in Fig. 5 below, at 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 and 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). EX1003, ¶175.

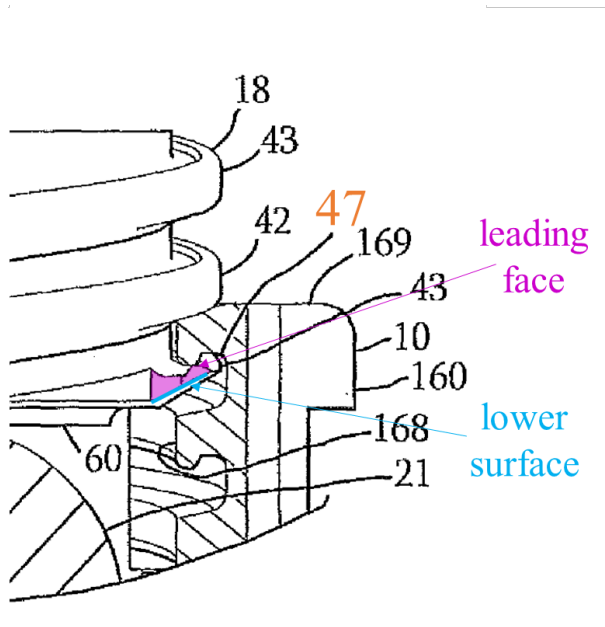


Figure 3

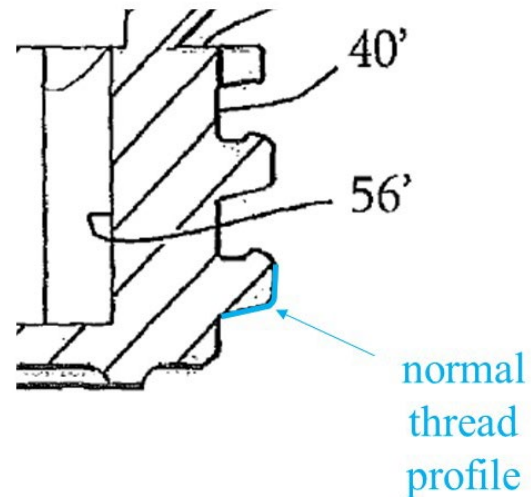
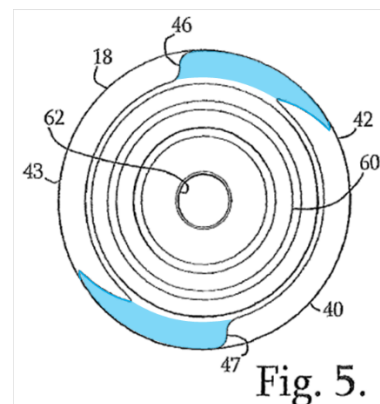
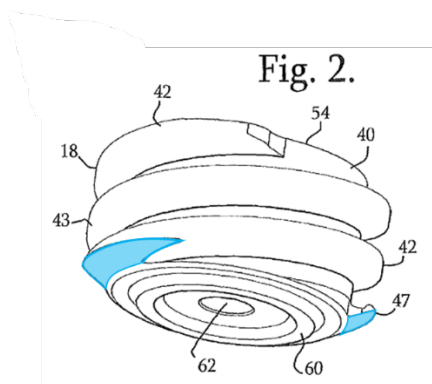


Figure 10

EX1001, Figs. 3 and 5. Figs. 2 and 5 also show the point at which the thread reaches its full thickness, with the less-than-full thickness segment highlighted in blue.

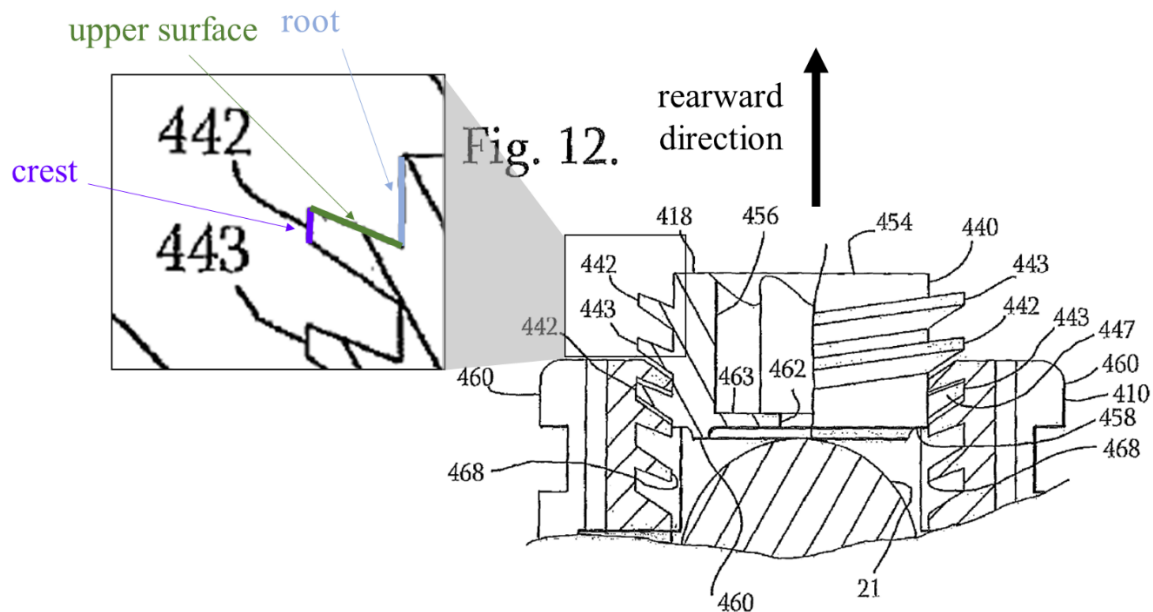


EX1001, Figs. 2, 5.

8. “the upper surface of the continuously helically wound thread form of the threaded plug slopes rearward from the root toward the crest” (Claim 6)

The specification never identifies an “upper surface of the helically wound thread form” or explains what it means for such a surface to “slope[] rearward from the root toward the crest.” Nevertheless, a POSA would have understood this language according to its plain meaning. EX1003, ¶176. “Thread,” “crest,” and “root” would have the same meanings discussed above. *Id.*, ¶177. The “upward surface” is the thread flank extending between the crest and the root located closest to the top of the closure top. *Id.* Because the closure top advances down into the receiver when it is turned, the “rearward” direction is up toward the top of the closure top. *Id.*

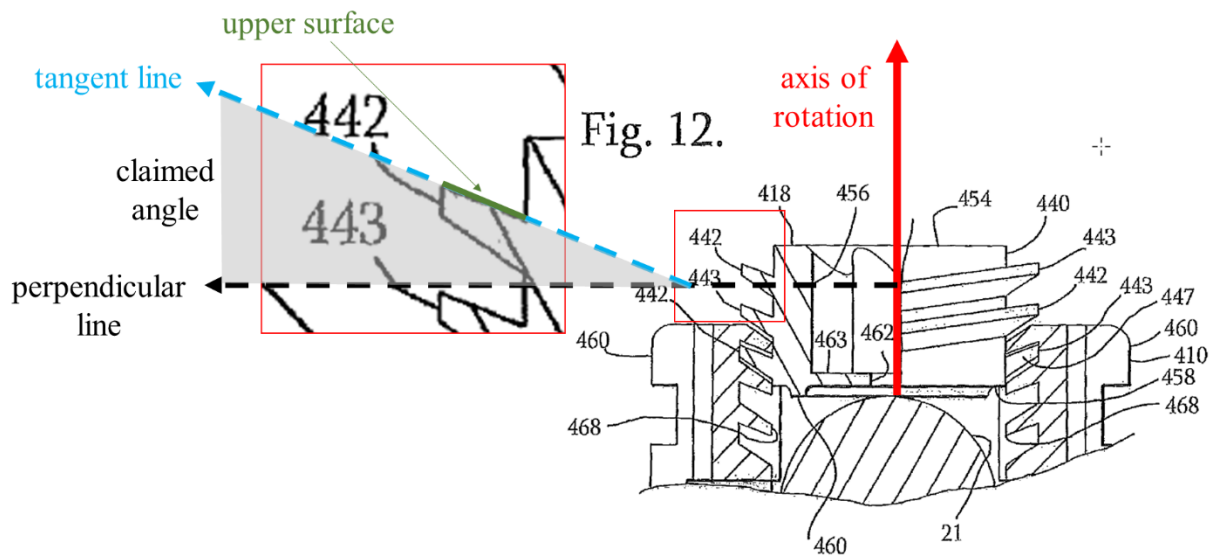
With this understanding of the plain meaning, a POSA would have understood this phrase to describe a reverse angle thread (“RAT”) of the type illustrated in Fig. 12, enlarged and annotated below. *Id.*, ¶178. The upward surface of this RAT “slopes rearward from the root toward the crest” because it is inclined outwardly and upwardly away from the direction that the closure top advances as viewed along the upper surface from the root to the crest.



EX1001, Fig. 12; EX1003, ¶178.

9. “a slope of the upper surface is at an angle greater than five degrees measured between a line drawn perpendicular to the axis of rotation of the plug and a tangent line drawn tangent along the upper surface” (Claim 7)

The specification never identifies the claimed angle. Nevertheless, a POSA would have understood this language according to its plain meaning. EX1003, ¶179. The phrases “upper surface” and “tangent” would have the same meanings discussed above. *Id.*, ¶180. With this, a POSA would have understood this phrase to describe the angle of inclination of the upper surface of a RAT of the type illustrated in Fig. 12, enlarged and annotated below. *Id.*, ¶181.



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

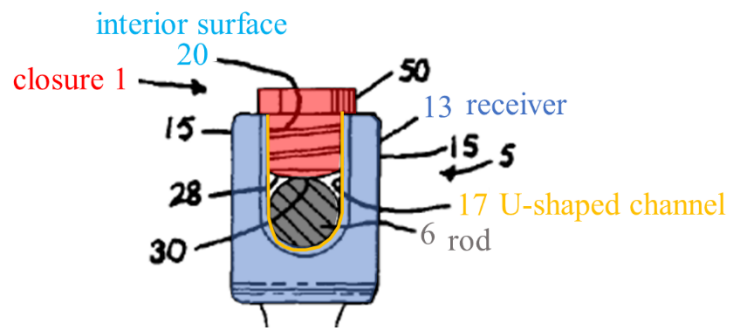
The grounds set forth in Sections VI-XI below, as supported by the Declaration of Dr. Carl McMillin (EX1003), demonstrate that the Challenged Claims are unpatentable.

VI. GROUND 1: CLAIMS 1-2 AND 4-9 ARE UNPATENTABLE OVER THE '477 PUBLICATION.

A. Overview of the '477 Publication

The '477 Publication (EX1005) published on December 1, 2005, and is prior art to the '646 Patent under Section 102(b). As described further below, because the '477 Publication discloses a closure to capture and lock a rod in a spinal implant, it is in the same field of endeavor as, and analogous art to, the '646 Patent. *Compare* EX1005, ¶[0007], *with* EX1001, 1:27-31; *see also* EX1005, ¶¶[0026]-[0029],[0039]-[0041].

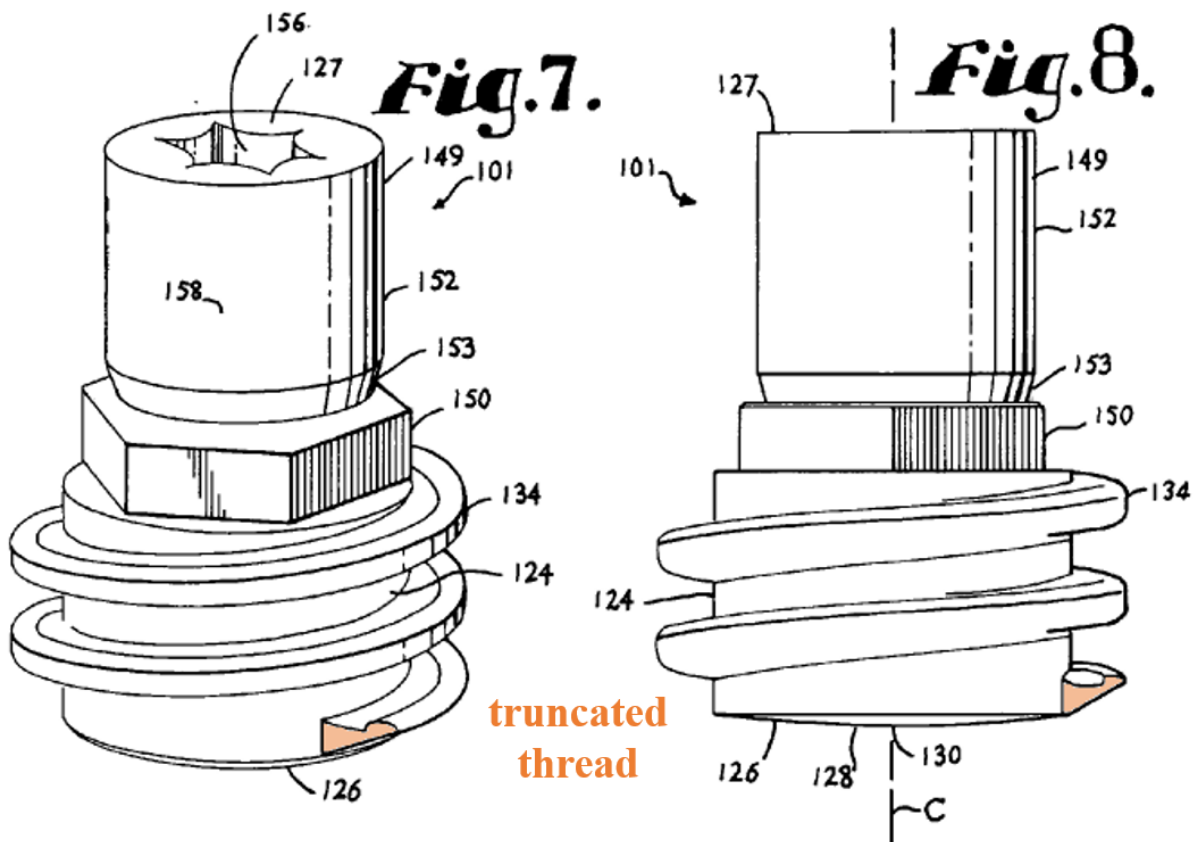
As shown in annotated Figure 6, the '477 Publication discloses a polyaxial screw that includes a receiver 13 with a pair of upstanding arms 15 forming a U-shaped channel 17 for receiving a rod 6. EX1005, ¶¶[0007],[0034]-[0045], Figs. 5-10. The inner surface 20 of each arm has a thread that mates with a similar structure on closure 1 when the closure is rotated. *Id.*, ¶¶[0026],[0030],



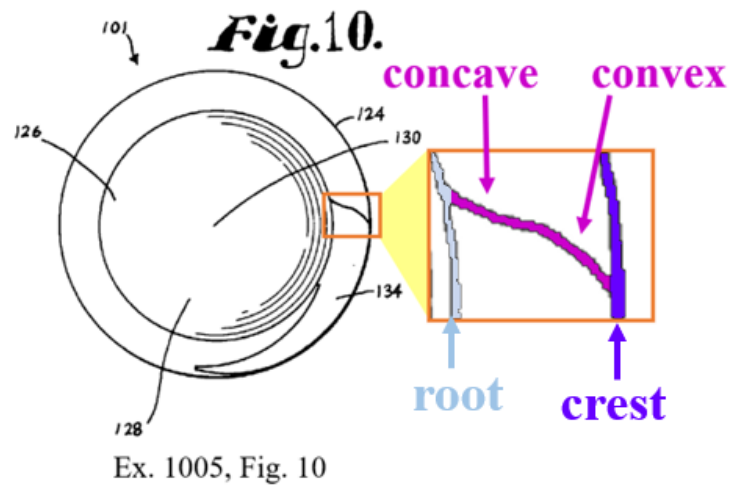
Ex. 1005, Fig. 6

[0039], Fig. 6. The thread could be one of a variety of different types, including a RAT. *Id.*, ¶[0030].

