

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ROGER P. JACKSON
Patent Owner

Patent No. 10,898,233
Filing Date: January 31, 2020
Issue Date: January 26, 2021
Title: MEDICAL IMPLANT RECEIVERS HAVING DUAL LEAD IN
CLOSURE MATING THREAD FORMS AND CURVATE EXTENDING
INSTRUMENT ENGAGING GROOVES

Inter Partes Review No. IPR 2023-01432

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

TABLE OF CONTENTS

I.	MANDATORY NOTICES (37 C.F.R. § 42.8)	1
A.	Real Party-in-Interest	1
B.	Related Matters.....	1
C.	Counsel	2
II.	STANDING AND FEES	3
A.	Certification of Grounds for Standing (37 C.F.R. § 42.104(a)).....	3
B.	Fees (37 C.F.R. § 42.103)	3
III.	THE '233 PATENT	3
A.	Overview	3
B.	Priority Date	11
IV.	Level of Ordinary Skill in the Art	11
A.	Qualifications of a Person of Ordinary Skill in the Art	11
B.	Knowledge of a POSA	11
V.	IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(b))	12
A.	Claims and Statutory Grounds (37 C.F.R. § 42.104(b)(1)-(2))	12
B.	Claim Construction (37 C.F.R. § 42.104(b)(3)).....	12
1.	“the [first/second] start structure having a leading face with a concave surface portion and a convex surface portion” (Claim 1); “each of the leading faces on the first and the second start structures has a concave surface adjacent a root and a convex surface adjacent a crest of the respective first and second continuously helically wound structures” (Claim 20)	12
2.	“a curvate extending groove” (Claim 1)	15
3.	“simultaneous mating” / “diametrically timed positioning” (Claim 1)	17
C.	Challenge and Support (37 C.F.R. § 42.104(b)(4)-(5))	18
VI.	GROUND 1: CLAIMS 1-7, 13, AND 15-20 ARE OBVIOUS IN VIEW OF THE '477 PUBLICATION, '287 PUBLICATION AND BOSCHERT	19

A.	Overview of the '477 Publication	19
B.	Overview of Boschert.....	23
C.	Overview of the '287 Publication	27
D.	Motivation to Combine the '477 Publication, the '287 Publication, and Boschert.	34
1.	Motivation to Use the '287 Publication Receiver and Inserts ..	37
2.	Motivation to Use Boschert's Dual Threads.....	39
E.	Claim Analysis	41
1.	Claim 1	41
2.	Claim 2	67
3.	Claim 3	68
4.	Claim 4.....	69
5.	Claim 5	70
6.	Claim 6.....	71
7.	Claim 7.....	72
8.	Claim 13	73
9.	Claim 15.....	75
10.	Claim 16.....	76
11.	Claim 17	77
12.	Claim 18.....	80
13.	Claim 19.....	85
14.	Claim 20	87

VII. GROUND 2: CLAIM 14 IS OBVIOUS IN VIEW OF THE '477 PUBLICATION, '287 PUBLICATION, BOSCHERT, AND JOHNSON.
89

A.	Overview of Johnson.....	89
B.	Motivation to Combine Johnson with the '477 Publication, the '287 Publication, and Boschert.....	91
C.	Claim Analysis.	94
1.	Claim 14.....	94

VIII. SECONDARY CONSIDERATIONS	95
IX. DISCRETIONARY DENIAL IS NOT APPROPRIATE	96
A. 35 U.S.C. §325(d).....	96
B. Fintiv.....	97
X. CONCLUSION	98

TABLE OF AUTHORITIES

Cases	Page(s)
<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH,</i> IPR2019-01469, Paper 6 at 8-9 (PTAB Feb. 13, 2020).....	96, 97
<i>Apple Inc. v. Fintiv, Inc.,</i> IPR2020-00019, Paper 11 at 6 (PTAB Mar. 20, 2020)	97
<i>Becton, Dickinson & Co. v. B. Braun Melsungen,</i> IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017)	96
<i>Jackson v. ZimVie Inc.,</i> No. 1:22-cv-00891-RGA (D. Del. Filed June 30, 2022)	1
<i>Sotera Wireless, Inc. v. Masimo Corporation,</i> No. IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020)	97
<i>Thorne Res., Inc. v. Trs. of Dartmouth Coll.,</i> IPR2021-00491, Paper 18 (PTAB Aug. 12, 2021).....	97
Statutes, Rules & Regulations	
35 U.S.C. § 102	12
35 U.S.C. § 102(b)	19, 23, 27, 89
35 U.S.C. § 103	12
35 U.S.C. § 325(d)	96
37 C.F.R. § 42.8	1
37 C.F.R. §§ 42.8(b)(3).....	2
37 C.F.R. §§ 42.10(a).....	2
37 C.F.R. § 42.100(b)	12
37 C.F.R. § 42.103	3
37 C.F.R. § 42.104(a).....	3

Petition for *Inter Partes* Review of U.S. Patent No. 10,898,233
Filed September 22, 2023

37 C.F.R. § 42.104(b)	12
37 C.F.R. § 42.104(b)(1)-(2).....	12
37 C.F.R. § 42.104(b)(3).....	12
37 C.F.R. § 42.104(b)(4)-(5).....	18

LIST OF EXHIBITS

Exhibit 1001:	U.S. Patent No. 10,898,233 (“the ’233 Patent”)
Exhibit 1002:	File History U.S. Patent No. 10,898,233
Exhibit 1003:	Declaration of Dr. Carl McMillin
Exhibit 1004:	Dr. Carl McMillin Curriculum Vitae
Exhibit 1005:	U.S. Patent Application Pub. No. 2005/0267477 (“the ’477 Publication”)
Exhibit 1006:	U.S. Patent No. 7,857,834 (“Boschert”)
Exhibit 1007:	U.S. Patent Application Pub. No. 2010/0312287 (“the ’287 Publication”)
Exhibit 1008:	U.S. Patent Application Pub. No. 2007/0088357 (“Johnson”)
Exhibit 1009:	U.S. Patent No. 8,911,479
Exhibit 1010:	U.S. Patent No. 10,548,641
Exhibit 1011:	U.S. Patent No. 11,129,646
Exhibit 1012:	German Patent No. 29810798
Exhibit 1013:	U.S. Patent Application Publication No. 2004/0167526
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

Petition for *Inter Partes* Review of U.S. Patent No. 10,898,233
Filed September 22, 2023

- Exhibit 1018: File History U.S. Patent Application No. 15/397,959 (“the ’959 Application”) (*Excerpt*)
- Exhibit 1019: U.S. Patent No. 7,250,052 (“Landry”)
- Exhibit 1020: U.S. Patent Application Publication No. 2006/0069391 (“the ’391 Publication”)
- Exhibit 1021: U.S. Patent Application Pub. No. 2004/0162560 (“Raynor”)
- Exhibit 1022: U.S. Patent Application Pub. No. 2011/0106179 (“Prevost”)
- Exhibit 1023: U.S. Patent Application Pub. No. 2006/0058794 (“Jackson ’794”)
- Exhibit 1024: U.S. Department of Commerce’s 1969 Handbook H28 (“Handbook H28”)
- Exhibit 1025: U.S. Patent No. 4,707,001 (“the ’001 Patent”)
- Exhibit 1026: U.S. Patent No. 6,010,502 (“Bagby”)
- Exhibit 1027: U.S. Patent No. 5,697,929 (“Mellinger ’929”)
- Exhibit 1028: U.S. Patent No. 6,726,687
- Exhibit 1029: American Heritage Dictionary, Fifth Edition (2011)
- Exhibit 1030: U.S. Patent No. 7,854,751 (“Sicvol”)
- Exhibit 1031: American Society of Mechanical Engineering (ASME) Standard B1.7-2006 (“ASME B1.7-2006”) (*Excerpt*)
- Exhibit 1032: U.S. Patent Application Pub. No. 2006/0036244 (“Spitler”)
- Exhibit 1033: U.S. Patent Application Publication No. 2011/0152947 (“’947 Kirschman Publication”)

- Exhibit 1034: European Patent No. 1,743,584 (“Matthis”)
- Exhibit 1035: U.S. Patent Application Publication No. 2007/0270813 (“Garamszegi ’813”)
- Exhibit 1036: U.S. Patent Application Publication No. 2008/0319490
- Exhibit 1037: U.S. Patent Application Publication No. 2008/0045953 (“Garamszegi ’953”)
- Exhibit 1038: U.S. Patent Application Publication No. 2010/0137918 (“Wilcox”)
- Exhibit 1039: The Compact Edition of the Oxford English Dictionary, Vol. 1 (1971)
- Exhibit 1040: U.S. Patent No. 7,862,595 (“Foley”)
- Exhibit 1041: U.S. Patent No. 7,160,300 (“Jackson ’300”)
- Exhibit 1042: U.S. Patent No. 6,716,214 (“the ’214 Patent”)
- Exhibit 1043: U.S. Patent No. 6,488,681
- Exhibit 1044: U.S. Patent No. 6,280,442
- Exhibit 1045: U.S. Patent No. 6,074,391
- Exhibit 1046: U.S. Patent No. 4,545,374 (“Jacobson”)
- Exhibit 1047: Stipulation Regarding Invalidity Contentions (“Sotera Stipulation”)
- Exhibit 1048: June 21, 2022 Memorandum regarding Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (“Sotera Memo”)
- Exhibit 1049: U.S. Patent Application Publication No. 2005/0286984

Petition for *Inter Partes* Review of U.S. Patent No. 10,898,233
Filed September 22, 2023

Exhibit 1050: U.S. Patent No. 6,726,689 (“Jackson ’689”)

ZimVie, Inc. and Zimmer Biomet Spine, Inc. (“Petitioners”) respectfully request *inter partes* review (“IPR”) of Claims 1-7 and 13-20 (“the Challenged Claims”) of U.S. Patent No. 10,898,233 (“the ’233 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 ’233 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 11,129,646 (EX1011) (the “’479,” “’646,” and “’641 Patent,” respectively; collectively, “the Related Patents”), to be filed concurrently herewith. The Related Patents are also at issue in the Litigation. The ’233 Patent is a continuation of the ’479 Patent and the ’641 Patent.

C. Counsel

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

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

II. STANDING AND FEES

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

Petitioners certify that the '233 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)

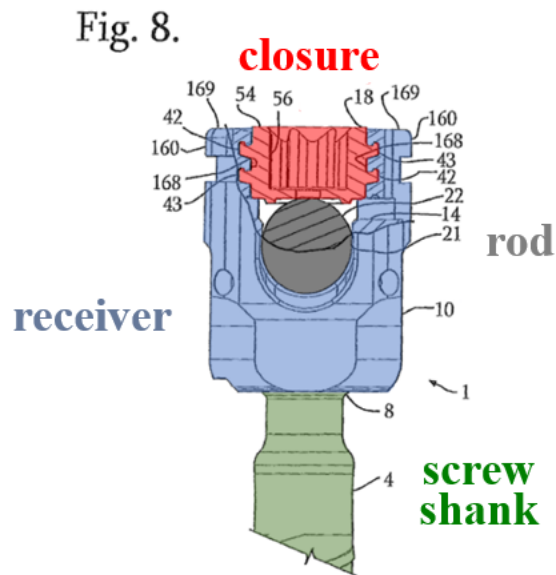
Petitioners authorize the Director to charge the request and post-institution fees, and any additional required fees, to Deposit Account No. DA060029.

III. THE '233 PATENT

A. Overview

The '233 Patent is directed to threaded closures (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 acknowledges that the use of “[b]one anchors, such as bone screws” is well-known for spinal surgery. EX1001, 1:31-34. The specification states that “*open-ended bone anchors are known*,” EX1001, 1:38-39, and, as shown in annotated Figure 8 below, 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

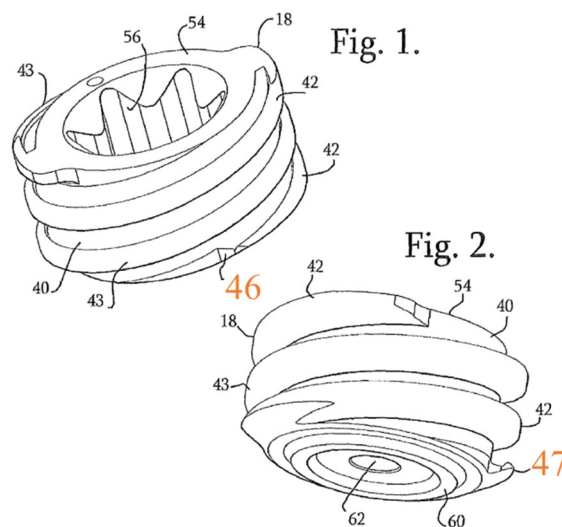
channel to receive a rod or other longitudinal connecting member.”¹ EX1001, 1:53-57. As taught in the prior art, this U-shaped channel is “closed by a closure member after the rod or other longitudinal connecting member is placed in the channel.” EX1001, 1:60-64.



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

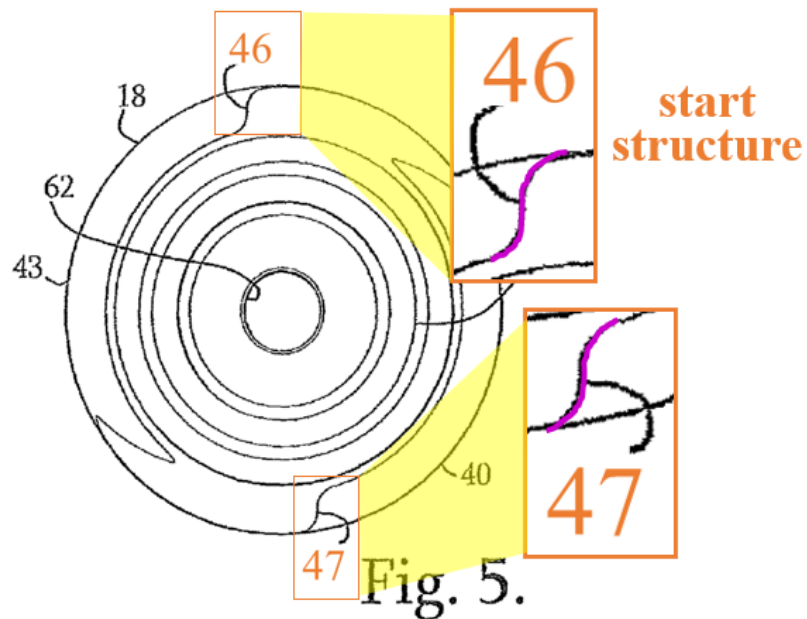
¹ Emphases and text coloring added unless specified.

pulling the rod back out of the implant.” EX1001, 2:17-25. The specification proposes 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.” EX1001, 2:46-49. The “start structures 46 and 47” are identified in annotated Figures 1, 2 and 5 below.



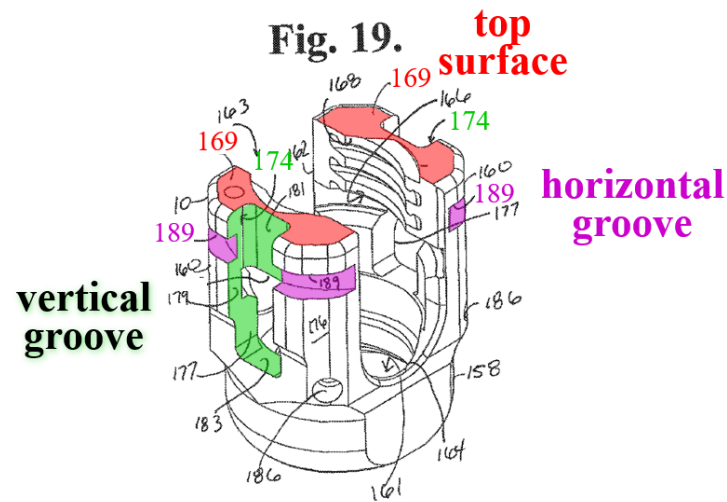
Id., Figs. 1, 2, 5.

These start structures each “includes a leading face having at least one curvate surface,” which can be “both concave and convex.” *Id.*, 9:38-42. The only figure showing the curves of the leading faces is Figure 5, as enlarged/annotated below.



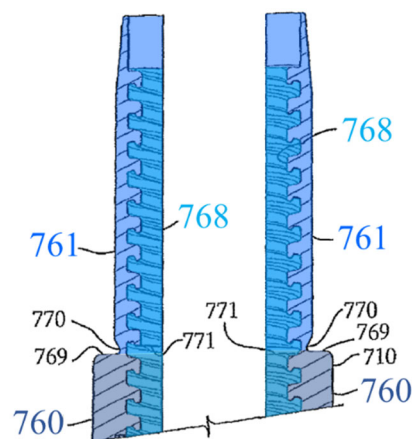
Id., Fig. 5.

Beyond the “double-start closure,” the specification discusses several available design choices for the assembly but does not ascribe any inventive significance to these design choices. For instance, the ’233 Patent describes the arms 160 of the receiver including both vertical and horizontal grooves, depicted in annotated Fig. 19 below.



Id., Fig. 19. Similarly, the '233 Patent describes the addition of integral break-off tabs to the arms of the receiver, as depicted in annotated Figure 15 below.

Fig. 15.



Id., Fig. 15. Further, the '233 Patent discusses the use of a top-loaded insert with arms and wings to secure the rod within the channel of the receiver, shown annotated Figures 18 and 38 below.

Fig. 18.

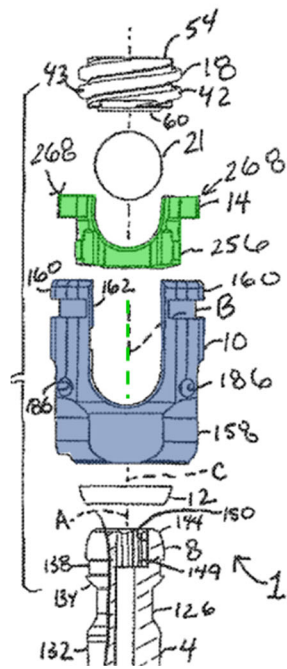
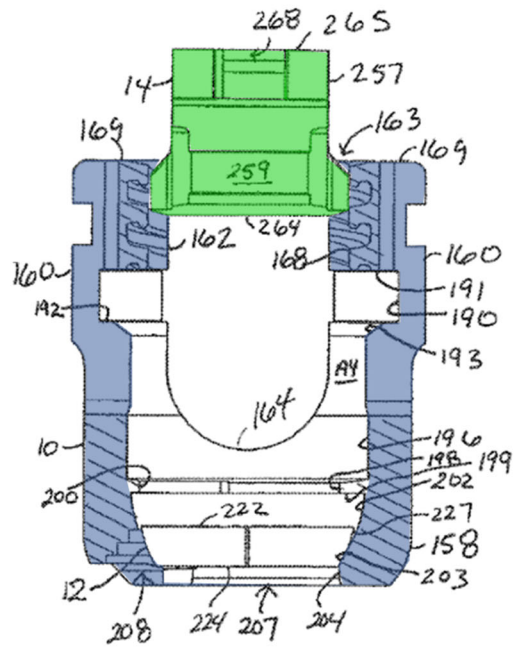
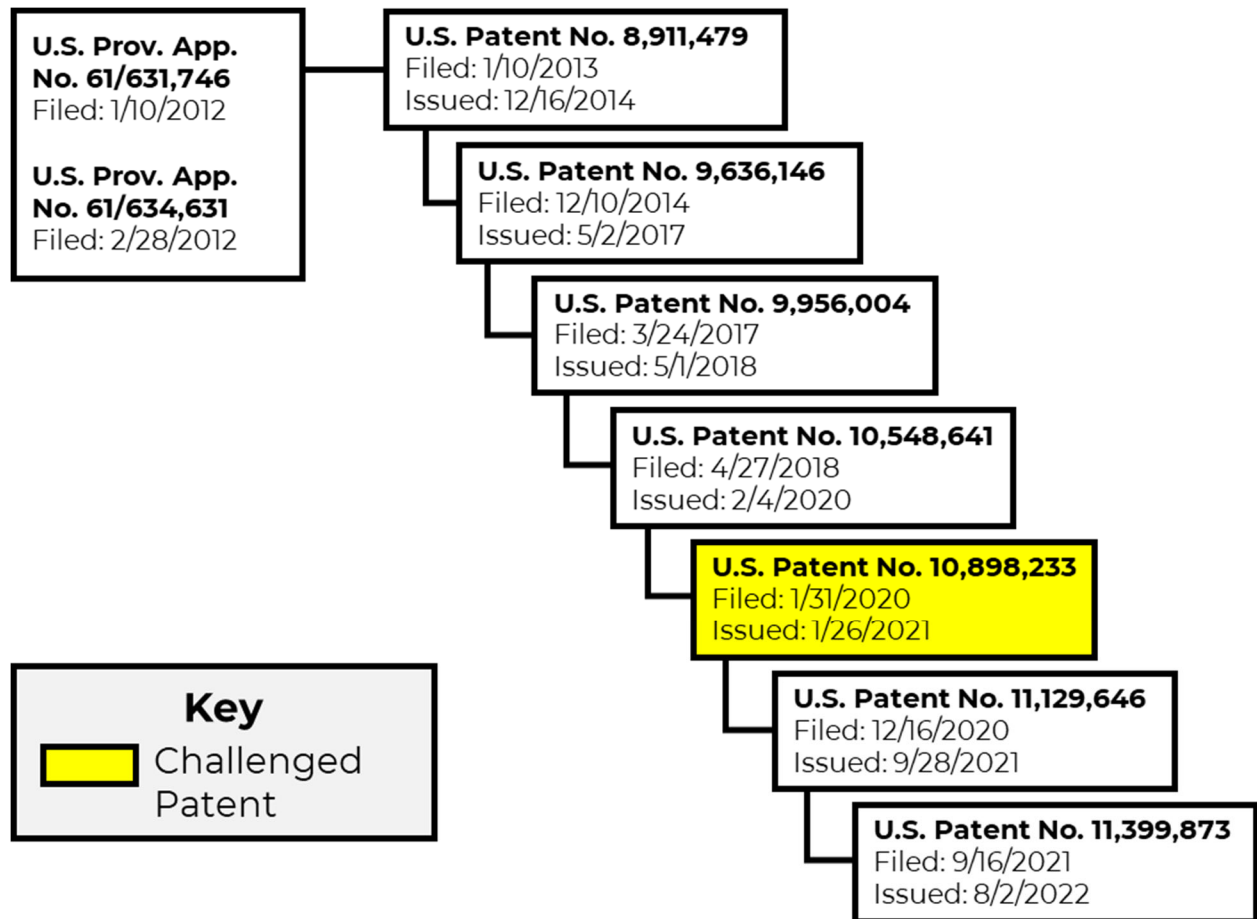


Fig. 38.



Id., Figs. 18&38.

