

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. 8,911,479
Filing Date: January 10, 2013
Issue Date: December 16, 2014
Title: MULTI-START CLOSURES FOR OPEN IMPLANTS

Inter Partes Review No. IPR 2023-01430

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

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LIST OF EXHIBITS

Exhibit 1001	U.S. Patent No. 8,911,479
Exhibit 1002	File History U.S. Patent No. 8,911,479
Exhibit 1003	Declaration of Dr. Carl McMillin
Exhibit 1004	Dr. Carl McMillin Curriculum Vitae
Exhibit 1005	U.S. Patent Application Publication No. 2005/0267477 (“the ‘477 publication”)
Exhibit 1006	U.S. Patent No. 7,857,834 (“Boschert”)
Exhibit 1007	U.S. Patent Application Publication No. 2011/0152947 (“Kirschman”)
Exhibit 1008	U.S. Patent Application Publication No. 2007/0088357 (“Johnson”)
Exhibit 1009	U.S. Patent Application Publication No. 2006/0069391 (“the ‘391 Publication”)
Exhibit 1010	U.S. Patent No. 10,548,641
Exhibit 1011	U.S. Patent No. 10,898,233
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Exhibit 1015	U.S. Patent No. 6,726,689 (“Jackson ‘689”)
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Exhibit 1017	U.S. Patent No. 6,302,888 (
Exhibit 1018	U.S. Patent No. 5,697,929 (“Mellinger ’929”)
Exhibit 1019	U.S. Patent No. 7,250,052 (“Landry”)
Exhibit 1020	U.S. Patent Application Publication No. 2004/0167526
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Exhibit 1022	American Society of Mechanical Engineering Standard B1.7-2006 (“ASME B1.7-2006”)
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Exhibit 1031	U.S. Patent No. 7,862,595 (“Foley”)
Exhibit 1032	File History of U.S. Patent Application No. 15/397,959 (“the ’959 Application”)
Exhibit 1033	German Patent No. 29810798
Exhibit 1034	U.S. Patent No. 7,854,751 (“Sicvol”)
Exhibit 1035	U.S. Patent Application Publication No. 2007/0270813 (“Garamszegi”)

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Exhibit 1036	File History U.S. Patent No. 10,898,233
Exhibit 1037	U.S. Patent Application Publication No. 2006/0058794 (“Jackson ’794”)
Exhibit 1038	U.S. Patent Application Publication No. 2011/0106179 (“Prevost”)
Exhibit 1039	Stipulation Regarding Invalidity Contentions (“Sotera Stipulation”)
Exhibit 1040	June 21, 2022 Memorandum regarding Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (“Sotera Memo”)

ZimVie, Inc. and Zimmer Biomet Spine, Inc. (“Petitioners”) respectfully request *inter partes* review (“IPR”) of Claims 1-22 (“the Challenged Claims”) of U.S. Patent No. 8,911,479 (“the ’479 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 ’479 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. 10,548,641 (EX1010); 10,898,233 (EX1011); and 11,129,646 (EX1012) (the “’641,” “’233,” and “’646 Patent,” respectively; collectively, “the Related Patents”), to be filed concurrently herewith. The Related Patents are also at issue in the Litigation. The ’479 Patent is the parent of the Related Patents.

C. Counsel

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

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II. STANDING AND FEES

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

Petitioners certify that the '479 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)

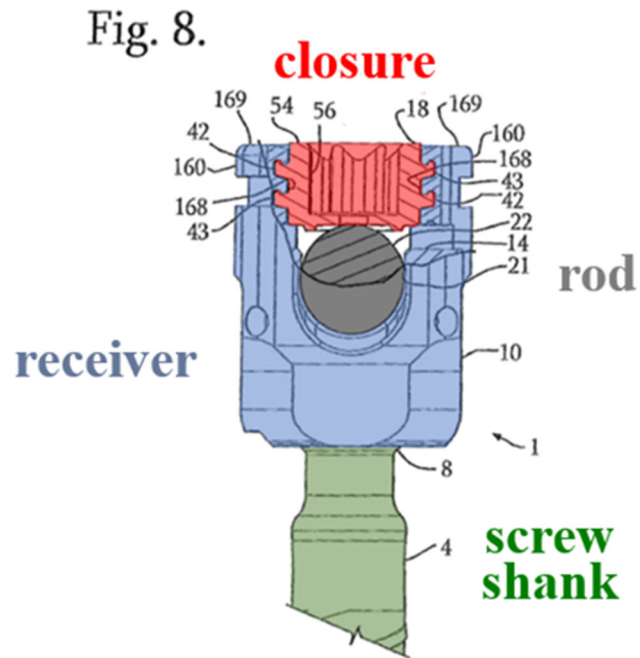
Petitioners authorize the Director to charge the request and post-institution fees, and any additional required fees, to Deposit Account No. DA060029.

III. THE '479 PATENT

A. Overview

The '479 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 admits that “[b]one anchors, such as bone screws ... are utilized in many types of spinal surgery in order to secure various implants to vertebrae along the spinal column for the purpose of stabilizing and/or adjusting spinal alignment.” EX1001, 1:21-24. The specification further admits that “open-ended bone anchors are known,” *Id.*, 1:28, 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 *Id.*, 1:42-46. As taught in the prior art, this U-shaped channel is “closed by a **closure member** after the **rod** or other longitudinal connecting member is placed in the channel.” *Id.*, 1:49-53. The

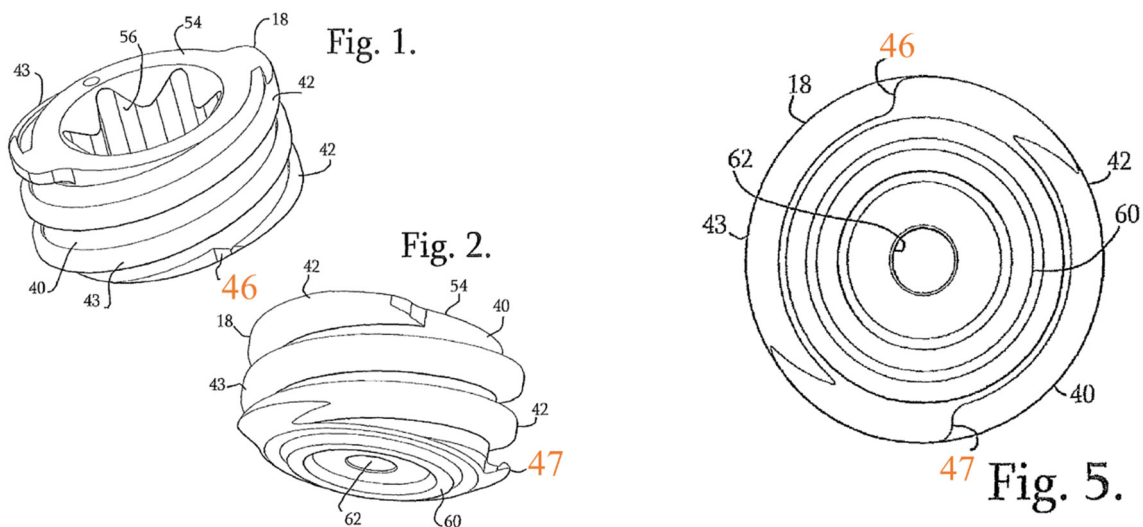


specification also states that “[*k*]nown *closures* include ... a variety of single start helically wound guide and advancement structures including, for example, thread forms having v-thread, reverse angle buttress or square thread forms, to name a few, as well as other non-threadlike helically wound forms.” *Id.*, 1:53-1:59.

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

¹ Emphases and text coloring added unless specified.

the closure is being pressed down on the rod while other forces are pushing and pulling the rod back out of the implant.” *Id.*, 2:4-12. The specification purports to address these issues by using a “double-start closure ... having two helically wound forms thereon, each form having a start structure for simultaneously engaging a mating helical form on a respective open implant arm.” *Id.*, 2:32-36. The “**start structures 46 and 47**” are identified in annotated Figures 1, 2 and 5 below.



During prosecution, Dr. Jackson’s patentability argument was based on the use of a pair of threadforms that provide a dual start. EX1002 at 2013. The Examiner did not issue a rejection based on any dual-start thread prior art. *Id.* at 2022-25. Yet later, during prosecution of a child application, Dr. Jackson’s patentability argument based on double-start threads fell flat when it was discovered that U.S. Patent No. 7,857,834 (“Boschert”) previously taught double-start closure

tops. EX1036 at 64-69. As a result, for that and other later patents, he pivoted to claiming other conventional elements of his preferred embodiments to overcome Examiner rejections. *Id.* at 321-30, 342-50. Dual-start threads were known in the prior art, but such art was never the basis for a rejection during the examination of the '479 Patent. EX1002 at 2022-25, 2103-09.

The '479 Patent includes four independent claims—Claims 1, 10, 18, and 21. These claims substantially overlap, but Claim 1 expressly requires two starts on the closure, while Claims 10, 18, and 21 require “at least two starts” and/or a “multi-start” closure. The dependent claims recite additional conventional components of closures and the receivers they thread into, including: additional characteristics of known threads (Claims 2-6, 11-15, and 20), a multi-start closure specified to be a double-start closure (Claim 19), a breakoff drive mechanism for the closure (Claims 7 and 16), breakoff extensions on the receiver arms (Claims 8 and 17), and attachable/detachable guide tool that transfers the closure from the guide tool to the bone screw (Claims 9 and 22).

Petitioners provide as an Appendix to the Petition a claim listing of all Challenged Claims. Because many limitations of Claims 1, 10, 18, and 21 are common, each of these limitations has been assigned a unique identifier. This claim listing, and the assignment of a unique identifier for each limitation, are intended for ease of reference. The Petition addresses every limitation of the Challenged Claims.

B. Priority Date

The '479 Patent claims priority to January 10, 2012 (“Priority Date”). EX1001. Although Petitioners do not concede that the '479 Patent is entitled to this priority date, Petitioners assume this date for purposes of this Petition.

IV. Level of Ordinary Skill in the Art

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

A person of ordinary skill in the art (“POSA”) would have had (1) a degree in Mechanical Engineering or equivalent technical background and (2) at least two years experience designing or implanting spinal implants with threaded connections. More education could substitute for less experience, and vice versa. EX1003, ¶¶37-43 (analyzing non-exhaustive factors for determining the level of skill in the art).

B. Knowledge of a POSA

Before the priority date of the '479 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, ¶¶45-50. Further, a POSA would have been aware of a number of options when designing such a system, including multi-start threads, *id.*, ¶¶51-62, various threadform types, *id.*, ¶¶63-70, breakoff closures, *id.*, ¶¶72-77, breakoff arm extensions, *id.*, ¶¶78, 88-94, and attachable/detachable guide tools, *id.*, ¶¶78-87.

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, 5, 10, 14, and 18-21	Anticipated or obvious in view of Boschert (EX1006)
2	2-4, 6, 7, 11-13, 15, and 16	Obvious in view of Boschert (EX1006) in combination with the '477 Publication (EX1005)
3	9 and 22	Obvious in view of Boschert (EX1006) in combination with the '391 Publication (EX1009)
4	8 and 17	Obvious in view of Boschert (EX1006) in combination with Johnson (EX1008)

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

The Challenged Claims are construed under the same standard used to construe claims in a civil action in federal district court. 37 C.F.R. § 42.100(b). For purposes of this Petition, Petitioners believe that no claim construction is required and that the Challenged Claims should be given their ordinary and customary meaning.

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

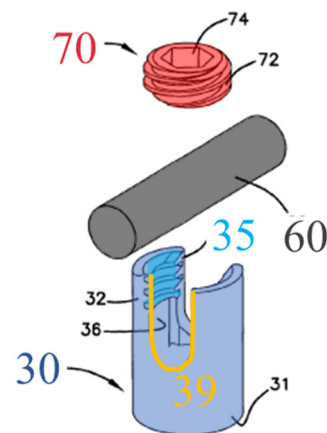
The grounds set forth in Sections VI-IX below, as supported by the Declaration of Dr. Carl McMillin (EX1003), demonstrate that the Challenged Claims are unpatentable.

VI. GROUND 1: CLAIMS 1, 5, 10, 14, AND 18–21 ARE UNPATENTABLE OVER BOSCHERT.

A. Overview of Boschert

Boschert published on December 15, 2005, and is prior art to the '479 Patent under Section 102(b). As described further below, because Boschert discloses a medical implant assembly that uses a closure to capture and lock a rod in a spinal implant, Boschert is in the same field of endeavor as, and analogous art to, the '479 Patent. *Compare* EX1006 at Abstract, 1:5-7, 4:26-28, *with* EX1001, 1:14-18; *see also* EX1003, ¶128.

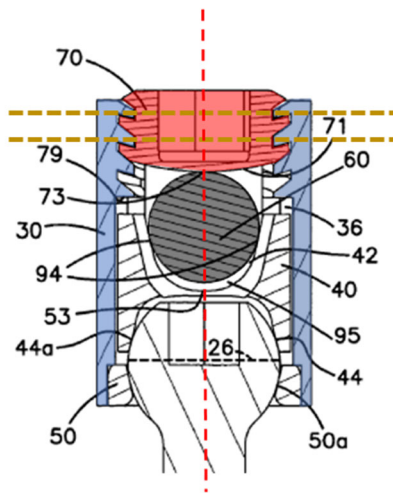
Boschert is directed to an orthopedic fixation device for securing a rod to a bone for stabilization of the spine. EX1006, Abstract, 1:5-7; EX1003, ¶¶128-29. Boschert discloses a receiver 30 (blue) with two upwardly extending legs defining the saddle 39 (yellow) (i.e. the channel) which is U-shaped for receiving the rod 60 (gray). EX1006, 6:20-24, Fig. 1;



Ex. 1006, Fig. 1

EX1003, ¶130. Boschert's legs have interior threads (light blue) that mate with corresponding exterior threads on the set screw 70 (red) (i.e., the closure), such that the set screw can be threaded into the saddle to lock the rod in place. EX1006, 6:24-48, 7:12-15; EX1003, ¶130.

Boschert discloses that it would be advantageous to design the threads of the set screw to have a “*double lead to allow the setscrew 70 to start more easily than with a single lead.*” EX1006, 7:21-23; EX1003, ¶130. As shown in annotated Figure 3 below, Boschert further discloses that the mirrored interior threads on the receiver provide for simultaneously receiving the double leads of the closure. EX1006, Fig. 3; EX1003, ¶130.