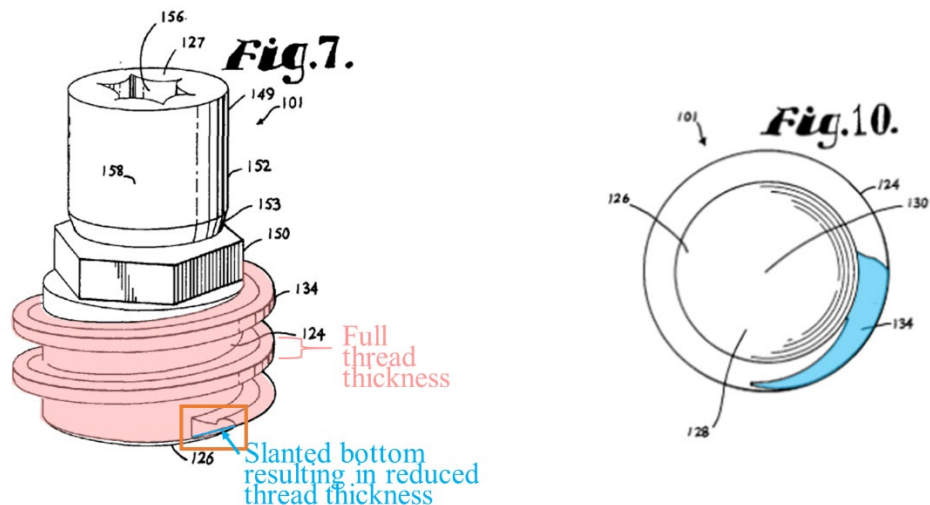
The '477 Publication discloses two embodiments of the closure. *See id.*, ¶[0039]; EX1003, ¶184. The primary difference between the embodiments is the shape of the break-off head. *Id.*, ¶[0033] (hexagonal), ¶[0043] (cylindrical); *compare id.*, Fig. 1, *with id.*, Fig. 7. Focusing on the second embodiment, the '477 Publication discloses a truncated thread start with a curvate leading face. EX1005, Figs. 7, 8; EX1003, ¶186.



The leading face is curvate and formed in an s-curve, with a partial concave surface adjacent the root and a partial convex surface adjacent the crest. EX1005, Fig. 10; EX1003, ¶186.



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; EX1003, ¶186.



The '477 Publication discloses that the bottom surface of its closure may be substantially flat and have a lateral rim. EX1005, ¶[0029] While the lateral rim is

not pictured, a POSA would have understood that the lateral rim projects below the start structure of the threads. EX1003, ¶187.

B. Claim Analysis.

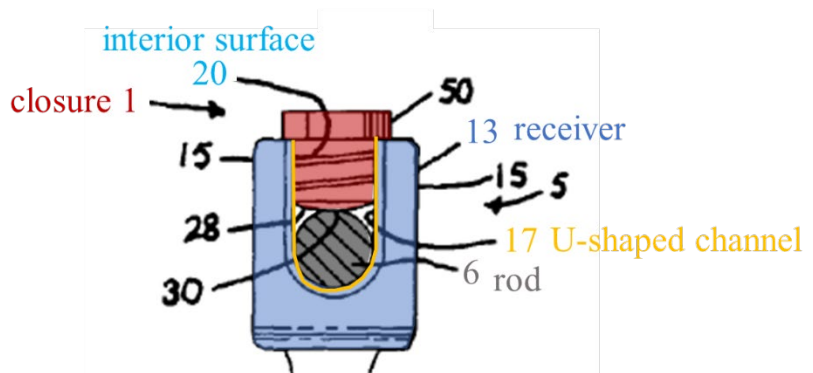
1. Claim 1

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

To the extent the preamble is limiting, the '477 Publication discloses this limitation. EX1003, ¶223. The '477 Publication is titled “Removeable Medical Implant Closure” and discloses “a closure and/or locking member for use in conjunction with medical implants.” EX1005, ¶[0002].

b. **1[A]:** “a receiver having an upper portion with an inner surface at least partially configured as a helically wound thread extending up to a top surface of the receiver, and a channel formed in the upper portion of the receiver and configured to receive a rod; and”

The '477 Publication discloses this limitation. EX1003, ¶¶224-25. The '477 Publication discloses that “receiver 13 has a pair of spaced and generally parallel arms 15 that form an open generally U-shaped channel 17 therebetween that is open at distal ends of the arms 15.” EX1005,



Ex. 1005, Fig. 6

¶¶[0026],[0039]. Further,

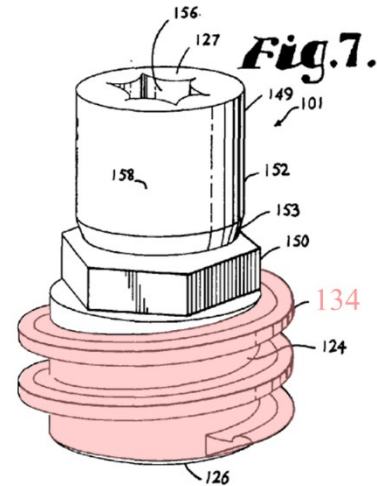
the '477 Publication discloses that the arms of the receiver “each include radially inward or interior surfaces 20 that have a discontinuous guide and advancement structure mateable with cooperating structure on the closure.” *Id.*, ¶¶[0026],[0039], Figs. 5, 6. A POSA would have understood that the interior surfaces of the receiver arms with the guide and advancement structures are located in the upper portion of the receiver, and that the threads on interior surfaces 20 extend to the top surface of the “distal ends of the arms 15,” as that is where those threads mate “with the cooperating structure on the closure.” *See, e.g., id.*, Fig. 6; EX1003, ¶225. A rod 6 is captured in the U-shaped channel. EX1005, ¶¶[0025],[0039].

- c. 1[B]: “a plug being threaded and configured to be positioned within the upper portion, the plug having an axis of rotation,”

The '477 Publication discloses this limitation. EX1003, ¶226. 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 '477 Publication states that “closures are externally threaded and are screwed into mating threads on the interior surfaces of the implant arms.” *Id.*, ¶¶[0005],[0041]. The closure is positioned within the upper portion of the receiver. *Id.*, Fig. 6; EX1003, ¶226. The '477 Publication also discloses “closure 101 ... has ... a central axis of rotation C.” EX1003, ¶[0040].

- d. 1[B1]: “a continuously helically wound thread form, and”

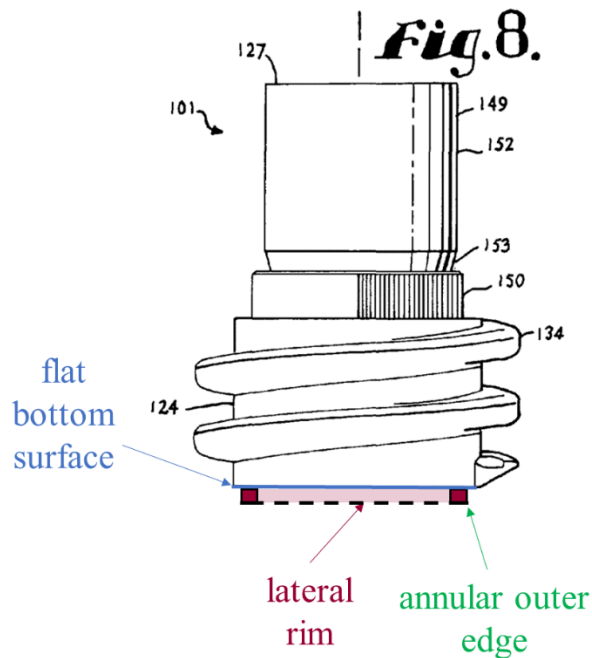
The '477 Publication discloses this limitation.
EX1003, ¶227. The '477 Publication discloses that “[l]ocated on the cylindrical closure body 124 is a guide and advancement structure 134 ...” EX1005, ¶[0041]. The guide and advancement structure is a continuously helically wound thread, as shown for example in EX1005, Figs. 7-8.



- e. 1[B2]: “a substantially flat bottom surface with an annular outer edge, the substantially flat bottom surface configured to engage the rod,”

The '477 Publication discloses this limitation under either construction.
EX1003, ¶¶228-32. The '477 Publication discloses that “the bottom surface may be flat and may have a central point and a lateral rim.” EX1005, ¶[0040]. A POSA would have understood the '477 Publication’s disclosure of a “lateral rim” as a downwardly projecting rim that is near the periphery of the closure top bottom and inset from the outer surface of the closure’s cylindrical body. EX1003, ¶¶228-29; *see also* EX1007, ¶¶[0043], [0049], Fig. 6. Figure 8, below, has been modified to illustrate this disclosure of a lateral rim to the flat bottom surface of the closure top.

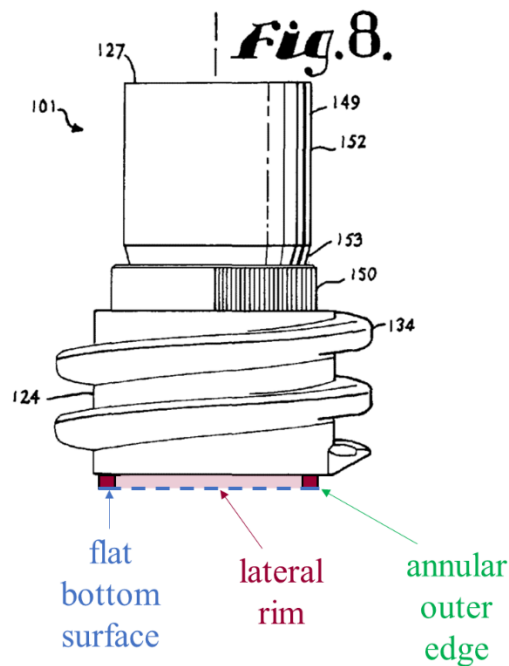
EX1003, ¶229. Under the preferred construction, the lateral rim is the claimed annular outer edge. EX1005, Fig. 8; EX1003, ¶¶229-30.



The '477 Publication discloses that this bottom surface with lateral rim is “configured to engage the rod.” *See, e.g.*, EX1005, ¶¶[0007],[0040], Fig. 6.

Under the alternative construction, the '477 Publication also discloses and/or renders this limitation obvious. Because it was known that there were only two principal design options for the bottom surfaces of conventional lateral rims—flat or pointed—a POSA would have understood the '477 Publication's “lateral rim” to include either option, and either would have been obvious to try. EX1003, ¶¶231-32. Moreover, a POSA would have understood that a lateral rim that was inset from the closure's outer surface would have been advantageous for guiding the closure

top and facilitating thread alignment. EX1003, ¶229. As illustrated below in Fig. 8, the known option of a lateral rim with a flat bottom surface includes an annular outer edge at the intersection of the lowermost surface and the side surface of the rim.

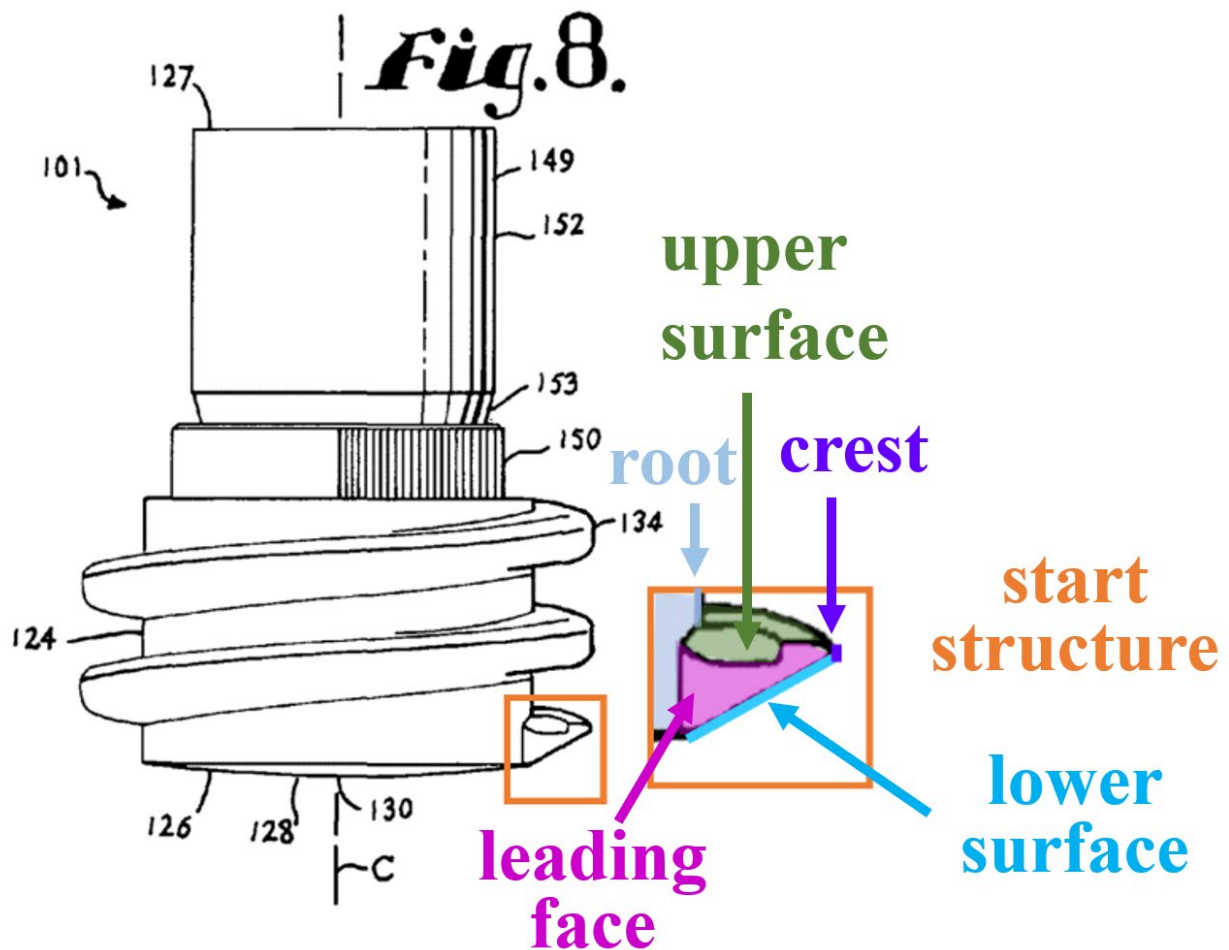


EX1005, Fig. 8; EX1003, ¶232.