The '233 Patent is part of a patent family shown below:



During prosecution of the '233 Patent, the proposed claims were rejected over Garamszegi (U.S. Pub. No. 2008/0045953) (“Garamszegi ’953”), which disclosed a tool groove on a conventional bone screw receiver, in view of Boschert, which discloses dual start threads. EX1002 at 61-70; *id.* at 315-330. Applicant distinguished Garamszegi ’953, stating that its figures “unambiguously show a *flat groove*, but *not a ‘curvate extending groove.’*” *Id.* at 324. Applicant acknowledged that “*Boschert states that the threads 72 of the setscrew 70 [i.e. closure] can be*

designed with a double lead to allow the setscrew 70 to start easier than one with a single lead.” *Id.* Applicant then amended his claims to require curvate leading surfaces on each thread and distinguished Boschert on this basis. *Id.* at 345-46, *id.* 324-25. The amended claims were allowed without further rejection. *Id.* at 351-55. However, neither a curvate leading face nor a curvate tool groove were inventive features. The ’477 Publication discloses the same curvate leading face and the ’287 Publication discloses the same curvate tool groove.

Claim 1 is the only independent claim of the ’233 Patent. The dependent claims recite additional conventional components of closures and the receivers they thread into, including additional characteristics of the curvate extending groove (Claims 2-7), known threadforms for the inside of the receiver arms (Claim 13), breakoff extensions on the receiver arms (Claim 14), additional characteristics of the receiver face surfaces (Claims 15-16), known inserts to be loaded into the receiver (Claims 17-19), and additional characteristics of known thread starts (Claim 20).

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 '233 Patent claims priority to January 10, 2012 (“Priority Date”). EX1001. Although Petitioners do not concede that the '233 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 a bachelor’s degree in mechanical engineering, or an equivalent discipline, and at least two years of experience designing or implanting spinal implants with threaded connections. More education could substitute for less experience, and vice versa. EX1003, ¶42; *see also id.*, ¶¶36-41.

B. Knowledge of a POSA

Before the priority date of the '233 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, ¶¶44-47. Further, a POSA would have been aware of a number of options when designing such a system, including multi-start threads, *id.*, ¶¶51-63, truncated threads with curvate leading faces, *id.*, ¶¶64-73, thread manufacturing techniques, *id.*, ¶¶74-78, various closure thread types, *id.*, ¶¶79-84, attachable/detachable guide tools and corresponding grooves,

id., ¶¶87-99, breakoff arm extensions, *id.*, ¶¶100-06, and top-loaded inserts, *id.*, ¶¶107-17.

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	1-7, 13 and 15-20	Obvious in view of the '477 Publication (EX1005), '287 Publication (EX1007), and Boschert (EX1006)
2	14	Obvious in View of the '477 Publication (EX1005), '287 Publication (EX1007), Boschert (EX1006), and Johnson (EX1008)

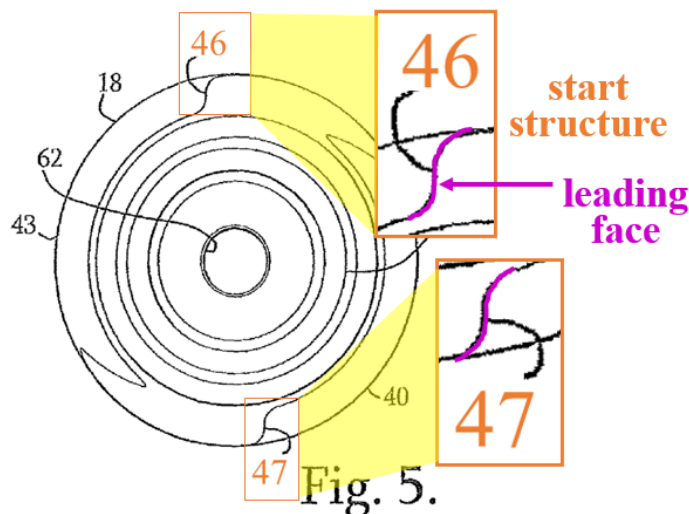
B. Claim Construction (37 C.F.R. § 42.104(b)(3))

The Challenged Claims are construed under the same standard used 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. “the [first/second] start structure having a leading face with a concave surface portion and a convex surface portion” (Claim 1); “each of the leading faces on the first and the second start structures has a concave surface adjacent a root and a convex surface adjacent a crest of the respective first**

and second continuously helically wound structures” (Claim 20)

The claimed “leading face” is never specifically identified by reference number in the ’233 Patent, and the only description of this feature states that each start structure “includes a leading face having at least one curvate surface” that “is both concave and convex.” EX1001, 9:38-42; EX1003, ¶151. Figure 5, enlarged/annotated below, is the only figure that shows the described concave and convex surfaces on the leading face. EX1003, ¶151.

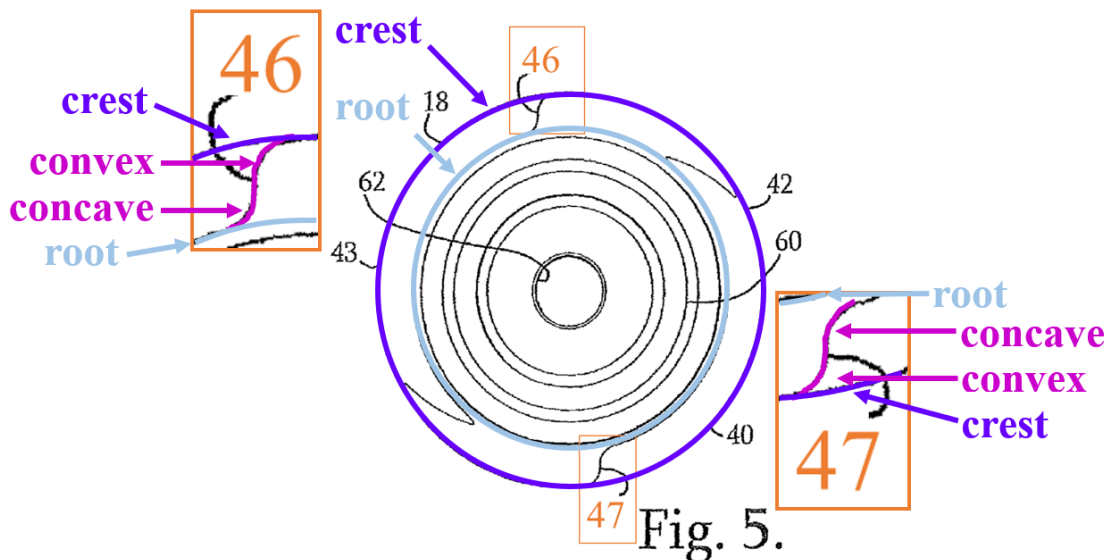


From this disclosure, and consistent with the plain meaning, a POSA would have understood that a “start structure” is the beginning of a thread and the “leading face” is the forward most surface of the thread in the direction the thread is to be rotated. EX1003, ¶152.

A “thread” is defined as a ridge in the form of a helix on the external or internal surface of a cylinder. EX1024 at 10; EX1003, ¶153. The “crest” of the thread is

defined as the surface of the thread which joins the flanks of the thread and is farthest from the cylindrical body from which the thread projects. EX1014 at 4; EX1003, ¶153. The “root” is defined as 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. EX1014 at 5; EX1003, ¶153.

Based on these plain meanings, a POSA would have understood that, when the closure is viewed from the bottom, the root has a smaller circumference and is located adjacent the concave (inwardly curving) portion of the leading face, while the crest has a larger circumference and is located at the perimeter of the thread near the convex (outwardly curving) portion of the leading face. EX1003, ¶154. The approximate location of the root and crest are illustrated below with reference to Fig. 5. EX1001, Fig. 5; EX1003, ¶154.

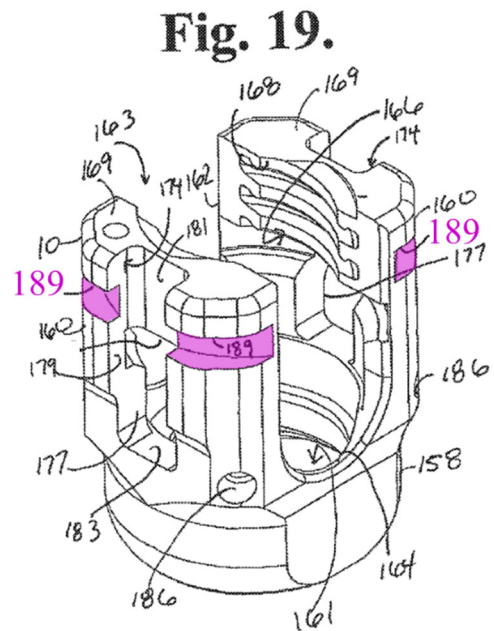


2. “a curvate extending groove” (Claim 1)

The claimed “curvate extending groove” is never specifically identified in the ’233 Patent. EX1003, ¶155. Nevertheless, a POSA would have understood this phrase to have its plain and ordinary meaning. *Id.*

The word “curvate” is generally defined as an adjective meaning “curved.” EX1039 at 3-4; EX1003, ¶156. A “curve” is generally defined as a surface that deviates from the straightness or planarity in a smooth, continuous fashion. EX1029 at 6; EX1003, ¶156. Neither the specification nor prosecution history of the ’233 Patent requires any departure from this plain and ordinary meaning. EX1003, ¶156.

The disclosure in the specification is consistent with the plain meaning. *Id.*, ¶157. Groove 189 is the only curved groove disclosed in the ’233 Patent. *Id.* The entirety of the written description on this feature states: “Also formed in each outer arm surface 176 near the top surface 169 is an undercut **tool receiving and engaging groove 189.**” EX1001, 13:7-9. In those figures showing the curved “groove extending horizontally” at a three-dimensional angle, it is clear that the groove deviates from straightness in a continuous fashion. *See id.*, Figs. 18, 19, 51-57; EX1003, ¶157.



The plain meaning is also consistent with statements made during prosecution of the '233 Patent. EX1003, ¶158. The claims were rejected over Garamszegi '953. EX1002 at 61-70 (6.12.20 Rejection). The disclosed receiver head from Garamszegi '953 is shown in Figure 11 below, with annotations added by Applicant during prosecution.

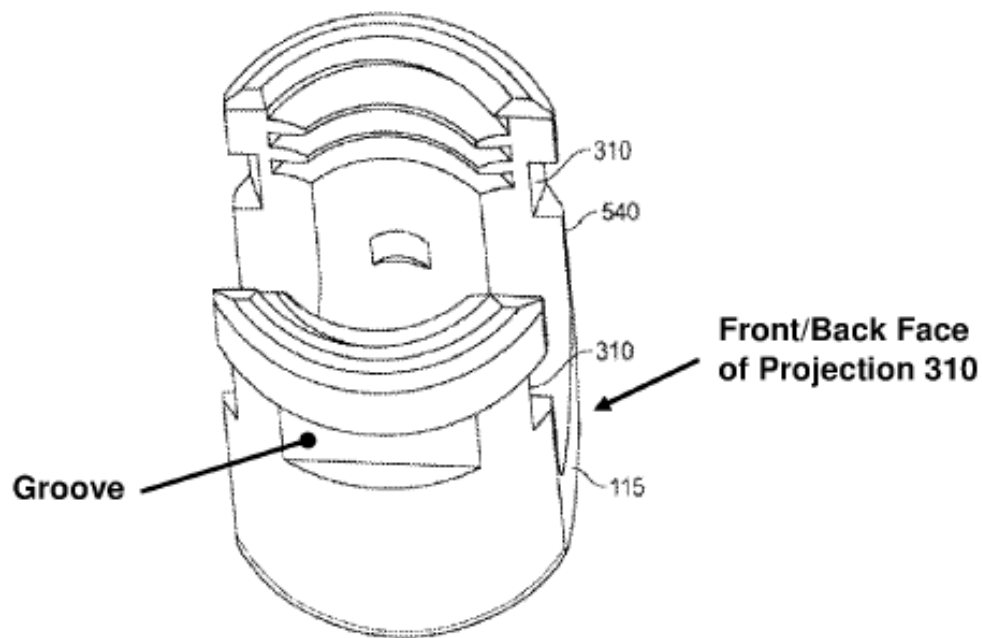


FIG. 11

EX1002 at 345. The Applicant argued that Garamszegi '953 was distinguishable because its grooves were flat, not curvate. *Id.* The claims were subsequently allowed. *Id.* at 351-55; EX1003, ¶158.

Therefore, a POSA reading the claims of the '233 Patent in view of the specification and prosecution history would have understood the claim language “curvate extending groove” to refer to a groove that is not straight or flat but that

deviates from straightness in a continuous fashion (e.g., a radiused groove).
EX1003, ¶159.

**3. “simultaneous mating” / “diametrically timed positioning”
(Claim 1)**

The terms “simultaneous mating” and “diametrically timed positioning” are never used in the ’233 Patent’s specification. Nevertheless, a POSA would have understood these phrases to have their plain and ordinary meaning. EX1003, ¶160.

The ’233 Patent discloses a closure that includes one or more helically wound guide and advancement features that each have a start surface, with “each start structure simultaneously engaging and being captured” by the spaced arms of the open implant upon initial rotation of the closure. *Id.*, 2:37-45; *see also id.*, 3:9-14. The ’233 Patent discloses that, “when the closure structure 18 is rotated into the receiver 10 . . . , the start 46 engages mating guide and advancement structure 168 on one arm 160 and the start 47 simultaneously engages guide and advancement structure 168 on the opposing arm 160, both forms 42 and 43 being simultaneously captured by the mating forms 168 on the opposed arms 160.” *Id.*, 9:19-27. Similarly: “the helical forms 168 on the opposing arm surfaces 166 that are configured to mate with the dual start closure top 18 are reverse or flipped images of one another, . . . so that each closure structure start and are simultaneously

engaged and captured at each arm 160 at the same time.” *Id.*, 12:10-17; *see also id.*, 22:57-65, 23:11-19, 23:32-39, 23:52-59, 24:51-56; EX1003, ¶161.

A POSA, having read the specification of the ’233 Patent would have understood “simultaneous mating” to mean that the first and second start engaged the first and second discontinuously helically wound structures at the same time. EX1003, ¶162. A POSA would have similarly understood “diametrically timed positioning” to mean positioning that allows for such “simultaneous mating.” *Id.* In other words, a POSA would have understood “diametrically timed positioning” to mean that the first and second starts were positioned 180 degrees apart on the closure. *Id.* This understanding is also confirmed by the ’233 Patent, which shows symmetrical threads on the receiver. *E.g.*, EX1001, Figs. 3, 8, 9, 11-15; EX1003, ¶162.

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

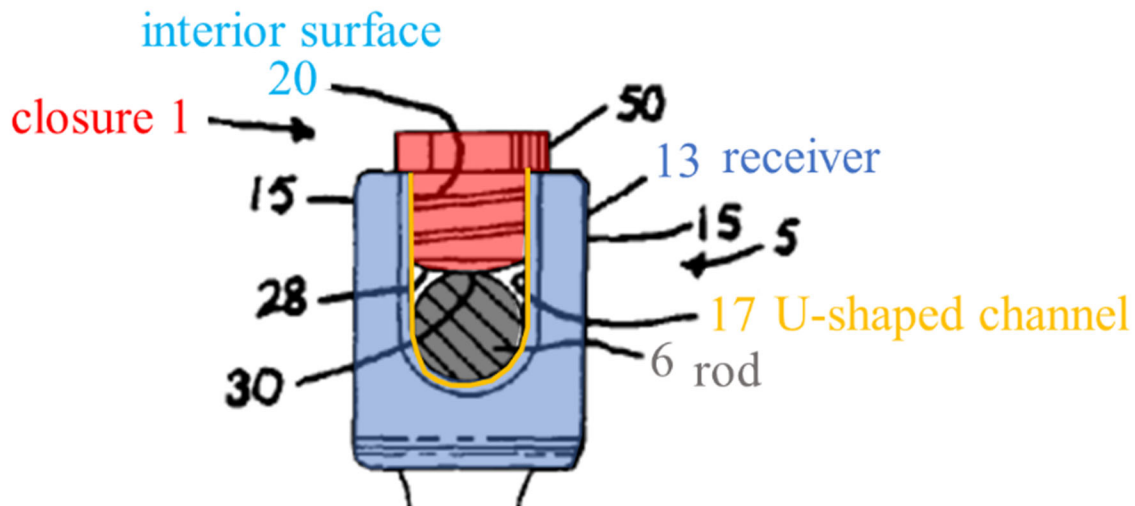
The grounds set forth in Sections VI-VII below, as supported by the Declaration of Dr. Carl McMillin (EX1003), demonstrate that the Challenged Claims are unpatentable.

VI. GROUND 1: CLAIMS 1-7, 13, AND 15-20 ARE OBVIOUS IN VIEW OF THE '477 PUBLICATION, '287 PUBLICATION AND BOSCHERT.

A. Overview of the '477 Publication

The '477 Publication, EX1005, published on December 1, 2005, is prior art to the '233 Patent under 35 U.S.C. § 102(b). The '477 Publication discloses a closure for use with a generic medical implant assembly to capture and lock a rod in the spinal implant. EX1005, ¶¶[0007], [0026]-[0029], [0039]-[0041]; EX1003, ¶163. The '477 Publication is in the same filed of endeavor as, and is analogous art to, the '233 Patent. *Compare* EX1005, ¶[0007] *with* EX1001, 1:26-30; *see also* EX1005, ¶¶[0026]-[0029], [0039]-[0041]; EX1003, ¶163.

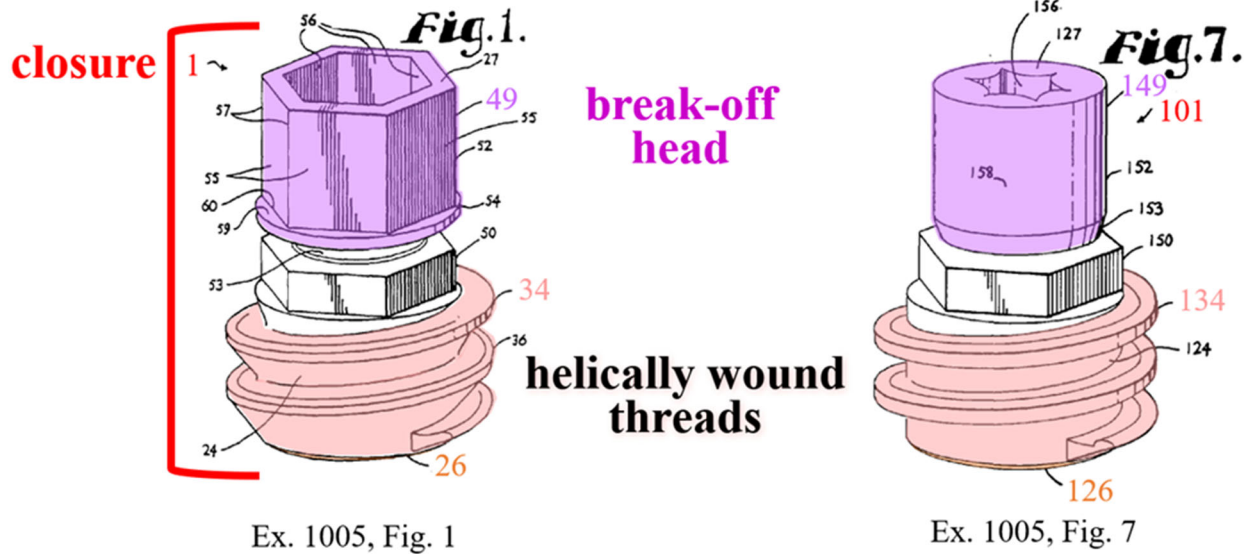
The '477 Publication discloses a polyaxial screw assembly that includes a receiver 13 with a pair of upstanding arms 15 forming a U-shaped channel 17 for receiving a rod 6. EX1005, ¶¶[0007], [0026]-[0038], Figs. 1-6; EX1003, ¶164.



Ex. 1005, Fig. 6

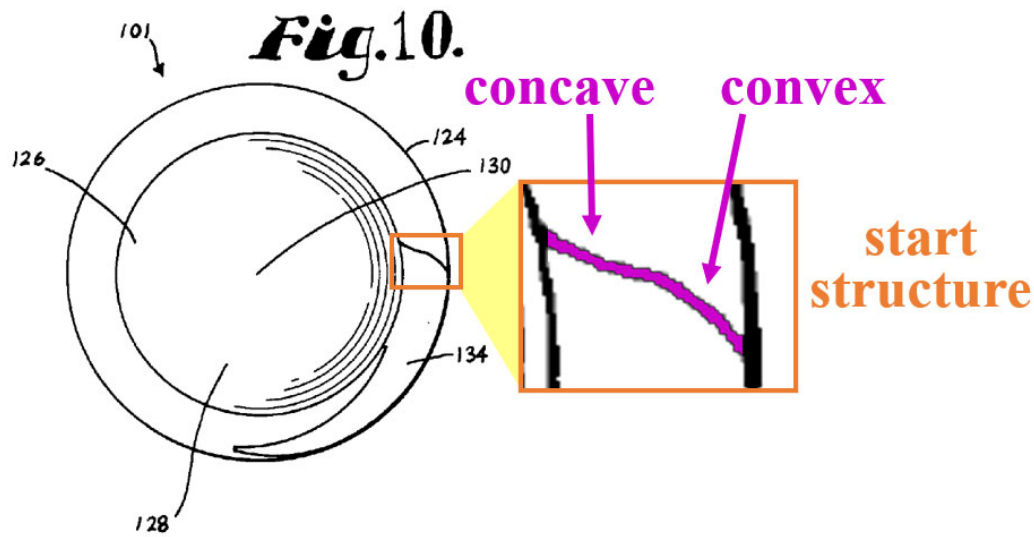
The inner surface 20 of each arm has a partial helically wound guide and advancement structure that mates with a corresponding structure on closure 1 to advance the closure when rotated. EX1005, ¶¶[0007], [0029], ¶[0030]; EX1003, ¶164.

The '477 Publication discloses two preferred closure embodiments, depicted as closures 1 and 101 below. *See* EX1003, ¶165.



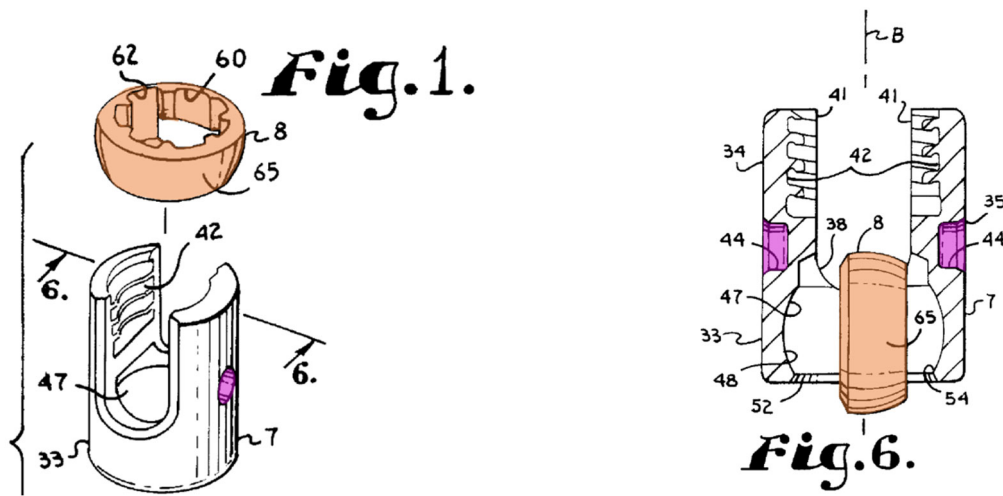
Both closures are cylindrical and have a central axis of rotation, with a single helically wound guide and advancement structure 34/134 along the outside. EX1005, ¶[0029], [0030], [0040], [0041], Fig. 1; *see also id.*, ¶[0039], ¶[0040]-[0045]; EX1003, ¶¶166-67. Both closures also have a break-off head. The primary difference between the embodiments is the shape of the closure break-off heads 49 and 149. EX1005, ¶[0033] (hexagonal), [0043] (cylindrical); *compare id.*, Fig. 1 *with id.*, Fig. 7; EX1003, ¶¶166-67.