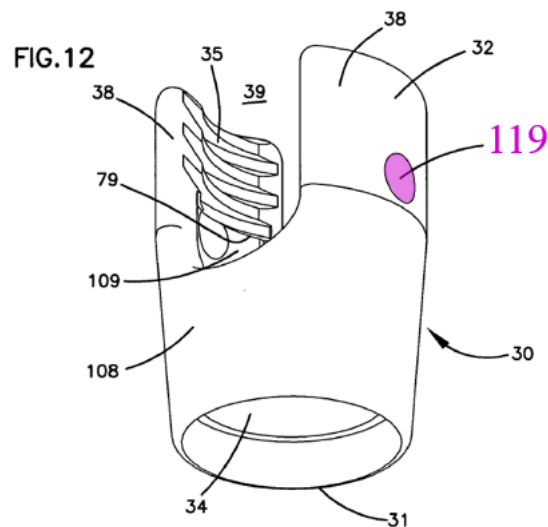


As discussed in more detail below, *see* §VI.B.1.d, the double threads of Boschert's closure are also symmetrical and diametrically opposed, and therefore

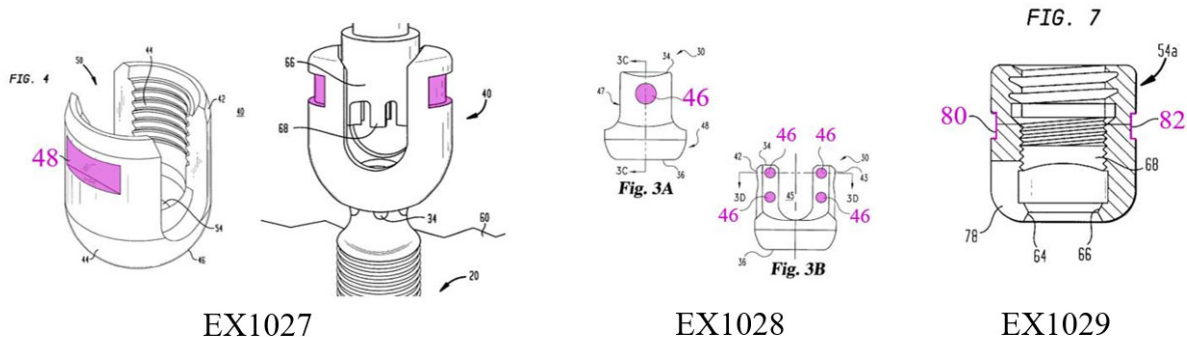
simultaneously mate into the symmetrical threads of the receiver. *See* Ex1003, ¶¶131-34; EX1006, Figs. 3, 7, 15; EX1014 at 3; EX1026 at 13:35-41.

Boschert also expressly contemplates potential modifications to its locking mechanism, 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, ¶135. Thus, the type of thread (e.g., reverse angle, buttress thread, square thread, etc.) used in Boschert is not material to the invention, and a POSA would have known that any thread type could be used in conjunction with Boschert. EX1003, ¶135.

Boschert also expressly contemplates the inclusion of “grasping features” on the outside surface of the receiver. EX1003, ¶136. Specifically, Boschert states that “[a]s illustrated in FIG. 12, the receiver 30 may also include grasping features 119 on the outer surface 108 that would accommodate instrumentation to facilitate grasping, holding or manipulating of the receiver 30.” EX1006, 6:15-19; EX1003, ¶136.



Boschert does not describe these “grasping features” in any more detail, but does incorporate by reference several patents disclosing exemplary grasping features, including U.S. Patent Nos. 6,488,681 (EX1027) (grooves 48, Figs 4 & 8 at left); 6,280,442 (EX1028) (indentations or holes 46, Figs. 3A & 3B at middle), and 6,074,391 (EX1029) (slots 80 and 82, Fig. 7 at right) pictured below. EX1006, 1:55-60; EX1003, ¶136.



From these disclosures, a POSA would have understood that that type of grasping feature was not material to Boschert and that any known grasping feature

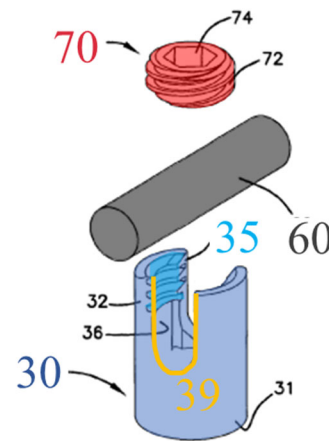
could be used. EX1003, ¶136. Boschert also does not discuss in any detail the type of instruments or tools to be used in conjunction with these grasping features, thereby inviting a POSA to look to tools and instruments that were otherwise known in the art. *Id.*

B. Claim Analysis.

1. Claim 1

- a. **1[Preamble]:** “In a medical implant having a substantially cylindrical closure member and a receiver member having first and second spaced arms forming an open channel, the closure member having an axis of rotation for closing the open channel, the improvement comprising:”

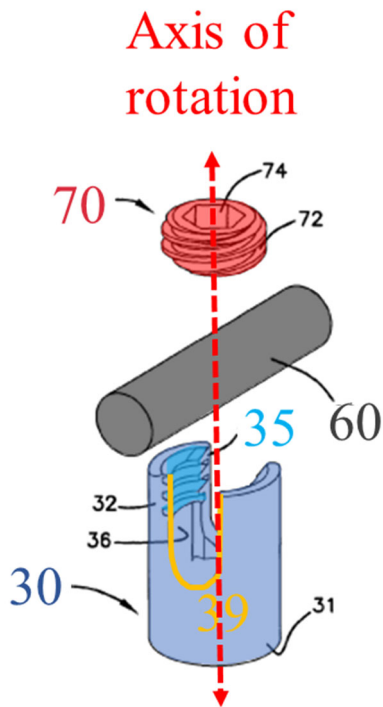
To the extent the preamble is limiting, Boschert discloses this limitation. EX1003, ¶¶171-74. Boschert, entitled “Spinal Fixation Implant Assembly,” expressly discloses a medical implant. EX1006 at Abstract, 1:34-37, 4:13-16; EX1003, ¶171. As shown in annotated Figure 1 (right), Boschert also



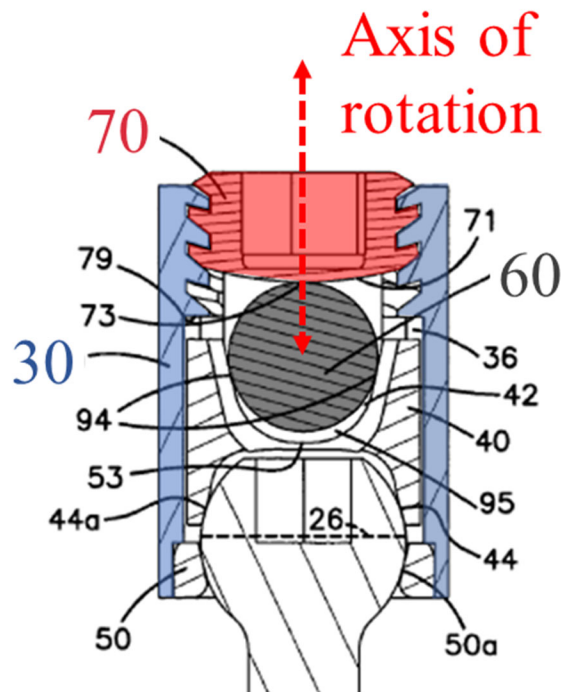
expressly discloses a receiver member 30 (blue) having first and second spaced arms forming an open channel (yellow). EX1006, Fig. 1; EX1003, ¶172. Boschert’s receiver 30 includes “a top portion 32 defining a saddle 39 (i.e., a pocket) [yellow] for receiving a rod 60 [gray].” EX1006 at 4:16-18, Figs. 1, 3, 4, 7, 12, 14, 15;

EX1003, ¶172. Boschert's receiver "includes two upwardly extending legs 38 between which the saddle 39 of the receiver 30 is defined. The saddle 39 of the receiver 30 provides an open region or pocket for receiving the rod 60." EX1006 at 6:11-23, Figs. 1, 3, 4, 7, 12, 14, 15; EX1003, ¶172.

Boschert expressly discloses a substantially cylindrical closure member having an axis of rotation for closing the open channel, as shown above in annotated Figure 1. EX1006, Fig. 1; EX1003, ¶173. Specifically, Boschert discloses a "fastener such as a setscrew 70 [red] for clamping the rod 60 within the saddle 39 of the receiver 30." EX1006, 4:26-28, Figs. 1, 2, 3, 4, 7, 12, 14, 15; EX1003, ¶173. Boschert's substantially cylindrical setscrews 70 "are threaded into the saddle 39 thereby forcing the rods 60 to seat against the top sides of the seat structures 40." EX1006, 4:47-50, *see also id.* 6:20-28; Figs. 1, 3, 4, 7, 15. As shown below in annotated Figures 1 and 3, because Boschert discloses that the set screws 70 "are threaded into the saddle 39," a POSA would have understood that Boschert discloses set screw (i.e., closure member) having an axis of rotation. *See id.* at 4:48-49, Figs. 1, 3; EX1003, ¶173.



EX1006, Fig. 1



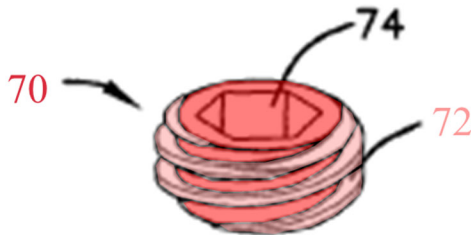
EX1006, Fig. 3

Thus, Boschert discloses this limitation. EX1003, ¶174.

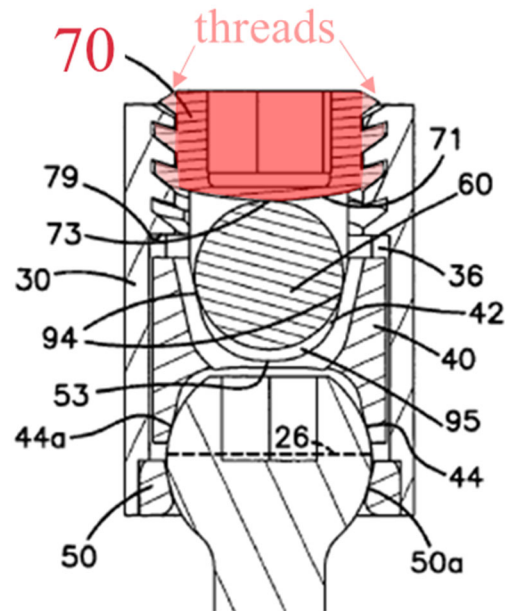
- b. 1[A1]: “a) first and second helically wound forms located on the closure member, the first form having a first start and the second form having a second start; and”

Boschert discloses this limitation. EX1003, ¶¶175-78. Boschert expressly discloses first and second helically wound forms located on the closure member. EX1003, ¶175. Boschert discloses that a setscrew 70 is “threaded into the saddle 39” by exterior threads 72. EX1006 at 6:20-28; EX1003, ¶175. As shown in annotated Figure 1 (excerpted) and Figure 3 (in profile) below, Boschert discloses that the exterior threads 72 of the setscrew 70 spiral around the cylindrical body of

the closure member and thus are helically wound. EX1006, Figs. 1, 3; EX1003, ¶175.



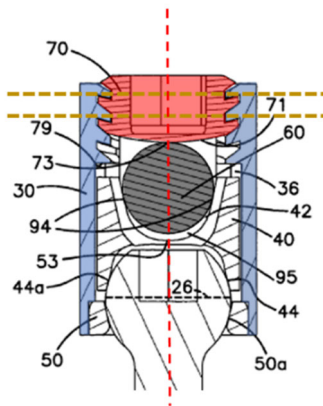
EX1006, Fig. 1



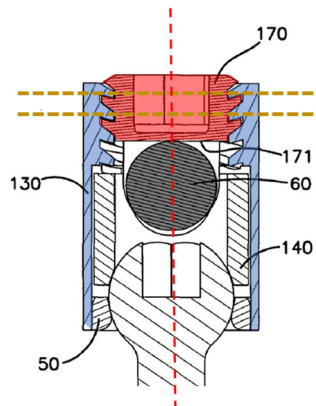
EX1006, Fig. 3

Boschert also expressly discloses first and second helically wound forms, or double threads, on the closure. EX1003, ¶176. In particular, Boschert discloses that “[t]he threads 72 of the setscrew 70 can also be designed with *a double lead* to allow the setscrew 70 to start more easily than with a single lead.” EX1006, 7:21-23; EX1003, ¶176. Boschert’s disclosure is consistent with a POSA’s understanding of the known benefits of multi-start threads. EX1003, ¶¶51-62, 176. As shown below in annotated Figures 3, 7, and 15, Boschert further discloses first and second helically wound forms on the closure by its disclosure of parallel threads on the closure and its disclosure of diametrically opposed thread ends (purple). EX1006,

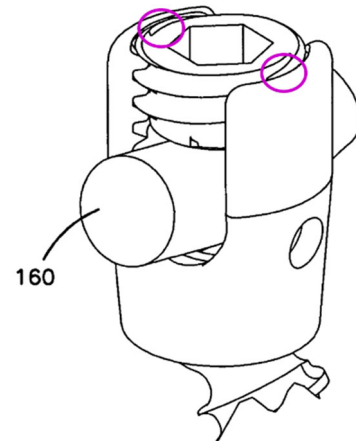
Figs. 3, 7, 15; EX1003, ¶176. A POSA would have understood that Boschert's disclosure of two thread ends necessarily discloses a first and second start. EX1003, ¶177.



EX1006, Fig. 3



EX1006, Fig. 15



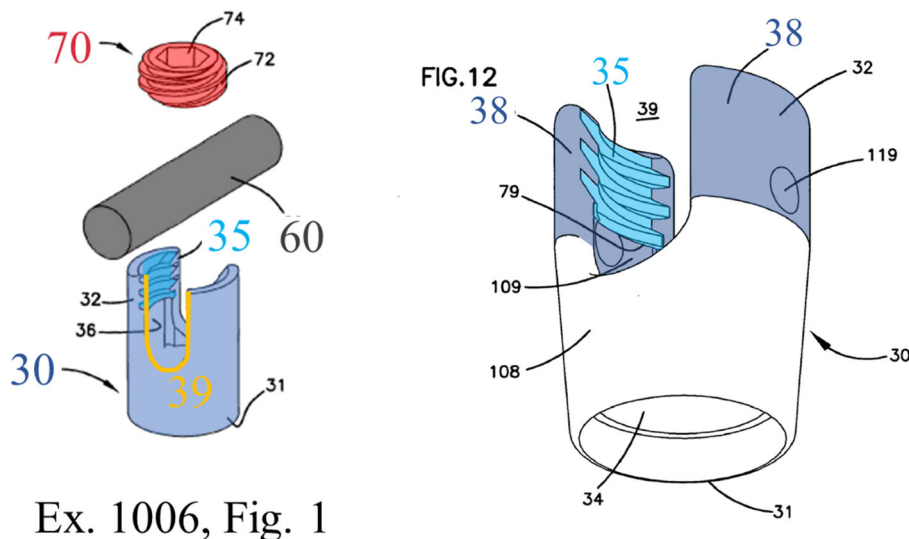
EX1006, Fig. 7

Accordingly, Boschert discloses this limitation. EX1003, ¶178

- c. 1[B1]: “b) a first discontinuous helically wound structure on the receiver first arm and a second discontinuous helically wound structure on the receiver second arm and”

Boschert discloses this limitation. EX1003, ¶¶179-80. Boschert expressly discloses a first discontinuous helically wound structure on the receiver first arm and a second discontinuous helically wound structure on the receiver second arm. EX1006, 6:11-28 (disclosing a receiver 30 that “includes two upwardly extending legs 38 [which] include fastening structure for interconnecting with the setscrew 70. For example, the legs 38 are shown defining interior threads 35 that mate with corresponding exterior threads 72 of the setscrew 70 to allow the setscrew 70 to be

threaded into the saddle 39 to lock the rod 60 and screw in place”); *id.*, Figs. 1, 3, 4, 12, 14, 15; EX1003, ¶179. As shown in annotated Figures 1 and 12 below, Boschert’s interior threads 35 are discontinuously helically wound structures. EX1006, Figs. 1, 12; EX1003, ¶179. A POSA would have understood that Boschert discloses discontinuous helically wound structures on each receiver leg. EX1003, ¶179.



