

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

DECLARATION OF DR. CARL MCMILLIN

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I, Dr. Carl McMillin, declare and state as follows:

I. INTRODUCTION AND SUMMARY OF OPINIONS

1. I am submitting this declaration in connection with a Petition filed by ZimVie, Inc. and Zimmer Biomet Spine, Inc. (“Petitioners”) for an *inter partes* review of U.S. Patent No. 8,911,479 (“the ’479 Patent”) (EX1001) before the Patent Trial and Appeal Board of the United States Patent Office (the “Board”). I have been asked by Petitioners to provide information and opinions on various topics, including (1) the level of ordinary skill in the art for the invention claimed in the ’479 Patent, (2) the general knowledge a person of ordinary skill in the art (“a POSA”) had at the effective filing date of the ’479 Patent (which I have been asked to assume is January 10, 2012), (3) the meaning a POSA would ascribe to the claims of the ’479 Patent, (4) the scope and content of the prior art references, and (5) whether Challenged Claims of the ’479 Patent, as of its effective filing date, would have been anticipated and/or obvious to a POSA.

2. This declaration summarizes the opinions that I have formed to date and is based on personal knowledge, skill, experience, and review of materials read and considered in connection with this opinion. I may modify my opinions if necessary, based on further review and analysis of information provided to me at a later date. If asked to give my sworn testimony in a deposition regarding the contents of this declaration, I will do so.

3. Based on the level of ordinary skill in the art, which I describe in more detail below, in it is my opinion that the Challenged Claims of the '479 Patent are anticipated and/or obvious. As explained further below, the '479 Patent relates to a closure top (also known as a cap, plug, closure, closure plug, or set screw) used to capture a rod in the U-shaped receiver of a spinal bone screw (commonly known as a polyaxial pedicle screw). This basic construct was well known in the prior art, as the '479 Patent admits. The '479 Patent purports to improve on prior art closure tops by using a dual-start or multi-start thread, rather than a single-start thread, to mate the closure top to the receiver. From my review of the prosecution history of the '479 Patent, the claims of the patent appear to have been allowed based on their use of dual-start threads. But dual- and multi-start threads were a well-known design choice and had previously been used in the context of closure tops for polyaxial pedicle screws. The additional features claimed in the '479 Patent, including different thread types, breakoff drive mechanisms on the closure top, breakoff receiver arms, and detachable guide tools were all conventional features readily available to a POSA when designing a pedicle screw system. The '479 Patent simply selects from amongst these well-known options and does so without suggesting any synergistic benefits of any particular combination of features described and claimed. Therefore, in my opinion the '479 Patent provides no inventive contribution, and all of the Challenged Claims are anticipated and/or obvious in view of the prior art.

4. U.S. Patent 7,857,834 (“Boschert”) (EX1006), which published as U.S. Patent Application Publication No. 2005/0277928 on December 15, 2005, and issued on December 28, 2010, discloses a polyaxial bone screw system that includes a threaded closure top (i.e., set screw) used to capture a rod in a U-shaped receiver. Within such a system, Boschert teaches that dual-start threads offer a benefit over single-start threads. EX1006, 7:21-23 (“The threads 72 of the setscrew 70 can also be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead.”). Boschert’s teaching of dual-start threads was not discussed during prosecution of the ’479 Patent and appears not to have been discovered by the Examiner until the prosecution of later patent family members when it was used to reject the proposed dual-start thread claims, as is further discussed below. Boschert also (1) expressly invites modifications to its locking arrangements, noting that “[t]he embodiments of the locking arrangements disclosed here (e.g., the set screw 70 []) are merely examples of the types of locking arrangements that can be used,” *id.*, 7:58-60, and (2) expressly teaches the inclusion on the receiver of “grasping features 119 on the outer surface 108 that would accommodate instrumentation to facilitate grasping, holding or manipulating of the receiver 30,” *id.*, 6:15-19.

5. U.S. Patent Application Publication No. 2005/0267477 to Jackson (“the ’477 Publication”) (EX1005), which published in 2005, discloses closure tops that

can be used with known bone screw receivers, such as those disclosed in Boschert. EX1005, ¶[0027] (“[I]t [is] foreseen that the closure 1 may be used in conjunction with any type of medical implant having an open or closed head.”). The ’477 Publication discloses that various different thread types can be used to connect closure tops to receivers, *id.*, ¶¶[0030], [0041], as well as disclosing a breakoff drive mechanism on the closure, *id.*, ¶¶[0032], [0042], all of which could be used in conjunction with known receivers, such as those disclosed in Boschert. The ’477 Publication was not cited or discussed during prosecution of the ’479 Patent.

6. U.S. Patent Application Publication No. 2006/0069391 (“the ’391 Publication”) (EX1009) is one of several prior art patents that disclose guide tools that (1) attach to grasping features on the receiver head, such as the grasping features disclosed in Boschert, during implantation of the rod; and (2) can then be detached and removed from the receiver after implantation. The ’391 Publication was not cited or discussed during prosecution of the ’479 Patent.

7. Finally, U.S. Patent Application Publication No. 2007/0088357 (“Johnson”) (EX1008) is one of several prior art references that disclose the conventional feature of breakoff receiver arm extensions that can be added to any known receiver, such as the receivers disclosed in Boschert, to facilitate implantation of a rod and to accommodate severe spinal deformities. Johnson is cited on the face

of the '479 Patent but was not discussed during prosecution of the '479 Patent, either alone or in combination with the other references discussed herein.

8. In my opinion, Boschert anticipated or rendered obvious Claims 1, 5, 10, 14, 18, 19, 20, and 21 of the '479 Patent. Additionally, in my opinion, before the effective filing date of the '479 Patent, it would have been obvious to combine the various thread types and the breakoff closure top of the '477 Publication with the dual-start threads taught by Boschert. Such a combination would have included every feature claimed in the '479 Patent with the exception of conventional breakoff receiver arm extensions described in claims 8 and 17 and conventional guide tools described in claims 9 and 22. Claims 9 and 22 were also obvious because guide tools were a conventional design option, as disclosed by the '391 Publication, and Boschert expressly taught the inclusion of grasping features to accommodate such guide tools. Finally, Claims 8 and 17 were obvious because breakoff receiver arm extensions were a conventional design option for addition to any receiver, as disclosed by Johnson.