- f. **1[B3]:** “the continuously helically wound thread form having a start structure with an upper surface extending between a root and a crest of the continuously helically wound thread form, the start structure having a leading face extending below the upper surface to a lower surface of the start structure, the leading face including a partial concave surface adjacent the root and a partial convex surface adjacent the crest,”

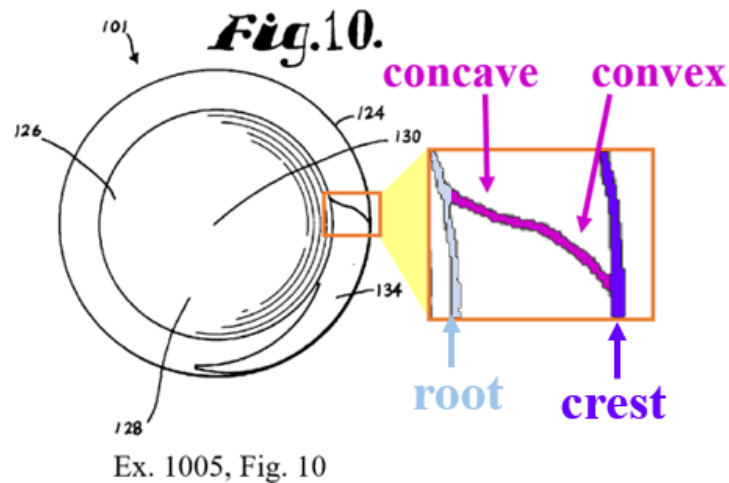
The '477 Publication discloses this limitation. EX1003, ¶¶233-34. As discussed above, the '477 Publication discloses a helically wound thread form on the closure top. That thread, like every thread, has a root and a crest. *Id.*, ¶233; see

also EX1005, ¶¶[0031],[0041]. The '477 Publication discloses a start structure on the closure thread with an upper surface extending between a root and a crest of the continuously helically wound thread form, the start structure having a leading face extending below the upper surface to a lower surface of the start structure. EX1005, Figs. 7, 8; EX1003, ¶233.



As shown in Figure 10 below, the leading face of the start structure is formed in an s-curve, with both concave and convex curves. In particular, the '477

Publication discloses a partial concave surface adjacent the root and a partial convex surface adjacent the crest. EX1005, Fig. 10; EX1003, ¶234.



- g. 1[B4]: “the partial concave and partial convex surfaces each defined by a radius of curvature that is substantially equal with respect to each other,”

The '477 Publication discloses this limitation. EX1003, ¶235. Annotated and enlarged Figure 10 shows that the partial concave surface adjacent the root and the partial convex surface adjacent the crest, *see supra* §VI.B.1.f, are each defined by a radius of curvature that is substantially equal with respect to each other.

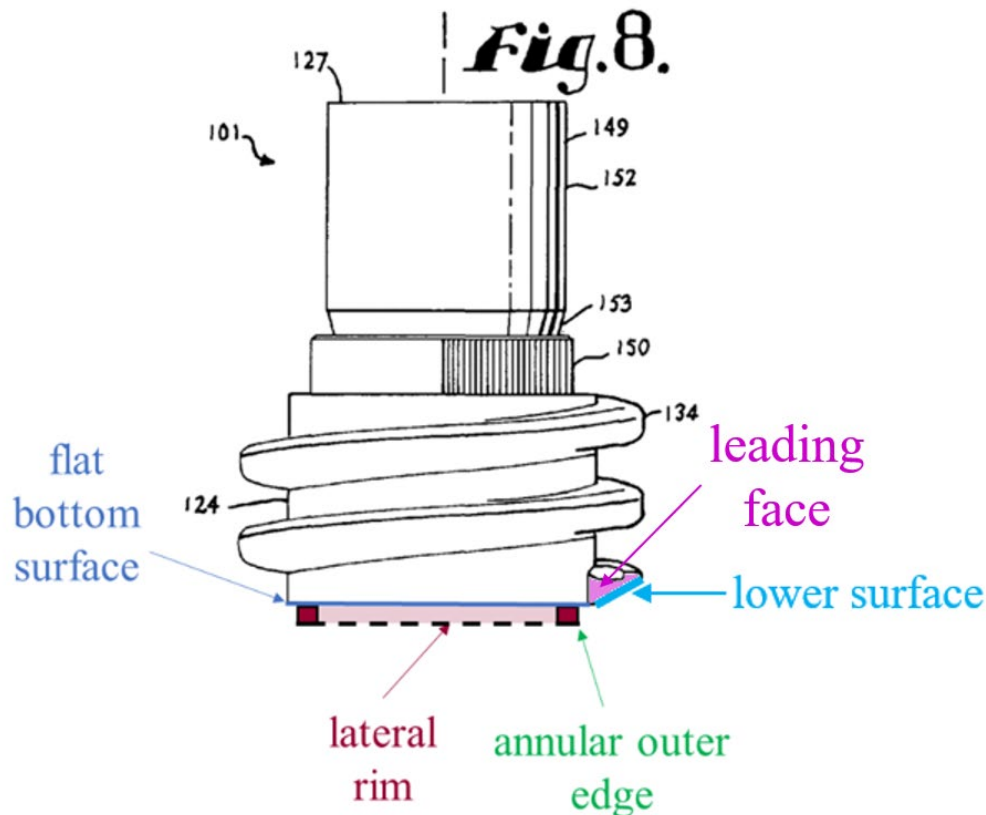
Fig. 10.

concave convex

EX1003, ¶235.

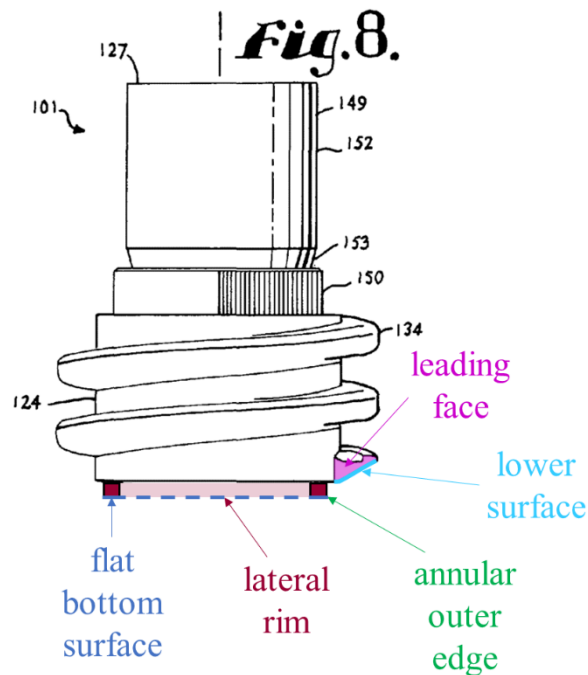
- h. 1[B5]: “the lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof.”

The '477 Publication anticipates or renders obvious this limitation under either construction. EX1003, ¶¶236-39. The '477 Publication discloses that “the bottom surface may be flat and may have a central point and a lateral rim.” EX1005, ¶[0040]. The lateral rim constitutes an annular outer edge under the preferred construction. *Supra* §VI.B.1.e; EX1003, ¶236. In annotated Figure 8, the disclosed lateral rim has been illustrated on the flat bottom surface of the closure top. EX1005, Fig. 8. EX1003, ¶236



As seen, the lateral rim (i.e., the annular outer edge) is below, spaced apart from, and not connected to the lower surface of the leading face, as would have been apparent to a POSA. EX1003, ¶236.

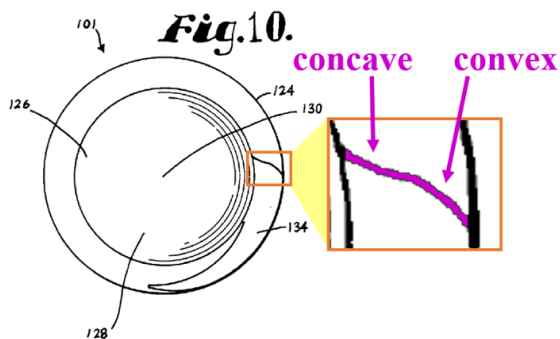
Under the alternative construction where the lowermost surface of the lateral rim is the disclosed and/or obvious flat bottom surface of the rim, *supra* §VI.B.1.e, the annular outer edge remains below, spaced apart from, and not connected to, the lower surface of the leading face of the start structure. EX1003, ¶¶237-38.



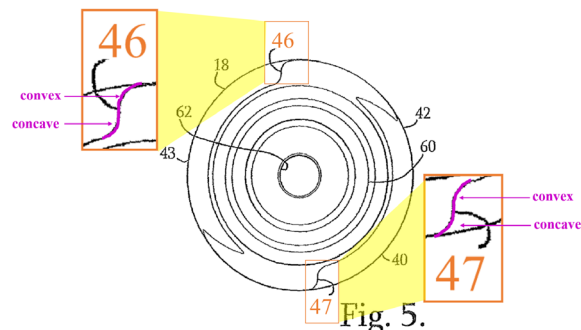
EX1005, Fig. 8. Accordingly, the '477 Publication anticipates or renders obvious Claim 1. EX1003, ¶239.

2. Claim 2

Claim 2 depends from Claim 1 and further recites: [B6] “wherein the partial concave surface tangentially blends with the partial convex surface.” The ’477 Publication discloses this limitation. EX1003, ¶¶240-41. As shown annotated Figure 10 below compared to Figure 5 of the ’646 Patent, the ’477 Publication discloses that the convex and concave curves of the leading face touch each other at a single point and are smoothly merged together at that point. Therefore, a POSA would have recognized that these two curves are tangentially blended. *Id.*, ¶240.



'477 Publication



'646 Patent

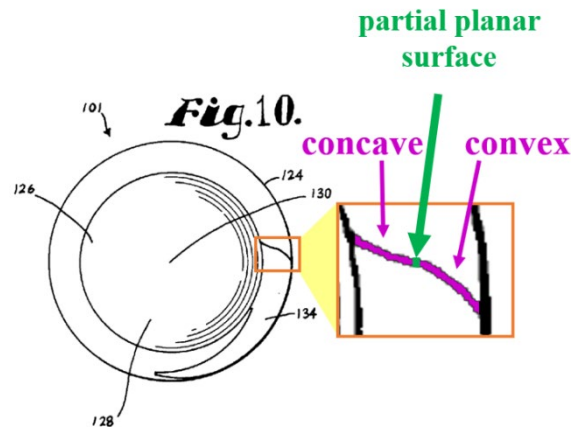
EX1005, Fig. 10; EX1001, Fig. 5. Accordingly, the '477 Publication anticipates or renders obvious Claim 2. EX1003, ¶241.

3. Claim 4

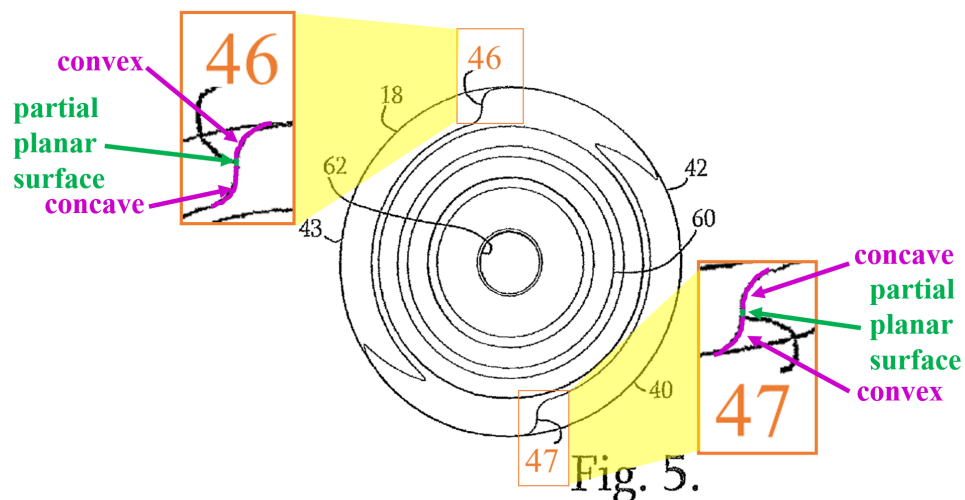
Claim 4 depends from Claim 1 and further recites: [B8] “wherein the leading face of the start structure includes at least a partial planar surface.” The '477 Publication discloses this limitation. EX1003, ¶¶242-43. As shown in annotated Figure 10 below compared to Figure 5 of the '646 Patent, the '477 Publication

discloses a leading face that includes a partial planar surface, at least at the point of inflection between the partial concave and convex surfaces. *See supra* §V.B.6; EX1003, ¶242.

'477 Publication



'646 Patent

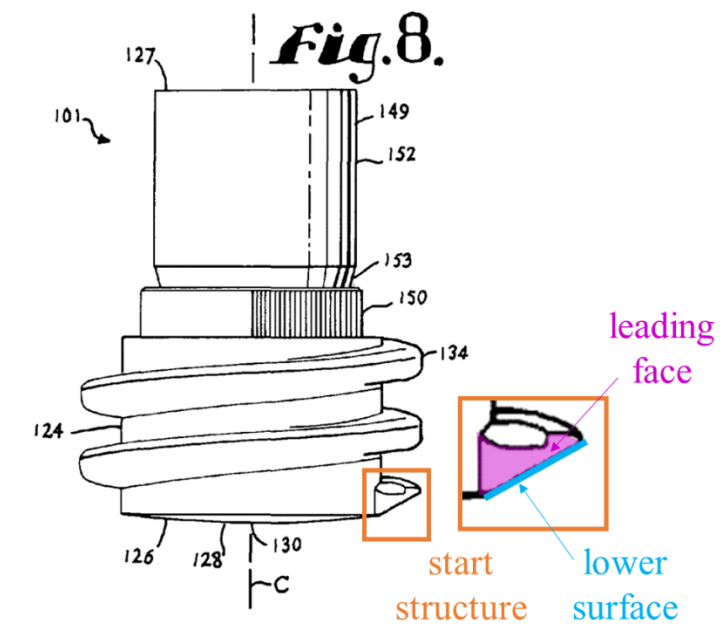


EX1005, Fig. 10; EX1001, Fig. 5. A POSA would have recognized that the convergence of the concave and convex curves at this portion of the leading face results in a surface without any substantial curvature and this that is approximately flat in all directions. EX1003, ¶242. Moreover, in manufacturing a truncated thread

cut, it would have been obvious to a POSA to use any tool path to transition from concave to convex, including paths that transition immediately and paths that include an elongated straight segment. *Id.* Accordingly, the '477 Publication anticipates or renders obvious Claim 4. *Id.*, ¶243.

4. Claim 5

Claim 5 depends from Claim 1 and further recites: [B9] “wherein the lower surface of the start structure includes a bottom beveled surface.” The '477 Publication discloses this limitation. EX1003, ¶¶244-45. As shown in annotated Figure 8 below, the lower surface of the start structure is sloped, rather than squared at 90 degrees. *See supra* §V.B.7; EX1003, ¶244.