Thus, Boschert discloses this limitation. EX1003, ¶180.

- d. 1[C]: “wherein simultaneous mating of the first start with the arm first helically wound structure and the second start with the arm second helically wound structure occurs when the closure member is rotated between the first and second arms of the receiver member.”

Boschert discloses and/or renders obvious this limitation. *Id.*, ¶¶181-88. Boschert expressly discloses double threads on its closure member. EX1006, 7:21-23; EX1003, ¶181. Boschert discloses to a POSA that the start structures of its

disclosed double threads simultaneously mate with the interior threads on the receiver legs. EX1003, ¶182. As shown in annotated Figures 3 and 15 below, Boschert discloses both that the threads of the receiver 30 are symmetrically and diametrically opposed to each other across the longitudinal axis (**yellow**) and that the threads on the closure 70 are symmetrically and diametrically opposed to other across the longitudinal axis (**red** line), as demonstrated by the horizontally parallel threads on each side of the receiver. EX1006, Figs. 3, 15; EX1003, ¶182. This discloses simultaneous starting and mating of the two closure thread starts with the two receiver threads. EX1003, ¶182.

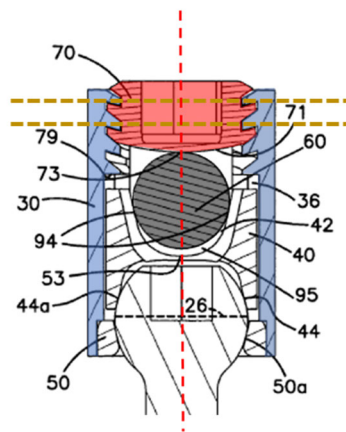


Fig. 3

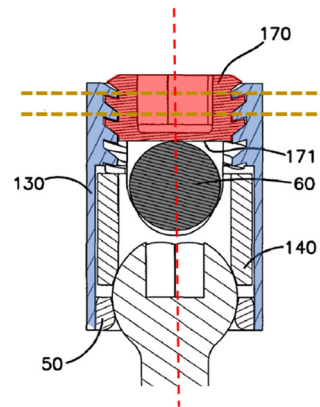
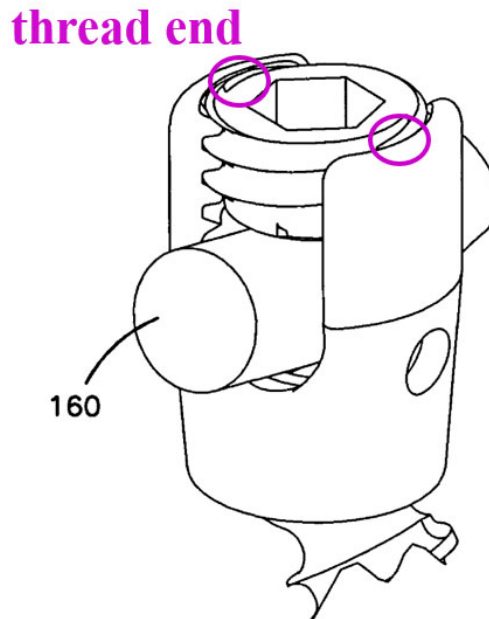


Fig. 15

Boschert's disclosure of diametrically opposed thread starts is further supported by the diametrically opposed trailing ends of Boschert's threads Figure 7, annotated below, which a POSA would have understood as disclosing diametrically opposed thread starts. EX1006, Fig. 7; EX1003, ¶183.



Further, based on the knowledge of a POSA of the conventional manner of making double start threads before the Priority Date, a POSA would have understood Boschert to disclose diametrically opposed thread starts. EX1003, ¶184; *see also id.*, ¶¶51-62. Specifically, a POSA would have known that “[i]n order to achieve proper distribution” for a multi-start thread, “each thread *has to start at an equal angle*, determined by the following calculation: Thread cylindrical spacing angle = $360 / \text{Number of starts}$.” EX1014 at 3; EX1003, ¶184. Accordingly, a POSA would have understood Boschert’s disclosure of a setscrew with a dual lead as teaching two starts having a cylindrical spacing angle 180° (*i.e.*, $360^\circ / 2$) and, thus, a first start structure that is disposed at a diametrically opposite location on the closure from the second start structure, which in turn results in simultaneous mating of one start structure on the closure with one receiver arm and the other start structure on the

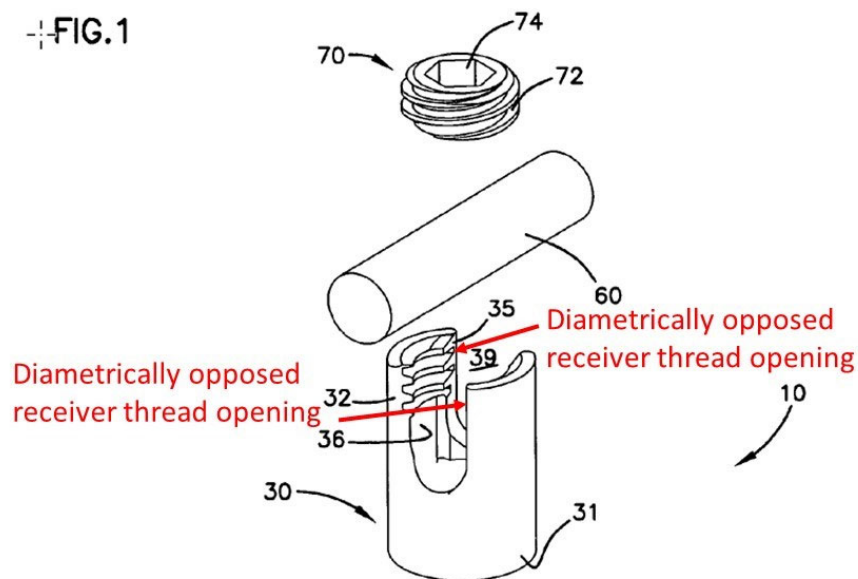
closure with the other receiver arm. EX1003, ¶184. This understanding is confirmed by the '479 Patent, which shows the same symmetrical threads on the receiver. *See* EX1001 Figs. 3, 8, 9, 11-15; EX1003, ¶184.

Based on Boschert's disclosures of diametrically opposed thread starts and of symmetrically and diametrically opposed receiver threads, a POSA would have understood that Boschert expressly discloses simultaneous mating of the first start with the arm first helically wound structure and the second start with the arm second helically wound structure when the closure member is rotated between the first and second arms of the receiver member. EX1003, ¶185. In view of Boschert's disclosed receiver and closure members' structures and the disclosed benefit of "a double lead to allow the setscrew 70 to start more easily than with a single lead," EX1006, 7:21-23, a POSA would have understood that Boschert discloses simultaneous mating. EX1003, ¶185.

To the extent that Boschert does not expressly disclose this limitation, Boschert necessarily discloses this limitation. EX1003, ¶186. A POSA would have understood that for the double start threads on the setscrew to engage with these receiver threads and to do so more easily than a single start thread, (1) the receiver threads would necessarily have to mirror each other, (2) the start structures would necessarily be spread equidistant around the closure's starting end, and (3) this positioning would result in simultaneous mating of each receiver thread start with

the first and second receiver thread. *Id.* Indeed, diametrically opposed thread starts was a conventional manner of making dual start threads before the Priority Date. EX1014 at 3; EX1026 at 13:35-41; EX1003, ¶¶51-62, 186.

To the extent that Boschert does not expressly or inherently disclose this limitation, it would have been obvious to a POSA to use closure double-thread starts that mate simultaneously with a first and second receiver arm in Boschert. EX1003, ¶187. As shown in annotated Figure 1 below, a POSA would have understood that the thread starts on the closure would be designed to be diametrically opposed to each other, as would the corresponding threads on the receiver arms. EX1006, Fig. 1; EX1003, ¶187.



This design configuration can only result in each of the thread starts on the closure simultaneously mating with the receiver threading. EX1003, ¶187. This is

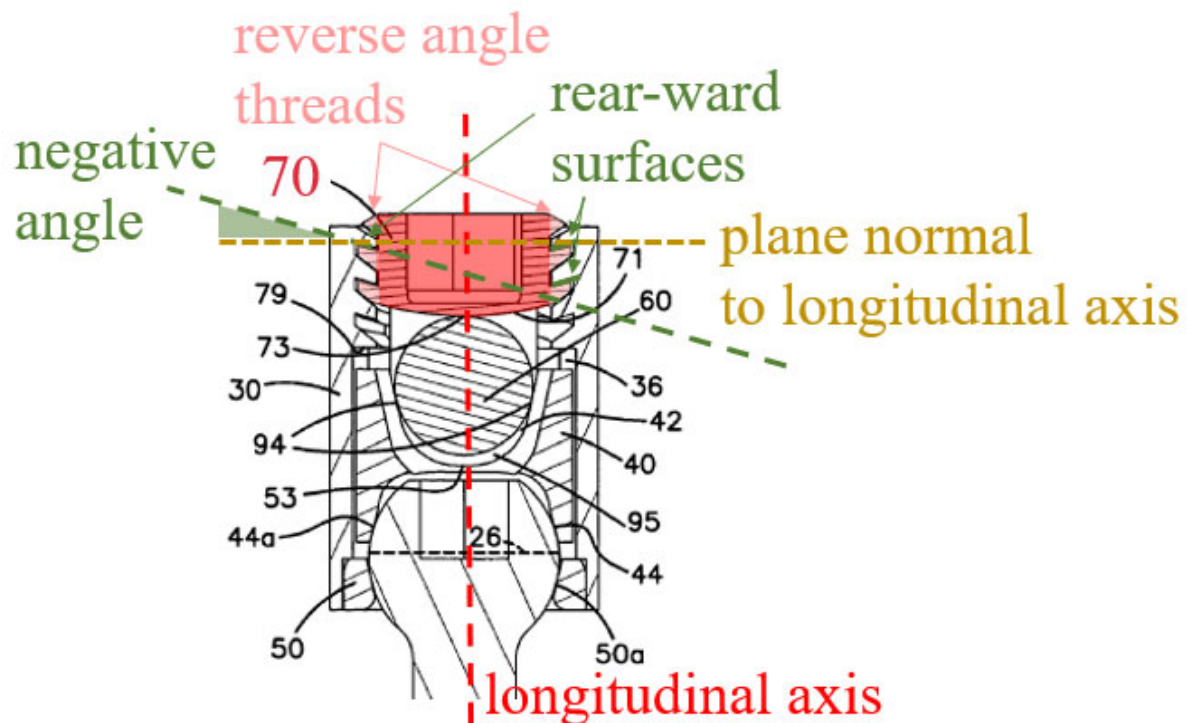
consistent with a POSA's understanding of the standard way to manufacture dual start threads that facilitate threading. *Id.*

Thus, Boschert anticipates and/or renders obvious Claim 1. *Id.*, ¶188.

2. Claim 5

Claim 5 depends from Claim 1 and further recites: [A5] “wherein the first and second helically wound forms are reverse angle threads.” Boschert discloses and/or renders obvious this limitation. *Id.*, ¶¶189-92.

As shown in annotated Figure 3 below and also shown in Figures 4 and 15, Boschert expressly discloses first and second helically wound forms that are reverse angle. EX1006, Figs. 3, 4, 15; EX1003, ¶190. Because the angle between a plane normal to the longitudinal axis (red line) and rearward surface is negative, a POSA would have understood that Boschert discloses reverse angle threads on its closure. EX1003, ¶190.



EX1006, Fig. 3

To the extent Boschert does not disclose this limitation, it would have been obvious to a POSA to select from among any of the well-known thread types disclosed in the '477 Publication, including a reverse angle threadform for the first and second helically wound forms. EX1003, ¶191. Moreover, a POSA would have understood a reverse angle thread was one of a variety of helically wound guide and advancement structures that could advantageously be used on a closure and was well known at the time of the '479 Patent. *See* EX1016, 2:48-51, 4:43-5:13, Fig. 3; EX1021, ¶¶[0028]-[0029]; EX1028, 8:16-21, Fig. 7; EX1003, ¶¶63-70, 191. Indeed, the '479 Patent itself concedes this. EX1001, 1:53-2:4 (“Known closures include . .

. a variety of single start helically wound guide and advancement structures including, for example, thread forms having . . . reverse-angle . . . thread forms . . .”); EX1003, ¶191. Based on these disclosures and in view of a POSA’s knowledge of various thread types and the design need for a closure to securely engage a receiver to lock a rod, to the extent Boschert does not disclose a reverse angle threadform, a POSA would have been motivated to use a reverse angle threadform on the closure when implementing Boschert at least because (1) it would have been nothing more than the simple substitution of one known element (the thread disclosed in Boschert to the extent the thread is not a reverse angle threadform) for another (a reverse angle threadform) to obtain a predictable result (allowing a closure to securely engage a receiver); (2) it would have been the mere application of a known technique (use of a reverse angle threadform) to a known device (Boschert) to yield a predictable result (allowing a closure to securely engage a receiver); and (3) there was a known design need for a closure to securely engage a receiver and a finite number of identified, predictable solutions (thread types, including a reverse angle threadform) that were known to a POSA and within their technical grasp. EX1003, ¶191.

Thus, Boschert discloses and/or renders obvious every limitation of Claim 5. *Id.*, ¶192.

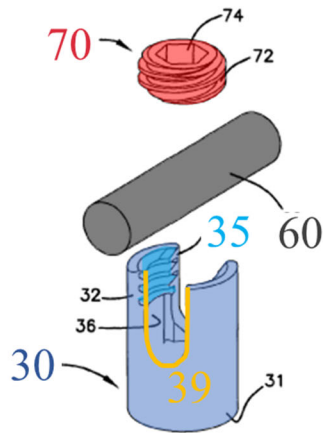
3. Claim 10

- a. **10[Preamble]:** “A medical implant assembly comprising:”

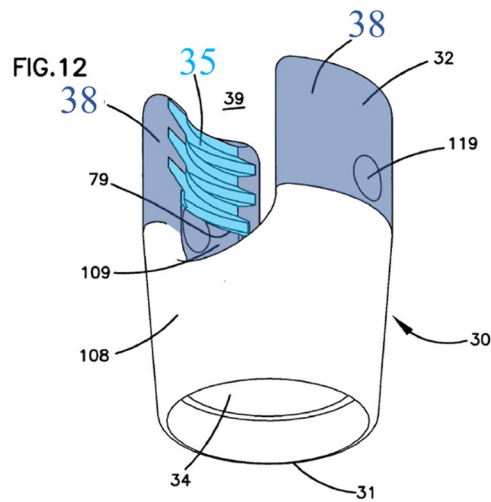
To the extent the preamble is limiting, Boschert disclose this limitation for the reasons discussed in Limitation 1[Preamble]. EX1003, ¶193; *see supra* §VI.B.1.a.