9. Furthermore, there is little that is synergistic or even related between the decision of whether or not to use breakoff screw tops to assist in rod alignment; the particular type of non-splaying thread used in the screw cap/set screw; the use of a single, double, or triple start for the set screw into the screw cap; and whether or not to use a guide tool. Nothing in the teaching of the '479 Patent describes any

benefit from particular combinations of these features. Therefore, in my opinion, each of the Challenged Claims of the '479 Patent are obvious.

10. I reserve the right to supplement this declaration as permitted to address any issues raised by expert(s) engaged by Patent Owner or resulting from further discovery. Additionally, I reserve my right to supplement this section if new information that would affect my opinions becomes available to me.

II. RELEVANT EXPERIENCE

11. I am a mechanical engineer with a Ph.D in macromolecular science from Case Western Reserve University and decades of experience designing medical devices, including spinal implants and screw threading systems. A complete summary of my educational background and work experience can be found in my Curriculum Vitae. EX1004.

12. From 1989 to 1997, I held positions as Senior Scientist, Director of Polymer Laboratory and Director of R&D at AcroMed Corporation in Cleveland, Ohio. In these roles, I conducted and directed research, development, evaluation and commercialization of many metal, polymer, polymer/carbon fiber composite and elastomer material based orthopedic products, primarily for the spine. During my time at AcroMed, I was involved in some of the design and implementation of the Isola spine screw and rod system, which used spinal pedicle screws that captured a rod to correct, reduce, or stabilize spinal deformities. The Isola System, along with

the Texas Scottish Rite Hospital System (“TSRH”) were the first pedicle screw and rod systems introduced worldwide—mostly replacing the Harrington rod and hook system in use from around 1975. These two systems rapidly evolved into many different polyaxial pedicle screw and rod systems such as the ones described in the Jackson patents.

13. During my time at AcroMed, I was also involved in the introduction of a tapered minor diameter and a switch from 316 stainless to 22-13-5 and the evaluation of thread rolling—changes resulting in the overall reduction of pedicle screw breakage from about 10% to less than 1%. These advances were used for pedicle screws in both plate and rod systems. I designed cervical spinal screws utilizing titanium instead of stainless steel with consideration of the differences in the materials properties. I designed the first poly(etheretherketone)(“PEEK”), and carbon fiber reinforced PEEK bone screws with unique threads based on the mechanical properties of bone, polymer and carbon fiber reinforced polymer. I had injection molds manufactured and produced screws that were used clinically in the spine. I co-invented and evaluated a new screw thread to resist fatigue-related screw backout. I designed and manufactured unique polymer-carbon fiber composite spine plates (McMillin U.S. 5,556,687) with specifically designed screws to interface with the carbon fiber composite plates. I oversaw the development of a novel screw/wire device used on a custom basis in the spine.

14. I helped develop rod bending systems used to bend stainless steel and titanium rods into the curvatures required for use in pedicle screw and rod systems intraoperatively and have scrubbed into operations where rods were bent and re-bent (sometimes to failure) in order to conform with patient's anatomy. Both polyaxial pedicle screws and pedicle screw extensions with appropriate instruments were developed to make this fitting easier.

15. I am currently an Independent Consultant and President of Synthetic Body Parts, Inc. in Brecksville, Ohio. I have held this position since 1997. In this time, I have conducted biomedical materials and device consulting for approximately 100 different companies from single person start-ups through small, medium, large, and multi-national corporations. This has included product development and evaluation, regulatory approval, patent infringement, product failure, and other related activities. Before Acromed (1983-1989), I conducted research, directed graduate students and post-doctoral students and taught graduate level courses in the Biomedical Engineering Department at the University of Akron. After AcroMed (1997-consulting), I also taught graduate level biomedical engineering courses at Cleveland State University in the Applied Biomedical Engineering Program.

16. In 2020, I was inducted as a Fellow of the International Union of Societies for Biomaterials Science and Engineering and am entitled to add FBSE

after my PhD on my business cards. I am the Recipient of the 2015 C. William Hall lifetime achievement award from the Society for Biomaterials “For significant contributions to the Society for Biomaterials and an outstanding record in establishing, developing, maintaining, and promoting the objectives and goals of the Society.” I was a Delegate on the first People-to-People program on Biomaterials to the Peoples Republic of China (2010). I was member of the Edison Biotechnology Center Omeris (State of Ohio) from 1992 through 2002, the Commercialization Cabinet from 1997-2002, the Scientific Advisory Council from 1992 through 1994, and the Executive Advisory Committee from 1992-1996. I was also a member of the External Advisory Board at the Center for Cardiovascular Biomaterials, Case Western Reserve University, Cleveland, OH, from 1994 through 1998. And I was an Executive Editor (U.S.A.) of the international journal, *Bio-Medical Materials and Engineering*, Pergamon Press, from 1990-1996.

17. I have published over 100 journal articles, book chapters, symposia, research papers and patents, and have authored or co-authored over 75 presentations with published abstracts for national and international meetings all over the world. My 14 patents include U.S. Patent Nos. 9,993,337, “Orthopaedic Implant and Method of Making Same”; 6,669,732, entitled “Spinal Disc”; 6,162,252, entitled “Artificial Spine Disc”; and 5,824,094, entitled “Spinal Disc.”

III. COMPENSATION

18. I have been retained by Petitioners as an expert in the above-captioned proceeding. I am being compensated at a rate of \$325 per hour through United Expert Holdings, LLC dba Round Table Group which collects additional fees. I am also being reimbursed for reasonable and customary expenses associated with my work and testimony in this matter. My compensation is not contingent on the outcome of this matter or the specifics of my testimony.

IV. DOCUMENTS AND INFORMATION CONSIDERED

19. In providing the information and opinions in this declaration, I have reviewed all of the Exhibits and prior art references I discuss in this Declaration. My opinions are also informed by my own knowledge and experience as a POSA in the pertinent field.

V. APPLICABLE LEGAL STANDARDS

20. I have not been asked to offer an opinion on the law; however, as an expert assisting the Board in determining patentability, I understand that I am obliged to follow existing law. I have therefore been asked to apply the following legal principles to my analysis.