EX1005, Fig. 8. Accordingly, the '477 Publication anticipates or renders obvious Claim 5. EX1003, ¶245.

5. Claim 6

Claim 6 depends from Claim 1 and further recites: **[B10]** “wherein the upper surface of the continuously helically wound thread form of the threaded plug slopes rearward from the root towards the crest.” The ’477 Publication discloses this limitation. EX1003, ¶¶246-47. A POSA would have understood this claim to refer to a RAT. *See supra* §V.B.8. The ’477 Publication discloses that the thread form on either preferred embodiment can be a RAT. EX1005, ¶[0041]. The ’477 Publication further discloses that “[i]n a reverse angle thread, the trailing surface 44 from the root 38 to the crest 40 extends at an angle rearwardly from a perpendicular line relative to the axis B. Typically, the trailing surface 44 is at an angle between 1 and 20 degrees relative to such a perpendicular.” *Id.*, ¶[0031]. Because trailing surface 44 is part of a RAT, a POSA would have understood that this surface slopes rearwardly (i.e., outwardly and upwardly) from the root toward the crest. EX1003, ¶246. Accordingly, the ’477 Publication anticipates or renders obvious Claim 6. *Id.*, ¶247.

6. Claim 7

Claim 7 depends from Claims 1 and 6 and further recites: **[B11]** “wherein a slope of the upper surface is at an angle greater than five degrees measured between a line drawn perpendicular to the axis of rotation of the plug and a tangent line drawn tangent along the upper surface.” The ’477 Publication discloses this limitation.

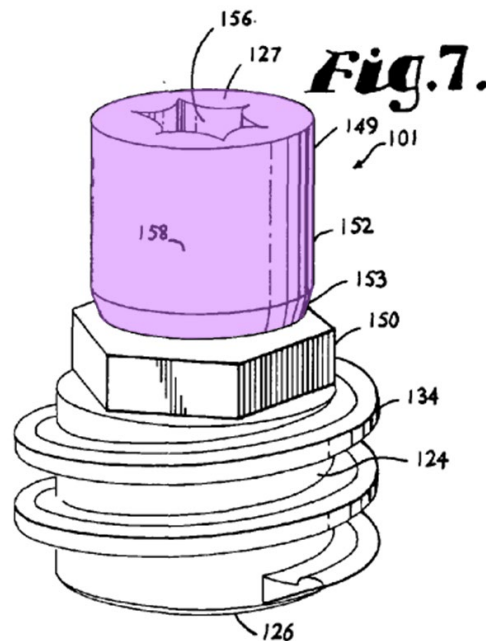
EX1003, ¶¶248-49. As discussed above, the '477 Publication discloses a RAT with a trailing surface “between 1 and 20 degrees,” which includes numerous angles greater than five degrees. *Id.*, ¶248. *See supra* §VI.B.9. This anticipates and/or renders obvious this claim limitation. *ModernaTx, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1352, 1364 (Fed. Cir. 2021) (range claims are anticipated if the prior art discloses any point within the claimed range); *UCB, Inc. v. Actavis Lab 'ys UT, Inc.*, 65 F.4th 679, 689 (Fed. Cir. 2023) (“A presumption of obviousness applies ‘[w]here a claimed range overlaps with a range disclosed in the prior art.’”) (quoting *Ormco Cop. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006)). A POSA would further understand the description of the trailing surface of a RAT as being between 1 and 20 degrees to describe the slope of the upper surface measured between a line drawn perpendicular to the axis of rotation of the plug and a tangent line drawn tangent along the upper surface. EX1003, ¶248.

Accordingly, the '477 Publication anticipates or renders obvious Claim 7. *Id.*, ¶249.

7. Claim 8

Claim 8 depends from Claim 1 and further recites: **[B12]** “wherein the plug is a breakoff plug.” The '477 Publication discloses this limitation. EX1003, ¶¶250-51. The '477 Publication discloses that the closure may include a break-off portion

designed to break away from the closure “subsequent to a predetermined torque being applied.” EX1006, ¶[0042], Fig. 7, 8.

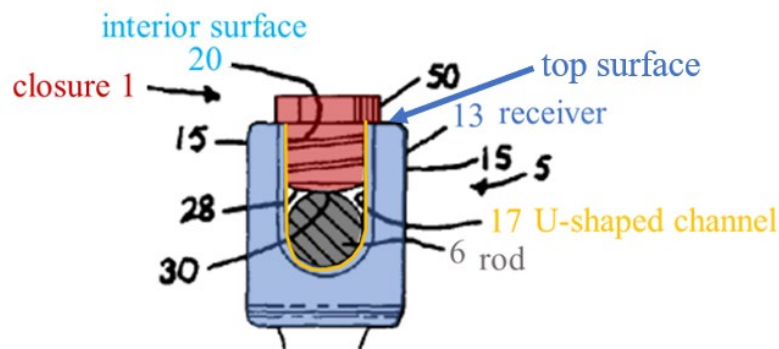


Accordingly, the 477 Publication anticipates or renders obvious Claim 8.
EX1003, ¶251.

8. Claim 9

Claim 9 depends from Claim 1 and further recites: [A1] “wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm.” For the reasons stated above, the ’477 Publication discloses this limitation. *See supra* §VI.B.1.b; EX1003, ¶¶252-54. As shown in

annotated Figure 6 below, the top surface of the receiver is formed on the arms of the receiver. EX1005, Fig. 6. Moreover, “the arms 15 each ... have a discontinuous guide and advancement structure” (which comprises a helically wound thread) on interior surfaces 20, which mate with the threads of the closure top. *Id.*, ¶[0026]. Given that the closure top sits in the top half of the receiver, a POSA would have understood that the upper portion of the receiver includes the requisite arms spaced apart by the u-shaped channel 17. EX1003, ¶253.



Ex. 1005, Fig. 6

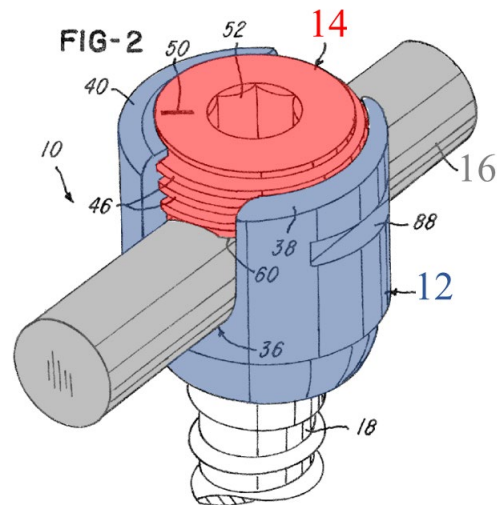
Accordingly, the '477 Publication anticipates or renders obvious Claim 9. *Id.*,
¶254.

VII. GROUND 2: CLAIMS 1-2 AND 4-9 ARE UNPATENTABLE OVER THE '477 PUBLICATION IN VIEW OF KIRSCHMAN.

A. Overview of Kirschman

Kirschman (EX1007) was filed on December 18, 2009, and published on June 23, 2011, and is prior art to the '646 Patent under Section 102(a) and (e). As described further below, because Kirschman discloses a polyaxial pedicle screw that uses a closure to capture and lock a rod in a spinal implant, Kirschman is in the same field of endeavor as, and analogous art to, the '646 Patent. *Compare* EX1007, ¶[0034], Fig. 2 *with* EX1001, 1:27-31.

Kirschman discloses various improvements to the prior art spinal bone screw with “three main components: a screw shaft, a polyaxial tulip head or receiver incorporating a female thread, and a locking cap incorporating a male thread. The purpose of the threaded locking cap is to affix a spinal stabilizing element, typically a cylindrical rod, to the screw assembly.” EX1007, ¶[0004], Fig. 2. Kirschman discloses several “locking aids” that can be optionally used in this context to provide “improved guidance, tactile or visual feedback or enhanced fixation and locking of a cap in a receiver of the implant.” *Id.*,



Abstract, ¶[0002]. The three locking aids are (1) an unthreaded surface between the closure-top threading and the bottom of the closure top to facilitate alignment, *id.*, ¶¶[0043], [0049]; (2) a flat bottom surface, optionally with a ring for enhanced engagement with the rod, *id.* ¶¶[0044], [0045], [0047]; and (3) a “blunt-tip thread” for prevention of cross-threading, *id.*, ¶[0008].

B. Motivation to Combine the ’477 Publication with Kirschman.

It would have been obvious to a POSA to combine the teachings of the ’477 Publication with a flat closure bottom surface having a downward projecting ring and unthreaded surface between the thread(s) and the closure bottom surface, as described in Kirschman before the priority date of the ’646 Patent. EX1003, ¶¶207-12, 255-59.

The ’477 Publication and Kirschman are in the exact same field as each other and the ’646 Patent. *Supra* §§VI.A, VII.A; EX1003, ¶¶208-09. The ’477 Publication teaches closures that could be used with any conventional bone screw receiver, EX1005, ¶[0007], and that “it is foreseen” that its closures may be modified to include a bottom surface that is “flat” and that includes a “lateral rim,” *id.*, ¶¶[0029], [0040]. Because the ’477 Publication does not depict a lateral rim, a POSA would naturally have looked to Kirschman, which discloses a lateral rim on the closure bottom. EX1003, ¶208. Kirschman discloses an improved polyaxial screw assembly with locking aids, EX1007, ¶¶[0002], [0012]-[0014], and that it

would be advantageous to design closures with (1) an unthreaded segment (i.e., Kirschman's frusto-conical surface) between the closure's thread start to facilitate alignment of the closure and the receiver and (2) a bottom of the closure and a downwardly projecting ring on the closure's bottom to enhance fixation between the closure and the rod, *id.*, ¶¶[0043], [0045], [0047], [0049]. EX1003, ¶210.

Based on the express teachings of the references and their complimentary disclosures, a POSA would have been motivated to combine the closure of the '477 Publication and the closure of Kirschman. EX1003, ¶211. A POSA implementing the combination of the closure of the '477 Publication and the closure of Kirschman would have been motivated to retain the various thread types discussed in the '477 Publication and add the closure locking aids disclosed by Kirschman, including Kirschman's unthreaded segment between thread starts and closure bottom and flat bottom surface with a lateral rim. *Id.* A POSA would have expected success with this combination because the use of a flat unthreaded surface to improve alignment and the use of a flat bottom with a projecting rim (and flat bottom surface) to engage the rod for better fixation result in a combination of familiar elements using known methods to yield predictable results. *Id.*, ¶¶202, 212.

C. Claim Analysis.

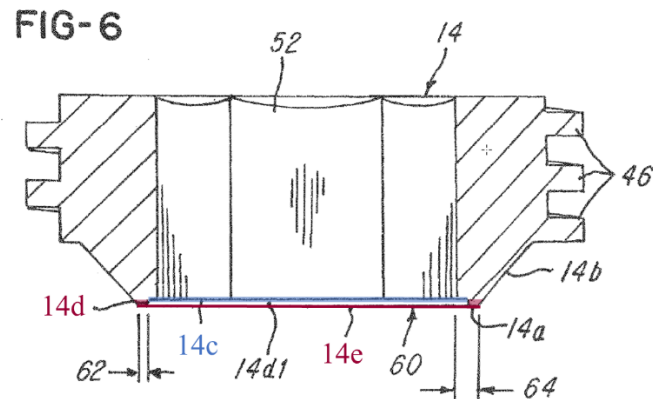
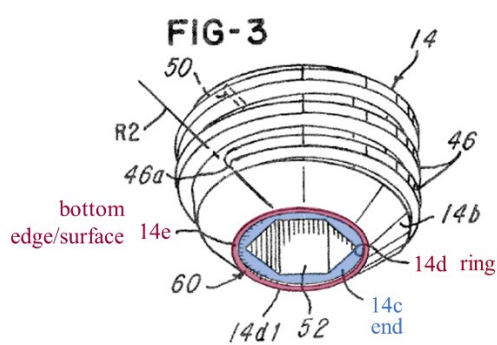
As set forth above, the '477 Publication already anticipates or renders obvious every limitation of Claims 1-2 and 4-9. The addition of Kirschman further reinforces

the obviousness of certain limitations discussed below and further enhances the motivation of POSA to use these features when designing a closure top. EX1003, ¶¶255-59,

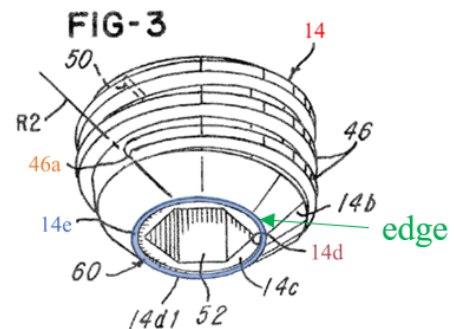
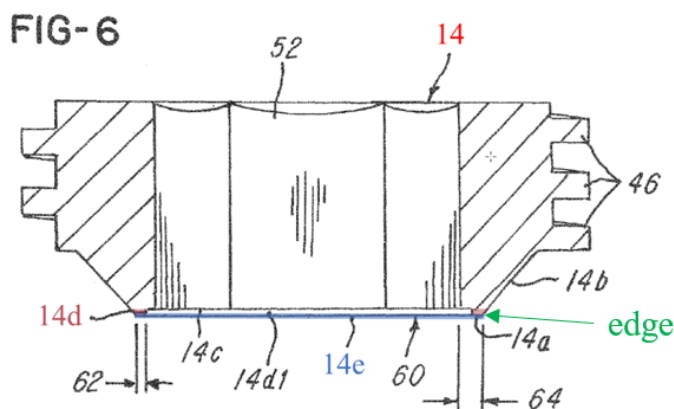
1. Claim 1

- a. 1[B2]: “a substantially flat bottom surface with an annular outer edge, the substantially flat bottom surface configured to engage the rod”

As discussed above, the '477 Publication discloses or renders obvious this limitation under either construction. *See supra* §VI.B.1.e. If this limitation requires a lateral rim positioned near the periphery of the closure and the '477 Publication is insufficient to anticipate or render obvious this limitation, then it would have been obvious to a POSA to modify the '477 Publication's closure to add such a lateral rim, as disclosed by Kirschman. EX1003, ¶¶260-66. Kirschman discloses a flat bottom “end 14c” that includes “deformable ring 14d that is monolithically and integrally formed with the cap 14.” EX1007, ¶¶[0044], [0045], Figs. 3, 6. Kirschman discloses that in “one illustrative embodiment, the monolithic ring comprises a width of between 0.120-0.280 inches.” *Id.*, ¶[0045]. This width is “bottom edge or surface 14e,” which is a ring-shaped rim, as shown in Figures 3 and 6 below, “[that] engages the rod 16.” *Id.*

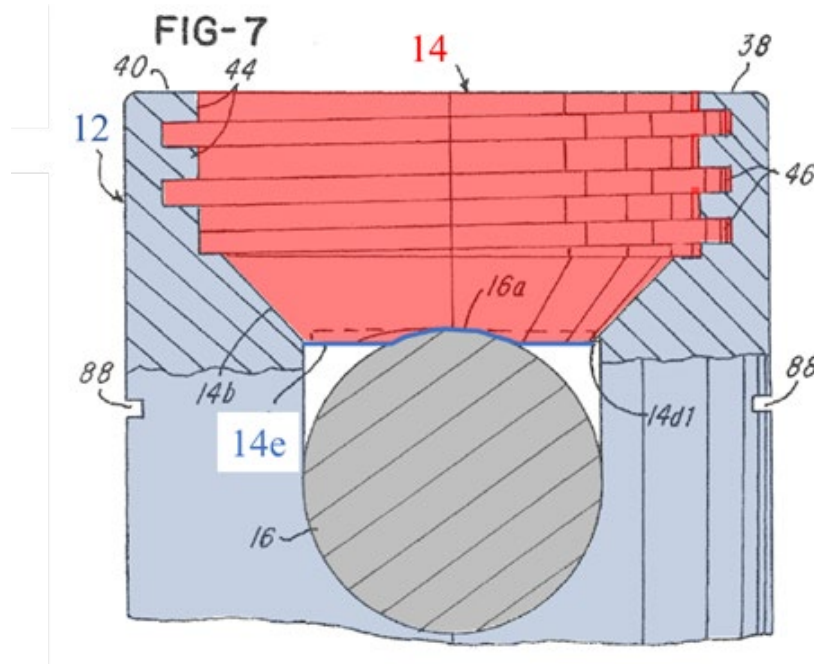


Under Petitioners’ preferred construction, end 14c is the “substantially flat bottom surface” and the ring 14d is the “annular outer edge.” EX1003, ¶261. Under the alternative construction, the bottom surface 14e of the ring 14d is the “substantially flat bottom surface” and the line where this surface meets surface 14b is the annular outer edge, because it is a ring-shaped line where the two planar surfaces join, as shown below. EX1007, Figs. 3, 6; *see also* EX1003, ¶¶262-63.