- b. **10[B3]:** “a) a receiver having a body and a pair of upstanding spaced arms forming a channel for receiving a longitudinal connecting member, each arm having an inwardly facing surface with a first discontinuous helically wound guide and advancement structure located thereon; and”

Boschert discloses this limitation. EX1003, ¶194. This limitation, while worded slightly differently, includes the same requirements as Limitations 1[Preamble] and 1[B1], except the limitation specifies a receiver having “a body” and “upstanding” spaced arms, adds that the channel is “for receiving a longitudinal connecting member,” and specifies that the arms have “inwardly facing surface[s].” EX1003, ¶194. As shown in annotated Figures 1 and 12 below, Boschert discloses a receiver having a body (i.e., bottom portion 31), EX1006, 4:16-19, a pair of upstanding spaced arms that form a channel (39) for receiving a longitudinal connecting member (i.e., rod 60), EX1006, 4:16-19, 6:11-28, and arms that have inward facing surfaces. EX1003, ¶¶195-96; EX1006, Figs. 1, 3, 4, 7, 12, 14, 15.



Ex. 1006, Fig. 1



Moreover, a POSA would have understood that a “guide and advancement structure” was substantially identical to a “helically wound structure.” EX1003, ¶194. For the reasons discussed here and above in Limitations 1[Preamble] and 1[B1], Boschert discloses this limitation. EX1003, ¶197; *see supra* §§VI.B.1.a, VI.B.1.c.

- c. 10[A8]: “b) a closure structure having a cylindrical body and a second helically wound guide and advancement structure having at least two starts.”

Boschert discloses this limitation. EX1003, ¶¶198-99. This limitation, while worded slightly differently, includes the same requirements as Limitations 1[Preamble] and 1[A1], except the limitation recites a closure structure having “at least two starts” instead of “a first start” and “second start,” as in Claim 1. EX1003, ¶198. For the reasons discussed in Limitations 1[Preamble] and 1[A1], Boschert discloses this limitation. *Id.*; EX1006, 4:13-18, 4:26-28, 4:47-50, 6:20-28, 7:21-23, Figs. 1, 3, 4, 7, 12, 14, 15; *see supra* §§VI.B.1.a, VI.B.1.b. As discussed above, *see*

§VI.B.1.b, Boschert discloses two starts and, therefore, also discloses a closure with at least two starts. EX1003, ¶198. Moreover, a POSA would have understood that where two starts can be used, any multi-start screw, such as a thread with two, three, or more starts, could be used. *Id.*; *see also* EX1014 at 3.

Thus, Boschert anticipates Claim 10. EX1003, ¶200.

4. Claim 14

Claim 14 depends from Claim 10 and further recites: [A5] “wherein the second helically wound guide and advancement structure includes at least two reverse angle threads.” This limitation recites the same start structure limitations as Claim 5, but does so in the context of a closure with “at least two starts” rather than the dual-start closure of Claim 1. *Id.*, ¶201. Boschert discloses a dual-start closure, which is a closure with at least two starts. *Id.*; EX1006, 7:21-23, Figs. 3, 7, 15. For the reasons discussed here and in Claim 5, Boschert discloses and/or renders obvious this limitation and, thus, discloses and/or renders obvious every limitation of Claim 14. EX1003, ¶201; *see supra* §VI.B.2.

5. Claim 18

a. 18[Preamble]: “In a medical implant, the improvement comprising:”

To the extent the preamble is limiting, Boschert discloses this limitation of the reasons discussed in Limitation 10[Preamble]. EX1003, ¶202; *see supra* §VI.B.3.a.

- b. 18[B3]: “a) an open receiver member with spaced arms having inwardly facing surfaces, each with a helically wound guide and advancement form located thereon; and”

This limitation, while worded slightly differently, recites the same requirements as Limitations 1[Preamble], 1[B1], and 10[B3]. EX1003, ¶203. Boschert discloses this limitation for the same reasons. *Id.*; *see supra* §§VI.B.1.a, VI.B.1.c, VI.B.3.b.

- c. 18[A9]: “a helically wound multi-start closure member having an axis of rotation, the closure member rotatably mounted on the receiver member at the spaced arm inwardly facing surfaces.”

This limitation, while worded slightly differently, recites the same requirements as Limitations 1[Preamble], 1[A1], and 10[A8], except the limitation describes the helically wound guide and advancement structure on the closure as “multi-start” instead of as having “a first start” and “a second start” (Claim 1) or “at least two starts” (Claim 10) and adds that the closure is “rotatably mounted on the receiver member at the spaced arm inwardly facing surfaces.” EX1003, ¶204. Boschert discloses this limitation. *Id.*, ¶¶204-07.

Boschert discloses a closure that is rotatably mounted on the receiver member at the spaced arm inwardly facing surfaces. EX1006, 4:47-50 (“[S]etscrews 70 are threaded into the saddles 39 thereby forcing the rods 60 to seat against the top sides of the seat structure 40.”); *id.*, 6:20-28, Figs. 1, 3, 4, 7, 15; EX1003, ¶205. Because

Boschert discloses two starts, as discussed above in Limitations 1[Preamble], 1[A1], and 10[A8], a POSA would have understood that Boschert discloses a multi-start closure member. EX1003, ¶206; *see also* EX1014 at 3; *supra* §§VI.B.1.a, VI.B.1.b, VI.B.3.c.

Thus, Boschert anticipates every limitation of Claim 18. EX1003, ¶208.

6. Claim 19

Claim 19 depends from Claim 18 and further recites: [A10] “wherein the multi-start closure is a double-start closure.” This limitation, while worded slightly differently, includes the same requirements as Limitation 1[A1]. EX1003, ¶209. Boschert discloses this limitation for the same reasons and, thus, anticipates Claim 19. *Id.*; *supra* §VI.B.1.b.

7. Claim 20

Claim 20 depends from Claim 18 and further recites: [A11] “wherein the multi-start closure includes at least two helically wound forms, each form being one of a flange form, a v-thread, a square thread, a reverse angle thread and a buttress thread, the form mating with the first helically wound guide and advancement form.” Boschert discloses this limitation. EX1003, ¶¶210-13.

For the reasons discussed in Claims 5 and 14, Boschert discloses a multi-start closure that includes two helically wound forms, each being a reverse angle thread. *Id.*, ¶211. Claim 20’s requirement that “the form mat[e]s with the first helically

wound guide and advancement form” recites the same requirements as Limitation 1[C], while worded slightly differently, and, thus, Boschert discloses this limitation for the same reasons. *Id.*, ¶212; *supra* §§VI.B.1.d, VI.B.2, VI.B.4.

Accordingly, Boschert anticipates Claim 20. EX1003, ¶213.

8. Claim 21

- a. **21[Preamble]:** “In a polyaxial bone anchor having a shank and a receiver, the shank being pivotable with respect to the receiver prior to locking of a position of the shank with respect to the receiver, the improvement wherein:”

To the extent the preamble is limiting, Boschert discloses this limitation. EX1003, ¶¶214-16. Boschert discloses polyaxial bone screws (i.e., polyaxial bone anchor) that include a receiver and a shank that is pivotable with respect to the receiver prior to locking of a position of the shank with respect to the receiver. EX1006, 2:42-45, 4:13-28, 4:44-47, 4:50-60, 5:5-11, Fig. 4; EX1003, ¶214. Moreover, the ’479 Patent concedes that, at least as of the Priority Date, “[b]one anchors, such as bone screws and hooks,” were well-known and included polyaxial bone screw assemblies. EX1001, 1:21-24; 1:27-35, 1:49-53; EX1003, ¶215. Thus, Boschert discloses all features recited in Claim 21’s preamble. EX1003, ¶216.

- b. **21[B3]:** “a) the receiver has spaced arms having inwardly facing surfaces, each surface having a helically wound guide and advancement form located thereon, each guide and advancement form being sized and shaped to mate

with a helically wound multi-start closure member
having at least two starts.”

This limitation, while worded slightly differently, includes the same requirements as Limitations 10[B3] and 10[A8], which recite a closure with “at least two starts,” and Limitations 18[B3] and 18[A9], which recite a multi-start closure. EX1003, ¶217. Boschert discloses and/or renders obvious this limitation for the same reasons and, thus, discloses and/or renders obvious every limitation of Claim 21. EX1003, ¶¶217-18; *supra* §§VI.B.3.b, VI.B.3.c, VI.B.5.b, VI.B.5.c.

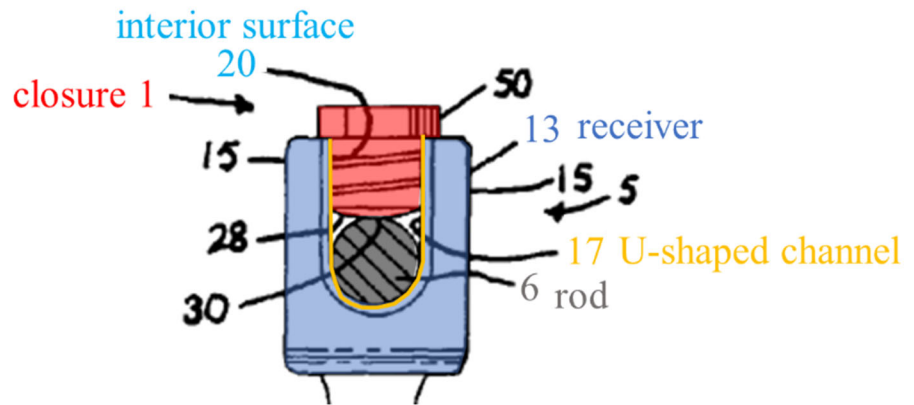
**VII. GROUND 2: CLAIMS 2-4, 6, 7, 11-13, 15 AND 16 ARE
UNPATENTABLE OVER BOSCHERT IN VIEW OF THE ’477
PUBLICATION.**

A. Overview of the ’477 Publication

The ’477 Publication was published on December 1, 2005, and is prior art to the ’479 Patent under Section 102(b). EX1005, Cover Page. As described further below, because the ’477 Publication discloses a medical implant assembly that uses a closure to capture and lock a rod in a spinal implant, the ’477 Publication is in the same field of endeavor as, and analogous art to, the ’479 Patent. *Compare* EX1005, ¶¶[0007], [0026]-[0029], [0039]-[0041], *with* EX1001, 1:16-20; EX1003, ¶137.

As shown in annotated Figure 6, the '477 Publication discloses a polyaxial screw that includes a receiver 13 with a pair of upstanding arms 15 forming a U-shaped channel 17 for receiving a rod 6. EX1005, ¶¶[0007], [0026]-[0038], Figs. 1-6; EX1003, ¶138. The

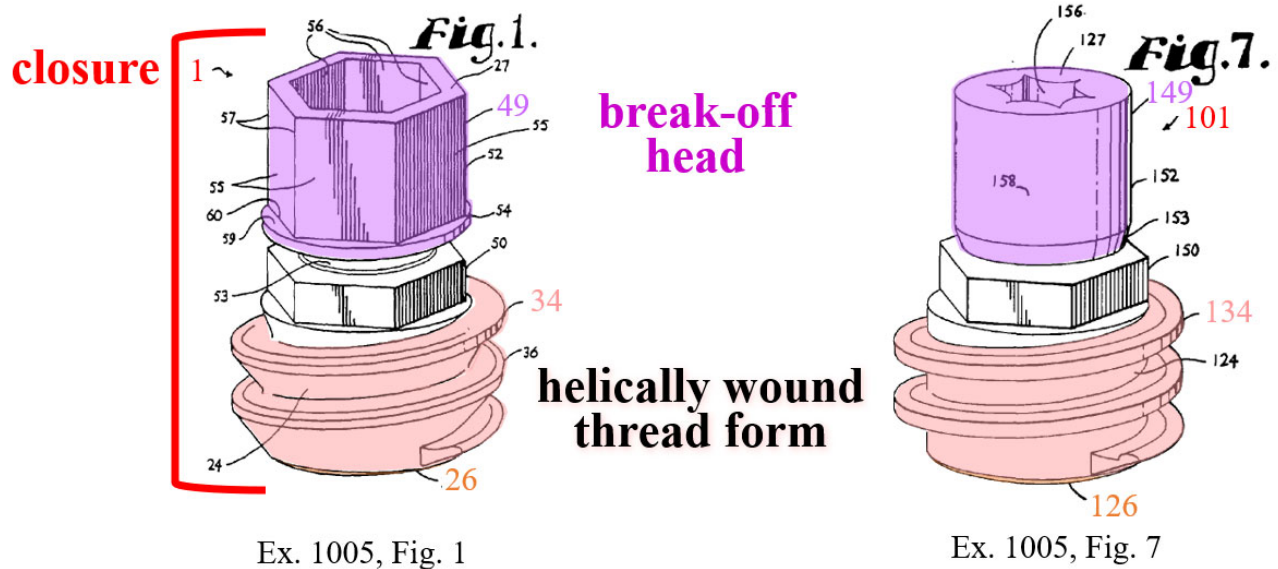
inner surface 20 of each arm has a partial helically wound guide and advancement structure that mates with a similar structure



Ex. 1005, Fig. 6

on a closure 1 when the closure is rotated. EX1005, ¶¶[0007], [0029], Fig. 5; EX1003, ¶138. The '477 Publication discloses that the guide and advancement structure could be any one of a variety of different thread types, including a reverse angle thread. EX1005, ¶[0030]; EX1003, ¶138.

The '477 Publication discloses two preferred embodiments of the closure as shown and annotated below.