A. Invalidity

21. I understand that the only grounds for invalidity that may be presented in a petition for *inter partes* review are those based on patents and/or printed

publications.¹ I further understand that for *inter partes* review, invalidity must be proven by a preponderance of the evidence, which I understand to mean “more likely than not.”

22. I understand that 35 U.S.C. § 102 (“§ 102”) provides the standard for determining whether a claim in a patent is invalid as anticipated. I understand that a claim in a patent is unpatentable as anticipated under the applicable version of § 102 if each and every element of the claim is found expressly or inherently in a single prior art reference. I understand that the single prior art reference must disclose all elements of a claim as arranged in the claim.

23. I understand that to be considered prior art under the applicable version of 35 U.S.C. § 102(b), a reference must have been patented or described in a printed publication in the United States or a foreign country or in public use or on sale in the United States, more than one year prior to the date of the application in the United States for the patent at issue. For purposes of this declaration, I have been asked to assume that the effective application date for the ’479 Patent is January 10, 2012.

24. I understand that to be considered prior art under the applicable version of 35 U.S.C. § 102(a) a reference must have been known or used by others in the

¹ I have been asked to apply the versions of § 102 and § 103 that I understand are known as pre-AIA (America Invents Act) §§ 102 and 103.

United States, or patented or described in a printed publication, before the invention thereof by the applicant for patent. For purposes of this declaration, I have assumed a date of first invention of the claimed subject matter by Dr. Roger Jackson (the named inventor of the '479 Patent) on January 10, 2012. If later presented with evidence purporting to support an earlier invention date, I will consider it.

25. I understand that to be considered prior art under the applicable version of 35 U.S.C. § 102(e) the invention must be described in a published patent application that was filed in the United States before the invention thereof by the applicant for patent. For purposes of this declaration, I have assumed a date of first invention of the claimed subject matter by Dr. Roger Jackson (the named inventor of the '479 Patent) on January 10, 2012. If later presented with evidence purporting to support an earlier invention date, I will consider it.

26. I understand that a prior art reference is prior art for all that it teaches to a skilled artisan. I further understand that, when determining whether a single item of prior art anticipates a patent claim, one may consider not only what is expressly disclosed in that prior art, but also what is inherently present in that prior art. I understand that claim limitations that are not expressly found in a prior art reference are inherent if the prior art necessarily functions in accordance with, or includes, the claim limitations, or if the missing element or feature would be the natural result of following what the prior art teaches to persons of ordinary skill in

the art. I also understand that it is acceptable to examine evidence outside the prior art reference, in determining whether a feature, while not expressly discussed in the reference, is necessarily present in the reference. I understand that mere probabilities that an element is present are not enough, but it is not required that persons of ordinary skill actually recognized the inherent disclosure at the time the prior art was first known or used.

27. I understand that 35 U.S.C. § 103 (“§ 103”) provides the standard for determining whether a claim in a patent is invalid as obvious. I understand that a claim in a patent is invalid as obvious under the applicable version of § 103 when the differences between the claimed subject matter and the prior art are such that the claimed subject matter as a whole would have been obvious to a POSA at the time the invention was made. I understand that an obviousness analysis must consider: (1) the scope and content of the prior art; (2) the differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) objective indicia (sometimes referred to as secondary considerations), if any, of non-obviousness.

28. I understand that for a reference to be used in an obviousness combination, it must be analogous art to the claimed invention. There are two ways to determine whether prior art is analogous. First, the art can be from the same field of endeavor as the claimed invention. Second, if the reference is not within the same

field of endeavor, the reference can still be analogous if it is reasonably pertinent to the particular problem faced by the inventor of the claimed invention such that a POSA would reasonably have sought a solution to the problem in that outside field.

29. I understand that a prior art reference may be considered in assessing a patent claim's obviousness if the reference discloses solving any problem or addressing any need addressed by the patent, or if the reference discloses information having obvious uses beyond its primary purpose that a POSA would have reasonably examined to solve a problem or address a need presented by the patent. I understand that a claimed combination of familiar elements using known methods is likely obvious when it does no more than yield predictable results. I understand that when a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same or a different field. I understand that if a POSA can implement a predictable variation of a claimed invention, then the claimed invention is likely obvious.

30. I understand that, in conducting the obviousness analysis, it is important to identify a reason that would have prompted a POSA to combine prior art references in a way that would have rendered the claimed invention obvious and where the person would have had a reasonable expectation of success in making the claimed invention. I also understand that whether or not it would have been obvious to combine or modify prior art may depend in part on whether a POSA would have

found the claimed invention to be a predictable use of prior art elements according to their established functions.

31. I understand that an obviousness analysis need not seek out precise teachings directed to the specific subject matter of the claimed invention, and that the Board can take account of the inferences and creative steps that a POSA would have employed at the time of the alleged invention. I understand that it is often necessary to look to interrelated teachings of multiple prior art references; the effects of demands known to those working in the relevant field of art or present in the marketplace; and the background knowledge possessed by a POSA, all to determine whether there was an apparent reason for a POSA to have combined elements in the manner claimed. I understand that any need or problem known in the field of endeavor at the time of the alleged invention or addressed by the patent-at-issue can provide a reason for a POSA to have combined elements in the manner claimed. I understand that one way in which a patent's subject matter can be proven obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims. I understand that when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a POSA has good reason to pursue the known options within his or her technical grasp. I further understand that, if this

leads to the anticipated success, it is likely the result not of innovation but of ordinary skill and common sense and, as such, likely is obvious.

32. I understand that someone assessing obviousness should be aware of and avoid the potential for distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. I understand that a party should not imbue a POSA with knowledge of the invention-in-suit when no prior art reference or reference of record conveys or suggests that knowledge. If there is no evidence that a POSA would have expected a problem in the field to exist at all, it is not proper to conclude that the invention that solves this problem, which is claimed as an improvement on the prior art, would have been obvious. I understand that when a prior art reference(s) does not recognize or disclose a problem, a POSA has less incentive to attempt to improve upon that reference by combining it with one or more additional references. I further understand that where one or more references each separately function or operate effectively, a POSA would have been less likely to combine the features of both devices into a single device.