Under either construction, engagement between rim and rod “provides an enhanced fixation or even a cold-weld between the cap 14 and the rod 16 when the

cap 14 is received on the receiver 12,” as shown in Figure 7 below. EX1007, ¶[0047], Fig. 7; EX1003, ¶264.

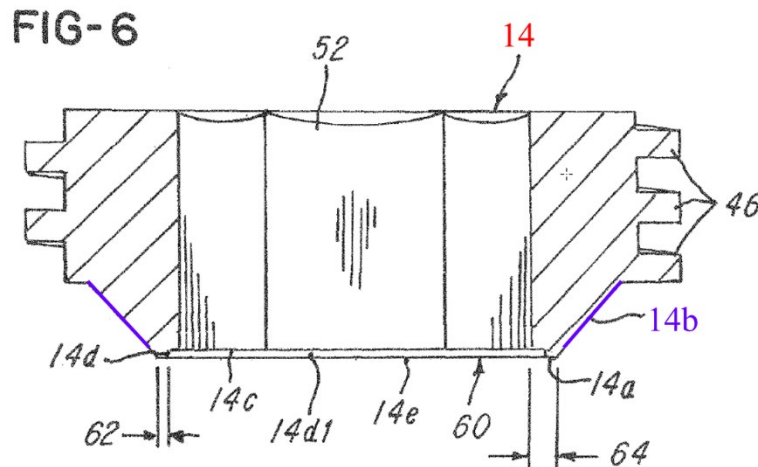


As explained above, a POSA would have been motivated by the teachings of Kirschman to include this feature in implementing the closure of the '477 Publication. *Supra* §VII.B; EX1003, ¶265. Moreover, a POSA would have been motivated to modify the '477 Publication's closure to add the lateral rim and flat closure bottom disclosed by Kirschman at least because (1) it would have been nothing more than the simple substitution of one known element (such as the domed closure bottom in the '477 Publication) for another (a lateral rim and flat closure bottom as disclosed by Kirschman) to obtain a predictable result (securely locking a rod); (2) it would have been the mere application of a known technique (use of a lateral rim and flat closure bottom as disclosed by Kirschman) to a known device

(the closure top of the '477 Publication) to yield a predictable result (securely locking a rod); and (3) there was a known design need for a closure to securely lock a rod and a finite number of identified, predictable solutions (a flat closure bottom, a domed closure bottom, a central point on the closure bottom, and a lateral rim with a flat closure bottom) that were known to a POSA and within their technical grasp. EX1003, ¶266. Therefore, the '477 Publication in view of Kirschman discloses this limitation under any construction. *Id.*

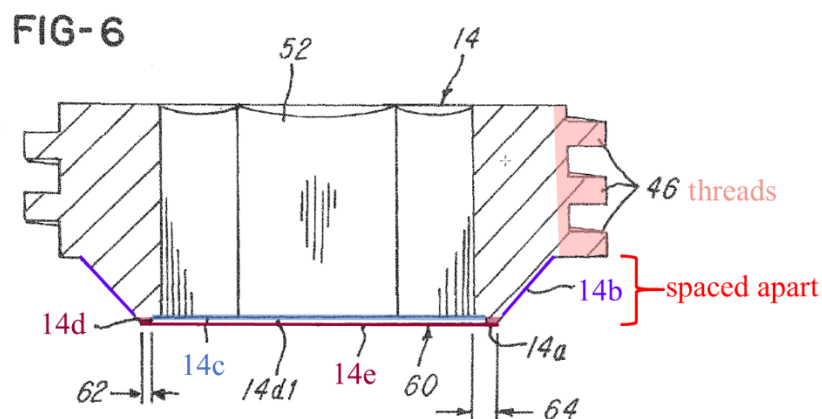
- b. **1[B5]:** “the lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof.”

The '477 Publication discloses or renders obvious this limitation under either construction. *Supra* §VI.B.1.h. If the '477 Publication is insufficient to anticipate or render obvious this limitation, then it would have been obvious to a POSA to modify the '477 Publication's closure to add this limitation in view of Kirschman. EX1003, ¶¶267-71. Kirschman reinforces the teachings of the '477 Publication by disclosing a closure top with an unthreaded surface between the thread start and the annular outer edge (under either construction). *Id.*, ¶¶255-57. Kirschman discloses a frusto-conical surface (purple) below the closure top threads and above the bottom of the closure top. EX1007, ¶¶[0043], [0049].



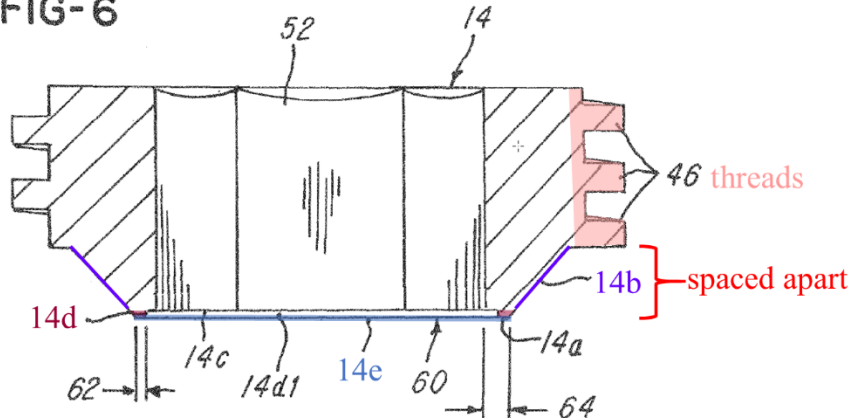
As the two annotated alternatives of Figure 6 below show, whether the substantially flat bottom surface is (1) the end 14c of the cap 14 (with rim 14d and its bottom surface 14e comprising the annular outer edge), or (2) surface 14e of the lateral rim 14d, the lower surface of the thread is spaced above and apart from the annular outer edge of the substantially flat bottom surface of the plug at least by a distance of the surface 14b. EX1007, Fig. 6; EX1003 ¶¶268-69.

(1)



(2)

FIG-6



As explained above, a POSA would have been motivated by the teachings of Kirschman to include these features in implementing the closure of the '477 Publication. *Supra* §§VII.B, VII.C.1.a; EX1003 ¶¶270-71. Therefore, the '477 Publication in view of Kirschman discloses this limitation. EX1003, ¶267.

The '477 Publication discloses every other limitation of Claims 1-2 and 4-9. *Supra* §VI.B.1-8. Accordingly, the '477 Publication in view of Kirschman renders obvious every element of these claims.

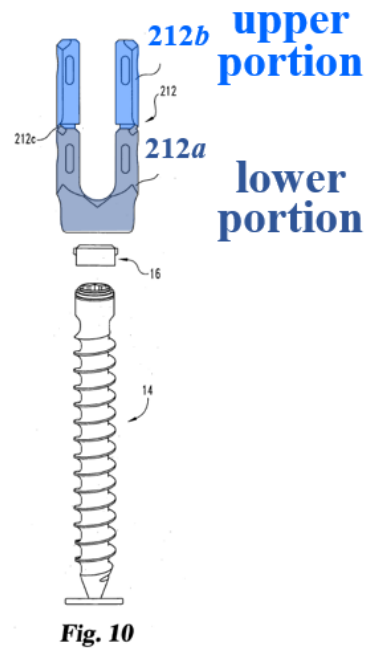
VIII. GROUND 3: CLAIMS 10 AND 11 ARE UNPATENTABLE OVER THE '477 PUBLICATION, ALONE OR IN COMBINATION WITH KIRSCHMAN, AND JOHNSON

A. Overview of Johnson

Johnson (EX1008) published on April 19, 2007, and is prior art to the '646 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 in a spinal implant, Johnson is in the same field of endeavor as, and analogous art

to, the '646 Patent. *Compare* EX1008, ¶[0031], with EX1001, 1:27-31; EX1003, ¶203.

Johnson discloses a receiver member 212 that, as shown in Fig. 10 at right, “has a **lower portion 212a** and an **upper portion 212b** separated by a thinned section 212c.” EX1008, ¶[0051], Fig. 10; EX1003, ¶204. As shown in Figure 12 below, “**internal threads 256** are formed in branches 250, 252 through substantially the entire length of upper portion 212b and into lower portion 212a.” EX1008, ¶[0052].

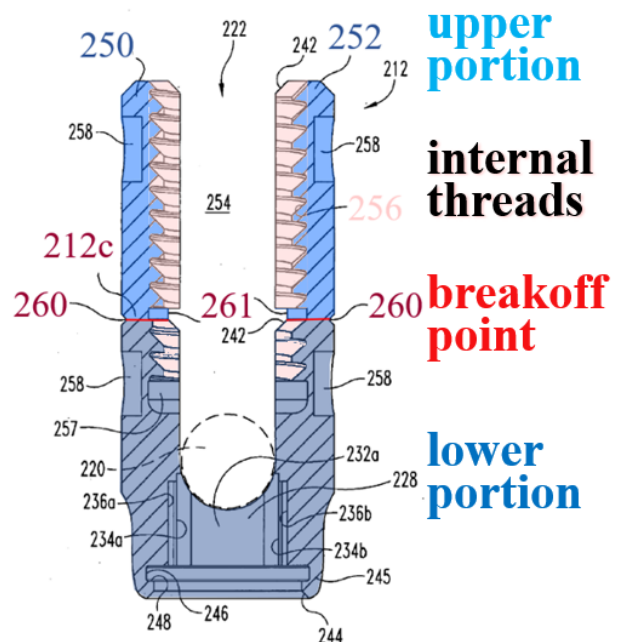


“Threads 256 may [be] configured so that they are **essentially continuous** from upper portion 212b to lower portion 212a” so that a compression member “can be

inserted into upper portion 212b and moved down to lower portion 212a.”

Id., ¶[0053]; *see also id.*, ¶[0055].

“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 212a.” *Id.*, ¶[0056]; EX1003, ¶205.
“Once separated, upper portion 212b may be removed from the surgical site and discarded.” EX1008, ¶[0056]; EX1003, ¶205.

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

A POSA would have been motivated to apply Johnson’s teachings of breakoff extension arms to the closure and receiver system taught by the ’477 Publication (with or without modifications in view of Kirschman) before the priority date of the ’646 Patent. EX1003, ¶¶213-17, 272-75. Johnson is in the exact same field as the ’477 Publication and Kirschman in that all three references disclose bone screws with an open U-shaped receiver for locking a rod with a closure. *Id.*, ¶¶214, 272. A POSA would have been motivated to add breakoff extension arms to an existing system at least based on the benefits of breakoff extensions as taught by Johnson. *Id.*, ¶¶214, 272.

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 212b of receiver member 212.” EX1008, ¶[0055]; EX1003, ¶¶215, 273. A compression member is then thread into threads 256 of receiver 212, forcing elongated member

all the way down. EX1008, ¶[0055]. 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 when implementing the '477 Publication (with or without Kirschman). EX1003, ¶¶215, 273.

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 and readily available. EX1003, ¶¶216, 274.

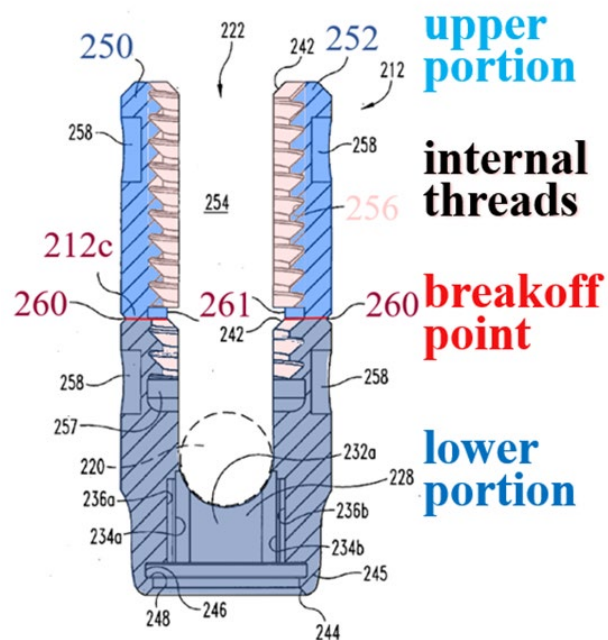
C. Claim Analysis.

1. Claim 10

Claim 10 depends from Claim 9 and further recites: [C] “wherein the first arm includes a first breakoff extension coupled to the top surface of the first arm, and the second arm includes a second breakoff extension coupled to the top surface of the second arm, each of the first and second breakoff extensions including an inner surface having a discontinuously helically wound thread form, the discontinuously helically wound thread form of the first breakoff extension configured to cooperate with the discontinuously helically wound thread of the first arm, and the discontinuously helically wound thread form of the second breakoff extension

configured to cooperate with the discontinuously helically wound thread of the second arm to rotatably transfer the plug therebetween prior to the first and second breakoff extensions being separated from the first and second arms, respectively.” The ’477 Publication, with or without Kirschman, in view of Johnson includes this limitation. EX1003, ¶¶276-85.