As shown in annotated and enlarged Figure 10 below, the second embodiment's closure 101 shows that the leading face of the start structure is formed in an s-curve, with both concave and convex curves. EX1005, Fig. 10; EX1003, ¶167.



Ex. 1005, Fig. 10

The '477 Publication further incorporates by reference U.S. Pat. No. 6,716,214 (“the '214 Patent”), which discloses the use of tool attachment grooves on the outer surface of the receiver head and top-loaded fixation elements. EX1005, ¶[0027]; EX1042. In particular, as shown in annotated Figures 1 and 6, the '214 patent teaches that tool engaging apertures 44 on receiver arms 34 and 35. EX1042, 7:2-4, Figs. 1&6. The '214 Patent discloses the use of additional fixation system elements top-loaded into the receiver for engaging with the shank and receiver, such as retainer ring 8 (orange). EX1005, Fig. 1; EX1003, ¶168.

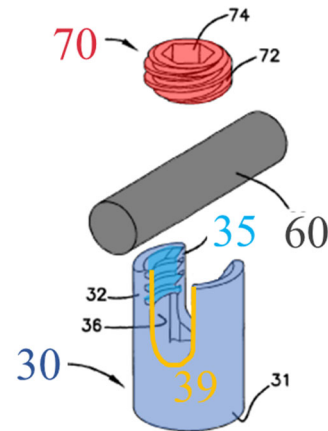


The '477 Publication expressly contemplates that the described closure would be used with “*any type of medical implant having an open or closed head.*” EX1005, ¶[0027]; *see also id.*, Abstract, ¶¶[0007], [0025]; EX1003, ¶169.

B. Overview of Boschert

Boschert, EX1006, published on December 15, 2005, is prior art to the '233 Patent under 35 U.S.C. § 102(b). Boschert discloses an orthopedic fixation device for securing a rod to a bone for stabilization of the spine. EX1006, Abstract, 1:5-7; EX1003, ¶170. Boschert is in the same filed of endeavor as, and is analogous art to, the '233 Patent. *Compare id.*, 4:26-28 with EX1001, 1:26-30; EX1003, ¶170.

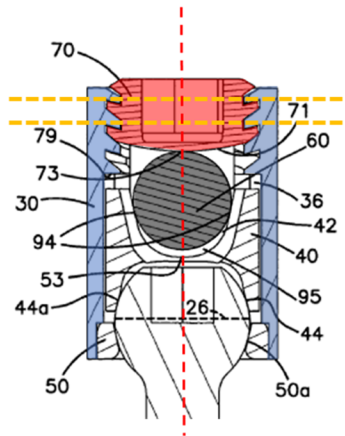
Specifically, Boschert discloses a receiver 30 (blue) with two upwardly extending legs defining the saddle 39 (yellow) (i.e., the channel) which is U-shaped for receiving the rod 60 (gray). EX1006, 6:20-24, Fig. 1; *see also id.*, 4:13-28; EX1003, ¶¶171-72. The legs have interior threads (light blue) that mate with corresponding exterior threads on the set screw 70 (red)



Ex. 1006, Fig. 1

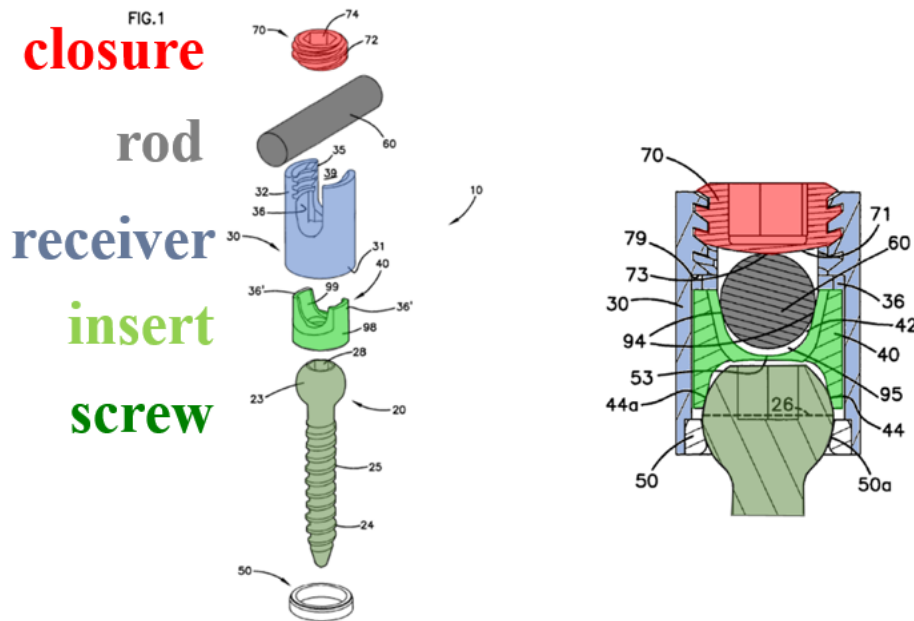
(i.e. the closure), such that the set screw can be threaded into the saddle to lock the rod in place. EX1006, 6:25-48; *see also id.*, 4:26-28, 4:48-50, 7:12-15; EX1003, ¶¶171-72.

Boschert discloses that it would be advantageous to design the set screw's threads to have a “*double lead to allow the setscrew 70 to start more easily than with a single lead.*” EX1006, 7:21-23. Relatedly, as shown below in annotated Figure 3, Boschert discloses that interior threads on the receiver that are mirrored along the longitudinal axis (red), such that the receiver simultaneously receives the double leads of the closure. *Id.*, Fig. 3; EX1003, ¶172.

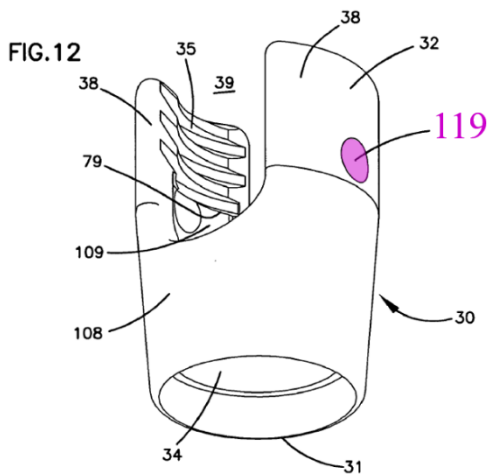


As discussed in more detail below, *see* §§VI.E.1.i-j, the double threads of Boschert’s closure are also symmetrical and diametrically opposed, and therefore simultaneously mate into the symmetrical threads of the receiver. *See* EX1003, ¶¶173-80; EX1006, Figs. 1, 3, 7, 15; EX1014 at 3; EX1026, 13:35-41. Boschert expressly contemplates potential modifications to its closure. *See* EX1006, 7:58-62; EX1003, ¶178.

Boschert further discloses a “seat structure 40” (i.e., the insert) that is loaded into the receiver “between the rod 60 and the head 23 of the screw 20.” EX1006, 4:20-22, Fig. 1. Tightening of the set screw 70 (i.e., the closure) in the receiver “forces the seat structures 40 downwardly within the receivers 30 causing the heads 23 of the bone screws 20 to be clamped between the bottom sides of the seat structures 40 and the retainers 50.” *Id.*, 4:47-56; Figs. 1, 3; EX1003, ¶179.

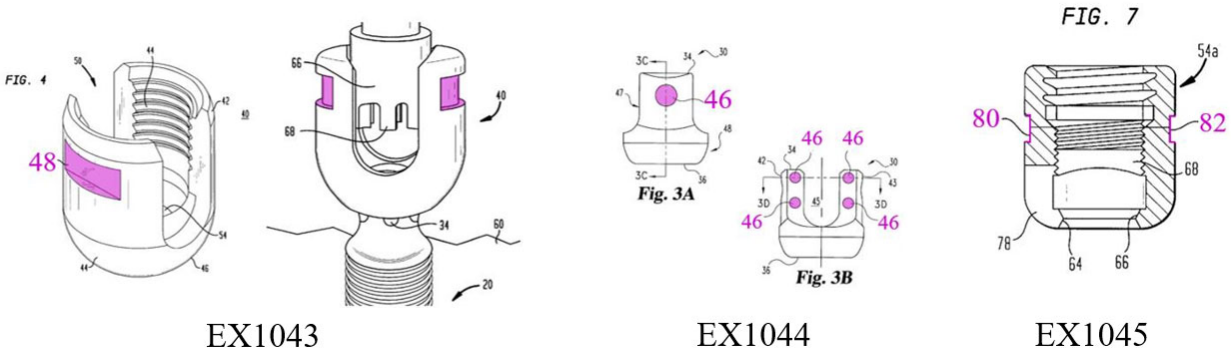


Boschert contemplates the use “grasping features 119 on the outer surface 108 [of the receiver] that would accommodate instrumentation to facilitate grasping, holding or manipulating of the receiver 30.” EX1006, 6:15-19; EX1003, ¶180.



Boschert does not describe these “grasping features” in any more detail, but incorporates several patents disclosing exemplary grasping features, including U.S. Patent Nos. 6,488,681 (EX1043) (grooves 48, Figs 4, 8 at left); 6,280,442 (EX1044)

(indentations or holes 46, Figs. 3A, 3B at middle), and 6,074,391 (EX1045) (slots 80 and 82, Fig. 7 at right) pictured below. EX1006, 1:55-60; EX1003, ¶180.

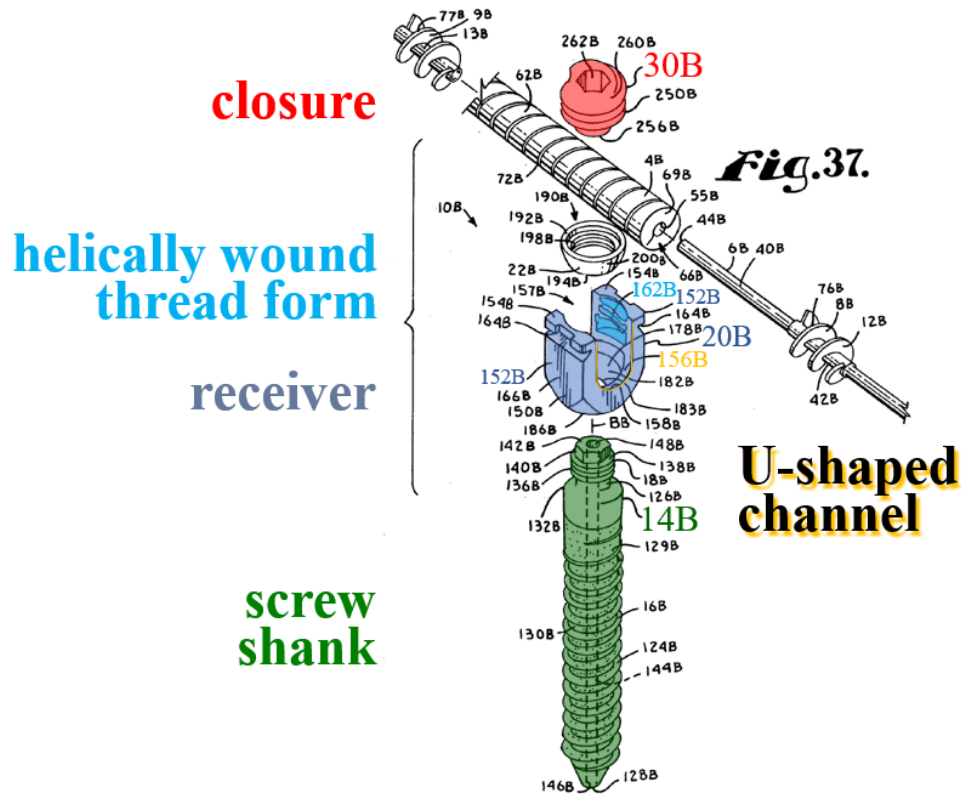


C. Overview of the '287 Publication

The '287 Publication, EX1007, published on December 9, 2010, is prior art to the '233 Patent under 35 U.S.C. § 102(b). The '287 Publication discloses a medical implant assembly that uses a closure to capture and lock a longitudinal connecting member, such as a rod, in a spinal implant. EX1007, ¶¶[0002], [0132]-[0158]; EX1003, ¶181. Therefore, the '287 Publication is in the same field of endeavor as, and is analogous art to, the '233 Patent. *Compare* EX1007, ¶¶[0133]-[0134] *with* EX1001, 1:26-30; *see also* EX1005, ¶¶[0026]-[0029], [0039]-[0041]; EX1003, ¶181.

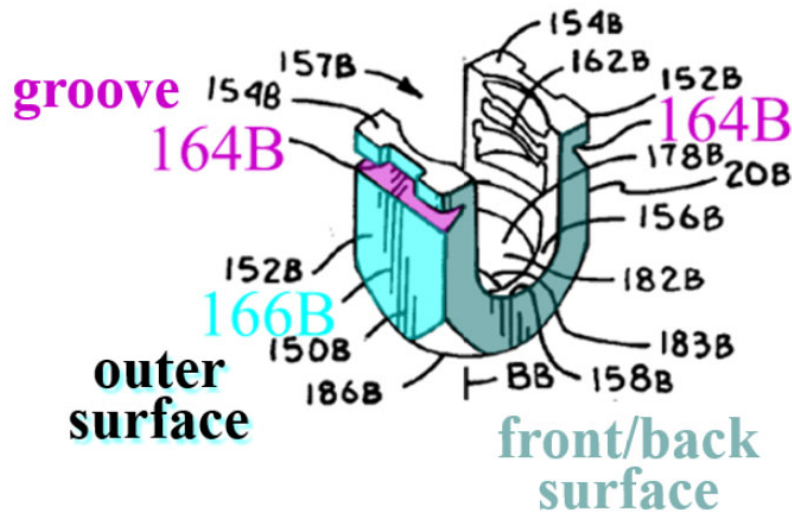
Like the '477 Publication, the '287 Publication discloses a polyaxial screw assembly that includes a receiver 20B with a pair of upstanding arms 152B forming a U-shaped channel 156B for receiving a longitudinal connecting member assembly and having a partial (i.e., discontinuous) helically wound guide and advancement

structure 162B that mates with a similar structure on a closure 30B when the closure is rotated. EX1007, ¶¶[0133]-[0134], [0150], [0151], [0156], Figs. 37-39; EX1003, ¶182.



In describing this polyaxial screw assembly, the '287 Publication describes bone screw receivers having tool grooves for temporarily attaching various tools during the surgical procedure. EX1003, ¶182. The '287 Publication discloses multiple preferred embodiments, each with one of two interchangeable receiver shapes. EX1007, ¶[0115]; EX1003, ¶183.

The first receiver shape is shown in cropped/annotated Figure 37, below:

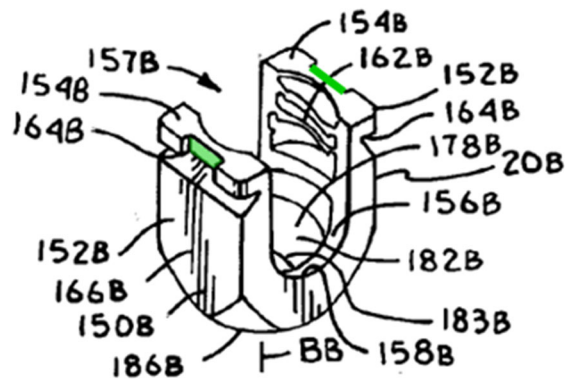


As shown, the receiver has “substantially planar outer surface 166B” and front/back surfaces. EX1007, ¶[0152], Fig. 37 (receiver 20B); *see also id.*, ¶[0078], Figs. 5, 14 (receiver 20); EX1003, ¶183. “Each of the arms 152B includes a V-shaped-like undercut tool engagement groove 164B formed on a [the] substantially planar outer surface 166B thereof which may be used for holding the receiver 20B with a holding tool (not shown) having projections that are received within the grooves 164B” EX1007, ¶[0152]; *see also id.* ¶[0078]. The groove extends to, and intersects with, the front/back surface of receiver 20B. *Id.* Fig. 37; *see also id.*, Figs. 5, 14; EX1003, ¶183.

The '287 Publication's “tool attachment receiving grooves or apertures may be configured in a variety of sizes and shapes, *including radiused*, and be disposed at other locations on the arms 152B.” EX1007, ¶[0152] (emphasis added); *see id.*, ¶[0078]; EX1003, ¶183. A POSA would have understood that a “radiused” tool

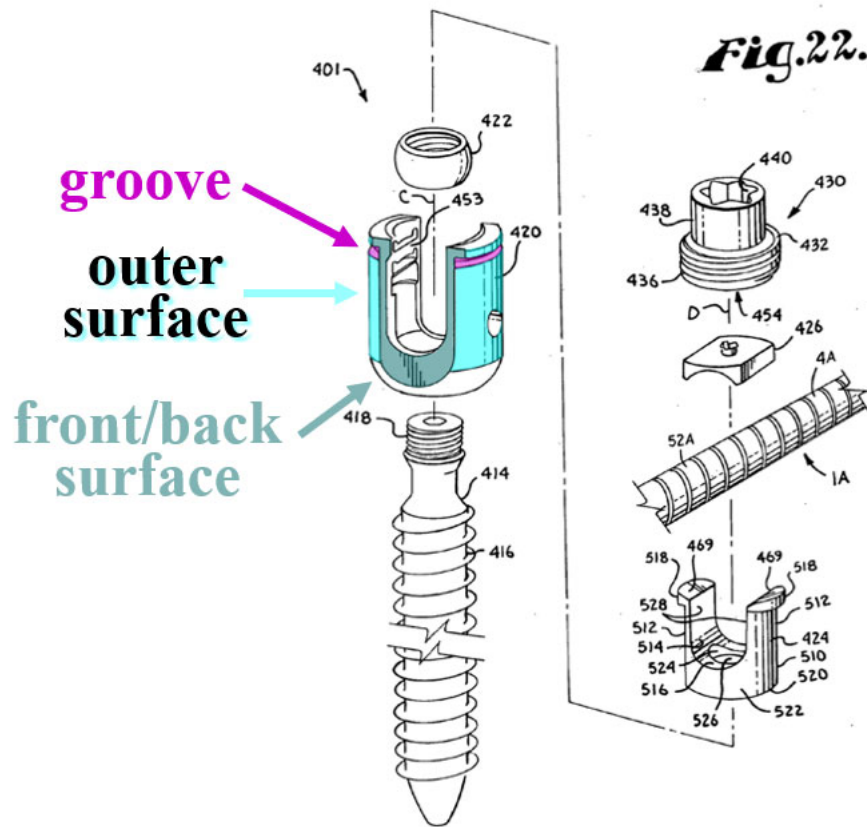
groove means that the groove is curved around the longitudinal axis of the receiver (i.e., it has a radius in that direction). EX1003, ¶183. Such a radiused, i.e., curvate, groove has a known advantage of allowing a tool with corresponding projections to be inserted over the front and back surfaces of the receiver and then rotated 90 degrees to fit the projections on the tool into the radiused tool groove on the sides of the receiver as explained above. EX1003, ¶183.

In addition to the horizontal v-cut groove, the outer surface of the receiver includes an additional vertical recessed groove (**green**) into the top edge of the v-cut groove, as shown in



cropped/annotated Figure 37 at right.
EX1007, Fig. 37; EX1003, ¶184.

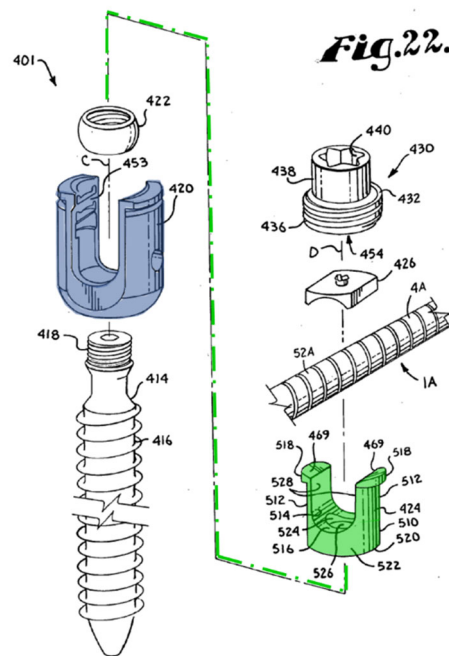
The second receiver shape is shown in annotated Figure 22, below:



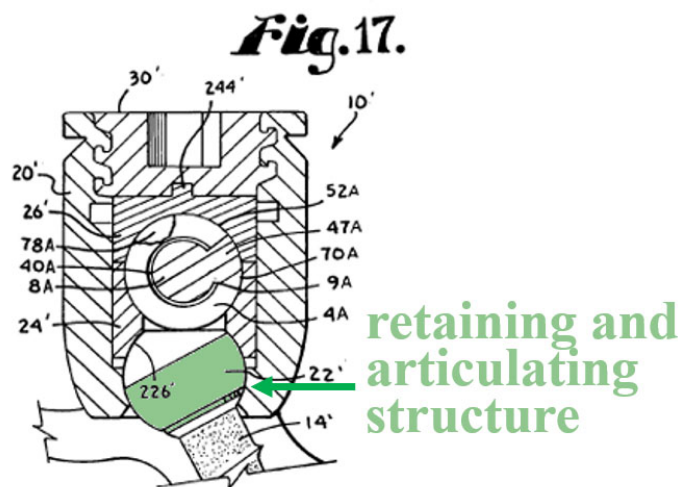
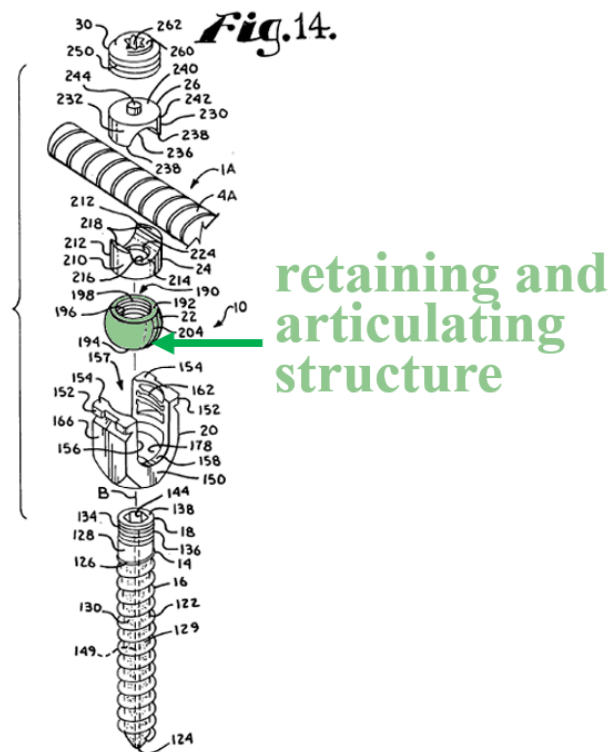
This receiver 420 is “identical or substantially similar” to receiver 20 (and receiver 20B), and the ’287 Publication incorporates the discussion as to those embodiments with respect to assembly 401. EX1007, ¶[0115]; EX1003, ¶185. As shown above, the outer side surfaces of receiver 420 are substantially cylindrical, the tool grooves on each arm are radiused (i.e., curvate), and the tool grooves extend to the front/back surfaces of the receiver. EX1007, Fig. 22; EX1003, ¶185.