33. I understand that the obviousness analysis relates not to whether a POSA *could* have made a claimed invention, but to whether a POSA *would* have been motivated to use combinations or modifications of prior art to arrive at the claimed invention.

34. I understand that where an invention would have been “obvious to try,” a design need or market pressure to solve a problem, and a finite number of identified, predictable solutions for that problem, must exist. Only then would a POSA have had good reason to pursue the known options within his or her technical grasp, thereby making that invention “obvious to try.” I understand that an invention is not “obvious to try,” however, where the prior art does not *guide* an inventor toward a particular solution. I further understand that a POSA must have good reason to pursue the known options within his or her technical grasp. I understand that the greater intervening time between the prior art reference’s or references’ teaching(s) of separate parts, components, and/or features, and the later combination of those separate parts, components, and/or features increases the likelihood of a finding of nonobviousness.

35. I understand that, before assessing the issue of obviousness, one must also consider certain objective factors—sometimes referred to as secondary considerations or indicia—that, if established, may indicate that the claimed invention may not have been obvious. Such secondary considerations include: (a) Were products covered by the claim commercially successful due to the merits of the claimed invention rather than due to other, unrelated factors, such as, for example, advertising, promotion or marketing, salesmanship, or unclaimed features of the product?; (b) Was there a long-felt but unresolved need for a solution to the

problem facing the inventors, which was resolved by the claimed invention?; (c) Did others try, but fail, to solve the problem solved by the claimed invention?; (d) Did others copy the claimed invention?; (e) Did the claimed invention achieve unexpectedly superior results over the closest prior art?; (f) Did others in the field praise the claimed invention or express surprise at the making of the claimed invention?; and (g) Did others accept licenses under the patent-at-issue because of the merits of the claimed invention? I understand that these factors are only relevant to obviousness if there is a connection, or nexus, between each of them and the claimed subject matter. I understand that, even if one could conclude that some of the above factors have been established, those factors should be considered along with all other available evidence when determining whether the claimed invention would have been obvious to a POSA at the time of the alleged invention.

B. Claim Construction

36. I understand that to date no court has construed the claim terms of the '479 Patent. I further understand that in determining the meaning of claim terms in a patent, the Board gives claim terms their "ordinary and customary meaning ... as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *See* 37 C.F.R. § 42.100(b). The patent's specification, prosecution history, and other evidence outside of the patent, such as dictionary definitions, may also be considered. As explained below, my opinions regarding the meaning of

claim terms of the '479 Patent are based on the ordinary and customary meaning of the claim terms in the context of the entire '479 Patent, including its specification and prosecution history.

VI. THE PERSON OF ORDINARY SKILL IN THE ART

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

37. It is my opinion that the relevant field of the invention of the '479 Patent is spinal implants and threaded connections.

38. I understand that there is a non-exhaustive list of factors that may guide a fact finder in finding the appropriate level of skill in the art. These factors include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. I considered these factors in arriving at my opinion regarding the qualifications of a person of ordinary skill in the art.

39. I understand that Dr. Roger Jackson, the named inventor of the '479 Patent, received his bachelor degree from the University of Kansas. I further understand that Dr. Jackson received his medical degree from School of Medicine at the University of Missouri, Columbia in 1973. I understand that, after receiving his medical degree from the University of Missouri, Columbia, Dr. Jackson attended graduate school at Kansas University Medical Center in 1978 and Toronto

University in 1979. I understand that Dr. Jackson began practicing medicine in 1979 and is currently retired.

40. Based on my experience and my review of the relevant prior art, it is my opinion that the problems typically encountered in the field, as of January 10, 2012, were mechanical engineering problems. Further, a number of prior art solutions to these problems had already been conceived and implemented by January 10, 2012, as discussed further below. For example, Google Patents lists over 55,000 patents or applications for spine and implant with a priority date in the decade leading up to January 10, 2012, with over 1,000 specifically for spine and polyaxial. Moreover, 280 patents with the terms spine and polyaxial are listed with priority dates in 2011 alone.

41. Based on my experience and my review of the relevant prior art, it is my opinion that technology for spinal implants and threaded connections, as of January 10, 2012, was not particularly complex. As I will discuss in more detail below (*see* Section VI.B), as of January 10, 2012, the basic framework of the device that the '479 Patent claims—i.e., an open-headed bone screw receiver and a closure top for locking a stabilization rod—was well-known. Within this framework, the technology for threaded connections for spinal implants in particular would have been relatively straightforward and simple. Indeed, as I discussed, the problems encountered in conceiving of and/or designing threaded connections for spinal

implants were typically mechanical engineering problems with a defined set of known solutions. In my opinion, as long as a POSA possessed a baseline understanding of the basics in mechanical engineering, innovations and alterations related to spinal implants and threaded connections between various implant components were relatively straightforward.

42. Based on my experience and my review of the relevant prior art, it is my opinion that the education level of active workers in the field as of January 10, 2012, covered a range of educational backgrounds and experience. Most workers in this field had at least a bachelor's degree in mechanical engineering, biomedical engineering, materials science, or an equivalent discipline, but some, including myself, had terminal degrees. Those working in this field also had a range of experience within the field, from newly hired engineers to those who had been designing or implanting spinal implants with threaded connections for decades. Medical doctors also frequently contributed to spinal implant and instrument designs, most often by defining the need for an instrument or an implant encountered in the operating room. For example, a doctor may suggest that they need a spinal screw with a wire coming out of it.

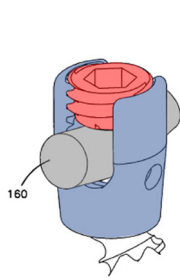
43. In view of the non-exhaustive list of factors discussed above, it is my opinion that a POSA would have had a bachelor's degree in mechanical engineering, or an equivalent discipline, and at least two years of experience designing or

implanting spinal implants with threaded connections. More education could substitute for less experience, and vice versa. Under this definition, I qualify as a POSA and qualified as a POSA as of January 20, 2012.