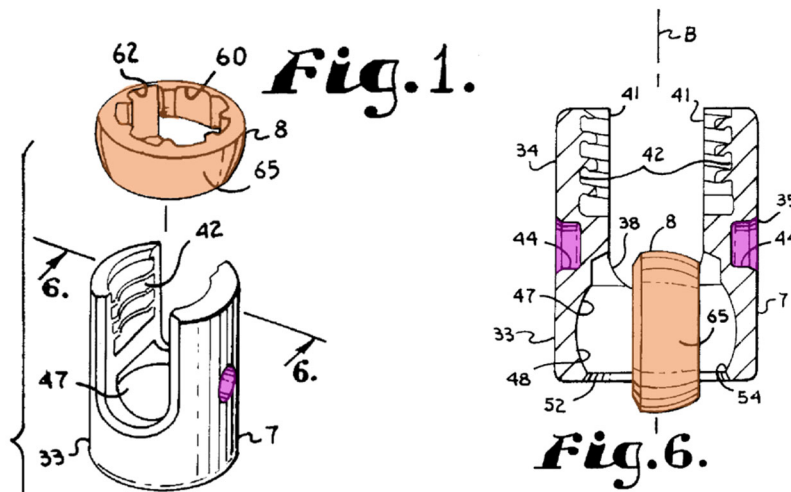


EX1005, Figs. 1, 7; EX1003, ¶139. In the first embodiment, the '477 Publication discloses that the closure body 24 of the closure 1 is cylindrical and has a central axis of rotation. EX1005, ¶[0029], Fig. 1; EX1003, ¶140. The closure has a break-off head and a single helically wound guide and advancement structure 34 along the outside, which could be one of a variety of thread types, including a reverse angle thread. EX1005, ¶[0030]; *see also, e.g., id.*, Fig. 1; EX1003, ¶140. The '477 Publication discloses that the closure top may include a break-off portion 49 designed to break away from the closure “subsequent to a predetermined torque being applied.” EX1005, ¶[0032]; *see also id.* ¶¶[0033], [0043], Figs. 1, 7; EX1003, ¶140.

The second embodiment of the closure 101 in the '477 Publication teaches many of the same elements as the first embodiment. *See* EX1005, ¶¶[0039]-[0045];

EX1003, ¶141. 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, ¶141. The '477 Publication teaches that the closure 101 is cylindrical and has a central axis of rotation. EX1005, ¶[0040], Figs. 7, 8; EX1003, ¶141. The closure has a single helically wound guide and advancement structure 134 along the outside, which could be one of a variety of thread types, including a reverse angle thread. EX1005, ¶[0041]; *see also, e.g., id.*, Figs. 7, 8; EX1003, ¶141.

The '477 Publication further incorporates by reference U.S. Pat. No. 6,716,214 (“the '214 Patent”). EX1005, ¶[0027]; EX1003, ¶142. In particular, the '214 Patent discloses the use of tool attachment grooves on the outer surface of the receiver head and top-loaded fixation elements. EX1005, ¶[0027]; EX1013, 7:2-4, Figs. 1, 6, 7; EX1003, ¶142. In particular, as shown in annotated Figures 1 and 6, the '214 Patent teaches that “[t]ool engaging apertures 44 [purple] are formed on the outsides of the arms 34 and 35 for holding the head 7 during assembly.” EX1013, 7:2-4, Figs. 1, 6; EX1003, ¶142.



The '477 Publication expressly contemplates that the described closure would be used with various known open receivers, stating “it [is] foreseen that the closure 1 may be used in conjunction with any type of medical implant having an open or closed head.” EX1005, ¶[0027]; *see also id.*, Abstract, ¶¶[0007], [0025]; EX1003, ¶143.

B. Motivation to Combine the '477 Publication with Boschert.

It would have been obvious to a POSA to combine the teachings of Boschert with the various thread types and breakoff closure of the '477 Publication before the priority date of the '479 Patent. EX1003, ¶154. Both Boschert and the '477 Publication are in the exact same field as the '479 Patent—the design of polyaxial pedicle screw and rod implant systems to treat spinal column disorders. EX1003, ¶¶155-57; EX1006, 6:20-24, Fig. 1; EX1005, Abstract, ¶¶[0007], [0025], [0027].

Boschert teaches advantages provided by certain features of closures used with polyaxial pedicle screws—including that designing closures with a double lead

provides the advantage of “start[ing] more easily than with a single lead,” EX1006, 7:21-23—and discloses symmetrical receiver threads for simultaneous mating with a closure’s double-lead threads, *id.*, Figs. 3, 15; EX1003, ¶155. Boschert expressly contemplates 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, ¶155.

Like Boschert, the ’477 Publication specifically teaches using its claimed closure with a polyaxial bone screw with a U-shaped receiver. EX1005, ¶[0025], Figs. 5&6; EX1006, 6:24-48, 7:12-15; EX1003, ¶162. Therefore, a POSA would have been motivated to use the closure of the ’477 Publication in conjunction with known medical implants, such as the polyaxial bone screw disclosed in Boschert. EX1003, ¶162. The closure of the ’477 Publication includes a breakoff top or head for a lower-profile closure and for tightening the closure to a desired torque, but not beyond, EX1005, ¶¶[0032], [0042], and further teaches threading of various disclosed types for mating with the arms of the receiver, *id.*, ¶¶[0030], [0041]. EX1003, ¶156.

Based on the express teachings of the references and their complementary disclosures, a POSA would have been motivated to combine the receiver of Boschert

with the closure of the '477 Publication. EX1003, ¶157. In particular, a POSA implementing Boschert's polyaxial pedicle screw would have looked to the teachings of the '477 Publication regarding the advantages of various available thread types and breakoff closures. *Id.* A POSA would have been motivated to use the dual-start threads of Boschert in combination with any of the various thread types discussed in the '477 Publication. *Id.* Further, in making this combination, a POSA would have been motivated to use a breakoff closure as taught in the '477 Publication. *Id.*

1. Motivation to Use Known Thread Types

A POSA would have been motivated to modify the double-start fixation device of Boschert by substituting or adding various types of threads as disclosed in the '477 Publication, including reverse angle threads, buttress threads, square threads, or flange forms. EX1003, ¶158. A POSA would have been familiar with these various thread types and their known advantages, including reducing outwardly directed forces that could cause splaying of the receiver arms. *Id.*, ¶¶63-70, 158. Indeed, the '477 Publication cites these known advantages of having "little or no radially outward directed forces, especially if the arms are thickened to resist splaying." EX1005, ¶[0030]; EX1003, ¶158. A POSA would have known that each of these thread types is compatible with the dual-start construct taught by Boschert, because the process for cutting the threads does not change when using dual starts

other than spacing of the two threads 180 degrees apart, as set forth above. *Supra* §VI.A; EX1003, ¶158. Therefore, POSA would have also been motivated to so modify Boschert to take advantage of known benefits of different types of thread types, including inhibiting splaying or spreading of the two arms of the receiver, EX1005, ¶¶[0030], [0041]; EX1016, 2:60-62; EX1019, 17:45-47; EX1003, ¶¶63-70, as well as retaining Boschert's dual starts and their the known benefits, including starting more easily, as disclosed in Boschert, as well as balancing rotation forces and speeding insertion, as was well-known in the art, EX1003, ¶¶51-62. EX1003, ¶158.

A POSA would have had an expectation of success with this combination, at least because various thread types on both closures and receivers, and techniques for manufacturing them, were well known in the art, readily available, and had been used in multi-axial pedicle screws. EX1003, ¶¶51-62, 159; EX1018, 2:60-61, Fig.1; EX1016, 2:48-62, 4:43-5:13, Fig. 3; EX1019, 17:22-41, Figs. 17A, B; EX1021, ¶¶[0028]-[0029], Figs. 4A-F. 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 '479 Patent that various thread types provided these advantages and could be successfully used in closures. EX1003, ¶159.

2. Motivation to Use a Known Breakoff Head

A POSA also would have been motivated to use the breakoff head of the '477 Publication in combination with the receiver of Boschert, at least based on the express invitations to use the '477 Publication's closure in combination with known receivers, such as those set forth in Boschert. EX1003, ¶160; EX1005, ¶¶[0007], [0025], [0027]. In addition, a POSA would have understood that breakoff heads such as those disclosed in the '477 Publication have known advantages, including (a) providing a lower-profile closure (after the breakoff head is removed), thereby increasing patient safety due to use of a low-profile device; (b) providing the ability to break off the closure head at a predetermined torque, thereby eliminating the need for a torque wrench to measure the tightening; and (c) ensuring that the closure would be tightened to the desired level, but not over torqued, when it was installed, as expressly taught by the '477 Publication. *See* EX1005 ¶¶[0009], [0011], [0035]; EX1003, ¶¶72-77, 160; EX1018, 1:37-40, 2:34-39, 3:6-19; EX1016 at 4:4-17; EX1003, ¶¶72-77, 160.

A POSA would have had an expectation of success with this combination, at least because breakoff closures, and techniques for manufacturing them, were well known in the art, readily available, and had been used in multi-axial pedicle screws. EX1003, ¶¶72-77, 161. 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 '479 Patent that breakoff tops provided these advantages and could be successfully used in closures. *Id.*, ¶161.

C. Claim Analysis.

As set forth above, Boschert already anticipates or renders obvious every limitation of Claims 1, 5, 10, 14, and 18-21. Boschert in view of the '477 Publication further renders obvious Claims 2-4, 6-7, 11-13, and 15-16. EX1003, ¶¶219-23.

1. Claim 2

Claim 2 depends from Claim 1 and further recites: [A2] “wherein the first and second helically wound forms are each a flange form that interlocks with the respective helically wound structures on the receiver.” Boschert in view of the '477 Publication renders this limitation obvious. *Id.*, ¶¶224-27.

The '477 Publication expressly discloses that its closure's guide and advancement structure could be “a flange form.” EX1005, ¶¶[0030], [0041]; EX1003, ¶225. The '477 Publication further discloses an embodiment with “helical interlocking form, such as that described in U.S. Pat. No. 6,726,689 [(“Jackson '689”)], incorporated by reference herein.” EX1005, ¶[0041], Figs. 7-8; EX1003, ¶225. Jackson '689 describes helically wound “flange” or “flange-like” shaped guide and advancement structures on a closure and on a receiver mating structure in a medical implant. EX1015, Abstract, 1:6-18, 13:12-15, 13:14-16, 14:48-60, Figs. 6&13; EX1003, ¶225.

The '477 Publication also discloses that a “discontinuous guide and advancement structure” on receiver arms that is “mateable” with the closure’s “guide and advancement structure 34.” EX1005, ¶¶[0026], [0030]; EX1003, ¶226. A POSA would have understood that the '477 Publication discloses that its closure’s guide and advancement structure, including a flange form, interlocks with the guide and advancement structures on the receiver arms. *Id.*, ¶226.

When combining Boschert and the '477 Publication, it would have been obvious to a POSA to select from among any of the well-known thread types disclosed in the '477 Publication, including to use a flange form that interlocks with the respective helically wound structures on the receiver for the first and second helically wound forms. *Id.*, ¶227. Moreover, based on the above disclosures and in view of a POSA’s knowledge of various thread types and the design need for a closure to securely engage a receiver to lock a rod, a POSA implementing Boschert would have been motivated to use a flange form on the closure as taught by the '477 Publication at least because (1) it would have been nothing more than the simple substitution of one known element (the thread disclosed in Boschert) for another (a flange form) to obtain a predictable result (allowing a closure to securely engage a receiver); (2) it would have been the mere application of a known technique (use of a flange form) to a known device (Boschert) to yield a predictable result (allowing a closure to securely engage a receiver); and (3) there was a known design need for a

closure to securely engage a receiver and a finite number of identified, predictable solutions (thread types, including a flange form) that were known to a POSA and within their technical grasp. *Id.* Accordingly, Boschert in view of the '477 Publication renders obvious every element of Claim 2. *Id.*

2. Claim 3

Claim 3 depends from Claim 1 and further recites: [A3] “wherein the first and second helically wound forms are v-threads.” The combination of Boschert in view of the '477 Publication renders this limitation obvious. *Id.*, ¶¶228-30.

The '477 Publication expressly discloses that, although its closure's guide and advancement structure could be a “reverse angle thread form 36,” “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.” EX1005, ¶[0030], [0041]; EX1003, ¶229. A POSA would have known that a v-thread was another type of guide and advancement structure that would have provided the advantage of allowing a closure to securely engage a receiver. EX1003, ¶¶63-70, 229. Indeed, the '479 Patent itself admits that use of a v-thread on a closure was well known. EX1001, 1:53-2:4; EX1003, ¶229.

When combining Boschert and the '477 Publication, it would have been obvious to a POSA to select from among any of the well-known thread types, including a v-thread for the first and second helically wound forms. EX1003, ¶230.

Moreover, based on the above disclosures and in view of a POSA's knowledge of various thread types and the design need for a closure to securely engage a receiver to lock a rod, a POSA implementing Boschert would have been motivated to use a v-thread on the closure at least because (1) it would have been nothing more than the simple substitution of one known element (the thread disclosed in Boschert) for another (a v-thread) to obtain a predictable result (allowing a closure to securely engage a receiver); (2) it would have been the mere application of a known technique (use of a v-thread) to a known device (Boschert) to yield a predictable result (allowing a closure to securely engage a receiver); and (3) there was a known design need for a closure to securely engage a receiver and a finite number of identified, predictable solutions (thread types, including a v-thread) that were known to a POSA and within their technical grasp. *Id.* Accordingly, Boschert in view of the '477 Publication renders obvious every element of Claim 3. *Id.*

3. Claim 4

Claim 4 depends from Claim 1 and further recites: [A4] "wherein the first and second helically wound forms are square threads." The combination of Boschert in view of the '477 Publication renders this limitation obvious. *Id.*, ¶¶231-33.

The '477 Publication expressly discloses that, although its closure's guide and advancement structure could be a "reverse angle thread form 36," "other types of guide and advancement structure [sic] could be utilized," including "a square thread

form.” EX1005, ¶[0030], [0041]; EX1003, ¶232. The ’479 Patent itself admits that use of a square thread on a closure was well known. EX1001, 1:53-2:4; EX1003, ¶232.

When combining Boschert and the ’477 Publication, it would have been obvious to a POSA to select from among any of the well-known thread types disclosed in the ’477 Publication, including a square thread for the first and second helically wound forms. EX1003, ¶233. Moreover, based on the above disclosures and in view of a POSA’s knowledge of various thread types and the design need for a closure to securely engage a receiver to lock a rod, a POSA implementing Boschert would have been motivated to use a square thread on the closure as taught by the ’477 Publication at least because (1) it would have been nothing more than the simple substitution of one known element (the thread disclosed in Boschert) for another (a square thread) to obtain a predictable result (allowing a closure to securely engage a receiver); (2) it would have been the mere application of a known technique (use of a square thread) to a known device (Boschert) to yield a predictable result (allowing a closure to securely engage a receiver); and (3) there was a known design need for a closure to securely engage a receiver and a finite number of identified, predictable solutions (thread types, including a square thread) that were known to a POSA and within their technical grasp. *Id.* Accordingly, Boschert in view of the ’477 Publication renders obvious every element of Claim 4. *Id.*

4. Claim 6

Claim 6 depends from Claim 1 and further recites: [A6] “wherein the first and second helically wound forms are buttress threads.” The combination of Boschert in view of the ’477 Publication renders this limitation obvious. *Id.*, ¶¶234-36.

The ’477 Publication expressly discloses that, although its closure’s guide and advancement structure could be a “reverse angle thread form 36,” “other types of guide and advancement structure [sic] could be utilized,” including “a buttress thread form.” EX1005, ¶[0030], [0041]; EX1003, ¶235. The ’479 Patent itself admits that use of a buttress thread on a closure was well known. EX1001, 1:53-2:4; EX1003, ¶235.