As seen in Figure 12, Johnson discloses a first breakoff extension coupled to the top surface of the first arm 250 and a second breakoff extension coupled to the top surface of the second arm 252. 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.” EX1008, ¶[0052], Fig. 12. Johnson discloses that the threads 256 “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]. Johnson discloses that a compression member is rotatably advanced because it is “threaded into threads 256, forcing elongated member 220

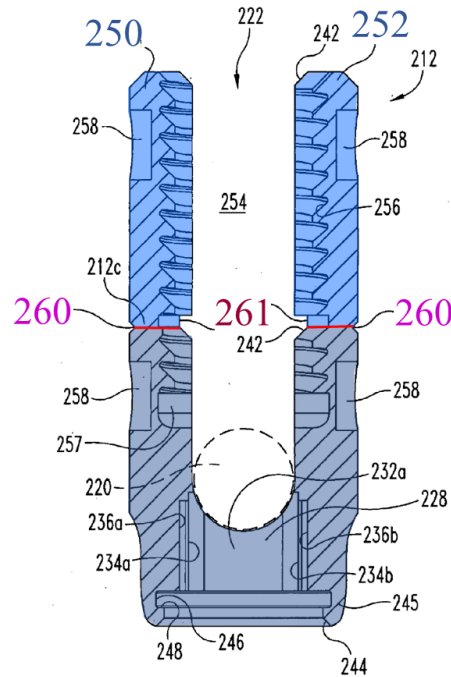
further down in channel 254” so that the “elongated member 220 is forced all the way through upper portion 212*b*, into lower portion 212*a*.” *Id.*, ¶[0055], Fig. 12.

As explained above, a POSA implementing the ’477 Publication would have been motivated to use breakoff extensions as taught by Johnson. *Supra* §VIII.B. Moreover, a POSA would have been motivated to modify the ’477 Publication (with or without Kirschman) to add breakoff extensions as taught by Johnson based on design demands for devices that facilitated surgeries while maintaining a low profile for the final implant. EX1003, ¶¶280-83. Accordingly, the ’477 Publication and Johnson, with or without Kirschman, renders obvious Claim 10. *Id.*, ¶¶284-85.

2. Claim 11

Claim 11 depends from Claim 10 and further recites: [C1] “wherein a first outer radiused notch is located at a convergence of the first breakoff extension and the first arm at the top surface thereof, and a second outer radiused notch is located at a convergence of the second breakoff extension and the second arm at the top surface thereof, the first outer radiused notch being located opposite a first inner radiused recess, and the second outer radiused notch being located opposite a second inner radiused recess.” The ’477 Publication in view of Johnson, with or without Kirschman, includes this limitation. EX1003, ¶¶286-89.

Johnson discloses “thinned section 212c” with an “external indentation or groove 260” and “[a]n interior indentation 261.” EX1008, ¶[0054], Fig. 12. A POSA would have understood that these indentations or grooves would be radiused. EX1003, ¶287. Thus, as annotated Figure 12 shows, Johnson discloses a first outer radiused notch that is located at a convergence of the first breakoff extension and the first arm at the top surface thereof and a second outer radiused notch that is located at a convergence of the second breakoff extension and the second arm at the top surface thereof, the first and second outer radiused notches being located opposite the first and second inner radiused recesses. EX1008, Fig. 12



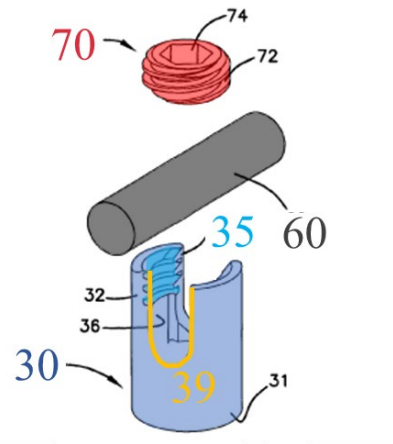
As explained above, a POSA implementing the '477 Publication would have been motivated to use the breakoff extensions as taught by Johnson. *Supra* §VIII.B. Accordingly, the '477 Publication and Johnson, with or without Kirschman, renders obvious Claim 11. EX1003, ¶¶288-89.

**IX. GROUND 4: CLAIMS 3, 12-18 ARE 20 ARE UNPATENTABLE
OVER THE '477 PUBLICATION IN VIEW OF BOSCHERT.**

A. Overview of Boschert

Boschert (EX1006) published on December 15, 2005, and is prior art to the '646 Patent under Section 102(b). As described further below, because Boschert discloses a bone screw with a U-shaped receiver that uses a closure to capture and lock a rod in a spinal implant, Boschert is in the same field of endeavor as, and analogous art to, the '646 Patent. *Compare* EX1006, Abstract, 4:26-28, with EX1001, 1:27-31; EX1003, ¶188.

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, ¶188. 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. 1. The legs have interior threads 35 that mate with



Ex. 1006, Fig. 1

corresponding exterior threads on the set screw 70, such that the set screw can be threaded into the saddle to lock the rod in place. *Id.*, 6:24-48, 7:12-15; EX1003, ¶190. Boschert discloses that it would be advantageous to design the set screw's

threads to have a “*double lead to allow the set screw 70 to start more easily than with a single lead.*” EX1006, 7:21-23; EX1003, ¶190.

As discussed in more detail below (*infra* §IX.C.1), 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, ¶¶190-95; EX1006, Figs. 1, 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.

B. Motivation to Combine Boschert with the ’477 Publication

It would have been obvious to a POSA to combine the closure of the ’477 Publication and the double lead thread of Boschert before the priority date of the ’646 Patent. EX1003, ¶¶218-22.

The ’477 Publication and Boschert are in the exact same field as each other and the ’646 Patent. *Supra* §§VI.A., IX.A. The ’477 Publication teaches closures that could be used with any conventional bone screw receiver, including a polyaxial bone screw with a U-shaped receiver. EX1005, Abstract, ¶¶[0007], [0025], [0027]. Boschert also teaches a polyaxial pedicle screw including a U-shaped receiver for capturing a rod. *Supra* §IX.A. 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, and discloses symmetrical threads on the receiver to mate simultaneously with the double-lead threads on the setscrew, *id.*, Figs. 13, 15. 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 Boschert’s disclosure of a closure with double lead threads and symmetrical threads on the receiver. EX1003, ¶221. 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, a POSA would have maintained the curvate leading faces of the ’477 Publication in order to obtain their known advantages for easing insertion, reducing thread deformation, and reducing sharp edges. *Id.*, ¶¶65-76, 221. A POSA would have had a reasonable expectation of success in making

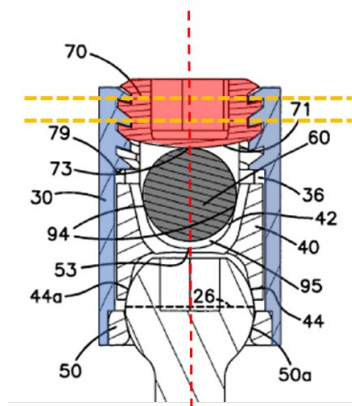
such a combination, at least because multi-start threads, and the techniques for machining them, were well known and readily available. *Id.*, ¶¶52-64, 222.

C. Claim Analysis.

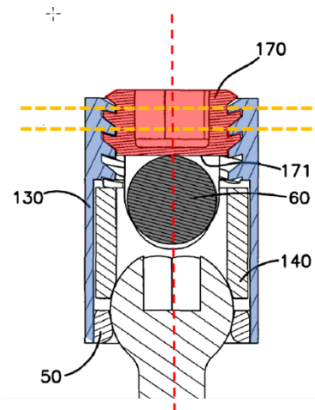
1. Claim 3

Claim 3 depends from Claim 1 and further recites: [B7] “wherein the start structure is a first start structure disposed at a diametrically opposite location on the plug from a second start structure.” The combination of the ’477 Publication and Boschert includes this limitation. EX 1003, ¶¶296. A POSA would have been motivated by Boschert’s teachings to add a second start structure diametrically opposite from the first start structure already disclosed by the ’477 Publication. *Id.*, ¶¶296-305.

Boschert teaches that a “double lead [] allow[s] the set screw 70 to start more easily than with a single lead.” EX1006, 7:21-23. Boschert discloses that the start structures of the disclosed double lead would be symmetrically and diametrically opposed to one another. As shown in cropped and annotated Figures 3 and 15, threads on either side of receiver 30 are symmetrically and diametrically opposed to each other (as illustrated by the yellow horizontal lines that are perpendicular to the red longitudinal lines). *Id.*, Figs. 3, 15.

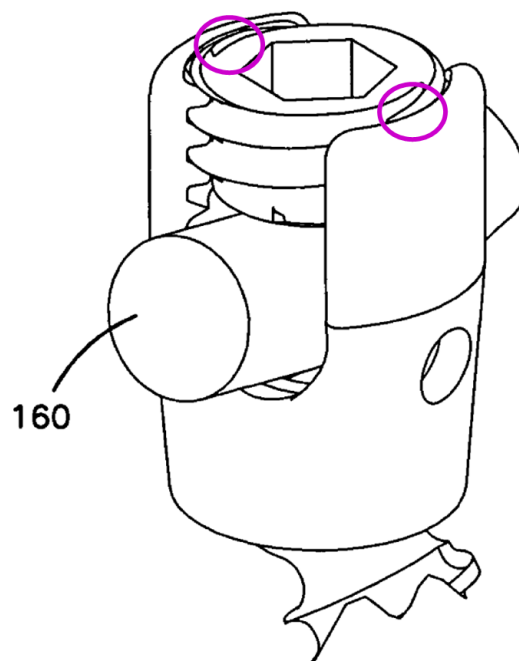


EX1006, Fig. 3



EX1006, Fig. 15

This disclosure is further supported by Figure 7, which shows, at the top of the closure, that the **trailing ends** of the double lead thread are diametrically opposed. EX1006, Fig. 7.



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 threads starts, EX1003, ¶300, and that would further have been the obvious choice when threading a double-start closure into two diametrically opposed receiver arms, *id.*, ¶301. A POSA would similarly understand that, for double-start threads on the setscrew to engage with the receiver, the receiver threads would necessarily have to mirror each other. *Id.*, ¶303. Thus, for its double-start setscrew, Boschert expressly discloses symmetrically and diametrically opposed starts around the closure body. *Id.*, ¶¶299-302.

To the extent that Boschert does not expressly disclose this limitation, a POSA would have understood that Boschert inherently discloses it. *Id.*, ¶303. A POSA would have understood that for the double-start threads on the setscrew to engage with the receiver threads, (1) the receiver threads would necessarily have to mirror each other, and (2) the start structures would necessarily be spread equidistant around the closure's starting end. *Id.* This understanding is further reinforced by the conventional manner of making double-start threads, i.e., diametrically opposing the thread starts. *Id.*

Finally, to the extent Boschert does not expressly or inherently disclose this limitation, it would have been obvious to a POSA to use diametrically opposed thread starts in the combination of the '477 Publication and Boschert to take advantage of the simultaneous threading of the starts with the corresponding threads of each receiver arm. *See* EX1005, Fig. 1; EX1003, ¶304.

As explained above, a POSA would have been motivated by the teachings of Boschert to include these features in implementing the closure of the '477 Publication. *Supra* §IX.B. Accordingly, the '477 Publication in view Boschert renders obvious Claim 3. EX1003, ¶¶305-06.

2. Claim 12

a. 12[Preamble]: “A medical implant assembly comprising:”

This limitation recites the same requirements of the receiver as Limitation 1[Preamble]. The '477 Publication discloses this limitation for the reasons set forth above. EX1003, ¶¶223, 307; *supra* §VI.B.1.a.

b. 12[A]: “a receiver having an upper portion with an inner surface, a top surface, and a channel, the inner surface having a helically wound thread extending up to the top surface, the channel configured to receive a rod; and”

While worded slightly differently, this limitation recites the same requirements of the receiver as Limitation 1[A]. The '477 Publication discloses this limitation for the reasons set forth above. EX1003, ¶¶224-25, 308-09; *supra* §VI.B.1.b.

- c. 12[B]: “a plug configured for positioning within the upper portion of the receiver, the plug having an axis of rotation,”

This limitation recites the same requirements of the plug as Limitation 1[B], without the requirement that the plug is threaded. The ’477 Publication discloses this limitation for the reasons set forth above. EX1003, ¶¶226, 310-11; *supra* §VI.B.1.c.

- d. 12[B1]: “a continuously helically wound thread form comprising a first thread and a second thread,”

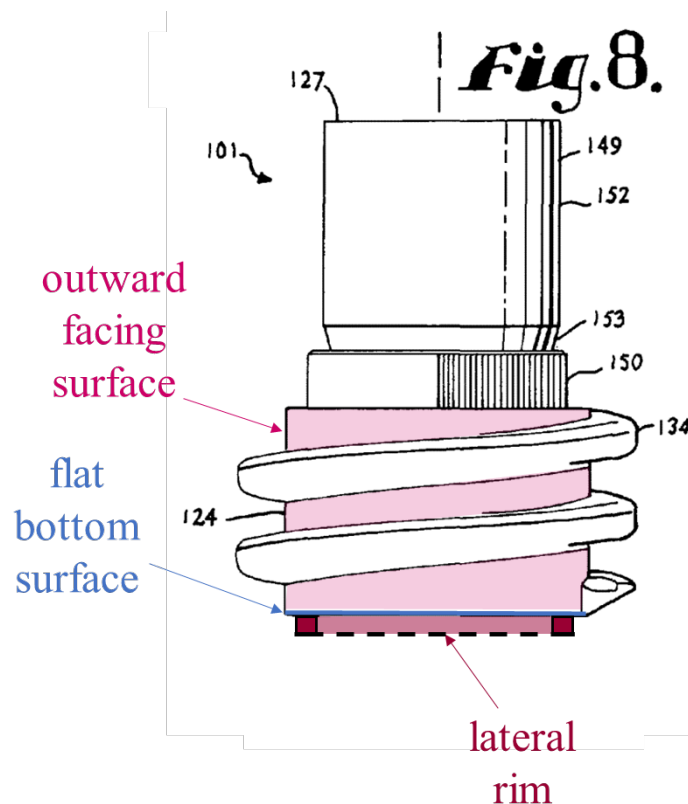
This limitation recites the same requirements as Limitation 1[B1], but with the requirement of a second thread. EX1003, ¶¶312-15; *supra* §VI.B.1.d. As discussed regarding Claim 3, the combination of the ’477 Publication and Boschert discloses this limitation. EX1003, ¶¶296-306, 312-15; *supra* §IX.C.1. As explained above, a POSA would have been motivated by the teachings of Boschert to include these features in implementing the fixation device of the ’477 Publication. EX1003, ¶315.