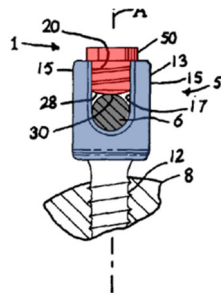
B. Knowledge of a Person of Ordinary Skill in the Art

44. I understand that a POSA is presumed to have known the relevant art at the time of the invention. Below is a brief description of some of the knowledge that a POSA would have had as of January 10, 2012.

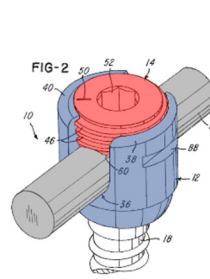
45. As the '479 Patent concedes, at least as of January 10, 2012, “[b]one anchors, such as bone screws and hooks,” were well-known. EX1001, 1:21-24. Known bone anchors included polyaxial bone screw assemblies. *Id.*, 1:37-41; *see also* EX1006, 4:44-47, 5:2-11, Figs. 4, 7, 9, 17; EX1005, ¶¶[0018], [0025]-[0027], [0039], Figs. 5-6; U.S. Patent Application Publication No. 2011/0152947 (“Kirschman”) (EX1007), ¶¶[0004], [0010]-[0011], [0012]-[0013], [0017]-[0018], [0020]-[0021], [0034]-[0036], [0047], [0049], Figs. 1-10; EX1008, ¶¶[0001]-[0004], [0046]-[0047], Fig. 7. Sample depictions of these representative prior art bone screws are shown with annotations below to highlight the receiver (**blue**), closure top (**red**), and rod (**grey**):



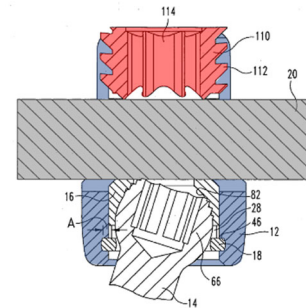
EX1006, Fig. 7



EX1005, Fig. 6

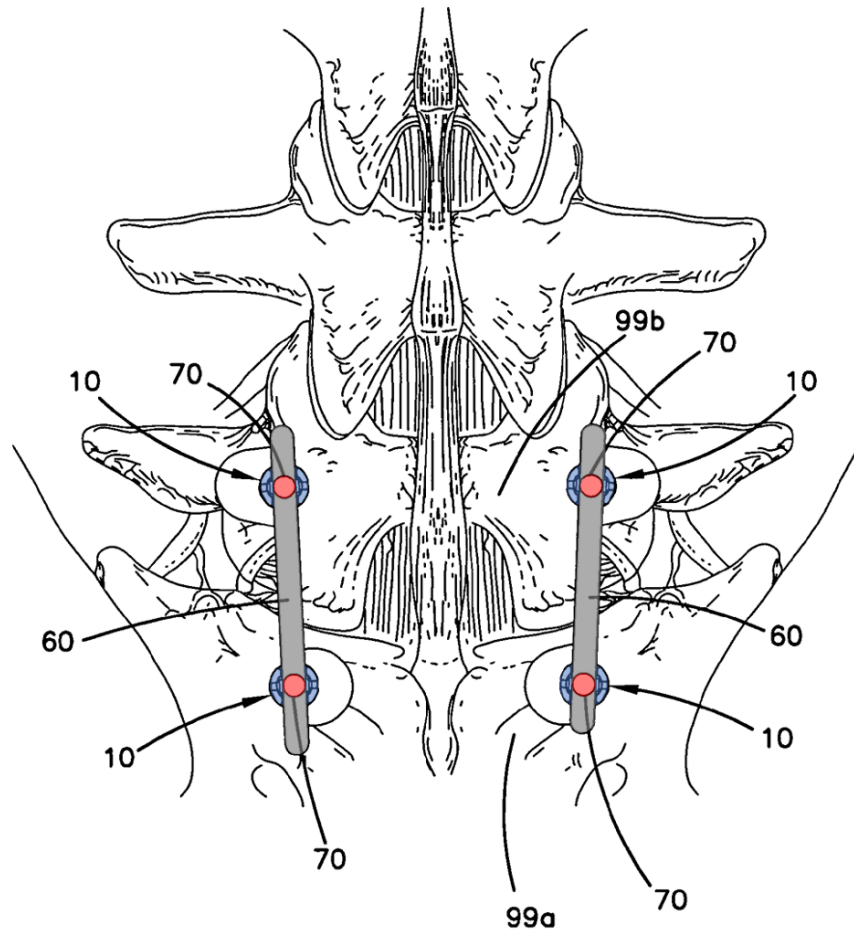


EX1007, Fig. 2



EX1008, Fig. 7

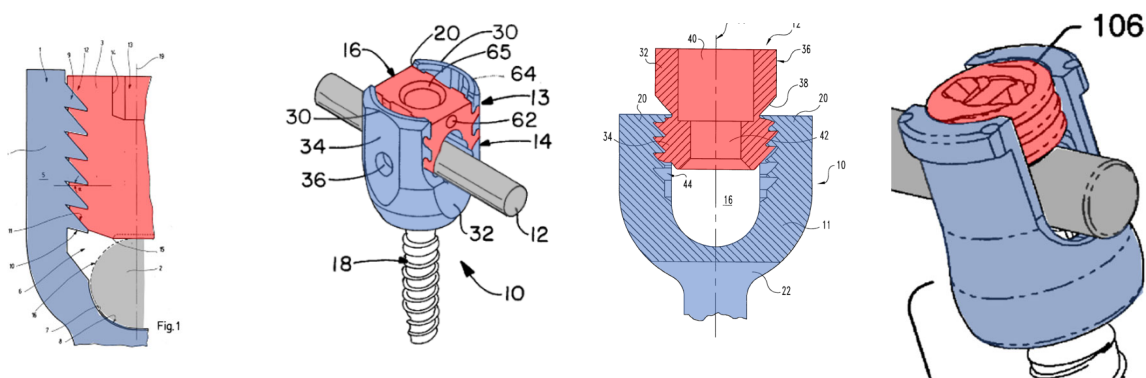
46. In addition, at least as of January 10, 2012, using a rod with bone screws for “providing vertebral support” was a “common mechanism.” EX1001, 1:24-27. It was also known that, “[a]lthough both close-ended and open-ended bone anchors” were known, open-ended anchors were “particularly well suited for connections to longitudinal connecting members such as hard, soft or deformable rods, dynamic or elastic connectors and connector arms, because such rods or other connector members do not need to be passed through a closed bore, but rather can be laid or urged into an open channel within a receiver or head of such a bone anchor.” *Id.*, 1:27-35. Fig. 2 of Boschert, annotated below, shows how open-ended anchors (**blue**) and set screws (**red**) can be used together with a longitudinal rod (**grey**) to correct and/or stabilize spinal deformities.