This embodiment further includes a compression insert 424 that is sized and shaped to be top-loaded into the receiver, to receive the longitudinal connecting member between the upwardly extending arms, and, on the bottom, to frictionally engages and mate with the shank and retaining structures. EX1007, ¶[0126], Fig.

22; EX1003, ¶186. As seen in Figure 22 below, the insert 424 has two upwardly extending arms with lateral projections at the tops thereof. EX1007, ¶[0126], Fig. 22; EX1003, ¶186.



The '287 Publication expressly discloses a “*retaining and articulating structure 22*” in “fixed frictional contact with the receiver 20, so as to substantially attach and orient [the implant] . . . relative to the vertebra 28.” EX1007, ¶[0063]; *see also id.*, ¶¶[0098], [0126]. The described engagement between retaining insert 22 and the head of a bone attachment shank is depicted in illustrative Figures 17 and 14 below:



EX1003, ¶186. The '287 Publication teaches that its receiver can be used with known closures. EX1007, ¶¶[0086], [0156]; EX1003, ¶187. The systems disclosed in the '287 Publication “provide a lightweight, reduced volume, low profile

assembly . . . [and] to provide apparatus and methods that are easy to use.” EX1007, ¶[0014], EX1003, ¶188.

D. Motivation to Combine the ’477 Publication, the ’287 Publication, and Boschert.

A POSA would have been motivated to combine the teachings of the ’477 Publication, the ’287 Publication, and Boschert before the priority date of the ’233 Patent. EX1003, ¶194. Specifically, a POSA would have been motivated to (i) combine the closure of the ’477 Publication with the receiver and inserts of the ’287 Publication and (ii) to modify the closure and receiver to have the double lead thread of Boschert. EX1003, ¶194.

The ’477 Publication and ’233 Patent are in the same field, as set forth above. *Supra* §§VI.A. The ’477 Publication teaches closures that could be used with any conventional bone screw receivers. *See* EX1005, ¶[0007]; EX1003, ¶195. The ’477 Publication states that a “receiver having a pair of spaced arms with an open channel” is a “typical implant for use with a closure of the invention.” EX1005, ¶[0007], Abstract, ¶[0025], ¶[0027]. The “medical implant” used with the claimed closure in the ’477 Publication is a polyaxial bone screw with a U-shaped receiver, as described in the ’287 Publication. EX1005, Abstract; EX1003, ¶195. A POSA would have been motivated to use the closure of the ’477 Publication in conjunction

with known medical implants, including those described in the '287 Publication. EX1003, ¶195.

The '287 Publication and '233 Patent are similarly in the same field, as discussed above. *Supra* §VI.C; EX1003, ¶196. Like the '477 Publication, the '287 Publication discloses a medical implant assembly that uses a closure to capture and lock a longitudinal connecting member, such as a rod, in a spinal implant. EX1007, ¶¶[0002], [0132]-[0158]; EX1003, ¶196. The '287 Publication discloses multiple preferred embodiments and two interchangeable receiver shapes. EX1007, ¶[0115]; EX1003, ¶196. The '287 Publication teaches the benefits of placing well-known tool attachment grooves on the outer surface of these receivers. EX1007, ¶[0152], Fig. 31, Fig. 37; EX1003, ¶196. The '287 Publication teaches that these grooves allow the use of a tool during implantation of the shank and installation of a rod and closure. EX1007, ¶[0152]; EX1003, ¶196. The '287 Publication further teaches utilizing well-known inserts within the receiver to facilitate capturing the rod and fixing the position of the shank, EX1007, ¶[0126]; EX1003, ¶196. The '287 Publication expressly contemplates that its bone screws can be used with other known closures, stating that “the *closure structure 30 can be any of a variety* of different types of closure structures for use in conjunction with the present invention with suitable mating structure on the upstanding arms 152 of the receiver 20.” EX1007, ¶¶ [0086], [0156]; EX1003, ¶196.

Boschert is also in the same field as the '233 Patent. *Supra* §VI.B; EX1003, ¶197. Boschert teaches a polyaxial pedicle screw with a U-shaped receiver that can be closed with a setscrew to capture a rod. EX1003, ¶197. Boschert further teaches that closures (setscrews) could be designed with a double, or multi-start, 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. 3, 15. EX1003, ¶197. 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. The locking arrangements can include any mechanism adapted to provide an axial locking force on the rod 60.” EX1006, 7:58-62; EX1003, ¶197.

Based on the express teachings of the references and their complementary disclosures, a POSA would have been motivated to combine the closure of the '477 Publication and the receiver of the '287 Publication. EX1003, ¶198. In making this combination, it would have been obvious to POSA to modify the closure (of the '477 Publication) and receiver (of the '287 Publication) in view of Boschert to engage with one another using dual-start threads as taught in Boschert, while also using the various thread types discussed in the '477 Publication, each with a curvate leading face. EX1003, ¶198.

1. Motivation to Use the '287 Publication Receiver and Inserts

A POSA would have been motivated to use the closure disclosed in the '477 Publication with the receiver and inserts disclosed in the '287 Publication. EX1003, ¶199. As set forth above, *supra* §§VI.A, VI.C, VI.D.1, the '477 Publication and the '287 Publication disclose complementary medical implant assemblies. EX1003, ¶199. The '287 Publication discloses spinal implant receivers and inserts with elements having various known advantages, giving a POSA reasons to make this combination. EX1003, ¶199.

First, both the '477 Publication and the '287 Publication expressly invite this combination, with the '477 Publication stating that its closures can be used with known implants (such as a U-shaped receiver of a bone screw), EX1005, Abstract, ¶¶[0007], [0025], [0027], [0086], [0156], and the '287 Publication stating that its U-shaped receiver of a bone screw can be used with known closures, EX1007, ¶¶[0086], [0156]. EX1003, ¶200.

Second, the '287 Publication discloses receivers with known tool-engaging grooves on the exterior surfaces of the receiver's upright arms. A POSA would have known that there were multiple well-known designs for facilitating implantation of spinal implant devices, including using a guide tool that attaches to—and detaches from—the spinal implant. EX1003, ¶201. A POSA would have understood that the use of such tools would have many advantages including facilitating implantation of

the receiver, enabling correction of the receiver after implantation, and maintaining the small size of the fixation device to permit minimally invasive techniques. *Id.*

With this knowledge, a POSA would have been motivated to attain the benefits of attachable/detachable guide tools to facilitate implantation by combining the '477 Publication's closure with the '287 Publication's receiver, which includes tool attachment grooves on the outer surfaces of the receiver. EX1003, ¶202.

Third, the '287 Publication discloses known inserts designed to be top-loaded into its receivers. *See supra* §VI.C; EX1003, ¶203. A POSA would have known that top-loaded receiver inserts could be added to a bone screw assembly in order to support the longitudinal connecting member, such as a rod, within the bone screw assembly and to fix the position of the receiver head in relation to the screw shank. EX1003, ¶203. A POSA would have further understood that using such inserts would provide several advantages, including by evenly distributing forces between the rod and the bone screw and by providing a downward force onto the head of the bone screw to lock the screw into a particular angular orientation with respect to the receiver (e.g., in the case of a polyaxial screw assembly). *Id.*

With this knowledge, a POSA would have been motivated to attain the benefits of such inserts by combining the '477 Publication's closure with the '287 Publication's receiver, which is configured to cooperate with top-loaded inserts to aid in securing a bone screw and rod within the receiver. *Id.*, ¶204.

A POSA would have expected success with combining the '477 Publication's closure with the '287 Publication's receiver and inserts because it merely involves the combination of familiar elements using known methods to yield predictable results. *Id.*, ¶205. Specifically, it was well-known to a POSA before the priority date of the '233 Patent that guide tools provided the above-described advantages and could be successfully used in medical implant devices. *Id.* Likewise, it was well-known to a POSA before the priority date of the '233 Patent that top-loaded inserts provided additional advantages and could be successfully used to separate a bone screw and a longitudinal connecting rod in an open-headed receiver assembly. *Id.* A POSA would have had a reasonable expectation of success in making such a combination because it would merely require machining the respective closure and receiver to have compatible engagement structures, while otherwise leaving the components unchanged. *Id.*

2. Motivation to Use Boschert's Dual Threads

As set forth above, *supra* §VI.A, the '477 Publication teaches that closures should include threading (of various disclosed types) for mating with the arms of the receiver, and a leading thread face that includes a concave surface near the root and a convex surface near the crest. EX1003, ¶206. A POSA would have been familiar with these various thread forms and their known advantages, including reducing outwardly directed forces that could cause splaying of the receiver arms. *Id.* A

POSA would have been familiar with truncated thread starts, such as the curvate leading face of the '477 Publication, and their advantages for easing thread insertion, reducing thread deformation, and eliminating sharp edges. *Id.*

Boschert teaches that closures could be designed with a double lead in order ***“to start more easily than with a single lead”*** when loaded into the top of an open receiver. EX1006, 7:21-23; *see also* EX1003, ¶207; *supra* §VI.B. In combining the closure of the '477 Publication with the receiver of Boschert, a POSA would thus have been motivated to modify the closure of the '477 Publication with the double lead thread disclosed in Boschert, given, at the very least, the POSA's understanding that such a change would result in more reliable threading of the fastener into the receiver, as was expressly taught by Boschert. EX1003, ¶207.

A POSA would also have been motivated to so modify the '477 Publication to take advantage of known benefits of double-lead threads of balancing insertion forces, (“Bagby”), EX1026, 13:35-41, and increasing insertion speed, EX1014 at 6. EX1003, ¶208. In making this combination, a POSA would also have retained the truncated thread starts of the '477 Publication with their curvate leading faces, in obtain their known advantages for further easing thread insertion, reduce thread deformation, and reducing sharp edges. EX1003, ¶208. The resulting closure would thus have dual-lead threads, each with a curvate leading face, that simultaneously mate with matching threads on the receiver. *Id.*

Such a combination of familiar elements using known methods would yield predictable results, as it was well known to a POSA before the priority date of the '233 Patent that double lead threads provided these advantages and could be successfully used in closures. *Id.*, ¶209. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for machining double lead threads were well known and readily available and already in use in multi-axial pedicle screws. *Id.*

E. Claim Analysis

1. Claim 1

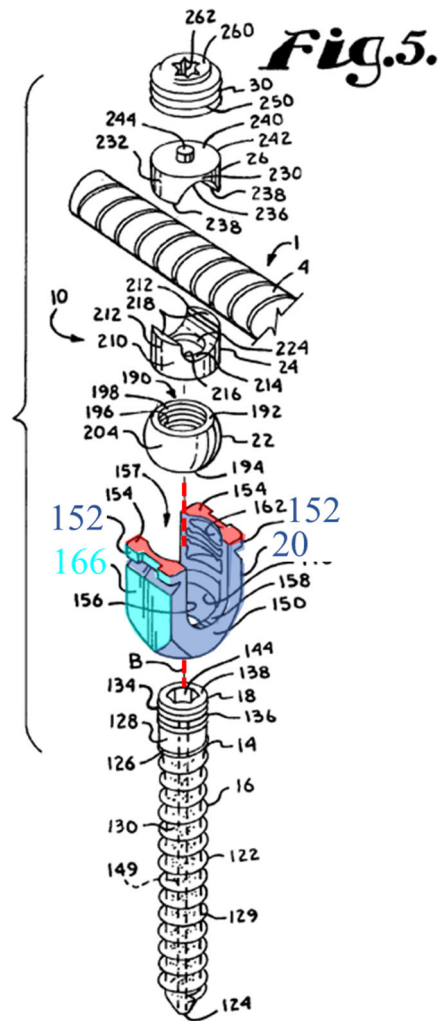
a. 1[Preamble]: “A medical implant assembly comprising:”

To the extent the preamble is limiting, the combination of the '477 Publication, Boschert, and '287 Publication includes this limitation. EX1003, ¶216. 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]; EX1003, ¶216. The '287 Publication discloses a medical implant assembly that uses a closure to capture and lock a longitudinal connecting member, such as a rod, in a spinal implant. EX1007, ¶¶[0002], [0132]-[0158]; EX1003, ¶216. Boschert discloses an orthopedic fixation device for securing a rod to a bone for stabilization of the spine. EX1006, Abstract, 1:5-7; 4:26-28; EX1003, ¶216.

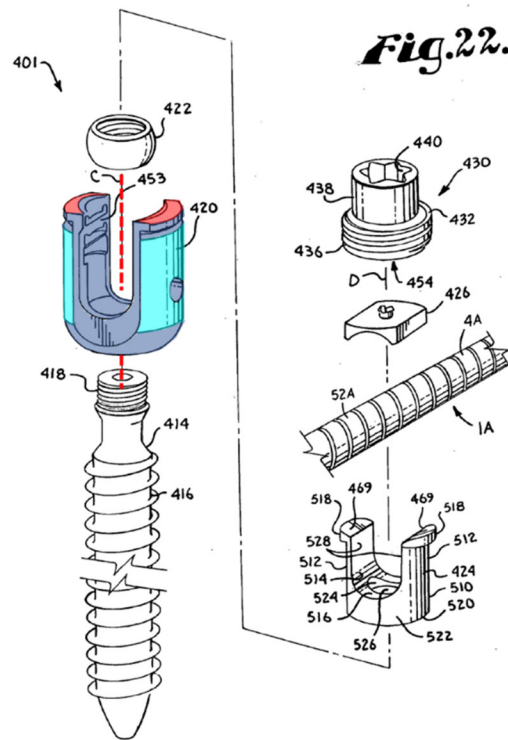
- b. 1[A]: “a receiver having a longitudinal axis, a first arm, and a second arm, the first and the second arms each extending in the same direction as the longitudinal axis and having a top side surface and an outer side face surface;”

The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶217. As discussed in §VI.D.1, a POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication. EX1003, ¶217.

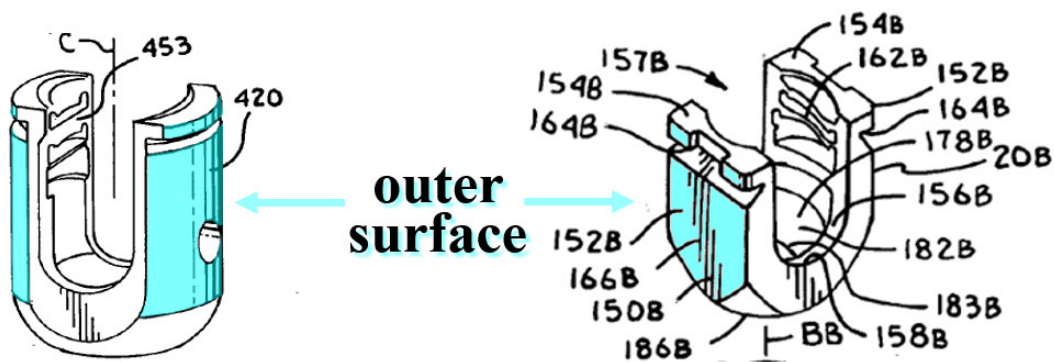
The resulting combination (with the receiver of the '287 Publication) would include this limitation. EX1003, ¶217. Specifically, as seen in annotated Figure 5, the '287 Publication discloses a “receiver 20” that “includes . . . a pair of opposed upstanding arms 152” (**blue**) extending in the same direction as the longitudinal axis and each with a top surface 154 (**red**) and outer side surfaces 166 (**light blue**). EX1007, ¶¶[0076], [0078], Fig. 5; *see also id.*, ¶[0150], Fig. 37; EX1003, ¶217.



The '287 Publication also discloses receiver 420, which the '287 Publication describes as being “identical or substantially similar to . . . receiver 20.” EX1007, ¶[0115]; EX1003, ¶220. As seen in annotated Figure 22, this receiver also has a pair of opposed upstanding arms (**blue**) extending in the same direction as the longitudinal axis and each with a top side surface (**red**) and outer side surfaces (**light blue**). EX1007, Fig. 22; EX1003, ¶219.



A POSA would have recognized that the '287 Publication's outer side surfaces as disclosing this limitation regardless of whether the outer side surfaces are required to be planar because the '287 Publication describes planar and non-planar faces (both pictured below in **light blue**) as being interchangeable, EX1003, ¶¶218-20:

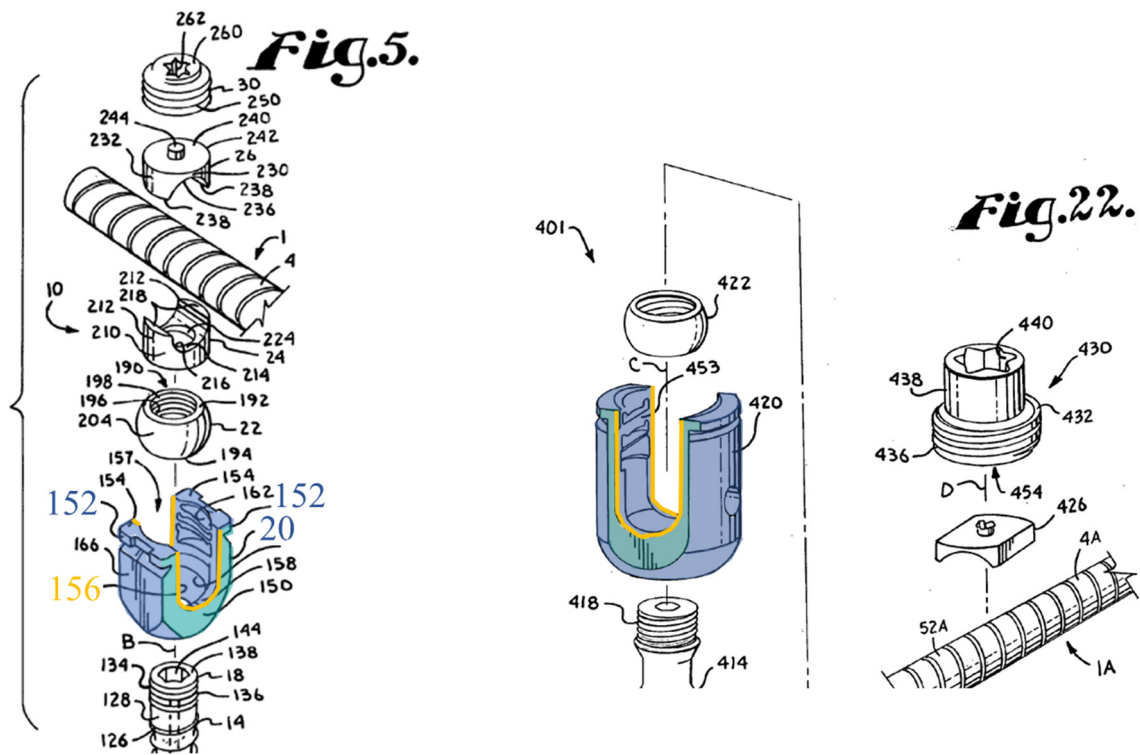


A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* §VI.D.1. EX1003, ¶221.

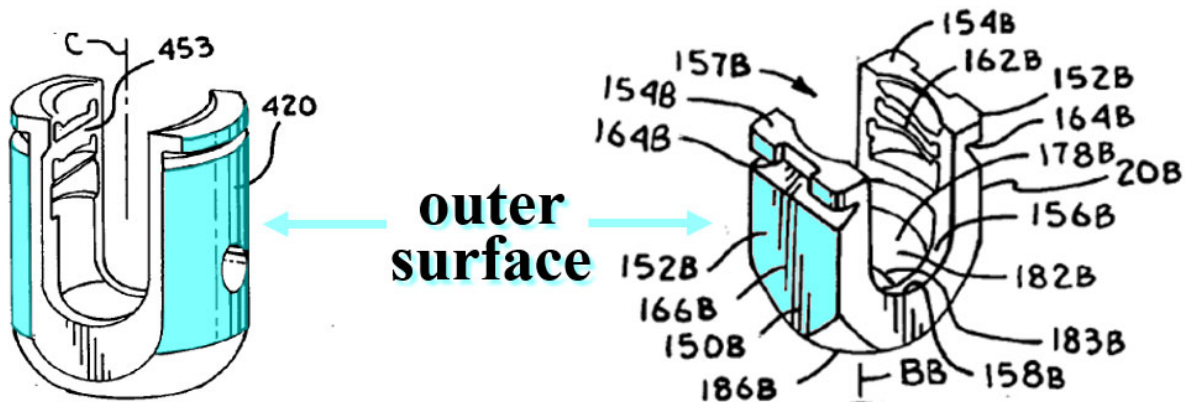
- c. 1[B] “a channel formed by the first arm and the second arm and opening between a front outer face surface adjacent the channel and a back outer face surface adjacent the channel opposite the front outer face surface of the receiver,”

The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶222. As discussed in above, *supra* §VI.D.1, a POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication. EX1003, ¶223.

The '287 Publication discloses a receiver with a pair of arms that have front and back outer face surfaces. EX1003, ¶223. As shown in annotated Figures 5 and 22 below, the '287 Publication receiver's “*arms 152 ... define a U-shaped channel 156 [in yellow],*” EX1007 ¶¶[0076], [0115], Figs. 5, 22; *see also id.*, ¶[0150], Fig. 37, which opens between the front outer face surface (**green**) and the oppositely facing back outer face surface (**green**), both of which are immediately adjacent the channel, EX1007, Fig. 5. EX1003, ¶223.



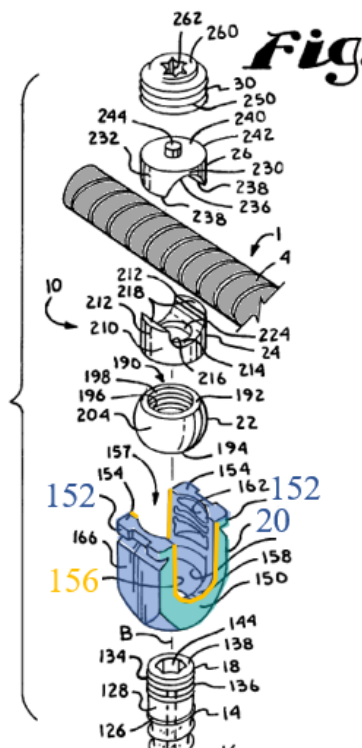
A POSA would have recognized that the '287 Publication's outer side surfaces as disclosing this limitation regardless of whether the outer front/back surfaces are required to be planar because the '287 Publication describes multiple embodiments with planar front/back outer surfaces, EX1003, ¶224-26:



A POSA would have been motivated to use the receiver of the '287 Publication with the closure of the '477 Publication for the reasons discussed above. *Supra* §VI.D.1. EX1003, ¶227.