- e. 12[B2]: “a substantially flat bottom surface with an annular outer edge, and”

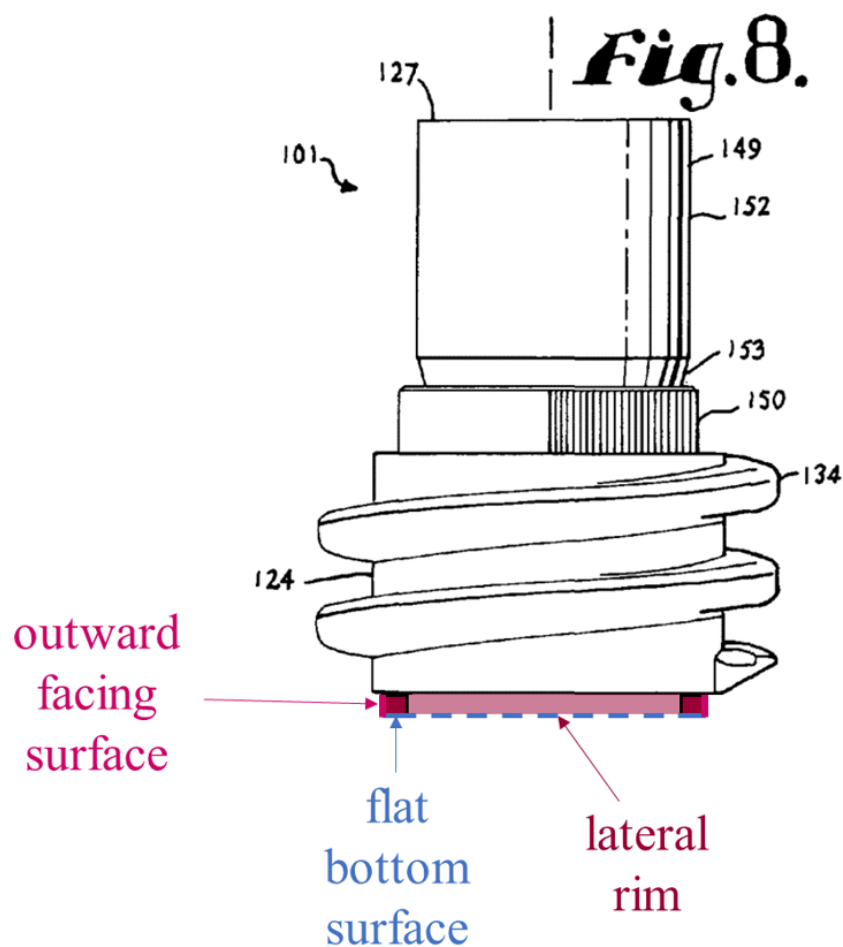
This limitation recites the same requirements as Limitation 1[B2], but without the requirement that the substantially flat bottom surface is “configured to engage the rod.” EX1003, ¶316. The ’477 Publication discloses this limitation under any construction for the reasons set forth above. EX1003, ¶¶228-32, 316-21; *supra* §VI.B.1.e.

f. **12[B13]: “an outward facing surface encircling the substantially flat bottom surface,”**

The combination of the '477 Publication and Boschert includes this limitation. EX1003, ¶¶322-26. Under the preferred construction, the '477 Publication discloses that “closure 1 includes a body 124 that has a generally cylindrical or plug shape with a substantially circular horizontal cross section.” EX1005, ¶[0040]. Thus, the disclosed body includes a surface that faces away from the center of the plug and that surrounds the bottom surface (which is substantially flat) in a circular fashion. This outward facing surface is shown in annotated Figure 8. *Id.*, Fig. 8; EX1003, ¶323.



Alternatively, where the substantially flat bottom surface is the lowermost surface of the downwardly projecting rim, the outer surface of the rim would also be an outward facing surface encircling the substantially flat bottom surface, as shown in annotated Figure 8 below, to which the disclosed rim has been illustrated. EX1005, Fig. 8; EX1003, ¶325.



- a. 12[B3]: “the first thread comprising a first start structure and a first upper surface extending between a first root and a first crest of the first thread, the first start structure including a first leading face extending below the first

upper surface to a first lower surface, the second thread comprising a second start structure and a second upper surface extending between a second root and a second crest of the second thread, the second start structure including a second leading face extending below the second upper surface to a second lower surface, the first and second leading faces each including a partial concave surface adjacent the first and second root, respectively, and a partial convex surface adjacent the first and second crest, respectively, the partial concave and partial convex surfaces of the first and second leading faces each defined by a radius of curvature,”

This limitation recites the same start structure requirements as Limitations 1[B3] and 1[B4] for the single start structure, but in addition requires those start structure elements for a second start structure on a double-start thread. EX1003, ¶¶327-33; *supra* §VI.B.1.f-g. While the ’477 Publication discloses the required start structure on a single thread, when the disclosures of the ’477 Publication are combined with Boschert, a POSA would have kept the same start structure on the second thread as on the first. *See supra* §IX.C.1. Thus, both start structures would have a leading face extending below the upper surface of the start structure, a partial concave surface adjacent the first and second root and a partial convex surface adjacent the first and second crest, and each concave and convex surface having a radius of curvature. *See supra* §VI.B.1.f-g.

Specifically, a POSA would have been motivated by the teachings of the ’477 Publication and Boschert to use the curvate leading face of the ’477 Publication as

the start structure on each of the two start threads taught by Boschert to benefit from the known mechanical and manufacturing benefits of the start structure shape of the '477 Publication. EX1003, ¶331. As explained above, a POSA would have been motivated by the teachings of Boschert and the knowledge of a POSA to include the same start structure on both the first and second threadforms. *Id.*, ¶¶293, 331. The resulting plug would thus meet each element of Limitation 12[B3]. *Id.*, ¶¶327-33.

- b. 12[B5]: “the first lower surface of the first thread and from² the second lower surface of the second thread are spaced above and apart from the annular outer edge of the substantially flat bottom surface of the plug.”

This limitation recites the same leading face requirements as Limitation 1[B5], but does so in the context of a double-start thread, rather than a single-start thread as required by Claim 1. The '477 Publication discloses or renders obvious the required spacing between a single thread start and the annular outer edge, EX1003, ¶334; *supra* §VI.B.1.h, and a POSA would have been motivated by the combined teachings of Boschert and the '477 Publication to include the same spacing on the second thread as on the first, under either construction of “substantially flat bottom surface.” EX1003, ¶337.

² “From” appears to be included in this limitation in error.

Accordingly, the '477 Publication in view of Boschert renders obvious Claim 12. *Id.*, ¶338.

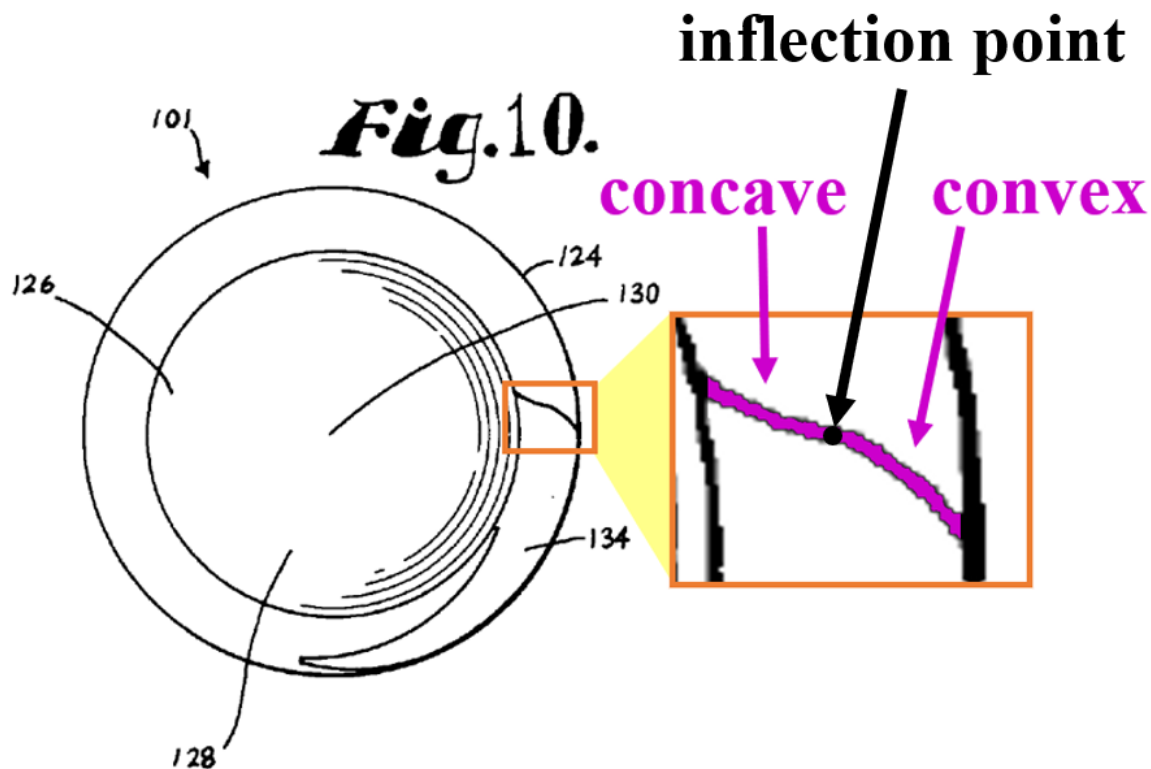
3. Claim 13

Claim 13 depends from Claim 12 and further recites: [B7] “wherein the first start structure and the second start structure are disposed at diametrically opposite locations from each other on the plug.” The combination of the '477 Publication and Boschert includes this limitation, as explained above. EX1003, ¶¶339-48; *supra* §IX.C.1. Accordingly, the '477 Publication in view Boschert renders obvious Claim 13. EX1003, ¶348.

4. Claim 14

Claim 14 depends from Claim 12 and further recites: [B14] “wherein the first leading face includes a first inflection point between the partial concave surface and the partial convex surface of the first leading face, and the second leading face includes a second inflection point between the partial concave surface and the partial convex surface of the second leading face.” The combination of the '477 Publication and Boschert includes this limitation. EX1003, ¶¶349-51.

The '477 Publication discloses an inflection point between the partial concave and convex surfaces of the leading face of the first start structure, as seen below in annotated Figure 10. *Id.*, ¶350; EX1005, Fig. 10.



Ex. 1005, Fig. 10

As explained above, a POSA would have been motivated by the teachings of Boschert and the knowledge of a POSA to include the same start structure on both the first and second threadforms. *Supra* §§IX.B, IX.C.1; EX1003, ¶¶293, 351. Accordingly, the '477 Publication in view Boschert renders obvious Claim 14. EX1003, ¶351.

5. Claim 15

Claim 15 depends from Claim 12 and further recites: [B8] “wherein the first and second leading faces each includes at least a partial planar surface.” The combination of the '477 Publication and Boschert includes this limitation. EX1003,

¶¶352-53. This limitation recites the same requirements as Claim 4 which are met by the '477 Publication, but with the requirement of a second thread. EX1003, ¶352; *see also supra* §VI.B.3. A POSA would have been motivated by the teachings of Boschert and the knowledge of a POSA to include the same start structure on both the first and second threadforms. *Supra* §IX.B; EX1003, ¶293. Accordingly, the '477 Publication in view Boschert renders obvious Claim 15. EX1003, ¶¶352-53.

6. Claim 16

Claim 16 depends from Claim 12 and further recites: **[B9]** “wherein the first lower surface includes a first bottom beveled surface and the second lower surface includes a second bottom beveled surface.” The combination of the '477 Publication and Boschert includes this limitation. EX1003, ¶¶354-55. The '477 Publication discloses that the lower surface of the start structure is a beveled surface. *See supra* §VI.B.4; *see also* EX1003, ¶354.

A POSA would have been motivated by the teachings of Boschert and the knowledge of a POSA to include the same start structure on both the first and second threadforms. *Supra* §IX.B; EX1003, ¶293. Accordingly, the '477 Publication in view Boschert renders obvious Claim 16. EX1003, ¶¶354-55.

7. Claim 17

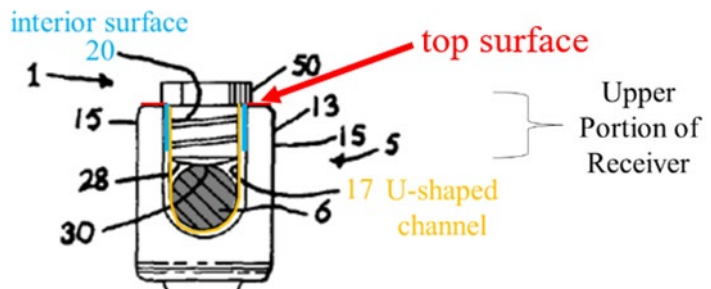
Claim 17 depends from Claim 12 and further recites: **[B12]** “wherein the plug is a breakoff plug.” The combination of the '477 Publication and Boschert includes

this limitation. EX1003, ¶356. The '477 Publication discloses that the closure may include a break-off portion designed to break away from the closure “subsequent to a predetermined torque being applied.” EX1006 ¶[0042]; *see supra* §VI.B.7. A POSA would have been motivated by the teachings of the '477 Publication and the knowledge of a POSA to include the breakoff function of the plug with double start threads. EX1003, ¶¶219, 294, 356337. Accordingly, the '477 Publication in view Boschert renders obvious Claim 17. *Id.*, ¶356.

8. Claim 18

Claim 18 depends from Claim 12 and further recites: [A1] “wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm.” The combination of the '477 Publication and Boschert includes this limitation. EX1003, ¶¶357-59.

The '477 Publication discloses each element of this limitation. *See supra* §VI.B.8. In particular, annotated Figure 6 shows the upper portion of receiver has first and second arms spaced apart from each other by **channel 17**, and the **top surface** of the receiver is shown on the



first and second arms of the receiver. EX1005, Fig. 6. The '477 Publication further discloses that the **interior surfaces 20** of the arms include discontinuous helically wound threads. EX1005, ¶[0007]; EX1003, ¶358. Accordingly, the '477 Publication in view Boschert renders obvious Claim 18. EX1003, ¶¶358-59.

9. Claim 20

Claim 20 depends from Claim 12 and further recites: [B4] “wherein the radius of curvature for the partial concave and partial convex surfaces of the first and second leading faces are substantially equal with respect to each other.” The combination of the '477 Publication and Boschert includes this limitation. EX1003, ¶¶360-61. This limitation recites the same requirements as Claim 1[B4] which are met by the '477 Publication, but with the requirement of a second thread start. EX1003, ¶360; *see also supra* §VI.B.3. A POSA would have been motivated to include the same shape of the start structure from the '477 Publication on a second start structure in order to benefit from the known mechanical and manufacturing advantages of that shape. *Supra* §IX.B; EX1003, ¶¶293, 361. Accordingly, the '477 Publication in view Boschert renders obvious Claim 20. EX1003, ¶¶360-61.

X. GROUND 5: CLAIMS 3, 12-18 AND 20 ARE UNPATENTABLE OVER THE '477 PUBLICATION IN VIEW OF BOSCHERT AND KIRSCHMAN.

A. Motivation to Combine Kirschman with the '477 Publication and Boschert.

For the reasons discussed above (*supra* §VII.B), it would have been obvious to a POSA to combine the '477 Publication and Kirschman, and, as also discussed above (*supra* §IX.B), it also would have been obvious to a POSA to combine the '477 Publication, with or without Kirschman, with the teachings of Boschert. For the same reasons, it would have been obvious to a POSA to combine the '477 Publication, as modified by Kirschman, with Boschert. EX1003, ¶¶362-66.

B. Claim Analysis.

The combination of '477 Publication and Boschert already renders obvious every limitation of Claims 3, 12-18, and 20. *Supra* §IX.C. The addition of Kirschman further reinforces the obviousness of certain limitations and enhances the motivation of a POSA to use these features when designing a closure top. EX1003, ¶366.