EX1006, Fig. 2.

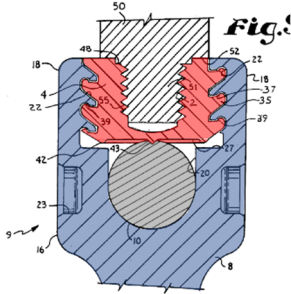
47. “Typical open-ended bone screws included a threaded shank with a head or receiver having a pair of parallel projecting branches or arms which form a yoke with a U-shaped slot or channel to receive a rod or other longitudinal connecting member.” EX1001 1:42-46; *see also* EX1006, Abstract, 4:13-28, 6:11-28, Figs. 1, 3-4, 7-12, 14-17; EX1005, ¶¶[0003]-[0004], Figs. 5-6. The head of these open-ended bone screws “typically include[d] a pair of spaced arms forming a

channel closed by a closure member^[2] after the rod or other longitudinal connecting member is placed in the channel.” EX1001 1:49-53. At least as of January 10, 2012, “[k]nown closures include[d] slide-on types, twist-on varieties that are rotated ninety degrees to a locked in position, and 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.” *Id.*, 1:53-1:59; *see also* EX1005, Abstract, ¶¶[0005]-[0011], [0025]-[0046], Figs. 1-10; U.S. Patent No. 6,296,642 to Morrison (“Morrison”) (EX1016), Abstract, 1:6-10, 2:30-34, 3:49-51, 3:64-4:61, 5:14-28, Figs. 1, 3-6C; U.S. Patent No. 6,302,888 to Mellinger (EX1017), Abstract, 1:63-65, 2:10-22, 4:38-60, 5:53-57, Figs. 1-2, 5-7, 9-10. In addition to those shown above, sample depictions of representative prior art receiver (**blue**) and closure top (**red**) constructs with a longitudinal rod (**gray**) are shown below, along with their publication dates:

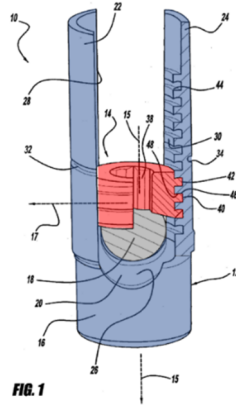


² Closure members have been referred to with a variety of terms in the prior art, including closure, closure top, closure plug, plug, set screw, and the like.

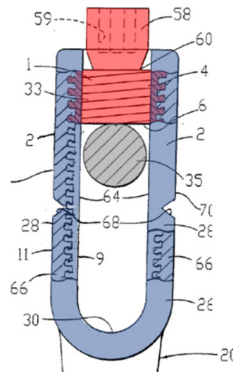
1999
EX1033, Fig. 1



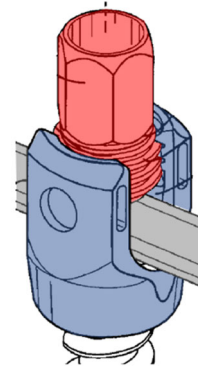
2001
EX1017 Fig. 1



2001
EX1016, Fig. 1



2004
EX1019, Fig. 1



2004
EX1020, Fig. 9

2004
EX1021, Fig. 1

2006
EX1037, Fig. 1

2011
EX1038 Fig. 1

48. Thus, before January 10, 2012, the general environment of a polyaxial bone screw assembly, including open-ended bone screws with a pair of spaced arms forming a channel, longitudinal connecting members such as rods, and closure tops with a variety of threads, were well-known. Before January 10, 2012, it was well-known that a POSA had a plethora of known tools and design choices that could be applied to a polyaxial bone screw assembly.

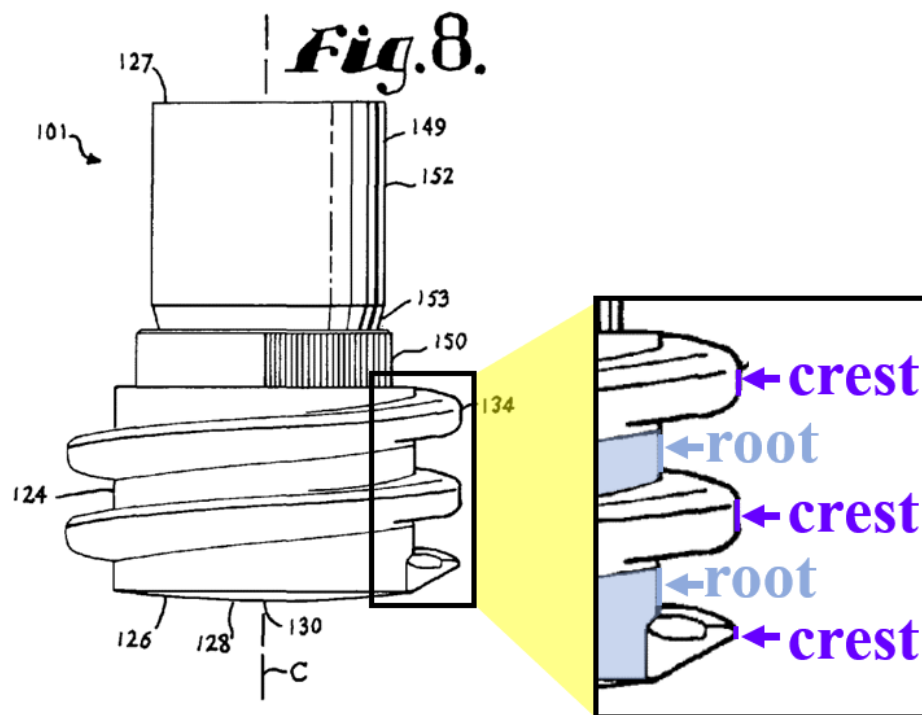
1. Threaded Connectors

49. Before January 10, 2012, threaded connectors were well known in the art. In particular, it was well known that spine correction and stabilization could be accomplished by screws placed into the pedicles of spinal vertebrae joined together by plates or rods. If a rod system was used (particularly for longer vertebral segments or multi-directional correction such as in scoliosis) pedicle screws with U-shaped

heads to contain the rod could be used to connect a series of vertebral bodies to each other—generally on both sides of the spine. The rods could be contoured or bent to match the desired curvature of the spine. Although the Acromed/DePuy Isola system used a sliding cap, the most common method of holding the rod within the channels of the screws was with a threaded connector either as a cap over the top of the screw or as a set screw within the top of the pedicle screw.