- d. 1[B1] “the channel adapted to receive a longitudinal connecting member,”

The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶228. The '287 Publication discloses a longitudinal connecting member (**gray**) received within the channel of the receiver, as shown below, EX1007, Fig. 5. EX1003, ¶229.



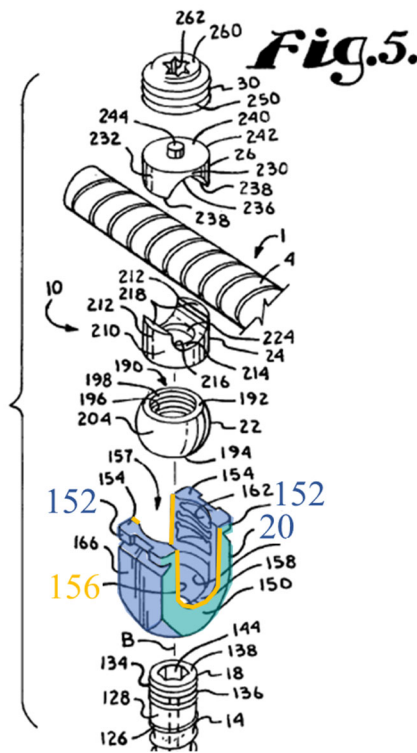
A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* §VI.D.1. EX1003, ¶230.

- e. 1[C] “the channel configured to be closed with a closure having an axis of rotation;”

The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶231. 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, ¶[0002], Fig. 6; EX1003, ¶231. The “closures are externally threaded and are screwed into mating threads on the interior surfaces of the implant arms.” EX1005, ¶[0005]. The “*closure 1* ... has ...

a central axis of rotation B,” id., ¶¶[0029], [0040], and, as shown in Figure 6, is configured to close the channel, *id.*, Fig. 6. EX1003, ¶231.

In the combination of the '477 Publication, the '287 Publication, and Boschert described above, a POSA would have combined the closure of the '477 Publication with the receiver of the '287 Publication, such as the receiver depicted below with U-shaped channel 156, EX1003, ¶232:



In the resulting combination, the closure of the '477 Publication would function in the same manner as described in the '477 Publication and would engage mating threads on the interior surfaces of receiver arms to close the channel created by those arms. EX1003, ¶233. However, instead of performing this function in

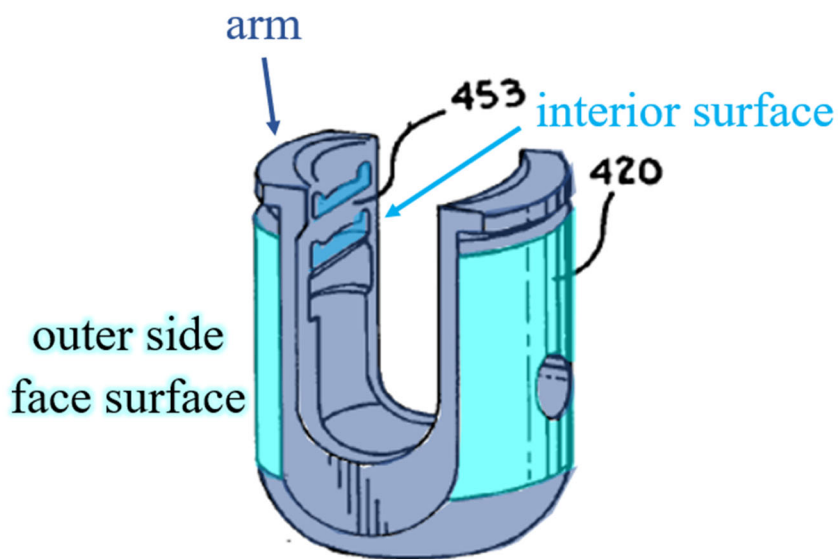
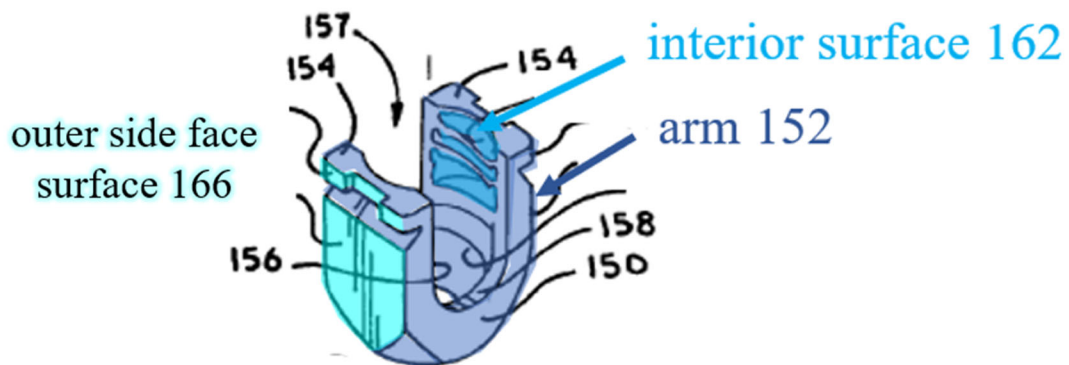
conjunction with the open receiver of the '477 Publication, the closure would perform this function in conjunction with the receiver (and channel) of the '287 Publication. *Id.* Indeed, as discussed in greater detail in the following section, the '287 Publication discloses that its receiver includes interior structures “***configured to mate under rotation with***” a closure such that the closure is “advanced into the U-shaped channel 156[,]” which reinforces the compatibility of the proposed combination, as well as the combination’s disclosure of this limitation. EX1007, ¶[0077]; EX1003, ¶233.

A POSA would have been motivated to use the receiver of the '287 Publication with the closure of the '477 Publication for the reasons discussed above. *Supra* §VI.D.1; EX1003, ¶234.

- f. 1[A1] “a first interior surface of the first arm opposite the outer side face surface thereof; a second interior surface of the second arm opposite the outer side face surface thereof; a first discontinuously helically wound structure on the first interior surface of the first arm,”

The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶235. The '287 Publication discloses that each of its “**arms 152** has an interior surface” that is opposite the outer side face surfaces and “includes a partial helically wound guide and advancement structure 162,” EX1007, ¶[0077], Fig 5; *see also id.*, ¶[0115], [0151], Fig. 37; EX1003, ¶235. As shown in annotated Figures 5 and 22, the partial helically wound guide and advance

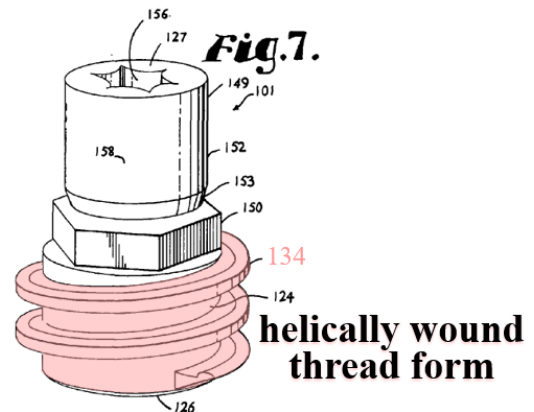
structure is opposite the outer side faces of the receiver arms and is discontinuous from one arm to the next. EX1003, ¶235.



A POSA would have been motivated to use the receiver of the '287 Publication with the closure of the '477 Publication for the reasons discussed above. *Supra* §VI.D.1. EX1003, ¶236.

- g. 1[C1] “the first discontinuously helically wound structure configured to engage a first start structure of a first continuously helically wound thread form disposed on the closure, the first start structure having a leading face with a concave surface portion and a convex surface portion;”

The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶237. In particular, the '477 Publication discloses that “[l]ocated on the cylindrical closure body 124 is a guide and advancement structure 134 mateable with the guide and advancement structure on the inner surfaces of the arms of the bone screw receiver.” EX1005, ¶[0041], Figs. 5&6; EX1003, ¶237. A POSA would have understood that in the context of the '477 Publication, “guide and advancement structure” is a synonym for a helically wound thread form, and, as shown in Figs. 7-8, the disclosed guide and advancement structure is helically wound and unbroken (i.e., continuous). EX1003, ¶237.

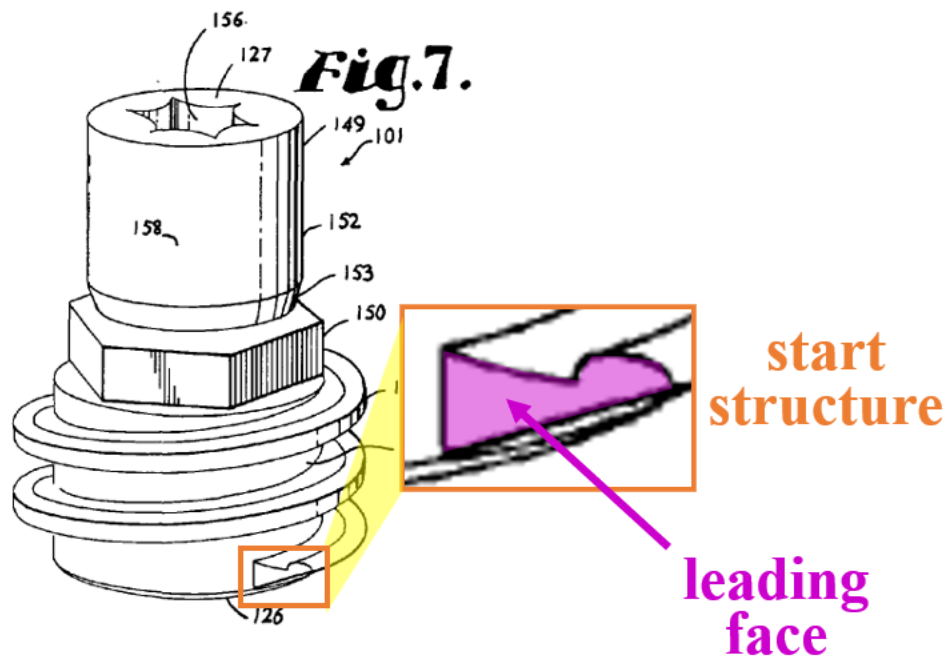


Ex. 1005, Fig. 7

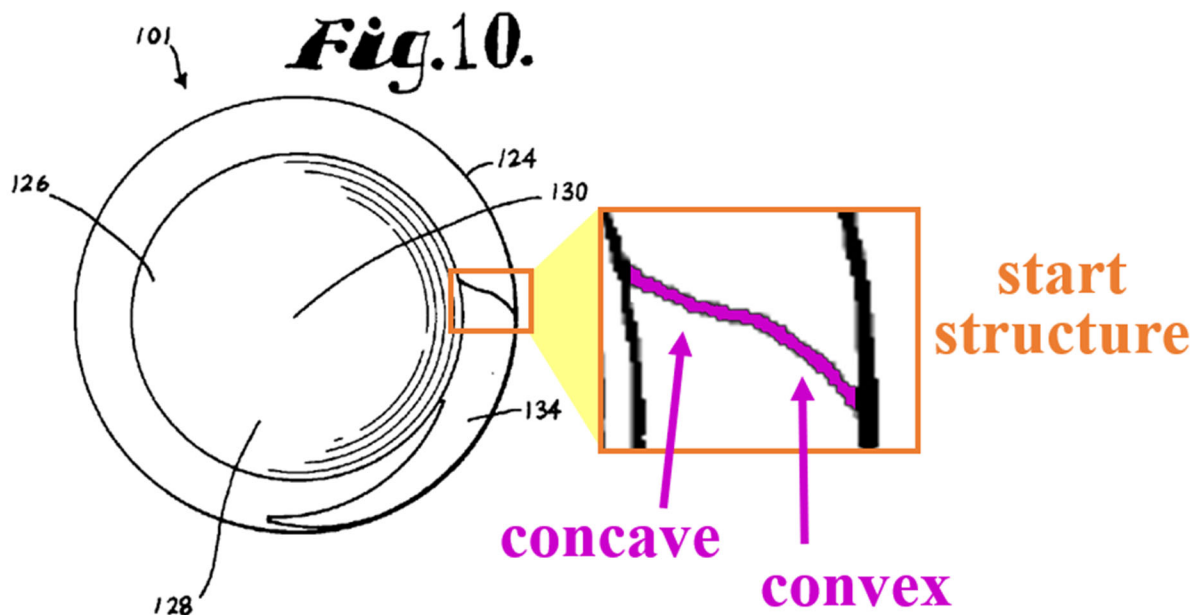
The '477 Publication also expressly discloses a first start structure of the first continuously helically wound thread form on the closure, the first start structure having a concave surface portion and a convex surface portion. EX1003, ¶238. As shown in annotated and enlarged Figure 7 below, the '477 Publication discloses a

start structure on the closure thread, the start structure having a leading face.

EX1005, Figs. 7&8; EX1003, ¶238.



Also, as shown in the annotated Figure 10 below, the leading face of the start structure includes a partial concave surface portion and a convex surface portion. EX1005, Fig. 10; EX1003, ¶238. A POSA would recognize this feature depicted in Fig. 10 to be the same leading face as shown in Fig. 7, at least because it is the only feature shown that matches the shape of the structure. EX1003, ¶238.



Ex. 1005, Fig. 10

The '287 Publication discloses that “[e]ach of the arms 152” of the receiver “has an interior surface that defines an inner cylindrical profile and includes a partial helically wound guide and advancement structure 162.” EX1007, ¶[0077]; EX1003, ¶239. The guide and advancement structure 162 is “*configured to mate under rotation with a similar structure on the closure member 30,*” such that the closure “is advanced into the U-shaped channel 156.” EX1007, ¶[0077]; EX1003, ¶239. Accordingly, upon combining the '477 Publication’s closure with the '287 Publication’s receiver, a POSA would have understood the resulting combination to include this limitation. EX1003, ¶239.

A POSA would have been motivated to use the receiver of the '287 Publication with the closure of the '477 Publication for the reasons discussed above. *Supra* §VI.D.1. EX1003, ¶240.

- h. 1[A2] “a second discontinuously helically wound structure on the second interior surface of the second arm,”

The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶241. As discussed above, the '287 Publication discloses that “*each* of the arms” of the receiver “includes a partial helically wound guide and advancement structure.” EX1007, ¶[0077]. EX1003, ¶241.

A POSA would have been motivated to use the receiver of the '287 Publication with the closure of the '477 Publication for the reasons discussed above. *Supra* §VI.D.1. EX1003, ¶242.

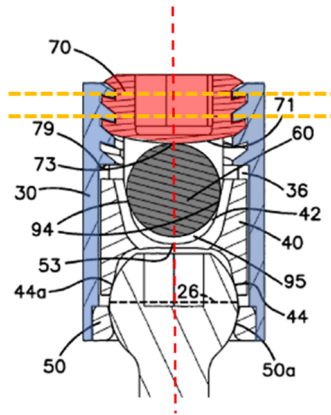
- i. 1[C2] “the second discontinuously helically wound structure configured to engage a second start structure of a second continuously helically wound thread form disposed on the closure, the second start structure having a leading face with a concave surface portion and a convex surface portion,

The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶243. As discussed above, *supra* §§VI.A, VI.E.1.g, the '477 Publication teaches a first discontinuously helically wound structure on the first arm of the receiver configured to engage the start structure of the first continuously helically wound structure on the closure, where the start

structure has a leading face with a concave surface portion and a convex surface portion. EX1003, ¶243.

While the '477 Publication does not expressly disclose a double-start closure, Boschert does, and a POSA would have been motivated to combine Boschert with the '477 Publication as discussed above. *Supra* §VI.D.2. EX1003, ¶244.

Boschert teaches a second continuously helically wound structure on the closure with a start structure configured for engagement with the second discontinuously wound structure on the receiver second arm. EX1003, ¶245; *supra* §VI.B. In particular, Boschert expressly discloses double threads on the closure (or, “set screw”) and specifically that a “***double lead*** // allow[s] the set screw 70 to start more easily than with a single lead.” EX1006, 7:21-23 (emphasis added); EX1003, ¶245. Boschert also discloses a receiver 30 with discontinuous helically wound guide and advancement structures that are symmetrically and diametrically opposed to other across the longitudinal axis, as demonstrated by the horizontally parallel threads on each side of the receiver. EX1006, Figs. 3, 15; EX1003, ¶245.



Boschert further discloses that the first and second threads of the closure threadably mate with the discontinuous receiver threads, EX1006, at 6:25-28; EX1003, ¶245. Therefore, the discontinuous guide and advancement structures on the receiver arms were configured to engage both the first and second start structures of the threads on the closure so as to be able to advance the closure into the channel of the receiver. EX1003, ¶245.

When the disclosures of the '477 Publication and the '287 Publication are combined with Boschert, a POSA would have kept the same leading face structure from the '477 Publication for use with the double-start threads and the symmetrically and diametrically opposed receiver threads taught by Boschert. EX1003, ¶246. Indeed, it was well known in the art that truncated thread starts with curvate leading faces, such as disclosed in the '477 Publication, have advantages for removing sharp edges and reducing the risk of thread damage or cross threading. *Id.* Therefore, in combining the '477 Publication, the '287 Publication, and Boschert, a POSA would

have configured the closure to have two starts—as taught by Boschert—each with a curvate leading face—as taught by the ’477 Publication—and would have configured the interior surfaces of the receiver’s arms to have discontinuous, symmetrical, and diametrically opposed threads—taught by Boschert—in order to mate with the closure’s dual-start threads for the reasons discussed above. *Supra* §VI.D.; EX1003, ¶246.

- j. 1[C3] “a rotation of the closure about the axis of rotation between the first arm and the second arm configured to cause a simultaneous mating of the first start structure under the first discontinuously helically wound structure and the second start structure with the second discontinuously helically wound structure due to a diametrically timed positioning of the first and second start structures on the closure,”

The combination of the ’477 Publication, the ’287 Publication, and Boschert includes this limitation. As discussed above, the ’477 Publication discloses a closure with an axis of rotation. *See supra* §VI.E.1.e; EX1003, ¶247. As also discussed above, the ’477 Publication does not disclose multiple thread starts, but a POSA would have combined the ’477 Publication with Boschert to include “double lead” threads on the closure. EX1006, 7:21-23, Fig. 15; EX1003, ¶248; *supra* §§VI.D.2, VI.E.1.i-j.

In combining the ’477 Publication with Boschert in this manner, the resulting double starts on the closure would simultaneously mate with the interior threads on

the receiver arms due to their diametrically timed positioning, as claimed. EX1003, ¶248-53. Specifically, Boschert's Figures 3 and 15, below, show that the receiver threads are symmetrically and diametrically opposed to each other across the longitudinal axis, as demonstrated by the horizontally parallel threads on each side of the receiver. EX1006, Figs. 3, 15; EX1003, ¶250. A POSA would have understood that this positioning results in simultaneous starting and mating of the two closure thread starts with the two receiver threads. EX1003, ¶249-50.

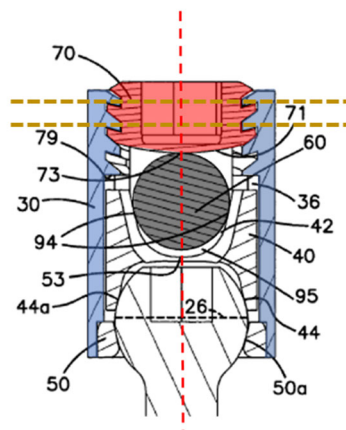


Fig. 3

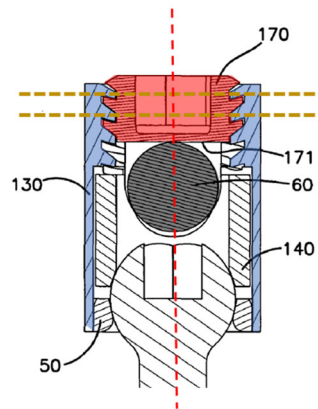
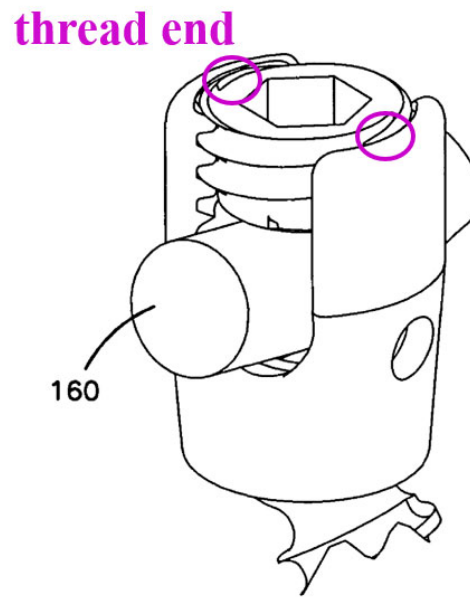


Fig. 15

Boschert's disclosure of diametrically timed thread starts is also supported by Figure 7, which, as seen below, shows that the trailing ends of the double lead thread are diametrically opposed. EX1003, ¶251. A POSA would have understood and expect that each of the double-start threads would be identical in length, such that diametrically opposed thread ends would be the result of diametrically opposed thread starts. *Id.*

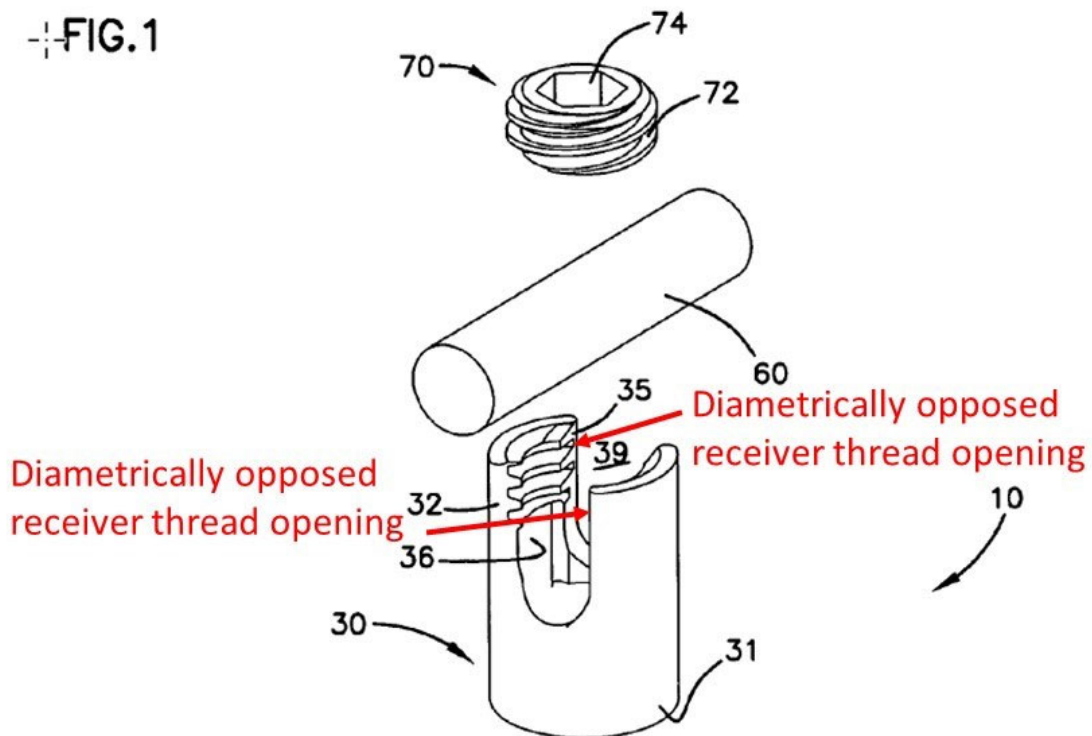


That Boschert discloses diametrically timed thread starts is further supported by a POSA's knowledge that this was the conventional manner of making double start threads before the priority date of the '233 Patent. EX1003, ¶252. As explained in contemporaneous publications, "proper distribution" for a multi-start thread requires that the "thread cylindrical spacing angle" be equal to " $360 / \text{Number of starts}$." EX1014 at 3; EX1003, ¶252. Accordingly, a POSA would have understood Boschert's "double lead" setscrew to have a cylindrical spacing angle of 180° (*i.e.*, $360^\circ / 2$) and, thus, to be positioned at diametrically opposed locations, thereby resulting in simultaneous mating of the first and second closure start structures with their respective corresponding receiver threads. EX1003, ¶¶252-53.