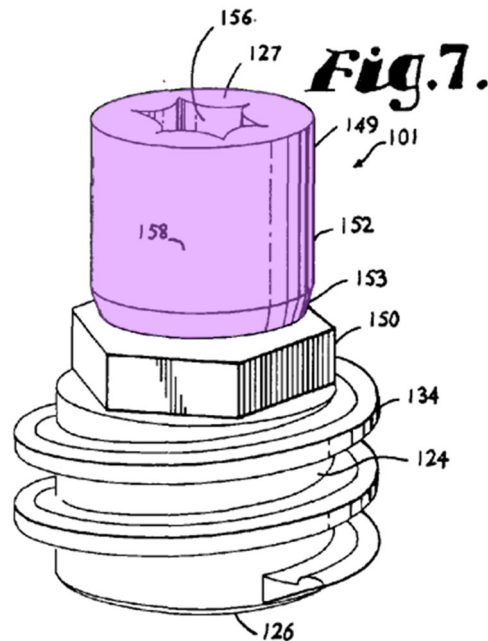
When combining Boschert and the ’477 Publication, it would have been obvious to a POSA to select from among any of the well-known thread types disclosed in the ’477 Publication, including a buttress thread for the first and second helically wound forms. EX1003, ¶236. Moreover, based on the above disclosures and in view of a POSA’s knowledge of various thread types and the design need for a closure to securely engage a receiver to lock a rod, a POSA implementing Boschert would have been motivated to use a buttress thread on the closure as taught by the ’477 Publication at least because (1) it would have been nothing more than the simple substitution of one known element (the thread disclosed in Boschert) for another (a buttress thread) to obtain a predictable result (allowing a closure to

securely engage a receiver); (2) it would have been the mere application of a known technique (use of a buttress thread) to a known device (Boschert) to yield a predictable result (allowing a closure to securely engage a receiver); and (3) there was a known design need for a closure to securely engage a receiver and a finite number of identified, predictable solutions (thread types, including a buttress thread) that were known to a POSA and within their technical grasp. *Id.* Accordingly, Boschert in view of the '477 Publication renders obvious every element of Claim 6. *Id.*

5. Claim 7

Claim 7 depends from Claim 1 and further recites: [A7] “wherein the closure member has a break-off head.” The combination of Boschert in view of the '477 Publication renders this limitation obvious. *Id.*, ¶¶237-39.

The '477 Publication discloses that a closure may include a break-off portion designed to break away from the closure “subsequent to a predetermined torque being applied.” EX1005 ¶[0042]; *id.* Figs. 5-8; EX1003, ¶238. Figure 7, annotated below, illustrates the breakoff portion of the closure. EX1005, Fig. 7; EX1003, ¶238.



Moreover, Figures 5 and 6 illustrate the removal of the break-off portion of closure 101, Figures 7 and 8 show the “driving or installation *break-off head* 149,” and Figures 9 and 10 show the top and bottom plan views of closure 101. EX1005, ¶¶[0039], [0042]-[0043]; EX1003, ¶238.

A POSA implementing Boschert would have been motivated to use a break-off head as disclosed in the '477 Publication because it would have provided the ability to more precisely install a closure with a predetermined level of torque while maintaining a lower-profile closure. EX1003, ¶239. Accordingly, Boschert in view of the '477 Publication renders obvious every element of Claim 7. *Id.*

6. Claim 11

Claim 11 depends from Claim 10 and further recites: [A2] “wherein the first and second helically wound guide and advancement structures are interlocking flange forms.” This limitation, while worded slightly differently, includes the same requirements as the limitations in Claim 2, but does so in the context of a closure with “at least two starts” rather than the double-start closure of Claim 1. *Id.*, ¶240. Moreover, based on the above disclosures and in view of a POSA’s knowledge of various thread types and the design need for a closure to securely engage a receiver to lock a rod, a POSA implementing Boschert would have been motivated to use an interlocking flange form on the closure as taught by the ’477 Publication at least because (1) it would have been nothing more than the simple substitution of one known element (the thread disclosed in Boschert) for another (an interlocking flange form) to obtain a predictable result (allowing a closure to securely engage a receiver); (2) it would have been the mere application of a known technique (use of an interlocking flange form) to a known device (Boschert) to yield a predictable result (allowing a closure to securely engage a receiver); and (3) there was a known design need for a closure to securely engage a receiver and a finite number of identified, predictable solutions (thread types, including an interlocking flange form) that were known to a POSA and within their technical grasp. *Id.* Boschert in view

of the '477 Publication renders obvious every element of Claim 11 for the same reasons as Claim 2. *Id.*; *supra* §VII.C.1.

7. Claim 12

Claim 12 depends from Claim 10 and further recites: [A3] “wherein the second helically wound guide and advancement structure includes at least two v-threads.” This limitation, while worded slightly differently, includes the same requirements as the limitations in Claim 3, but does so in the context of a closure with “at least two starts” rather than the double-start closure of Claim 1. EX1003, ¶241. Boschert in view of the '477 Publication renders obvious every element of Claim 12 for the same reasons as Limitation 10[A8] and Claim 3. *Id.*; *supra* §§VI.B.3.c, VII.C.2.

8. Claim 13

Claim 13 depends from Claim 10 and further recites: [A4] “wherein the second helically wound guide and advancement structure includes at least two square threads.” This limitation, while worded slightly differently, includes the same requirements as the limitations in Claim 4, but does so in the context of a closure with “at least two starts” rather than the double-start closure of Claim 1. EX1003, ¶242. Boschert in view of the '477 Publication renders obvious every element of Claim 13 for the same reasons as Limitation 10[A8] and Claim 4. *Id.*; *supra* §§VI.B.3.c, VII.C.3.

9. Claim 15

Claim 15 depends from Claim 10 and further recites: [A6] “the second helically wound guide and advancement structure includes at least two buttress threads.” This limitation, while worded slightly differently, includes the same requirements as the limitations in Claim 6, but does so in the context of a closure with “at least two starts” rather than the double-start closure of Claim 1. EX1003, ¶243. Boschert in view of the ’477 Publication renders obvious every element of Claim 15 for the same reasons as Limitation 10[A8] and Claim 6. *Id.*; *supra* §§VI.B.3.c, VII.C.4.

10. Claim 16

Claim 16 depends from Claim 10 and further recites: [A7] “wherein the closure structure has a break-off head.” This limitation, while worded slightly differently, includes the same requirements as the limitations in Claim 7, but does so in the context of a closure with “at least two starts” rather than the double-start closure of Claim 1. EX1003, ¶244. Boschert in view of the ’477 Publication renders obvious every element of Claim 16 for the same reasons as Limitation 10[A8] and Claim 7. *Id.*; *supra* §§VI.B.3.c, VII.C.5.

VIII. GROUND 3: CLAIMS 9 AND 22 ARE UNPATENTABLE OVER BOSCHERT IN VIEW OF THE '391 PUBLICATION.

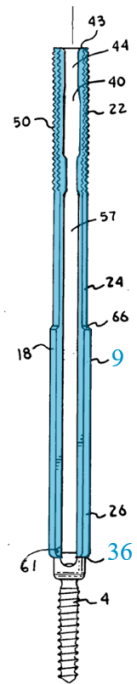
A. Overview of the '391 Publication

The '391 Publication published on March 30, 2006, and is prior art to the '479 Patent under Section 102(b). As described further below, because the '391 Publication discloses a tool set for implanting bone screws in a human spine, followed by the implantation of a rod into the bone screws, the '391 Publication is in the same field of endeavor as, and analogous art to, the '479 Patent. *Compare* EX1009 at Abstract, ¶¶[0007], with EX1001, 1:14-18; *see also* EX1003, ¶¶144-45.

As shown in excerpted and annotated Figure 1 (right), the '391 Publication discloses an attachable/detachable guide tool set consisting of multiple guide tool assemblies, which “include[] an end guide tool 9 or an intermediate guide tool 10,” as part of a system “for *percutaneously implanting spinal screws and for implanting a rod for spinal support and alignment, using minimally invasive techniques.*”

EX1009, ¶¶[0002], [0082]; EX1003, ¶146. Also “near the bottom 36 of each of the end guides 9 on inner surfaces of the side walls 32 and 33, is

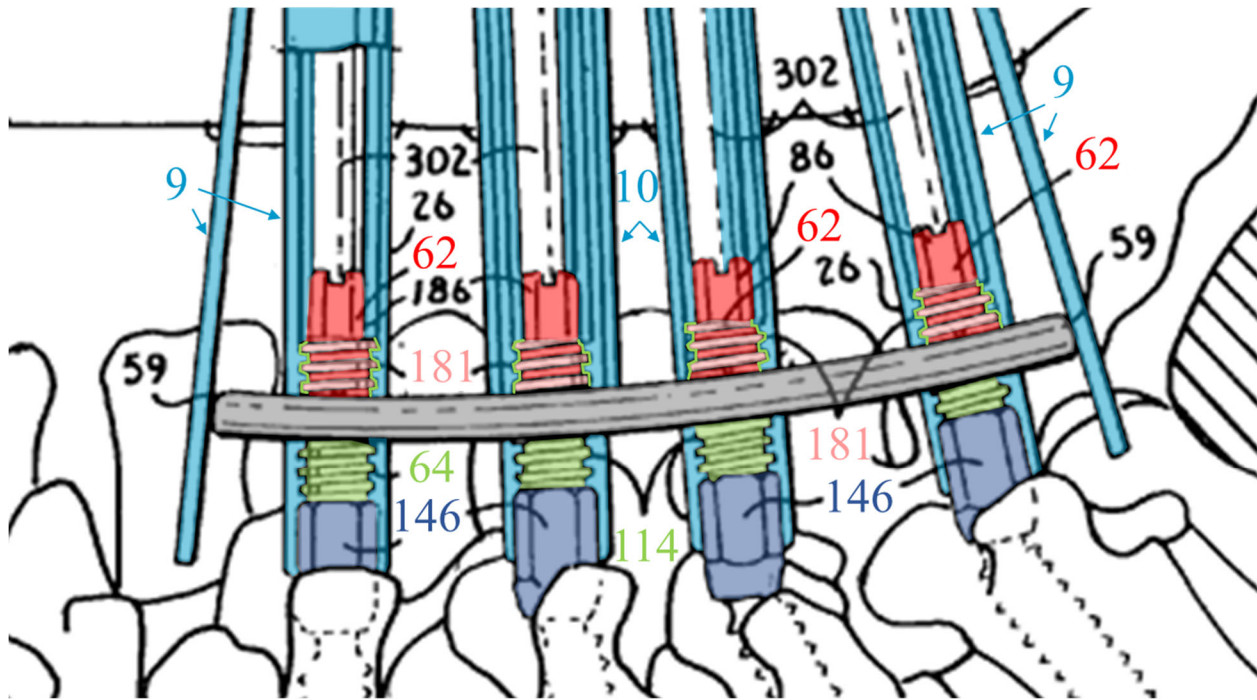
a helical [sic] wound, discontinuous guide and advancement structure 64 which may include conventional helically wound V-shaped threads, buttress threads, reverse angle threads, helically wound square threads, or other guide and advancement



structure to cooperate with equivalent or mateable structure within the bone screw heads 4 and on the closure top 62.” EX1009, ¶¶[0092], [0103]; EX1003, ¶146.

When the guide tool set is in use, “the closure top 62 engages the helically wound guide and advancement structures 64 and 114 of respective guide tools 9 and 10. The . . . mated closure tops 62 are then rotated, mating the closure tops 62 with associated guide tools 9 and 10 so as to drive the closure top 62 downward against the rod 8 and to urge the rod 8 downward into the bone screw channel 153.” EX1009, ¶[0171]; *see also id.* Fig. 42; EX1003, ¶147. “[A]t the bottom of the guide tool 9 or 10, the closure top mating structure 181 engages and begins to mate with the guide and advancement structure 183 on the respective bone screw 4,” and the rod 8 is driven downward and seated into bone screw head 146. EX1009, ¶[0172]; *see also id.*, ¶[0120], Fig. 43; EX1003, ¶147. Once the closure tops are finally seated, the guide tools are “removed by rotating each guide tools 9 and 10 ninety degrees . . . to disengage from the receiver portion 145 on the bone screw 4. The guide tool 9 or 10 is then pulled axially upward away from the bone screw 4, . . . and then out of the incision 350.” EX1009, ¶[0173]; EX1003, ¶147.

The guide tool (shown in **light blue** below) and how it interacts with the closure (shown in **red** below) and the receiver (shown in **blue** below) are shown below in annotated and excerpted Figure 42, which illustrates “an intermediate stage of implanting a rod.” EX1009, ¶[0062]; EX1003, ¶148.



See EX1009, Fig. 42; see also *id.* ¶[0063], Fig. 43 (illustrating the rod fully installed in the bone screws); EX1003, ¶148.

The '391 Publication discloses that the benefits of these guide tools are that they: (1) allow for supporting and installing bone screws, spinals rods, and other implants with minimal surgical invasion of the patent, EX1009, ¶[0018]; (2) provide support and stabilization for implant engaging members while being used for deployment of rod containment tangs and as a rod reducer, *id.*; (3) assist with guiding and securing a rod, *id.*; (4) are easily attached to and detached from bone screws, *id.*; (5) allow the several parts of the assembly to be easily aligned, positioned, and engaged with respect to the bone screw, and further disengaged from the bone screw

and other tools “by minimal manipulation of the surgeon,” *id.*; and (6) are easy to use and comparatively inexpensive to produce, *id.* EX1003, ¶149.

B. Motivation to Combine the '391 Publication with Boschert

A POSA implementing the closure and receiver taught by Boschert before the priority date would have looked to the '391 Publication's teachings of the advantages of providing guide tools for use with pedicle screws. EX1003, ¶162. In particular, a POSA would have been motivated to add a guide tool with discontinuous helically wound threads to an existing system at least based on the benefits of such a guide tool as taught by the '391 Publication. *Id.*

Like Boschert, the '391 Publication is directed to a system for a polyaxial spinal bone screw that receives a rod member. *See, e.g.*, EX1009 at Abstract; EX1003, ¶163. As in Boschert, the bone screw of the '391 Publication has a U-shaped open receiver that captures a rod when a closure is threaded into it. EX1009, ¶¶[0116], [0118], Figs. 12, 46; EX1003, ¶163. The '391 Publication teaches that using attachable/detachable guide tools allows for percutaneous installation of spinal implants, providing the benefits of minimal surgical invasion of the patient and ease of stabilizing, positioning, and securing implants. EX1003, ¶¶145-49, 163. Boschert already contemplates the use of various tools and instruments with its receiver, and therefore discloses “grasping features” that could “accommodate instrumentation to facilitate grasping, holding or manipulating of the receiver 30”

during implantation. EX1006 at 6:15-19; EX1003, ¶163. But Boschert does not disclose the details of the tools and instruments to be used with its receiver, and thereby invites a POSA to look to tools and instruments already known in the art. EX1003, ¶163. A POSA implementing Boschert would have naturally looked to the '391 Publication because the '391 Publication discloses the same type of closure and receiver and expressly teaches the advantages of using its guide tool with such a closure and receiver. *Id.* Therefore, a POSA would have been motivated to use an attachable/detachable guide tool as disclosed in the '391 Publication with the receiver of Boschert at least to obtain the recognized benefits of guide tools as taught by the '391 Publication and otherwise known in the art as discussed above. *Supra* §VIII.A; EX1003, ¶¶78-87, 145-49, 163.