50. In designing a threaded connector, including a closure top for a spinal implant, a POSA would have had the opportunity to choose the type of threads, the number of the threads, and the location of the start of each thread. However, regardless of the thread type, there are certain inherent qualities of all threads. All threads have a start that is called the “lead thread” that has a “leading flank.” The American Society of Mechanical Engineering (“ASME”) Standard B1.7-2006 “Screw Threads: Nomenclature, Definitions, and Letter Symbols” (published in 2006 and still the current standard in 2023) defines the “lead thread” as “that portion of the incomplete thread that is fully formed at the root but not fully formed at the crest that occurs at the entering end of external or internal threads.” EX1022 (“ASME B1.7-2006”) at 7. This standard defines the “leading flank” as “the flank that, when the thread is about to be assembled with a mating thread, faces the mating thread.” *Id.* In addition, all threads have a root and a crest. For example, the ’477 Publication describes the root and crest of a thread. EX1005, ¶[0031]. As shown in

annotated and enlarged Figure 8, the root is the surface of the thread which joins the flanks of adjacent threads and is immediately adjacent the cylindrical body from which the thread projects, and the crest is the surface of a thread which joins the flanks of the thread and is the furthest point from the cylindrical body from which the thread projects. *Id.*, Fig. 8.



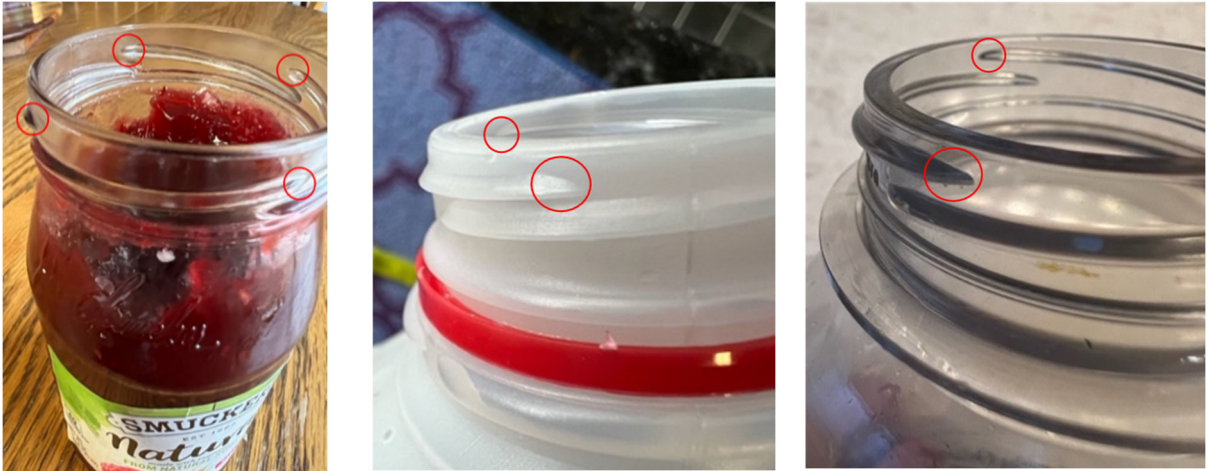
a. Multi-Start Threading

51. Before January 10, 2012, it was known that threaded connectors could use single, dual, or multiple helically wrapped threads as was desired for any given application. In particular, it was known that use of additional threads could present advantages in certain circumstances, including to facilitate easier thread engagement, balance threading forces, and increase the speed of insertion.

52. A “start” of a thread is the beginning structure of the thread. Multi-start threads and their advantages have long been known. For example, the Ferguson Rifle used by Britain in the American Revolutionary War with British Patent Office No.1139 filed in 1776 uses a multi-start thread to rapidly close the breach loading gun.³

53. Multi-start threads are quite common and are used in many commercial products. For example, they have long been used in camera lenses for quick change. They are commonly used in ship and submarine doors that need to be closed quickly in emergency. Multi-start threads are also in common use on everyday items in my refrigerator. For example, as shown below, Smucker’s raspberry jam (left), Marc’s gallon jugs of milk (center), and “Simply Orange” orange juice (right), include multiple threads with multiple starts.

³ See Institute of Military Technology, The Ferguson Rifle: A Revolutionary Weapon, <https://www.instmiltech.com/the-ferguson-rifle-a-revolutionary-weapon/> (accessed Apr. 14, 2023).



Of course, the lids or caps to these items have corresponding threads to engage the multiple starts.

54. Before January 10, 2012, well-known reference books had discussed multi-start threads as an available design choice. For example, the U.S. Department of Commerce’s 1969 Handbook H28 (EX1024) (“Handbook H28”), entitled “Screw-Thread Standards for Federal Services,” described a “Single-Start Thread” as “one having the lead equal to the pitch” and “Multiple-Start Thread” as “one in which the lead is an integral multiple (other than one) of the pitch.” EX1024 at 10.