To the extent that Boschert does not expressly disclose the claimed simultaneous mating, Boschert necessarily discloses this element. EX1003, ¶254.

Specifically, a POSA would have understood that for Boschert's double start threads to engage with receiver threads more easily than a single start thread (as expressly taught), (1) the receiver threads would necessarily have to mirror each other, (2) the start structures would necessarily be spread equidistance around the closure, and (3) this positioning would result in simultaneous mating of each receiver thread start with its corresponding receiver thread. *Id.* And, again, this was the conventional manner of making dual start threads at the relevant time. EX1014 at 3; EX1026, 13:35-41; EX1003, ¶254.

To the extent that Boschert does not expressly or inherently disclose the claimed simultaneous mating, it would have been obvious to a POSA before the priority date of the '233 Patent to configure the closure's double-thread starts to mate simultaneously with the receiver arms as claimed. EX1003, ¶255. Specifically, a POSA would have understood that the dual thread starts on the closure would be designed to be diametrically opposed to each other and that each of the corresponding threads at the edge of the opposed receiver arms would also be diametrically opposed, as illustrated in Fig. 1 below. EX1006, Fig. 1; EX1003, ¶255.



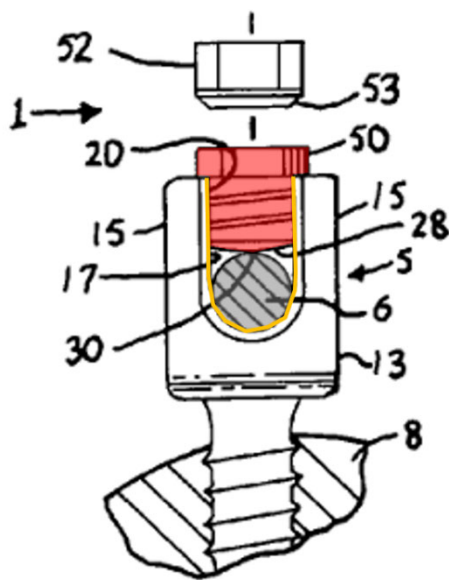
This design configuration can only result in each of the thread starts on the closure simultaneously mating with the receiver threading. EX1003, ¶255. Indeed, diametrically opposed starts is the standard way to manufacture dual start threads, and such a configuration would not facilitate threading if the starts did not simultaneously mate with the receiving threads. *Id.*

When the disclosures of the '477 Publication and '287 Publication are combined with the disclosure of Boschert in the manner described above, the resulting closure would have included Boschert's symmetrically and diametrically opposed closure starts and receiver threads. EX1003, ¶256.

- k. 1[C4] “the closure configured to be rotationally advanced within the channel until the bottom surface engages and

locks the longitudinal connecting member within the channel; and”

The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶257. The '477 Publication's "closure" is expressly configured for "capturing and locking a rod in the implant." EX1005, Abstract; *see also id.*, ¶[0002]; EX1003, ¶258. To that end, the receiver's guide and advancement structure "allow[s] the closure 1 to be inserted into and rotated relative to the bone screw receiver 13" to "guide and *advance the closure 1* along the axis B as the closure 1 is *rotated clockwise.*" EX1005, ¶¶[0030], [0039]; EX1003, ¶258. As shown in the excerpted, annotated Figure 5 below, after closure 1 is driven (i.e., rotatably advanced), closure 1 "*lock[s] the rod 6 in position* relative to the bone screw" and within the channel. EX1005, ¶[0037], Fig. 5; *see also id.*, ¶¶[0018]-[0019], [0039] Fig. 6; EX1003, ¶258.

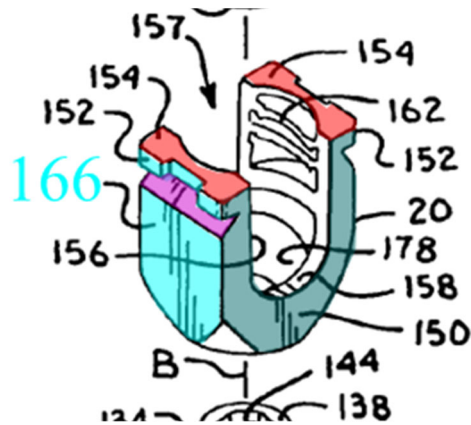


Thus, based on the above disclosures, the closure resulting from the combination of the disclosures of the '477 Publication, the '287 Publication, and Boschert would have included a closure rotationally advanceable within the channel until the bottom surface of the closure locks the longitudinal connecting member within the channel. EX1003, ¶259.

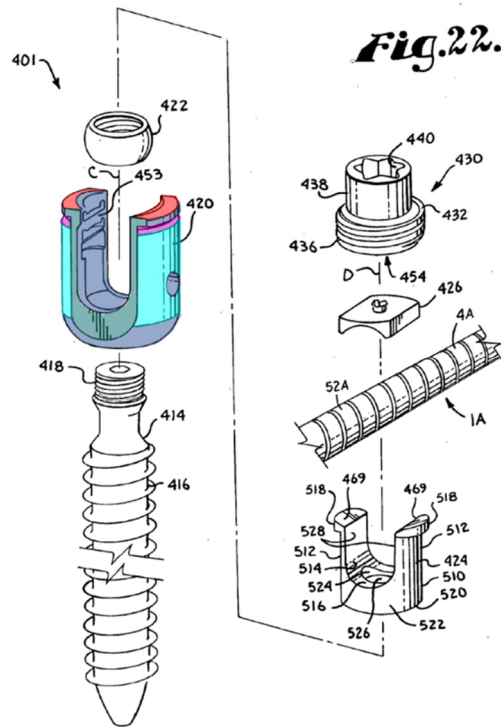
- I. 1[D] “the first and second arm outer side face surfaces each having a curvate extending groove configured to be engaged by an instrument, each groove extending horizontally to at least one of the front or back outer face surface of each arm and being located adjacent the top side surface on each arm, wherein an entirety of each groove is configured to be located above a top surface of the longitudinal connecting member when the longitudinal connecting member is received and locked in the channel by the closure.”

The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶260.

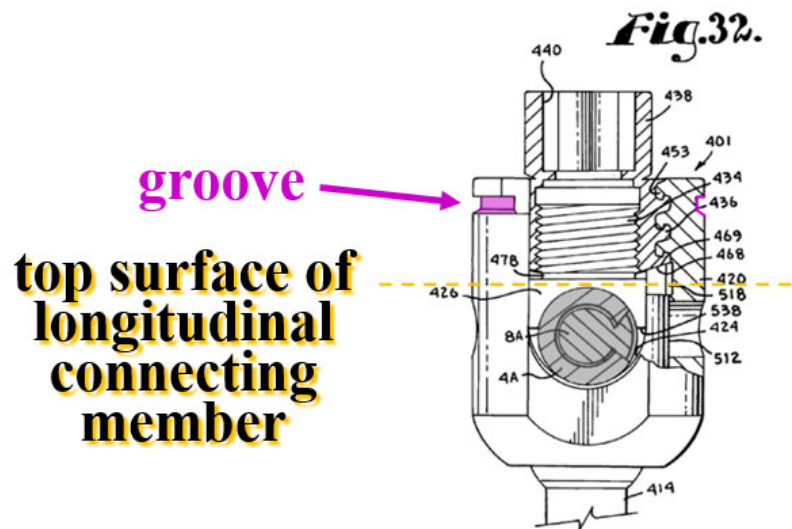
As seen in annotated Figure 14, the '287 Publication discloses that “[e]ach of the arms 152 includes a V-shaped or undercut *tool engagement groove* 164 [purple] formed on a *substantially planar outer surface* 166 [light blue] thereof which may be used for holding the receiver 20 with a holding tool (not shown) having projections that are received within the grooves 164” EX1007, ¶[0078], Figs. 5-7, 14-17; *see also id.*, ¶[0152], Fig. 37; EX1003, ¶260.



Receiver 420, shown in the embodiment of Figures 22 (below), 31-35, is “identical or substantially similar to . . . receiver 20,” EX1007, ¶[0115]; includes a curvate (or, “radiused”) groove (purple) that is adjacent the top side surface of each arm; and extends horizontally across the (light blue) to the front outer face surface of receiver 420. *Id.*, *see also id.* ¶[0152] (“grooves . . . may be . . . ***radiused***”), Figs. 5, 14, 22; EX1003, ¶¶260-61.



Additionally, as shown in annotated Figure 32 below, the entirety of each groove is located above the top surface of the longitudinal connecting member when that member is received and locked in the channel by the closure. EX1003, ¶262.



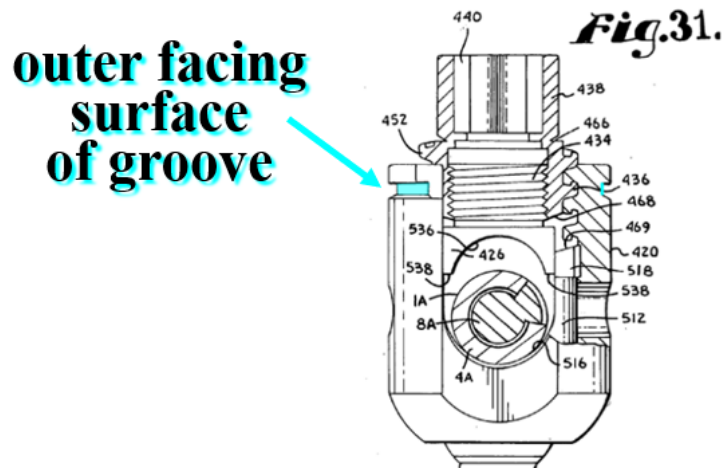
When the disclosures of the '477 Publication and Boschert are combined with the '287 Publication, a POSA would have used the receiver of the '287 Publication, including because the curvate extending groove on the outer side face surfaces of the receiver provides benefits known and disclosed by the '287 Publication as discussed above. *Supra* §VI.D.1; EX1003, ¶263. Therefore, the receiver resulting from the combination of the disclosures of the '477 Publication, the '287 Publication, and Boschert would have included the curvate extending groove disclosed in the '287 Publication. EX1003, ¶263.

* * *

The combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 1. EX1003, ¶264.

2. Claim 2

Claim 2 depends from Claim 1 and additionally recites: **[D1]** “wherein each groove includes an outer facing surface.” The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶265. Specifically, the '287 Publication states that groove 164B “may be configured in a variety of sizes and shapes,” EX1007, ¶[0152], and, as shown in Figure 31 below, discloses a groove with an outer facing surface, *id.*, Fig. 31. EX1003, ¶265.



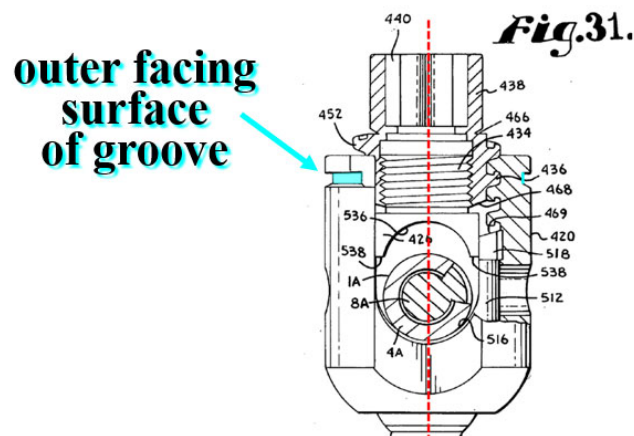
A POSA would have been motivated to use the three-sided groove of this embodiment as a design choice to make the groove “cooperate with a holding tool during bone screw assembly,” as disclosed in the ’287 Publication. EX1007, ¶[0152]; *supra* §VI.D.1. Specifically, because the groove can be “a variety of sizes and shapes,” EX1007, ¶[0152], a POSA would have included a three-sided groove if the corresponding tool guide so required, EX1003, ¶266.

Accordingly, the combination of the ’477 Publication, the ’287 Publication, and Boschert renders obvious every element of Claim 2. EX1003, ¶267

3. Claim 3

Claim 3 depends from Claim 2 and additionally recites: [D2] “wherein the outer facing surfaces of the grooves extend in a direction parallel to the longitudinal axis.” The combination of the ’477 Publication, the ’287 Publication, and Boschert includes this limitation. EX1003, ¶268. Specifically, the ’287 Publication states

that groove 164B “may be configured in a variety of sizes and shapes,” EX1007, ¶[0152], and as shown in annotated Figure 31, discloses that outer facing surfaces of the grooves extend in a direction parallel to the longitudinal axis, *id.*, Fig. 31. EX1003, ¶268.

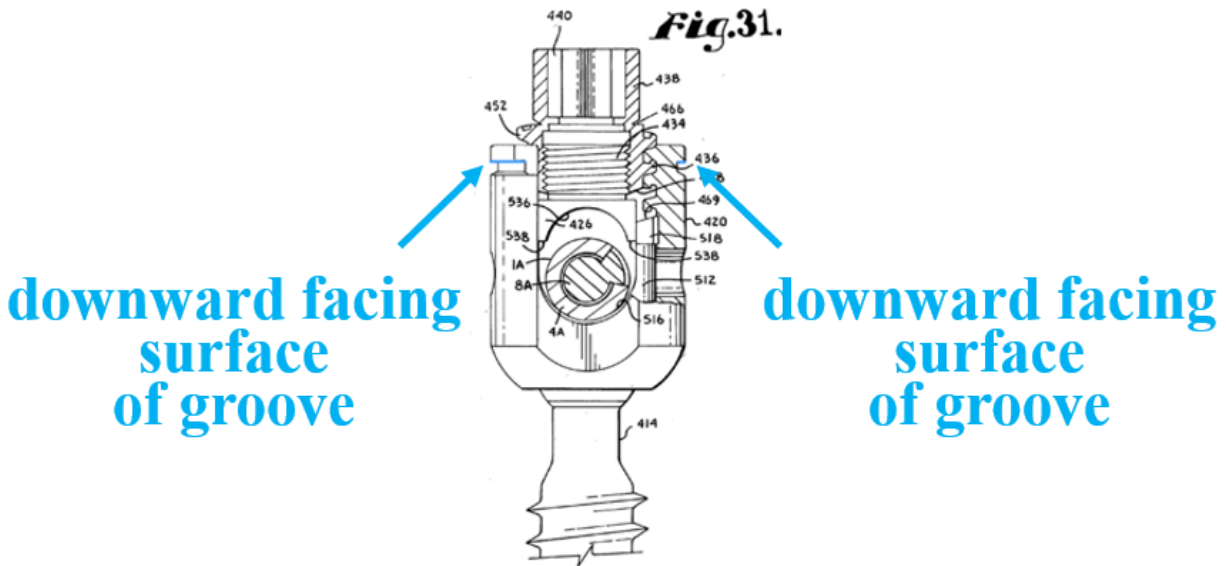


Accordingly, the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 3. EX1003, ¶269.

4. Claim 4

Claim 4 depends from Claim 1 and additionally recites: [D3] “wherein each groove includes a downward facing surface.” The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶270. Specifically, the '287 Publication states that groove 164B “may be configured in a variety of sizes and shapes,” EX1007, ¶[0152], and a shown in annotated Figure

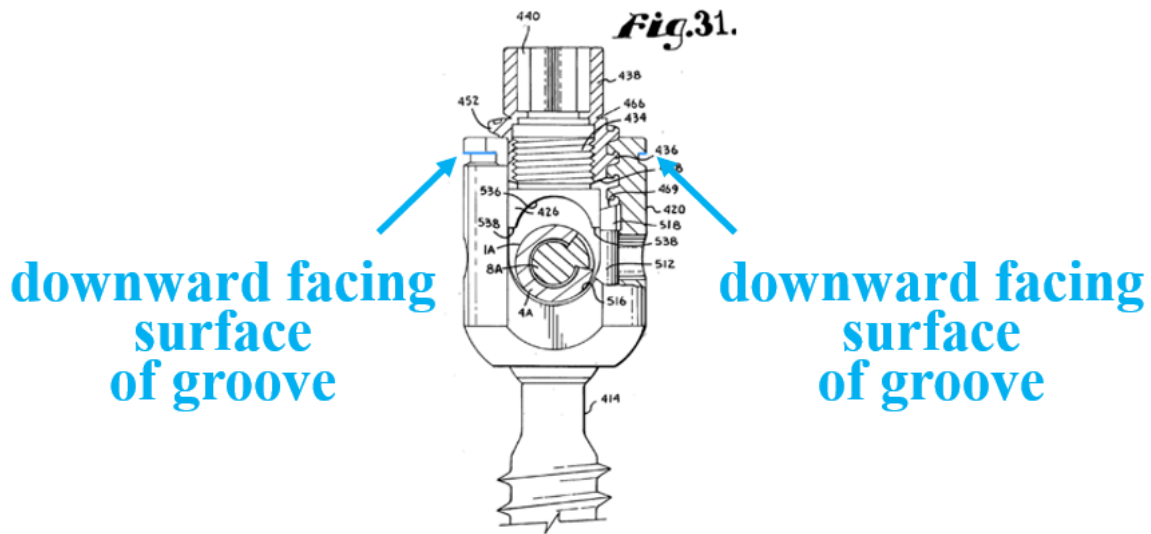
31, discloses horizontal grooves each include a downward facing surface, *Id.*, Fig. 31. EX1003, ¶270.



Accordingly, the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 4. EX1003, ¶271.

5. Claim 5

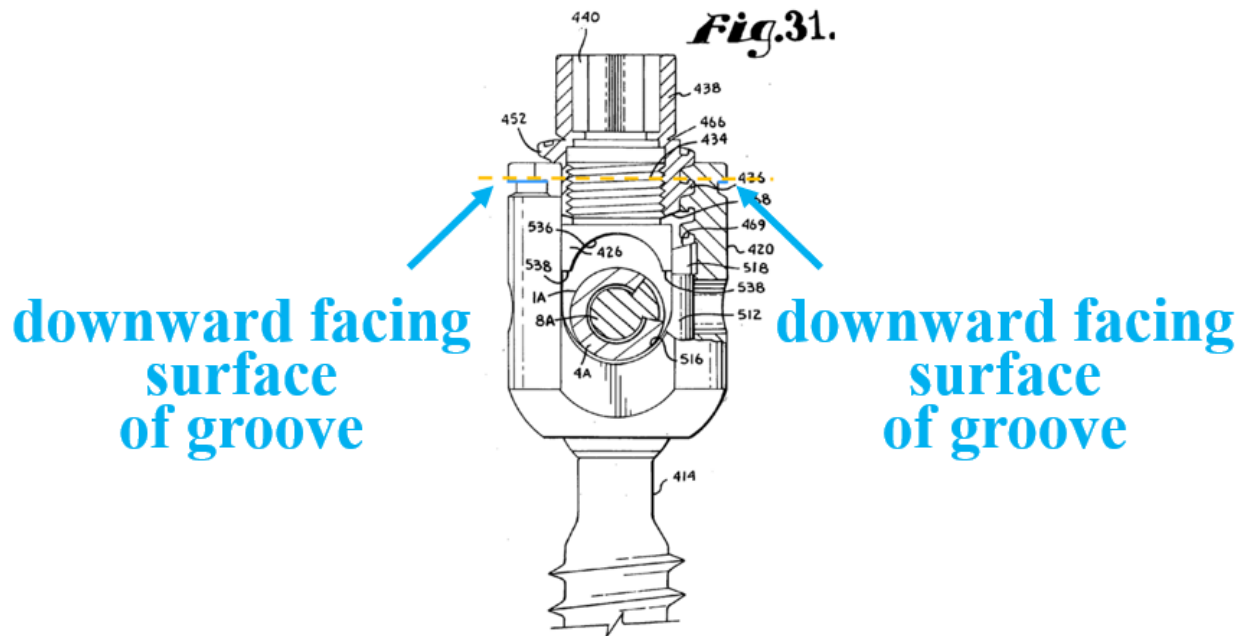
Claim 5 depends from Claim 4 and additionally recites: [D4] “wherein the downward facing surfaces of the grooves are planar.” The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶272. Specifically, the '287 Publication states that groove 164B “may be configured in a variety of sizes and shapes,” EX1007, ¶[0152], and as shown in Figure 31, discloses downward facing surfaces of the undercut grooves that are planar, *id.*, Fig. 31. *See supra* §VI.E.4; EX1003, ¶272.



Accordingly, the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 5. EX1003, ¶273.

6. Claim 6

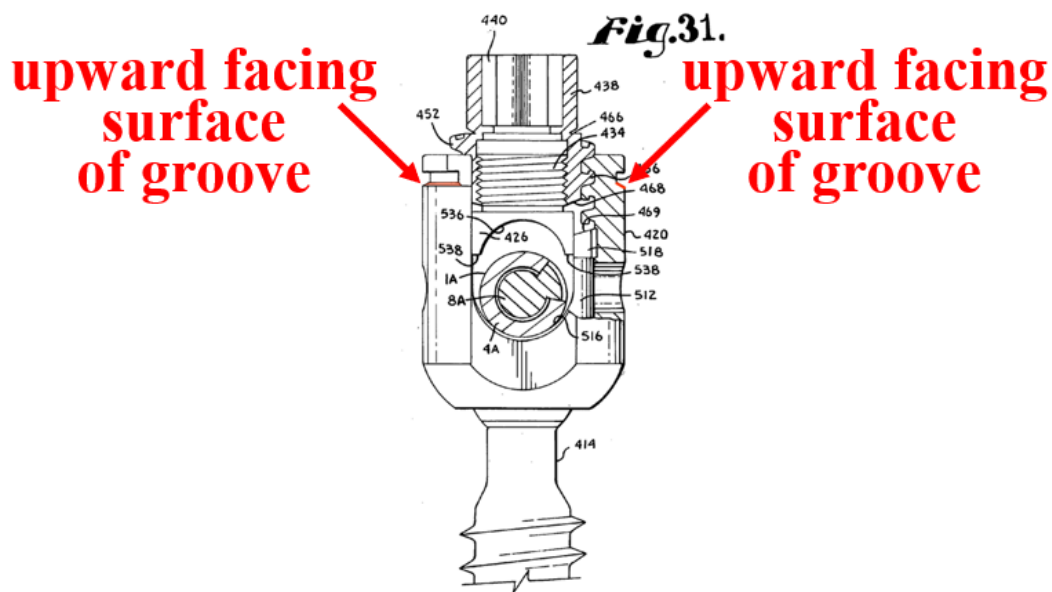
All of the limitations of Claim 6 are recited in Claim 1, except Claim 6 further recites: [D5] “wherein each downward facing surface of the grooves are parallel with one another.” The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶274. Specifically, the '287 Publication states that groove 164B “may be configured in a variety of sizes and shapes,” EX1007, ¶[0152], and as shown in Figure 31, discloses that the planes of the downward facing surfaces are colinear and therefore, parallel to each other, *see id.*, Fig. 31. EX1003, ¶274.