A POSA would have had an expectation of success with this combination, at least because attachable/detachable guide tools, and techniques for manufacturing them, were well known in the art, readily available, and had been used in combination with multi-axial pedicle screws. EX1003, ¶¶78-87, 164. 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 '479 Patent that guide tools provided these advantages and could be successfully used with polyaxial bone screw receivers. *Id.* ¶164.

Moreover, a POSA would have been motivated to combine the teachings of the '391 Publication with the '477 Publication and Boschert based on the demands known to the medical device design community for medical devices that allow minimal surgical incision of the skin and less invasion into the body of the patient. *Id.*, ¶¶78-87, 165.

C. Claim Analysis.

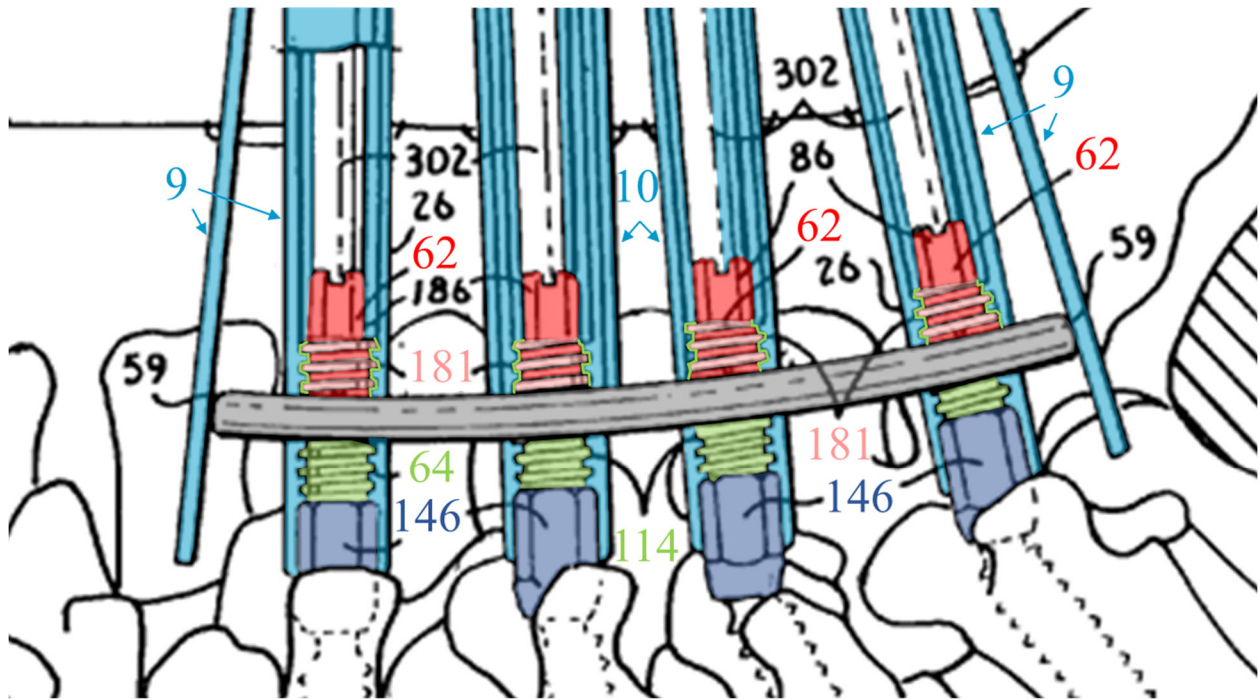
1. Claim 9

Claim 9 depends from Claim 1 and further recites: **[D]** “further comprising a guide tool having third and fourth arms detachably attached to the receiver, the guide tool having a third discontinuous helically wound structure on the guide tool third arm and a fourth discontinuous helically wound structure on the guide tool fourth arm and wherein simultaneous mating of the first start with the third helically wound structure and the second start with the fourth helically wound structure occurs when the closure member is rotated between the third and fourth arms of the guide tool, the guide tool third and fourth helically wound structures sized and shaped to provide transfer of the closure member between the guide tool and the bone screw upon rotation of the closure.” The combination of Boschert in view of the '391 Publication renders this limitation obvious. EX1003, ¶¶250-56.

The '391 Publication discloses a guide tool having third and fourth arms that is detachably attached to the receiver head. *Id.*, ¶251. The guide tool mates with the

bone screw receiver with pins on “implant engaging leg member 102 and 103.” EX1009, ¶[0103]; EX1003, ¶258. Once implantation is complete, the guide tool is “removed by rotating each guide tools 9 and 10 ninety degrees ... to disengage from the receiver portion 145 on the bone screw 4.” EX1009, ¶[0173]; EX1003, ¶252.

The '391 Publication also expressly discloses that the third and fourth arms have discontinuous helically wound threads and transmit the closure from the guide tool and into the receiver head upon rotation of the closure. EX1003, ¶253. In particular, “near the bottom” of each of the guides 9 and 10 are “helical [sic] wound, discontinuous guide and advancement structure 64” and “helically wound but discontinuous ... thread 114.” EX1009, ¶¶[0092], [0103]; EX1003, ¶253. These threads cooperate with the closure top 62. EX1009, ¶¶[0092], [0103]; EX1003, ¶253. “[T]he closure top 62 engages the helically wound guide and advancement structures 64 and 114 of respective guide tools 9 and 10. The ... mated closure tops 62 are then rotated, mating the closure tops 62 with associated guide tools 9 and 10 so as to drive the closure top 62 downward” EX1009, ¶[0171]; *see also id.* Fig. 42; EX1003, ¶253. As shown below in annotated Figure 42, “at the bottom of the guide tool 9 or 10, the closure top mating structure 181 engages and begins to mate with the guide and advancement structure 183 on the respective bone screw 4,” and the rod 8 is driven downward and seated into bone screw head 146. EX1009, ¶[0172]; *see also id.*, ¶[0120], Fig. 43; EX1003, ¶253.



For the same reasons Boschert expressly or inherently discloses, or renders obvious, simultaneous mating of the first and second starts with the arm first and second helically wound structures when the closure member is rotated between the arms of the receiver, *supra* §VI.B.1.d, simultaneous mating would also result from use of Boschert’s double-start closure with a guide tool designed to pass the double-start closure from the guide tool to the receiver head. EX1003, ¶254. The ’391 Publication discloses that on the end guide tool 9, the guide and advancement structure near the bottom 36 of the tool on the inner surface of the side walls 32 and 33 “is a helical wound, discontinuous guide and advancement structure 64 ... to cooperate with equivalent or mateable structure within the bone screw heads 4 and on the closure top 62.” EX1009, ¶[0092]; EX1003, ¶254. Similarly, “[n]ear the

bottom 112 of each implant engaging leg member 102 and 103 of the intermediate guide tool 10 is a helically wound but discontinuous square thread 114 and it is foreseen that other type of guide and advancement structure [sic] may be utilized such as helically wound flange forms, reverse angle threads, buttress threads, etc. The thread form 114 cooperates with the closure top 62, as described below.” EX1009, ¶[0103]; EX1003, ¶254. In order for a guide tool to “cooperate” with this closure and successfully transfer the closure from the guide tool to the bone screw, the guide tool would also have simultaneous mating of the two starts with the two arms of the guide tool. EX1003, ¶254.

Based on the above disclosures, a POSA implementing Boschert would have been motivated to use a guide tool having third and fourth arms detachably attached to the receiver, the guide tool having a third discontinuous helically wound structure on the guide tool third arm and a fourth discontinuous helically wound structure on the guide tool fourth arm and wherein simultaneous mating of the first start with the third helically wound structure and the second start with the fourth helically wound structure occurs when the closure member is rotated between the third and fourth arms of the guide tool, the guide tool third and fourth helically wound structures sized and shaped to provide transfer of the closure member between the guide tool and the bone screw upon rotation of the closure as taught by the ’391 Publication. EX1003, ¶255. A POSA would have been motivated to do so at least to obtain the

recognized benefits of guide tools as taught by the '391 Publication and otherwise known in the art as discussed above and would have had an expectation of success with the combination, at least because attachable/detachable guide tools, and techniques for making them, were well known in the art, readily available, and had been used in combination with multi-axial pedicle screws. *Id.*, ¶¶79-87, 162-65, 255; *supra* §VIII.B.

Accordingly, Boschert in view of the '391 Publication renders obvious every element of Claim 9. EX1003, ¶256.

2. Claim 22

Claim 22 depends from Claim 21 and further recites: **[D]** “further comprising an attachable and detachable guide tool cooperating with the receiver, the guide tool having at least two arms, each arm having helically wound guide and advancement structure thereon in synchronized relationship with the receiver helically wound guide and advancement forms to provide transfer of the multi-start closure member between the guide tool and the bone anchor upon rotation of the closure.” This limitation, while worded slightly differently, includes the same requirements as the limitations in Claim 9, but does so in the context of a guide tool with “each arm having helically wound guide and advancement structure thereon in synchronized relationship with the receiver helically wound guide and advancement forms.” EX1003, ¶257. This limitation is not substantively different than Claim 9’s

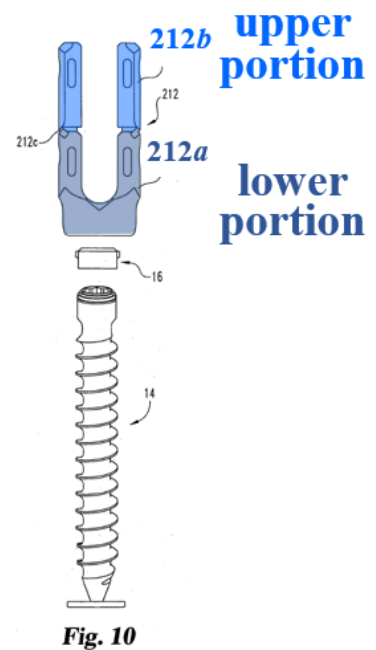
requirements and the '391 Publication discloses a guide tool having at least two arms, each arm having helically wound guide and advancement structure thereon in synchronized relationship with the receiver helically wound guide and advancement forms to provide transfer of the multi-start closure member between the guide tool and the bone anchor upon rotation of the closure. *Id.*; EX1009. ¶¶[0092], [0103], [0120], [0172], Fig. 42. Thus, Boschert in view of the '391 Publication renders obvious every element of Claim 22 for the reasons discussed here and for the same reasons as Claim 9. *Supra* §VIII.C.1; EX1003, ¶257.

IX. GROUND 4: CLAIMS 8 AND 17 ARE UNPATENTABLE OVER BOSCHERT IN VIEW OF JOHNSON

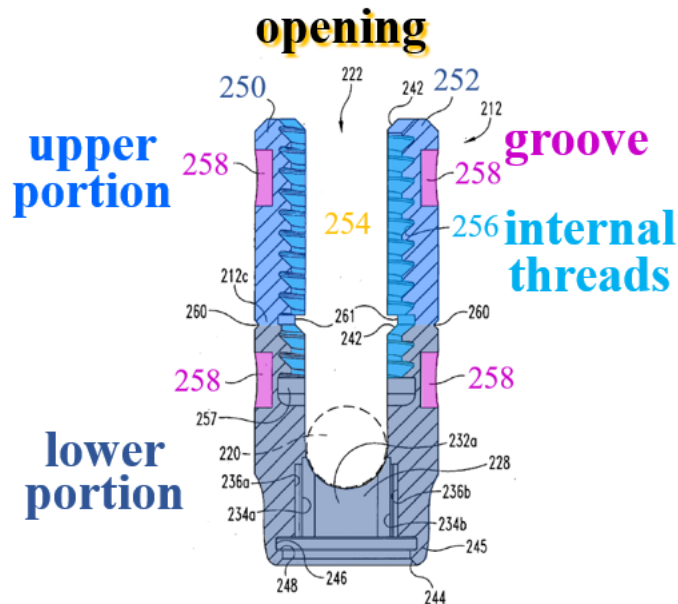
A. Overview of Johnson

U.S. Patent Publication 2007/0088357 (“Johnson”) (EX1008) published on April 19, 2007, and is prior art to the '479 Patent under Section 102(b). EX1003, ¶150. As described further below, because Johnson discloses a medical implant assembly that uses a closure to capture and lock a rod in a spinal implant, Johnson is in the same field of endeavor as, and analogous art to, the '479 Patent. *Compare* EX1008, ¶[0031], *with* EX1001, 1:14-18; EX1003, ¶150.

As shown in the annotated Figure 10 (right), Johnson discloses a receiver member 212 that “has a lower portion 212a and an upper portion 212b separated by a thinned section 212c.” EX1008, ¶[0051]; EX1003, ¶151. As shown in Figure 12 below, 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]; EX1003, ¶151. Johnson discloses that “internal threads 256 are formed in branches 250, 252 through substantially the entire length of upper portion 212b and into lower portion 212a.” EX1008, ¶[0052]; EX1003, ¶151. Johnson discloses that the threads 256 “can be a reverse angle thread.” EX1008, ¶[0052]; EX1003, ¶151. As shown below in annotated Figure 12, Johnson further discloses that the “[t]hreads 256 may [be] configured so that they are essentially continuous from upper portion 212b to lower portion 212a” so that a compression member “can be inserted into upper portion 212b and moved down to lower portion 212a.” EX1008, ¶[0053]; EX1003, ¶151.



EX1008, Fig. 12; EX1003, ¶151.

Johnson discloses that, “[o]nce the compression member is tightened against elongated member 220 to lock the assembly to the surgeon’s satisfaction, *upper portion 212b may be cut or sheared off or otherwise removed from lower portion 212a.*” EX1008, ¶[0056]; EX1003, ¶152. Johnson discloses that, “[o]nce separated, upper portion 212b may be removed from the surgical site and discarded.” EX1008, ¶[0056]; EX1003, ¶152. As further shown in annotated Figures 11 and 13 (right), Johnson discloses tool attachment grooves 258 (purple) “which allow the surgeon to grip receiver member 212 (on either or-

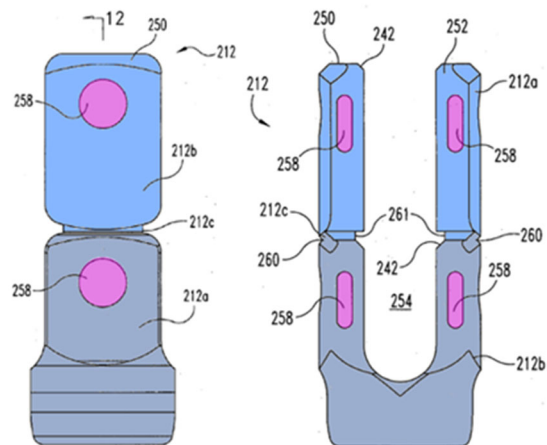


Fig. 11

Fig. 13

both of portions 212*a*, 212*b*) with an appropriate forceps, wrench or other gripping or turning tool.” EX1008, ¶¶[0052]-[0053], Figs. 11&13; EX1003, ¶153.