1. Claim 3 (depending from Claim 1)

- a. 1[B2]: “a substantially flat bottom surface with an annular outer edge, the substantially flat bottom surface configured to engage the rod,”

The '477 Publication and Boschert combination in view of Kirschman renders this limitation obvious for the same reasons explained above with respect to Ground

2. *See supra* §VII.C.1.a. Specifically, Kirschman reinforces the '477 Publication's disclosure of a lateral rim, and further renders obvious the use of a flat bottom surface on the lateral rim disclosed in the '477 Publication. EX1003, ¶¶367-69.

- b. 1[B5]: “the lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof.”

The '477 Publication and Boschert combination in view of Kirschman renders this limitation obvious for the same reasons explained above with respect to Ground

2. *See* §VII.C.1.b. Specifically, Kirschman would motivate a POSA to further separate the substantially flat bottom surface of the closure from the thread starts. EX1003, ¶¶370-71.

Accordingly, the '477 Publication in view of Boschert and Kirschman renders obvious Claim 3.

2. Claim 12

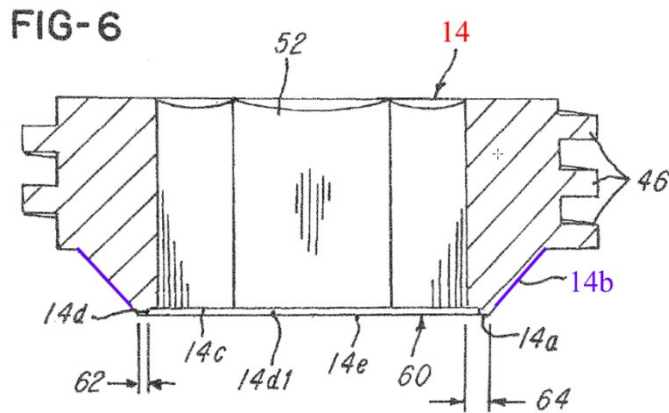
- a. 12[B2]: “a substantially flat bottom surface with an annular outer edge, and”

This element of Claim 12 is the same as Limitation 1[B2] except it does not require “the substantially flat bottom surface configured to engage the rod.” Therefore, Kirschman, in combination with the '477 Publication and Boschert, renders this limitation obvious for the reasons explained above. *Supra* §X.B.1.a; *see also* EX1003, ¶372.

b. **12[B13]: “an outward facing surface encircling the substantially flat bottom surface,”**

In addition to the disclosures of the '477 Publication and Boschert, the disclosure of Kirschman further substantiates the obviousness of this feature.

EX1003, ¶¶373-74. Kirschman discloses an unthreaded surface 14b (purple) below the closure top threads and above the substantially flat bottom surface of the closure



top. Kirschman discloses that this surface “is adapted to provide the lock aid by facilitating guiding the cap 14 on the receiver 12 to facilitate aligning” the cap, the threads 46, and the thread start 46a in the receiver. EX1007, ¶¶[0043], [0049]. In the preferred embodiment, this unthreaded surface is frusto-conical, but “the surface shape could be any suitable shape adapted to guide the cap 14 into the bore 22 and onto the receiver 12.” *Id.* The disclosed surface 14b is outward facing and, whether the substantially flat bottom surface is the end 14c or the surface 14e, encircles the substantially flat bottom surface, as it encloses the entirety of those surfaces.

A POSA would have been motivated by the teachings of Kirschman to include this feature in implementing the closure of the '477 Publication and Boschert. *Supra*

§X.A. Therefore, the combination of the '477 Publication in view of Boschert, and Kirschman discloses this limitation. EX1003, ¶¶373-74.

- c. 12[B5]: “the first lower surface of the first thread and from³ the second lower surface of the second thread are spaced above and apart from the annular outer edge of the substantially flat bottom surface of the plug.”

This limitation of Claim 12 is the same as Limitation 1[B5] except it requires two thread starts. Therefore, Kirschman, in combination with the '477 Publication and Boschert, renders this limitation obvious for the reasons explained above. *Supra* §X.B.1.b; EX1003, ¶¶375-77.

Accordingly, the '477 Publication in view of Boschert and further in view of Kirschman renders obvious Claims 12-18 and 20.

XI. GROUND 6: CLAIM 19 IS UNPATENTABLE OVER THE '477 PUBLICATION IN VIEW OF BOSCHERT, ALONE OR IN COMBINATION WITH KIRSCHMAN, AND JOHNSON.

A. Motivation to Combine Johnson with the '477 Publication, Boschert, and Kirschman

For the reasons discussed above (*supra* §VIII.B), it would have been obvious to a POSA to combine the '477 Publication and Johnson, and, as also discussed above (*supra* §§IX.B, X.A), it also would have been obvious to a POSA to combine the '477 Publication, with or without Kirschman, with the teachings of Boschert.

³ “From” appears to be included in this limitation in error.

For the same reasons, it would have been obvious to a POSA to combine the '477 Publication, as modified by Kirschman and Boschert, with Johnson. EX1003, ¶¶378-82.

B. Claim Analysis.

1. Claim 19

Claim 19 depends from Claim 18 and further recites: [C] “wherein the top surfaces of the first and second arms each include a breakoff extension with an inner surface having a discontinuously helically wound thread form, the first and second arm breakoff extension thread forms being continuous with the respective discontinuous helically wound thread form on the inner surface of the first and second arms.” Adding the disclosure of Johnson to those of the '477 Publication and Boschert, with or without Kirschman, would also render Claim 19 obvious. Johnson discloses that “[t]hreads 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.” EX1008, ¶[0053]; EX1003 ¶¶383-86; *supra* §VIII.C.1.

A POSA would have been motivated by the teachings of Johnson to include this feature in implementing the receiver of the '477 Publication and Boschert. *Supra* §XI.A. Therefore, the combination of the '477 Publication and Boschert, with

or without Kirschman, and Johnson discloses renders obvious Claim 19. EX1003, ¶¶383-86.

XII. SECONDARY CONSIDERATIONS

Petitioners are not aware of any evidence of secondary considerations in support of non-obviousness. EX1003, ¶¶387-92. 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.*

XIII. DISCRETIONARY DENIAL IS NOT APPROPRIATE

A. 35 U.S.C. §325(d)

Denial under 35 U.S.C. § 325(d) would not be appropriate 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).

Boschert is the only reference in this Petition that was the subject of a rejection during prosecution of the '646 Patent, and the Examiner relied on Boschert solely for its disclosure of double-start threads. *See* EX1002 at 243-45. Patent Owner did not address or refute this disclosure, but rather amended the claims to include two

new limitations: (1) a substantially flat bottom surface of the closure with an annular outer edge, and (2) the start structure spaced above and apart from the annular outer edge (the “Final Amendments”). *Id.* at 283-86. The Examiner allowed the pending claims on this basis. *Id.* at 305-11.

None of Johnson, Kirschman, or the ’477 Publication were the basis for any rejection. Johnson was not before the Examiner; Kirschman was identified in Patent Owner’s Information Disclosure Statement (“IDS”), *id.* at 85; and the Examiner listed the ’477 Publication in a Notice of References Cited. *See id.* at 252. The Examiner did not consider whether the ’477 Publication, Kirschman, or Johnson disclosed the Final Amendments.

Part one of the *Advanced Bionics* test favors institution, as the Grounds set forth herein rely on combinations of art and arguments that 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 ’646 Patent over these disclosures. As set forth above, the ’477 Publication, alone or in combination with Kirschman, teaches the claimed (1) substantially flat bottom and annular edge, and (2) spacing between the annular edge and the start structure. *Supra* §§VI.B.1.e,

VI.B.1.h, VII.C. In addition, Boschert expressly discloses the double-start limitations. *Supra* §IX.C. These disclosures render obvious the Challenged Claims for the reasons set forth above. When the Patent Owner amended the claims to require the Final Amendments, the Examiner failed to consider the '477 Publication or Kirschman's teachings as to those limitations, and as a result, overlooked specific material teachings of the relevant prior art. *See Samsung Elecs. Am., Inc., and Apple, Inc. v. Neonode Smartphone LLC*, IPR2021-00145, Paper No. 24 at 17-19 (PTAB June 16, 2021). This material error supports institution. *Alzheon Inc. v. Risen (Suzhou) Pharma Tech Co., Ltd.*, IPR2021-00347, Paper 10 at 54 (PTAB July 10, 2021); *Sony Interactive v. BOT M8, LLC*, IPR2020-00726, Paper 13 at 12; *Satco Prods. v. Seoul Semiconductor Co., LTD.*, IPR2020-00410, Paper No. 8 at 27-31 (PTAB Aug. 10, 2020); *10X Genomics, Inc. v. Bio-Rad Laboratories, Inc.*, IPR2021-00133, Paper No. 11 at 14-19, 23 (PTAB May 13, 2021).

B. Fintiv

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11, 6 (PTAB Mar. 20, 2020) (precedential) should not apply here 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.

EX1033; EX1034, 2, 4-5; *Sotera Wireless, Inc. v. Masimo Corp.*, No. IPR2020-01019, Paper 12 at 17 (PTAB Dec. 1, 2020) (precedential).

XIV. CONCLUSION

Petitioners respectfully request that IPR of the '646 Patent be instituted and that Claims 1-20 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 13,974 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. 11,129,646 and Exhibits 1001 – 1036 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 1-20

Identifier	Element
1[Preamble]	A medical implant assembly comprising:
1[A]	a receiver having an upper portion with an inner surface at least partially configured as a helically wound thread extending up to a top surface of the receiver, and a channel formed in the upper portion of the receiver and configured to receive a rod; and
1[B]	a plug being threaded and configured to be positioned within the upper portion, the plug having an axis of rotation,
1[B1]	a continuously helically wound thread form, and
1[B2]	a substantially flat bottom surface with an annular outer edge, the substantially flat bottom surface configured to engage the rod,
1[B3]	the continuously helically wound thread form having a start structure with an upper surface extending between a root and a crest of the continuously helically wound thread form, the start structure having a leading face extending below the upper surface to a lower surface of the start structure, the leading face including a partial concave surface adjacent the root and a partial convex surface adjacent the crest,
1[B4]	the partial concave and partial convex surfaces each defined by a radius of curvature that is substantially equal with respect to each other,
1[B5]	the lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof.
2[Preamble]	The medical implant assembly of claim 1,
2[B6]	wherein the partial concave surface tangentially blends with the partial convex surface.
3[Preamble]	The medical implant assembly of claim 1,
3[B7]	wherein the start structure is a first start structure disposed at a diametrically opposite location on the plug from a second start structure.
4[Preamble]	The medical implant assembly of claim 1,
4[B8]	wherein the leading face of the start structure includes at least a partial planar surface.
5[Preamble]	The medical implant assembly of claim 1,
5[B9]	wherein the lower surface of the start structure includes a bottom beveled surface.
6[Preamble]	The medical implant assembly of claim 1,
6[B10]	wherein the upper surface of the continuously helically wound thread form of the threaded plug slopes rearward from the root towards the crest.
7[Preamble]	The medical implant assembly of claim 6,
7[B11]	wherein a slope of the upper surface is at an angle greater than five degrees measured between a line drawn perpendicular to the axis of rotation of the plug and a tangent line drawn tangent along the upper surface.

Identifier	Element
8[Preamble]	The medical implant assembly of claim 1,
8[B12]	wherein the plug is a breakoff plug.
9[Preamble]	The medical implant assembly of claim 1,
9[A1]	wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm.
10[Preamble]	The medical implant assembly of claim 9,
10[C]	wherein the first arm includes a first breakoff extension coupled to the top surface of the first arm, and the second arm includes a second breakoff extension coupled to the top surface of the second arm, each of the first and second breakoff extensions including an inner surface having a discontinuously helically wound thread form, the discontinuously helically wound thread form of the first breakoff extension configured to cooperate with the discontinuously helically wound thread of the first arm, and the discontinuously helically wound thread form of the second breakoff extension configured to cooperate with the discontinuously helically wound thread of the second arm to rotatably transfer the plug therebetween prior to the first and second breakoff extensions being separated from the first and second arms, respectively.
11[Preamble]	The medical implant assembly of claim 10,
11[C1]	wherein a first outer radiused notch is located at a convergence of the first breakoff extension and the first arm at the top surface thereof, and a second outer radiused notch is located at a convergence of the second breakoff extension and the second arm at the top surface thereof, the first outer radiused notch being located opposite a first inner radiused recess, and the second outer radiused notch being located opposite a second inner radiused recess.
12[Preamble]	A medical implant assembly comprising:
12[A]	a receiver having an upper portion with an inner surface, a top surface, and a channel, the inner surface having a helically wound thread extending up to the top surface, the channel configured to receive a rod; and
12[B]	a plug configured for positioning within the upper portion of the receiver, the plug having an axis of rotation,
12[B1]	a continuously helically wound thread form comprising a first thread and a second thread,
12[B2]	a substantially flat bottom surface with an annular outer edge, and
12[B13]	an outward facing surface encircling the substantially flat bottom surface,
12[B3]	the first thread comprising a first start structure and a first upper surface extending between a first root and a first crest of the first thread, the first start structure including a first leading face extending below the first upper surface to a first lower surface, the second thread comprising a second start structure and a second upper surface extending between a second root and a second crest of the second thread, the second start structure including a second leading face extending below the second upper surface to a second lower

Identifier	Element
	surface, the first and second leading faces each including a partial concave surface adjacent the first and second root, respectively, and a partial convex surface adjacent the first and second crest, respectively, the partial concave and partial convex surfaces of the first and second leading faces each defined by a radius of curvature,
12[B5]	the first lower surface of the first thread and from the second lower surface of the second thread are spaced above and apart from the annular outer edge of the substantially flat bottom surface of the plug.
13[Preamble]	The medical implant assembly of claim 12,
13[B7]	wherein the first start structure and the second start structure are disposed at diametrically opposite locations from each other on the plug.
14[Preamble]	The medical implant assembly of claim 12,
14[B14]	wherein the first leading face includes a first inflection point between the partial concave surface and the partial convex surface of the first leading face, and the second leading face includes a second inflection point between the partial concave surface and the partial convex surface of the second leading face.
15[Preamble]	The medical implant assembly of claim 12,
15[B8]	wherein the first and second leading faces each includes at least a partial planar surface.
16[Preamble]	The medical implant assembly of claim 12,
16[B9]	wherein the first lower surface includes a first bottom beveled surface and the second lower surface includes a second bottom beveled surface.
17[Preamble]	The medical implant assembly of claim 12,
17[B12]	wherein the plug is a breakoff plug.
18[Preamble]	The medical implant assembly of claim 12,
18[A1]	wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm.
19[Preamble]	The medical implant assembly of claim 18,
19[C]	wherein the top surfaces of the first and second arms each include a breakoff extension with an inner surface having a discontinuously helically wound thread form, the first and second arm breakoff extension thread forms being continuous with the respective discontinuous helically wound thread form on the inner surface of the first and second arms.
20[Preamble]	The medical implant assembly of claim 12,
20[B4]	wherein the radius of curvature for the partial concave and partial convex surfaces of the first and second leading faces are substantially equal with respect to each other.