Accordingly, the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 6. EX1005, ¶275.

7. Claim 7

Claim 7 depends from Claim 1 and additionally recites: [D6] “wherein each groove includes an upward facing surface.” The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶276. Specifically, the '287 Publication states that groove 164B “may be configured in a variety of sizes and shapes,” EX1007, ¶[0152], and as shown in annotated Figure 31, discloses upward facing surfaces of the horizontal grooves, *id.*, Fig. 31. EX1003, ¶276.



Accordingly, the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 7. EX1003, ¶277.

8. Claim 13

Claim 13 depends from Claim 1 and additionally recites: [C5] “wherein the first and second discontinuously helically wound structure comprises one of a reverse angle thread, a square thread, a buttress thread, or a helical flange form.” The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶278.

The '477 Publication discloses that “[l]ocated on the cylindrical closure body 24 is a guide and advancement structure 34 mateable with the guide and advancement structure on the inner surfaces 20 of the arms 15 of the bone screw receiver 13.” EX1005, ¶¶[0030], [0039]. The '477 Publication teaches that the

guide and advancement structure can be a “***reverse angle thread form***” and also that “other types of guide and advancement structure could be utilized,” including “a ***buttress thread form, a square thread form or some other type*** of structure such as a flange form[.]” *Id.*, ¶[0030]. For instance, Figure 7 below, the guide and advancement structure can be a helical flange thread form. Alternatively, the ’477 Publication discloses that the structure can be “a helically wound reverse angle thread form 36.” *Id.* As the ’477 Publication explains, the guide and advancement structure helps the receiver to “resist[] splaying . . . as forces applied to the closure 1 are conveyed by the reverse angle thread form 36 during application of clockwise rotational torque into a downward axial force and inwardly directed radial force.” *Id.*, ¶[0030]. EX1003, ¶279.

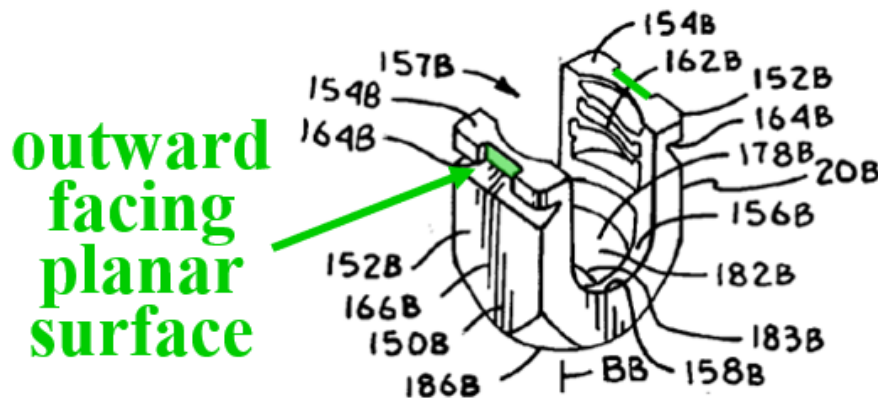
In the above-described combination of the ’477 Publication, the ’287 Publication, and Boschert, a POSA would have looked to Boschert to add a second helically wound thread to the ’477 Publication’s closure, but would have otherwise retained the thread characteristics disclosed in the ’477 Publication. EX1003, ¶280; *supra* §VI.D.1. In particular, the combination would retain the ’477 Publication’s “helically wound reverse angle thread form 36” on both the first and second closure thread, at least in part because of its splay-resistant benefits. EX1003, ¶280; *supra* §VI.D.1. Additionally, both Boschert and the ’287 Publication teach reverse-angle threads, indicating that the retention of the ’477 Publication’s reverse-angle

threading would not affect or prevent the combination with Boschert and the '287 Publication. EX1006, Fig. 15; *see also id.*, Figs. 3-4, 9-10 (single reverse angle thread on closure); EX1007, ¶¶[0073], [0077], [0086], [0151], [0156]; EX1003, ¶280; *supra* §VI.D.1.

Accordingly, the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 13. EX1003, ¶281.

9. Claim 15

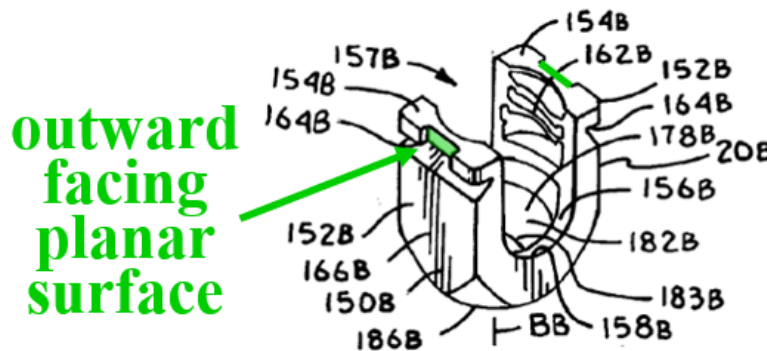
Claim 15 depends from Claim 1 and additionally recites: [D7] “wherein each outer side face surface has an outward facing planar surface.” The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶282. Specifically, the '287 Publication states its tool grooves “may be configured in a variety of sizes and shapes,” EX1007, ¶[0152], and as shown in Figure 37 below, discloses a vertical tool groove that is a recessed outward facing planar surface at the top of the outer side surfaces, *id.*, Fig. 37. EX1003, ¶282.



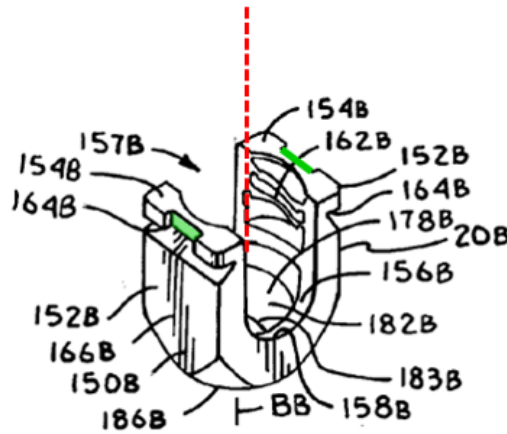
Accordingly, the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 15. EX1003, ¶283.

10. Claim 16

Claim 16 depends from Claim 15 and additionally recites: [D8] “wherein the outward facing planar surface on each arm is recessed and parallel with respect to the longitudinal axis of the receiver and to each other.” The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶284. As discussed for Claim 15, the '287 Publication discloses an outward facing planar surface on each receiver arm. EX1007, Fig. 37; *supra* §VI.E.9.



Further, as shown in Figure 37 below, these planar surfaces are recessed and run parallel to the longitudinal axis and to each other. EX1007, Fig. 37; EX1003, ¶284.



Accordingly, the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 16. EX1003, ¶285.

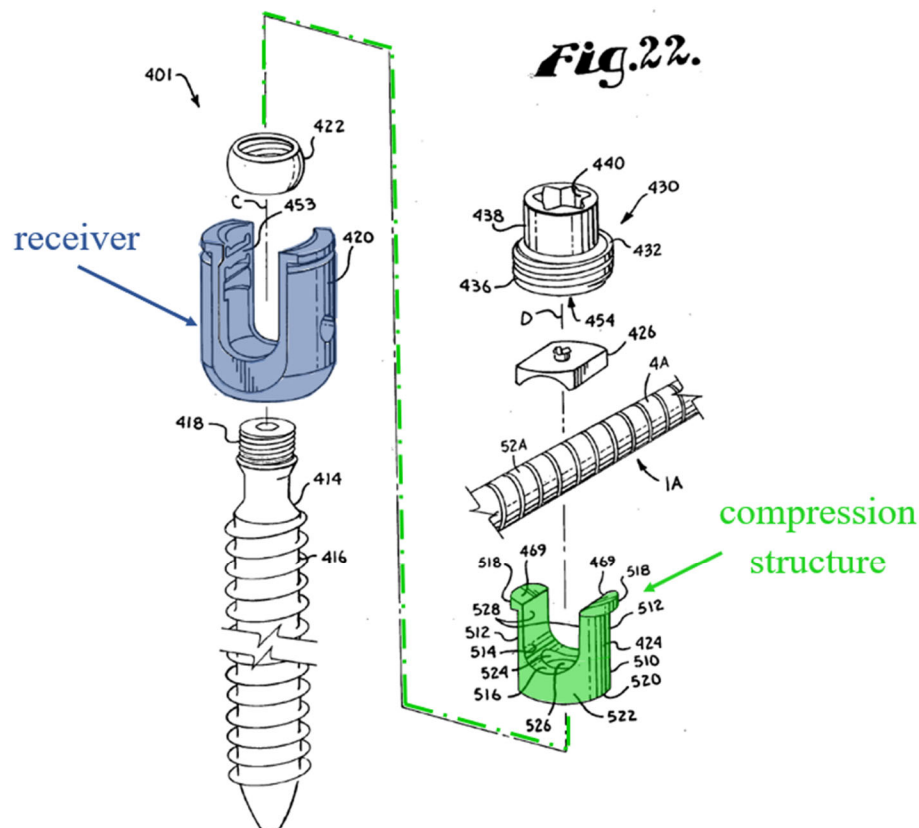
11. Claim 17

Claim 17 depends from Claim 1 and additionally recites: [F] “further including an insert configured to be top loaded into the receiver, the insert having first and second opposed upright arms with top surfaces and lateral protrusions with top surfaces contiguous with the top surfaces on the upright arms of the insert.” The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX1003, ¶286.

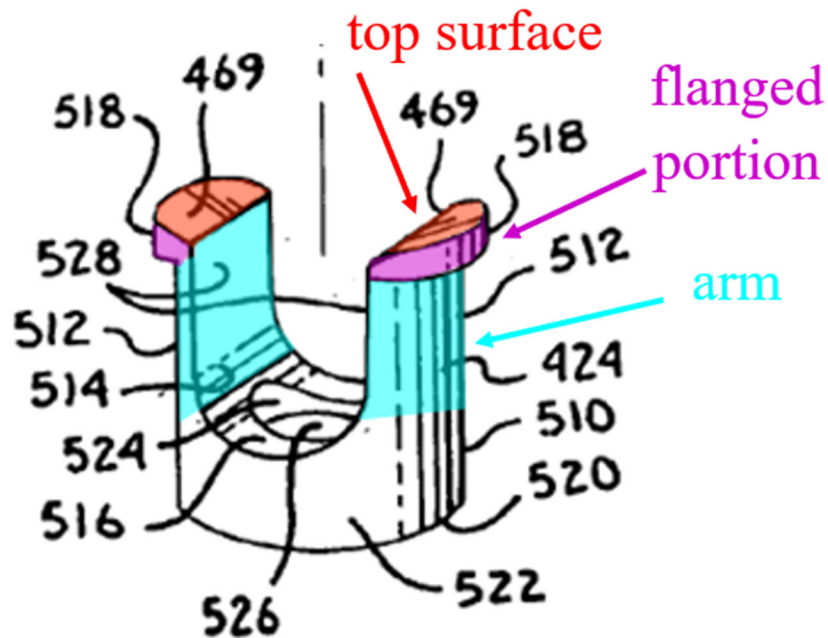
As discussed above, *supra* §VI.D.1, a POSA would have combined the closure of the '477 Publication with the receiver and inserts of the '287 Publication. In making this combination, a POSA would have had reason to utilize the '287 Publication's receiver and its corresponding top-loaded inserts because, as discussed below, these structures operate in combination to secure a bone screw and

connecting rod in the receiver. Thus, in the above-described combination of the '477 Publication, '287 Publication, and Boschert, the resulting insert of the '287 Publication would meet this limitation. EX1003, ¶286.

For example, as shown in annotated Figure 22 below, the '287 Publication discloses an insert with “an outer diameter slightly smaller than a diameter between crests of the guide and advancement structure 453 of the **receiver 420**,” which “*allow[s] for top loading of the compression structure 424*” into the receiver. EX1007, ¶[0126], Fig. 22; EX1003, ¶287.



The '287 Publication also discloses that the insert has first and second opposed upright arms with lateral protrusions and contiguous top surfaces, as claimed. As seen in cropped and annotated Figure 22, insert 424 includes “arms 512 ... [that] each include a top flanged portion 518, each portion 518 including the ramped or inclined surface 469.” EX1007, ¶[0126], Fig. 22. The flanged portion 518 extends laterally beyond the limit of arms 512, and the top surface of each projection is co-extensive with the top surface 469 of the arms. EX1003, ¶288.



A POSA would have been motivated to use an insert such as that disclosed in the '287 Publication when combining the '477 Publication's closure with the '287 Publication's receiver because the use of such an insert had known benefits. *Supra* §VI.D.1; EX1003, ¶289. In particular, POSA would have known the benefits of using an insert as disclosed in the '287 Publication would have been consistent with

the stated objectives of the '477 Publication, including because the insert would facilitate seating of the rod within the receiver and evenly distributing the pressure from the closure to the shank in order to fix the desired angle of the shank. *Supra* §VI.D.1; EX1003, ¶289. Given that the benefits of inserts with lateral protrusions were known in the art, a POSA would have been motivated to add such an insert because it would not change the double-start closure. *Supra* §VI.D.1; EX1003, ¶289; *see also* EX1007, ¶[0126], Fig. 31 (recesses for lateral protrusions located below discontinuously helically wound structures on receiver and apart from any grooves).

Accordingly, the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 17. EX1003, ¶290.

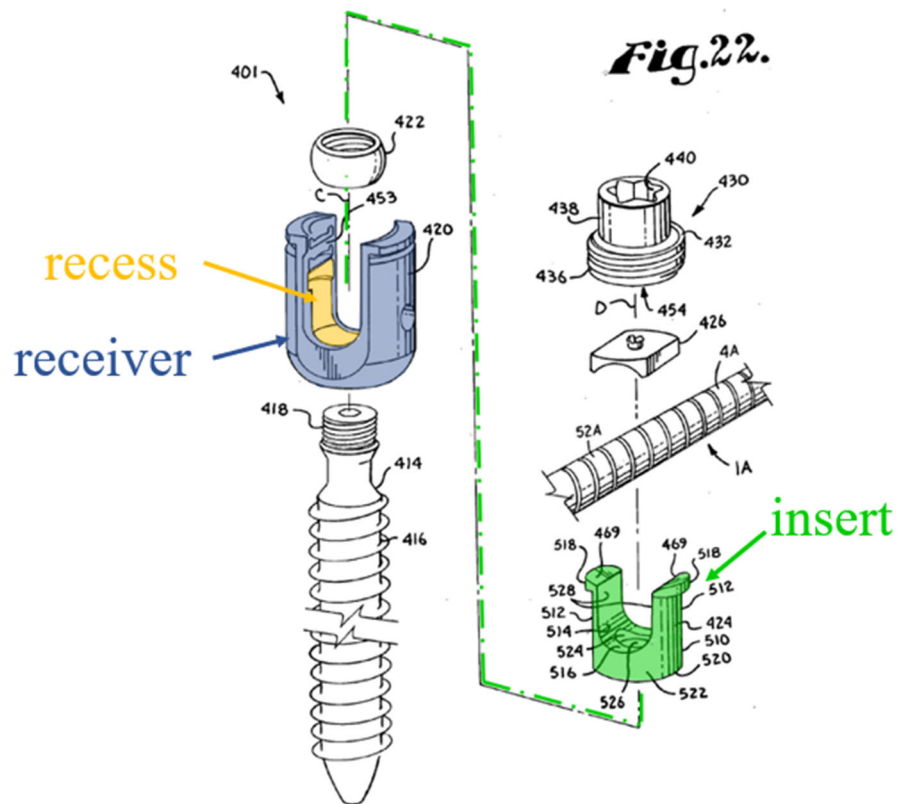
12. Claim 18

Claim 18 depends from Claim 1 and additionally recites: [F1] “wherein the receiver includes a central bore having a recess into which an insert is configured to be at least partially positioned by being down loaded into the receiver through the channel.” The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. EX 1003, ¶291.

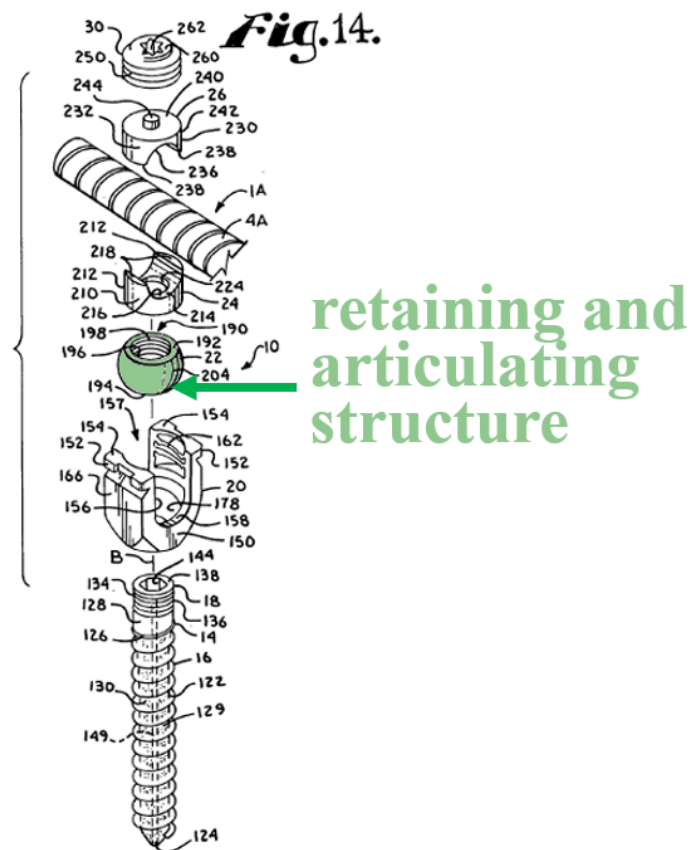
The '287 Publication expressly discloses a receiver with a central bore. Specifically, the '287 Publication discloses that “[c]ommunicating with the U-shaped channel 156 and located within the base 150 of the receiver 20 is a chamber

or cavity 178 . . . , ***the cavity 178 opening upwardly*** into the U-shaped channel 156. The base 150 further includes a restrictive neck 183 The neck 183 defines an ***opening or bore*** communicating with the cavity 178[.]” EX1007, ¶[0079], Fig. 16; *see also id.*, ¶[0153], Fig. 37. Receiver 420 is shown in the embodiment of Figures 22, 31-35 and is described as “identical or substantially similar to . . . receiver 20.” *Id.*, ¶[0115]; EX1003, ¶292.

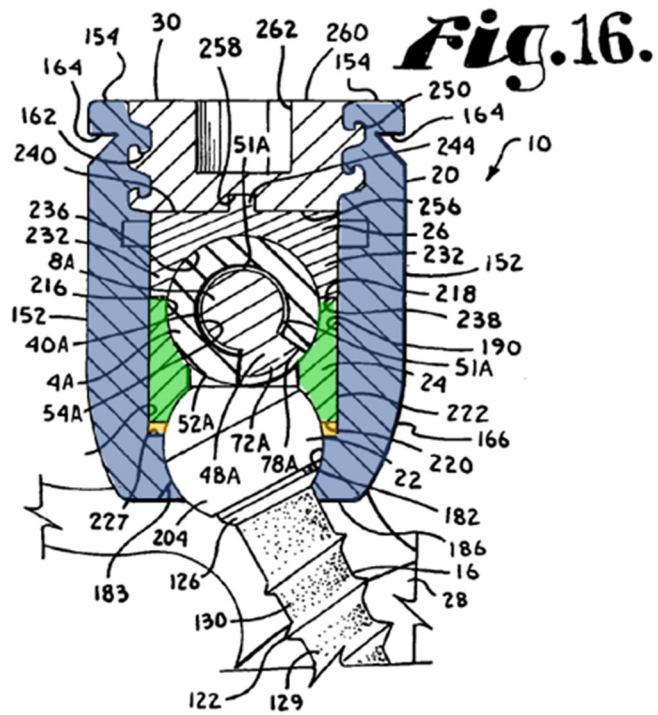
The ’287 Publication also expressly discloses a recess into which two inserts are configured to be downloaded (or top-loaded) into the receiver. EX1003, ¶293. As shown for example in annotated Figure 22 below, insert 424 is downloaded into the receiver and into a recess in the receiver. EX1007, Fig. 22.



Similarly, “retaining and articulating structure 22 [or 422],” as shown below, is also downloaded through the channel into the central bore of the receiver. EX1007, ¶¶[0079], [0090], [0115], Fig. 14; EX1003, ¶293.

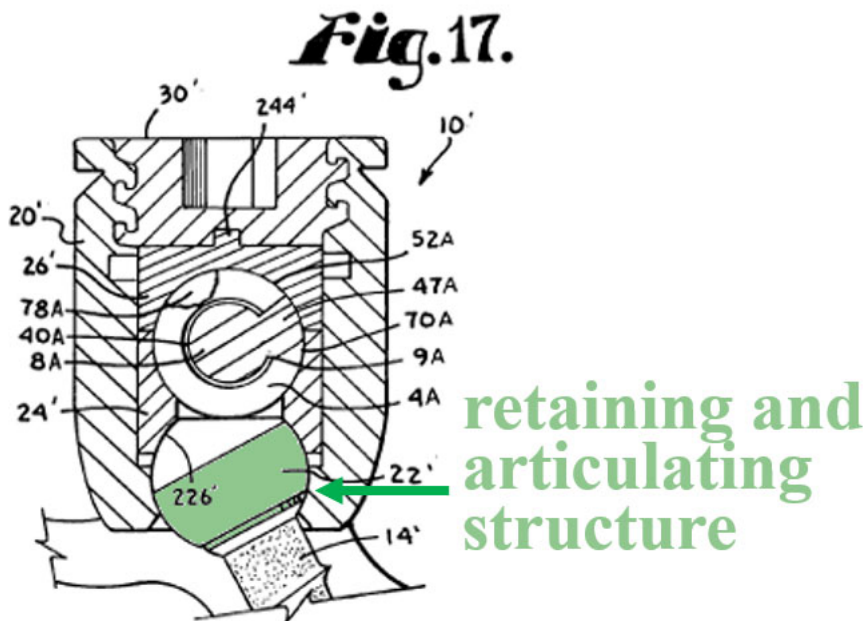


Further, the '287 Publication discloses that “[c]ommunicating with the U-shaped channel 156 and located within the base 150 of the receiver 20 is a chamber or cavity 178 partially defined by an inner cylindrical surface 180 and a substantially spherical seating surface 182, the cavity 178 opening upwardly into the U-shaped channel 156.” EX1007, ¶[0079], Fig. 16; *see also id.*, ¶[0153], Fig. 37. As seen in annotated Figure 16, retaining insert 24 is downloaded into the receiver 20 and to sit in recess or cavity 178. *Id.*, ¶[0079], Figs. 16, 37; *see also id.*, ¶[0153].