Johnson discloses that the benefit of these extended arms is that, “[w]hen the surgeon wishes to insert an elongated member 220 into receiver member 212, he or she need not bend it or use a special reducing tool to insert it into the lower end of a receiving channel. Rather, he or she places a portion of the elongated member 220 into channel 254 in upper portion 212*b* of receiver member 212.” EX1008, ¶[0055]; EX1003, ¶153. 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.” EX1008, ¶[0055]; EX1003, ¶153.

B. Motivation to Combine Johnson with Boschert

A POSA implementing the closure and receiver taught by Boschert before the priority date would have looked to Johnson’s teachings of the advantages of providing break-off arm extensions for use with pedicle screws. EX1003, ¶166. In particular, a POSA would have been motivated to add break-off arm extensions to an existing system at least based on the benefits of such break-off arm extensions as taught by Johnson. *Id.*

Like Boschert, Johnson is directed to a polyaxial pedicle screw implant that receives a rod member. EX1008, Abstract; EX1003, ¶167. As in Boschert, the bone screw of Johnson has a U-shaped open receiver that captures a rod when a closure is threaded into it. EX1003, ¶167. A POSA would have been motivated to add break-off extension arms to an existing system at least based on the benefits of break-off extensions in multi-axial pedicle screws as taught by Johnson and as was otherwise known in the art. *Id.*, ¶¶78, 88-94, 167.

For example, Johnson teaches that break-off extension arms provide the benefit of simplifying the introduction of an elongate member or rod. *Id.*, ¶168. Johnson discloses that, “[w]hen the surgeon wishes to insert an elongated member 220 into receiver member 212, he or she need not bend it or use a special reducing tool to insert it into the lower end of a receiving channel. Rather, he or she places a portion of the elongated member 220 into channel 254 in upper portion 212*b* of receiver member 212.” EX1008, ¶[0055]; EX1003, ¶168. Johnson discloses that a compression member is then “threaded into threads 256, forcing elongated member 220 further down in channel 254” so that the “elongated member 220 is forced all the way through upper portion 212*b*, into lower portion 212*a*, and against a crown member and/or anchor member in chamber 228.” EX1008, ¶[0055]; EX1003, ¶168. Johnson also discloses that “[o]nce separate, upper portion 212*b* may be removed from the surgical site and discarded.” EX1008, ¶[0056]; EX1003, ¶168. Thus, based

on these teachings, a POSA would have recognized the benefits of including break-off extension arms in an existing device, including easier delivery of a rod while maintaining a low-profile device, and would have been motivated to use this feature with Boschert. EX1003, ¶¶78, 88-94, 168.

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 '479 Patent that break-off extension arms provided these advantages and could be successfully used in medical implant devices. *Id.*, ¶¶78, 88-94, 169. 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.*, ¶¶78, 88-94, 169.

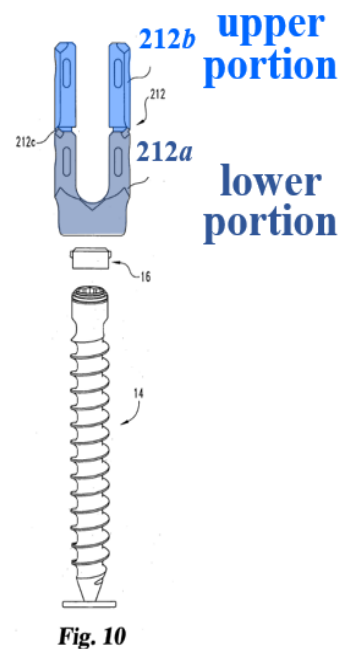
Moreover, a POSA would have been motivated to combine the teachings of Johnson with Boschert based on the demands known to the medical device design community for medical devices with low profiles and that minimize the difficulty of use. *Id.*, ¶¶78, 88-94, 170.

C. Claim Analysis.

1. Claim 8

Claim 8 depends from Claim 1 and further recites: **[B2]** “wherein the receiver has break-off extensions.” The combination of Boschert in view of Johnson renders this limitation obvious. EX1003, ¶¶262-66.

As shown in annotated Figure 10 (right), Johnson discloses a receiver member 212 that “has a lower portion 212a and an upper portion 212b separated by a thinned section 212c,” which are breakoff extensions. EX1008, ¶[0051], Fig. 10; EX1003, ¶263. Johnson further discloses that “[o]nce the compression member is tightened against elongated member 220 to lock the assembly to the surgeon’s satisfaction, the upper portion 212b may be cut or sheared off or otherwise removed from lower portion 212a.” EX1008, ¶[0056]; EX1003, ¶264.



When combining Boschert and the '477 Publication, a POSA would have included breakoff extensions, such as those taught by Johnson, on the receiver of Boschert. EX1003, ¶265. A POSA would have been motivated to do so based at least to obtain the recognized benefits of breakoff extensions as taught by Johnson and otherwise known in the art as discussed above and would have had an

expectation of success with the combination, at least because breakoff extensions, and techniques for making them, were well known in the art, readily available, and had been used in combination with multi-axial pedicle screws. *Id.*, ¶¶78, 88-94, 16670, 265; *supra* §IX.B.

Accordingly, Boschert in view of Johnson renders obvious every element of Claim 8. EX1003, ¶266.

2. Claim 17

Claim 17 depends from Claim 10 and further recites: [B2] “wherein the receiver has break-off extensions.” The limitation added by Claim 17 is the same requirement as the limitation added by Claim 8. EX1003, ¶267. Boschert in view of Johnson renders obvious every element of Claim 17 for the same reasons as Claim 8. *Id.*; *Supra* §IX.C.1.

X. SECONDARY CONSIDERATIONS

Petitioners are not aware of any evidence of secondary considerations in support of non-obviousness. EX1003, ¶¶268-73. 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.*

XI. 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).

None of Boschert, the '477 Publication, Johnson, or the '391 Publication were the basis for any rejection. The publication that issued as Boschert, U.S. Patent Application Publication No. 2005/0277928, and Johnson, as well as the patent that issued from Johnson, U.S. Patent No. 8,075,599, were identified in Patent Owner's Information Disclosure Statement ("IDS"), EX1002 at 89, 122, 1128, 1161 (U.S. Patent Application Pub. No. 2005/0277928); *id.* at 53, 127, 148, 1092, 1166, 1187 (Johnson or U.S. Patent No. 8,075,599); and the Examiner noted these references, along with hundreds of others, as having been considered, *id.* at 2058, 2063, 2084. Neither the '477 Publication nor the '391 Publication were before, and thus were necessarily not considered by, the Examiner.

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 '479 Patent over these disclosures. As set forth above, Boschert alone or in combination with the '477 Publication, Johnson, or the '391 Publication renders obvious each and every limitation of the Challenged Claims. *Supra* §§VI-IX. The error is apparent from the later prosecution history of the '233 Patent, the fifth patent in the family: the Examiner rejected proposed claims based, in part, on Boschert's disclosure of a dual-start closure, EX1036 at 61-69 (6.12.20 Rejection); EX1003 ¶102, and Applicant acknowledged that "Boschert states that the threads 72 of the setscrew 70 can be designed with a double lead to allow the setscrew 70 to start easier than one with a single lead," EX1036 at 324 (9.1.2020 Amendment); EX1003 ¶102. Applicant amended the claims to require curvate leading surfaces on each thread and distinguished Boschert on this basis, EX1036 at 324-25, 327-28 (9.1.2020 Claim Amendment); *id.* 345-46 (9.4.2020 Supplemental Amendment Remarks); EX1003 ¶102, and the amended claims were allowed, EX1036 at 351 (9.17.2020 Allowance);

EX1003 ¶102. For the same reasons Boschert was the basis for a rejection of proposed claims during prosecution of the '233 Patent, Boschert should have been the basis for a rejection of the claims during prosecution of the '479 Patent. This material error supports institution. *See Alzheon Inc. v. Risen (Suzhou) Pharma Tech Co., Ltd.*, IPR2021-00347, Paper 10 at 53 (PTAB July 14, 2021) (“Given the express teachings of [certain prior art references before the Examiner], we find [the Examiner’s] failure to evaluate the teachings of [these references] to be probative of material error on the part of the Examiner, and weighing in favor of institution.”); *Sony Interactive Ent. LLC v. Bot M8, LLC*, No. IPR2020-00726, Paper 13 at 13 (PTAB Oct. 6, 2020) (“Because the record is silent as to the Examiner’s specific reasons for allowance and the extent of Examiner’s consideration of the full teachings of [a certain prior art reference], we determine that if [the prior art reference] was previously presented to the Office, the Examiner overlooked these specific teachings of [the prior art reference].”); *10X Genomics, Inc. v. Bio-Rad Laboratories, Inc.*, IPR2021-00133, Paper No. 11 at 14-19, 23 (PTAB May 14, 2021).

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 Litigation of invalidity based on the grounds in this Petition, or any grounds that could have reasonably been raised in this Petition. EX1039; EX1040 at 2, 4-5; *Sotera Wireless, Inc. v. Masimo Corp.*, No. IPR2020-01019, Paper 12 at 17 (PTAB Dec. 1, 2020) (precedential).

XII. CONCLUSION

Petitioners respectfully request that IPR of the '479 Patent be instituted and that Claims 1-22 be cancelled.

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LLP

Dated: September 22, 2023

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Petition for *Inter Partes* Review of U.S. Patent No. 8,911,479
Filed 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 13,717 words, excluding the parts of the Petition exempted by 37 C.F.R. § 42.24(a), as calculated by Microsoft Office 2016, the word processing system used in its preparation, and including the word count in images calculated by hand.

Dated: September 22, 2023

By: / Victor P. Jonas /
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. ¶ 42.105, I hereby certify that on September 22, 2023, I caused a true and correct copy of the Petition for *Inter Partes* Review in connection with U.S. Patent No. 8,911,479 and Exhibits 1001 – 1040 to be served via:

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

I. Challenged Claims 1-22

Identifier	Element
1[Preamble]	In a medical implant having a substantially cylindrical closure member and a receiver member having first and second spaced arms forming an open channel, the closure member having an axis of rotation for closing the open channel, the improvement comprising;
1[A1]	a) first and second helically wound forms located on the closure member, the first form having a first start and the second form having a second start; and
1[B1]	b) a first discontinuous helically wound structure on the receiver first arm and a second discontinuous helically wound structure on the receiver second arm and
1[C]	wherein simultaneous mating of the first start with the arm first helically wound structure and the second start with the arm second helically wound structure occurs when the closure member is rotated between the first and second arms of the receiver member.
2[Preamble]	The improvement of claim 1
2[A2]	wherein the first and second helically wound forms are each a flange form that interlocks with the respective helically wound structures on the receiver.
3[Preamble]	The improvement of claim 1
3[A3]	wherein the first and second helically wound forms are v-threads.
4[Preamble]	The improvement of claim 1
4[A4]	wherein the first and second helically wound forms are square threads.
5[Preamble]	The improvement of claim 1
5[A5]	wherein the first and second helically wound forms are reverse angle threads.
6[Preamble]	The improvement of claim 1
6[A6]	wherein the first and second helically wound forms are buttress threads.
7[Preamble]	The improvement of claim 1
7[A7]	wherein the closure member has a break-off head.
8[Preamble]	The improvement of claim 1
8[B2]	wherein the receiver has break-off extensions.
9[Preamble]	The improvement of claim 1
9[D]	further comprising a guide tool having third and fourth arms detachably attached to the receiver, the guide tool having a third discontinuous helically wound structure on the guide tool third arm and a fourth discontinuous helically wound structure on the guide tool fourth arm and wherein simultaneous mating of the first start with the third helically wound structure and the second start with the fourth helically wound structure occurs when the closure member is rotated between the third and fourth arms of the guide tool, the guide tool third and fourth helically wound structures sized and shaped to provide transfer of the closure member between the guide tool and the bone screw upon rotation of the closure.
10[Preamble]	A medical implant comprising:

Identifier	Element
10[B3]	a) a receiver having a body and a pair of upstanding spaced arms forming a channel for receiving a longitudinal connecting member, each arm having an inwardly facing surface with a first discontinuous helically wound guide and advancement structure located thereon; and
10[A8]	b) a closure structure having a cylindrical body and a second helically wound guide and advancement structure having at least two starts.
11[Preamble]	The implant of claim 10
11[A2]	wherein the first and second helically wound guide and advancement structures are interlocking flange forms.
12[Preamble]	The improvement of claim 10
12[A3]	wherein the second helically wound guide and advancement structure includes at least two v-threads.
13[Preamble]	The improvement of claim 10
13[A4]	wherein the second helically wound guide and advancement structure includes at least two square threads.
14[Preamble]	The improvement of claim 10
14[A5]	wherein the second helically wound guide and advancement structure includes at least two reverse angle threads.
15[Preamble]	The improvement of claim 10
15[A6]	wherein the second helically wound guide and advancement structure includes at least two buttress threads.
16[Preamble]	The improvement of claim 10
16[A7]	wherein the closure structure has a break-off head.
17[Preamble]	The improvement of claim 10,
17[B2]	wherein the receiver has break-off extensions.
18[Preamble]	In a medical implant, the improvement comprising:
18[B3]	a) an open receiver member with spaced arms having inwardly facing surfaces, each with a helically wound guide and advancement form located thereon; and
18[A9]	b) a helically wound multi-start closure member having an axis of rotation, the closure member rotatably mounted on the receiver member at the spaced arm inwardly facing surfaces.
19[Preamble]	The improvement of claim 18
19[A10]	wherein the multi-start closure is a double-start closure.
20[Preamble]	The improvement of claim 18
20[A11]	wherein the multi-start closure includes at least two helically wound forms, each form being one of a flange form, a v-thread, a square thread, a reverse angle thread and a buttress thread, the form mating with the first helically wound guide and advancement form.
21[Preamble]	In a polyaxial bone anchor having a shank and a receiver, the shank being pivotable with respect to the receiver prior to locking of a position of the shank with respect to the receiver, the improvement wherein:
21[B3]	a) the receiver has spaced arms having inwardly facing surfaces, each surface having a helically wound guide and advancement form located thereon, each

Identifier	Element
	guide and advancement form being sized and shaped to mate with a helically wound multi-start closure member having at least two starts.
22[Preamble]	The improvement of claim 21
22[D]	further comprising an attachable and detachable guide tool cooperating with the receiver, the guide tool having at least two arms, each arm having helically wound guide and advancement structure thereon in synchronized relationship with the receiver helically wound guide and advancement forms to provide transfer of the multi-start closure member between the guide tool and the bone anchor upon rotation of the closure.