Similarly, as seen in Figure 17, the retaining and articulating structure 22 (also 422) is downloaded into the receiver 20 to sit in the same recess or cavity. *Id.*, Fig. 167.

EX1003, ¶294.

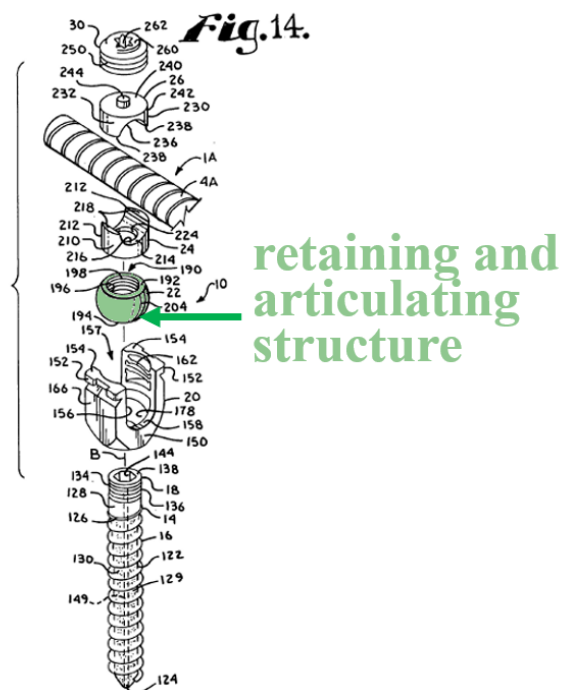
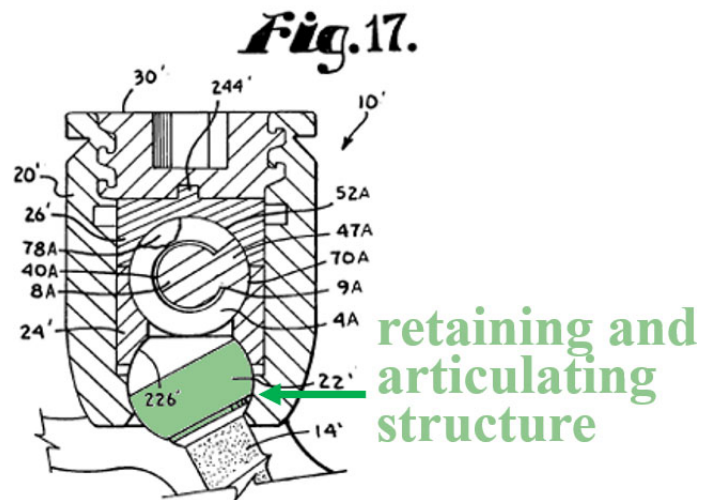


Accordingly, the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 18. EX1003, ¶295.

13. Claim 19

Claim 19 depends from Claim 18 and additionally recites: [F2] “wherein the insert is a retainer configured to engage a head of a bone attachment shank.” The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. *Id.*, ¶296.

The '287 Publication discloses a “*retaining and articulating structure 22*” in “fixed frictional contact with the receiver 20, so as to substantially attach and orient [the implant] relative to the vertebra.” EX1007, ¶[0063]; *see also* ¶¶[0098], [0129]; EX1003, ¶297. The described engagement between retaining insert 22 and the head of a bone attachment shank is depicted in illustrative Figures 17 and 14 below:



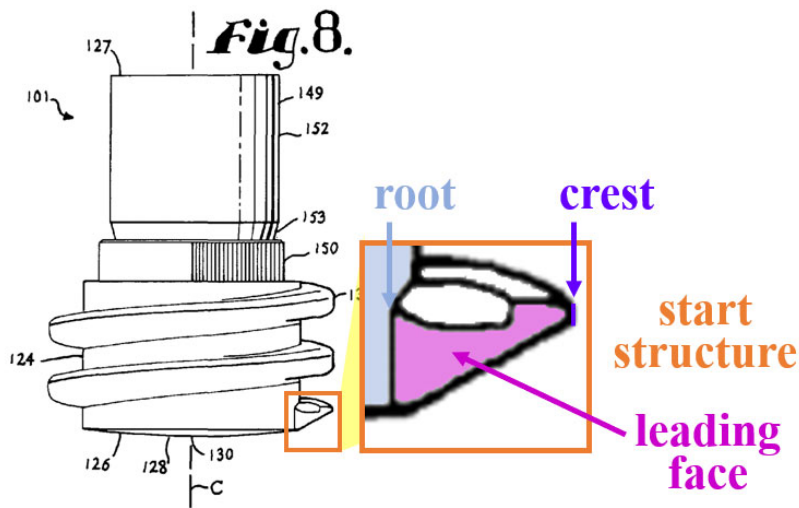
EX1003, ¶297.

As discussed above, *supra* §VI.D.1, a POSA would have combined the closure of the '477 Publication with the receiver and inserts of the '287 Publication. EX1003, ¶298. Accordingly, the combination of the '287 Publication, '477 Publication, and Boschert renders obvious every element of Claim 19. *Id.*, ¶299.

14. Claim 20

Claim 20 depends from Claim 1 and additionally recites: [C6] “wherein each of the leading faces on the first and the second start structures has a concave surface adjacent a root and a convex surface adjacent a crest of the respective first and second continuously helically wound structures.” EX1003, ¶300.

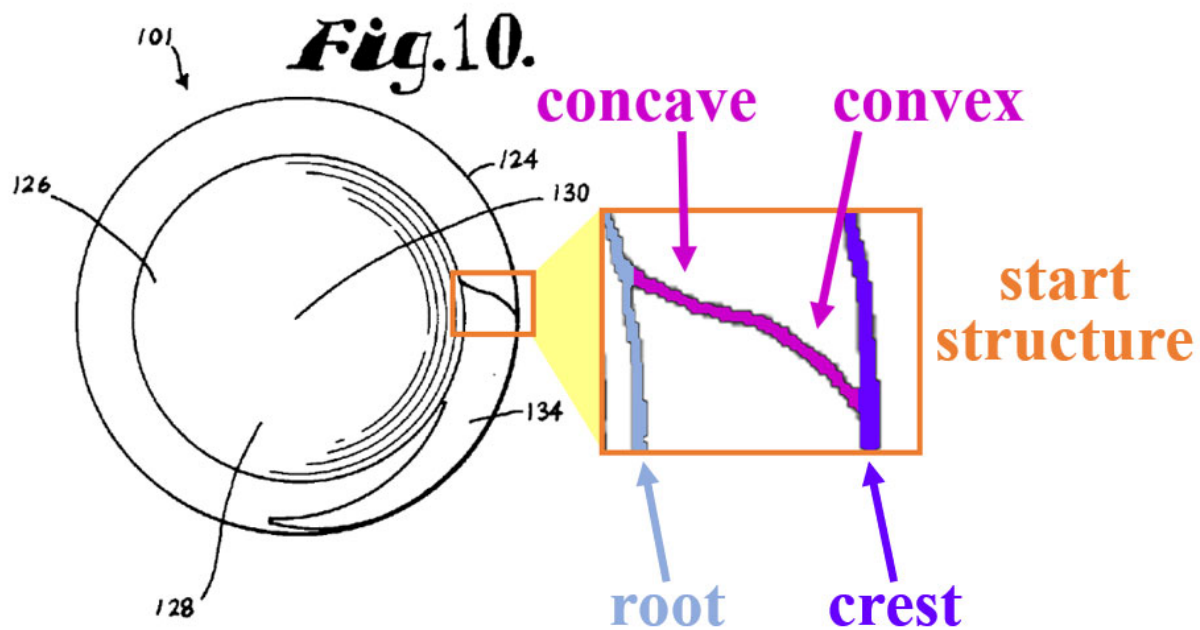
The combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. As shown in annotated and enlarged Figure 8 below, the '477 Publication's continuously helically wound closure thread has a start structure with a leading face extending between a root and a crest. EX1005, Figs. 7, 8; EX1003, ¶300.



Ex. 1005, Fig. 8

As shown in the bottom-up view of Figure 10, the leading face of the start structure includes a partial concave surface adjacent the root and a partial convex

surface adjacent the crest. EX1005, Fig. 10. A POSA would recognize this feature of Fig. 10 as the leading face of the thread, at least because it is the only feature shown that matches with leading face shown in Fig. 8 and extends continuously from the root to the crest. EX1003, ¶301.



Ex. 1005, Fig. 10

When combining the '477 Publication with Boschert and the '287 Publication, a POSA would have modified the '477 Publication to include double-start threads—as taught in Boschert—but would have otherwise kept the thread design of the '477 Publication, including the leading face structure described above. *Supra* §VI.D.2; EX1003, ¶303. Therefore, the start structure in the combination would have included the claimed leading faces with concave and convex surfaces. EX1003, ¶303.

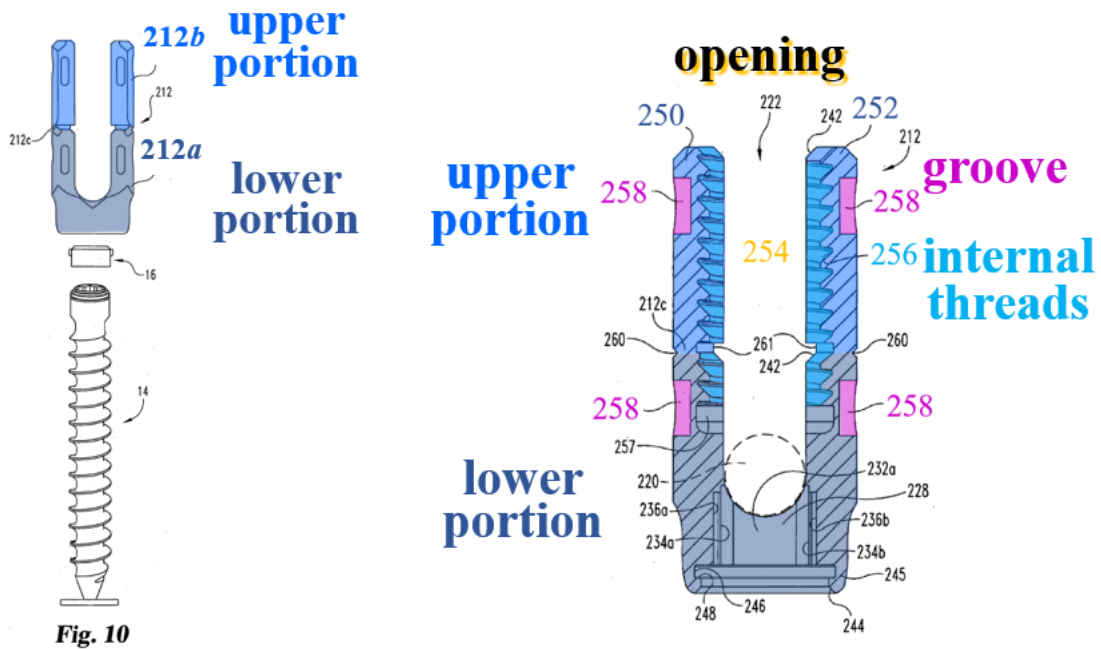
Accordingly, the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 20. *Id.*, ¶304.

VII. GROUND 2: CLAIM 14 IS OBVIOUS IN VIEW OF THE '477 PUBLICATION, '287 PUBLICATION, BOSCHERT, AND JOHNSON.

A. Overview of Johnson

Johnson, published on April 19, 2007, is prior art to the '233 Patent under 35 U.S.C. § 102(b). Johnson discloses a “medical implant device [including] a receiver member for receiving an elongated member, a crown member, an anchor member and a retaining member.” EX1008, Abstract. Therefore, Johnson is in the same field of endeavor as, and is analogous art to, the '233 Patent. *Compare* EX1008, ¶[0031], *with* EX1001, 1:26-30; EX1003, ¶189.

As shown in the annotated Figures 10 and 12 below, Johnson discloses a receiver member 212 with “a lower portion 212*a* and an upper portion 212*b* separated by a thinned section 212 *c*.” EX1008, ¶[0051]; EX1003, ¶190.



The receiver member includes a “pair of upright branches 250, 252 between which opening 222 extends,” wherein “[a] portion of each branch 250, 252 forms at least a portion of lower portion 212a of receiver member 212, and a portion of each branch 250, 252 forms at least a part of upper portion 212b of receiver member 212.” EX1008, ¶[0052]. Johnson discloses that internal threads 256 on the upper portion 212b and lower portion 212a. *Id.* The threads 256 “can be a reverse angle thread” and “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.*, ¶[0052], [0053]; EX1003, ¶190.

Johnson discloses that its upper portion 212b “may be cut or sheared off” from lower portion 212a. EX1008, ¶[0056]. Thereafter, “upper portion 212b may be removed from the surgical site and discarded.” *Id.*; EX1003, ¶191. Johnson also

discloses tool attachment grooves 258. EX1008, ¶¶[0052]-[0053], Figs. 11&13; EX1003, ¶192.

Johnson discloses that extended receiver arms are beneficial because “[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” but, rather, can simply “place[] a portion of the elongated member 220 into channel 254 in upper portion 212*b* of receiver member 212.” EX1008, ¶[0055]; EX1003, ¶193.

B. Motivation to Combine Johnson with the ’477 Publication, the ’287 Publication, and Boschert.

Like the ’477 Publication, the ’287 Publication, and Boschert, Johnson is in the same field as the ’233 Patent, as set forth above. *Supra* §VII.A. A POSA would have combined the teachings of the ’477 Publication, Boschert, the ’287 Publication, and Johnson by including Johnson’s break-off extensions on the receiver arms of the ’287 Publication. EX1003, ¶¶210, 3005-09.

Like the ’477 Publication, the ’287 Publication, and Boschert, Johnson is directed to a medical implant device that receives a longitudinal connecting member, such as a rod. EX1008, Abstract; EX1003, ¶211; *supra* §VII.A. Johnson additionally teaches that using break-off extension arms in such medical implants provides the benefit of simplifying the introduction of an elongate member or rod. 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]. Johnson discloses that a compression member is then “thread 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, and against a crown member and/or anchor member in chamber 228.” *Id.* Johnson also discloses that “[o]nce separated, upper portion 212 b may be removed from the surgical site and discarded.” *Id.*, ¶[0056]. EX1003, ¶211; *see also supra* §VII.A.

A POSA would have known that in certain situations (e.g., in the case of a severe spinal deformity or when the surgeon wishes to perform a minimally invasive operation), longer U-shaped arms of the receiver are needed to capture a longitudinal connecting rod and allow for a longer tightening distance of the closure. EX1003, ¶212. A POSA would have known that break-off arm extensions were developed before the priority date of the '233 Patent to address this issue by enabling the receiver to capture the rod between them and allow the closure to be tightened along their length before being broken off from the receiver and leaving a low-profile receiver in the patient's body. *Id.* A POSA would have known the benefit of including both break-off arm extensions and a tool groove(s) on a receiver to allow

for the efficiency of break-off extensions during implantation, with the option to attach additional tools during implantation or later for later repair or removal. *Id.*

With this knowledge, a POSA would have recognized that it would be possible to realize these benefits in the open-ended receiver assembly by adding break-off receiver extensions to the top of the '287 Publication's receiver arms, as taught in Johnson. *Id.*, ¶213.

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, as it was well-known to a POSA before the priority date of the '233 Patent that break-off extension arms provided these advantages and could be successfully used in medical implant devices. *Id.*, ¶214. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for machining break-off extension arms were well known and readily available. *Id.*, ¶214. Moreover, a POSA would have been motivated to combine the teachings of Johnson with the '287 Publication, the '477 Publication, and Boschert based on the demands known to the medical device design community for medical devices with low profiles and that minimize the difficulty of use. *Id.*, ¶215.

C. Claim Analysis.

As set forth above, *supra* §VI.E.1, the combination of the '477 Publication, the '287 Publication, and Boschert already renders obvious every limitation of Claim 1. The addition of Johnson further renders obvious Claim 14. EX1003, ¶¶305-09.

1. Claim 14

Claim 14 depends from Claim 1 and additionally recites: [E] “wherein the first and second arm each has a breakoff extension.” The combination of the '287 Publication, the '477 Publication, Boschert, and Johnson includes this limitation. EX1003, ¶310.

In particular, as discussed above and as seen in Figure 12, Johnson discloses a first breakoff extension coupled to the first arm 250 and a second breakoff extension coupled to the second arm 252. EX1008, Figs. 10, 12; *see also id.* ¶¶[0052]-[0053], Figs. 11, 13; EX1003, ¶311.



Based on the above disclosures and for the reasons discussed above, *supra* §VII.B, when combining the disclosures of the '287 Publication, the '477 Publication, Boschert, and Johnson a POSA would have included on each of the first and second arms a breakoff extension. EX1003, ¶312.

Accordingly, the '287 Publication, the '477 Publication, Boschert, and Johnson renders obvious every element of Claim 14. *Id.*, ¶313.

VIII. SECONDARY CONSIDERATIONS

Petitioners are not aware of any evidence of secondary considerations in support of non-obviousness. EX1003, ¶¶314-18. 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.*

IX. 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).

The '477 Publication and '287 Publication were not before the Examiner. Thus, the Examiner necessarily did not consider whether the '477 Publication or '287 Publication disclosed the claims of the '233 Patent that were ultimately allowed.

Boschert was discussed during prosecution of the '233 Patent, but its disclosure of dual-start threads was not considered in combination with the disclosures of the '477 Publication, '287 Publication, or Johnson. Johnson was cited but not discussed during prosecution.

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 '233 Patent over these disclosures. As set forth above, the '477 Publication in combination with Boschert and the '287 Publication and in further combination with Johnson renders obvious each and every limitation of the Challenged Claims. *Supra*, §§VI-VII.

B. Fintiv

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 at 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. EX1047; EX1048 at 2, 4-5; *Sotera Wireless, Inc. v. Masimo Corporation*, No. IPR2020-01019, Paper 12 at 17 (PTAB Dec. 1, 2020) (precedential).

X. CONCLUSION

Petitioners respectfully request that IPR of the '233 Patent be instituted and that Claims 1-7 and 13-20 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 13,984 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 /
Victor P. Jonas, Reg. No. 58,590

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. ¶ 42.105, I hereby certify that on September 22, 2023, I caused a true and correct copy of the Petition for *Inter Partes* Review in connection with U.S. Patent No. 10,898,233 and Exhibits 1001 – 1050 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 1-7 and 13-20

Identifier	Element
1[Preamble]	A medical implant assembly comprising:
1[A]	a receiver having a longitudinal axis, a first arm, and a second arm, the first and the second arms each extending in the same direction as the longitudinal axis and having a top side surface and an outer side face surface;
1[B]	a channel formed by the first arm and the second arm and opening between a front outer face surface adjacent the channel and a back outer face surface adjacent the channel opposite the front outer face surface of the receiver,
1[B1]	the channel adapted to receive a longitudinal connecting member,
1[C]	the channel configured to be closed with a closure having an axis of rotation;
1[A1]	a first interior surface of the first arm opposite the outer side face surface thereof; a second interior surface of the second arm opposite the outer side face surface thereof; a first discontinuously helically wound structure on the first interior surface of the first arm,
1[C1]	the first discontinuously helically wound structure configured to engage a first start structure of a first continuously helically wound thread form disposed on the closure, the first start structure having a leading face with a concave surface portion and a convex surface portion;
1[A2]	a second discontinuously helically wound structure on the second interior surface of the second arm,
1[C2]	the second discontinuously helically wound structure configured to engage a second start structure of a second continuously helically wound thread form disposed on the closure, the second start structure having a leading face with a concave surface portion and a convex surface portion,
1[C3]	a rotation of the closure about the axis of rotation between the first arm and the second arm configured to cause a simultaneous mating of the first start structure under the first discontinuously helically wound structure and the second start structure with the second discontinuously helically wound structure due to a diametrically timed positioning of the first and second start structures on the closure,
1[C4]	the closure configured to be rotationally advanced within the channel until the bottom surface engages and locks the longitudinal connecting member within the channel; and
1[D]	the first and second arm outer side face surfaces each having a curvate extending groove configured to be engaged by an instrument, each groove extending horizontally to at least one of the front or back outer face surface of each arm and being located adjacent the top side surface on each arm, wherein an entirety of each groove is configured to be located above a top surface of the longitudinal connecting member when the longitudinal connecting member is received and locked in the channel by the closure.
2[Preamble]	The medical implant assembly of claim 1,

Identifier	Element
2[D1]	wherein each groove includes an outer facing surface.
3[Preamble]	The medical implant assembly of claim 2,
3[D2]	wherein the outer facing surfaces of the grooves extend in a direction parallel to the longitudinal axis.
4[Preamble]	The medical implant assembly of claim 1,
4[D3]	wherein each groove includes a downward facing surface.
5[Preamble]	The medical implant assembly of claim 4,
5[D4]	wherein the downward facing surfaces of the grooves are planar.
6[Preamble]	The medical implant assembly of claim 5,
6[D5]	wherein each downward facing surface of the grooves are parallel with one another.
7[Preamble]	The medical implant assembly of claim 1,
7[D6]	wherein each groove includes an upward facing surface.
13[Preamble]	The medical implant assembly of claim 1,
13[C5]	wherein the first and second discontinuously helically wound structure comprises one of a reverse angle thread, a square thread, a buttress thread, or a helical flange form.
14[Preamble]	The medical implant assembly of claim 1,
14[E]	wherein the first and second arm each has a breakoff extension.
15[Preamble]	The medical implant assembly of claim 1,
15[D7]	wherein each outer side face surface has an outward facing planar surface.
16[Preamble]	The medical implant assembly of claim 1 and 15,
16[D8]	wherein the outward facing planar surface on each arm is recessed and parallel with respect to the longitudinal axis of the receiver and to each other.
17[Preamble]	The medical implant assembly of claim 1,
17[F]	further including an insert configured to be top loaded into the receiver, the insert having first and second opposed upright arms with top surfaces and lateral protrusions with top surfaces contiguous with the top surfaces on the upright arms of the insert.
18[Preamble]	The medical implant assembly of claim 1,
18[F1]	wherein the receiver includes a central bore having a recess into which an insert is configured to be at least partially positioned by being down loaded into the receiver through the channel.
19[Preamble]	The medical implant assembly of claim 1 and 18,
19[F2]	wherein the insert is a retainer configured to engage a head of a bone attachment shank.
20[Preamble]	The medical implant assembly of claim 1,
20[C6]	wherein each of the leading faces on the first and the second start structures has a concave surface adjacent a root and a convex surface adjacent a crest of the respective first and second continuously helically wound structures.