55. As another example, in 1987, U.S. Patent No. 4,707,001 to Johnson (“Johnson ’001”) (EX1025), which was filed on June 20, 1986, and which issued on November 17, 1987, disclosed a “well liner pipe” with “multiple starting helixes spaced equidistantly apart around the 360 [degree] circumference.” EX1025, Abstract, 2:17-20, 2:34-39. Johnson ’001 disclosed that “the superiority” of the multi-start threads is that they “prevent differential strain rates caused by the sudden

one-side discontinuity of single start threads,” which “reduces the load bearing capacity of the joint.” *Id.* at 2:34-39, 2:50-54. “[B]y introducing two separate thread helixes that start and finish 180 [degrees] apart, the load the connection will carry has found to increase.” *Id.* at 2:54-56; *see also id.* at 4:28-39, Fig. 4 (showing diametrically opposed thread starts). Accordingly, Johnson ’001 teaches that multi-start threads with thread starts equidistant around the 360-degree circumference of a fastener were known to strengthen the connection of the fastener.

56. As another example, the 28th Edition of the Machinery’s Handbook, which is a “reference book for the mechanical engineer, designer, manufacturing engineer, draftsman, toolmaker, and machinist,” disclosed multi-start threads at least as early as 2008. Machinery’s Handbook 28th Edition (“Machinery’s Handbook”) (EX1014). The Machinery’s Handbook disclosed “[t]hreads with more than one start.” EX1014 at 3. In particular, the Machinery’s Handbook disclosed that, “[i]n order to achieve proper distribution of each start around the cylinder, each thread ***has to start at an equal angle***, determined by the following calculation: Thread cylindrical spacing angle = 360 / Number of starts.”⁴ *Id.* Accordingly, for a dual

⁴ Emphases and text coloring in quotations added unless specified throughout.

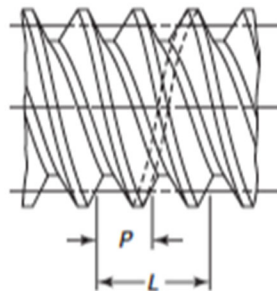
start thread,⁵ the Machinery's Handbook disclosed that, in order to achieve proper distribution, the starts' spacing angle needs to be 180 degrees. In other words, the Machinery's Handbook teaches that the starts of a dual-start thread should be diametrically opposed with respect to one another. The Machinery's Handbook further taught that one advantage of multi-start threads is that they "provide fast relative traversing motion when this is necessary." *Id.* at 4. In other words, multi-start threads are inserted more quickly and with fewer turns, due to their steeper pitch as compared to a comparable single start thread.

57. Double lead, or dual start or two start threads were well known well before 2012, as evidenced by their description in the ASME standard B1.7-2006. "On a single lead thread, the lead is equal to the pitch. On a double lead thread (double start), the lead is equal to twice the pitch." EX1022 at 7. ASME B1.7-2006 defines a multiple start thread as "a screw thread with two or more threads where the pitch is equal to the thread lead divided by the number of thread starts (*see* Fig. 42).

⁵ Dual start threads have been referred to with a variety of terms in the prior art and in this field, including dual start, double start, two start, dual thread, double thread, two thread, dual lead, double lead, and two lead. A POSA would have understood these phrases to be synonymous with each other.

Also called multiple lead thread.” *Id.* at 8. ASME B1.7-2006 Fig. 42 is shown below.

SCREW THREADS: NOMENCLATURE, DEFINITIONS, AND LETTER SYMBOLS



GENERAL NOTE: Two-start thread illustrated.

Fig. 42 Multiple Start Thread

Id. at 9.

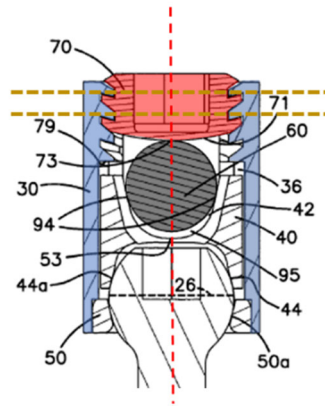
58. Before January 10, 2012, it was known that multi-start threading could be used in spinal implants. For example, U.S. Patent No. 6,010,502 to Bagby (EX1026) (“Bagby”), which was filed on September 29, 1997, and issued on January 4, 2000, disclosed a “bone joining implant” that includes a “base body” that “is cylindrical” and includes a “spline” that “is an undercut thread helically configured about the body.” *Id.*, Abstract. Bagby disclosed one “construction” of the implant that “has a pair of threads extending about the implant. With such a dual thread construction, the threads start **180 degrees apart**, such that cutting forces produced by self-tapping threads will substantially offset one another. Hence, a self-tapping implant will tend to rotate into a pilot hole in a **balanced manner, tending to follow the pilot hole.**” *Id.*, at 13:35-41. Thus, Bagby reinforces that dual-start threads use

start structures that are diametrically opposed and offer advantages over a single start.

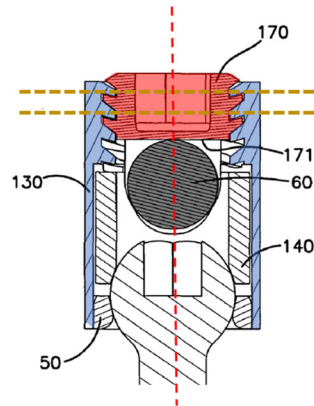
59. Moreover, before January 10, 2012, it was known that multi-start threads could be used in the specific context of the set screw to hold the rod in place in polyaxial spinal pedicle screw and rod spinal implants, the same as described by Jackson in the '479 Patent. For example, Boschert disclosed a medical device comprising a receiver with a top portion that defines a pocket, or saddle, for receiving a rod, a bone fastener (such as a bone screw), a seat structure, a retainer (such as a retaining ring), and a setscrew. EX1006, 4:13-28. Boschert disclosed that the set screw is threaded into the saddle, forcing the rod to seat against the top of the seat structure. *Id.*, 4:26-28, 48-50. Boschert further disclosed that the threads of the set screw can include two thread leads, rather than one, in order “to start more easily than with a single lead.” *Id.*, 7:21-23.

60. A POSA would have recognized that Boschert discloses simultaneous mating of the first and second starts. Specifically, as shown below in annotated Figs. 3 and 15, (1) the reverse angle threads on either side of the receiver are symmetrically and diametrically opposed to each other across the longitudinal axis, and (2) the reverse angle threads on either side of the setscrew are also symmetrically and diametrically opposed to each other across the longitudinal axis, which

therefore defines that the two threads leads are 180 apart (as illustrated by the yellow horizontal lines that are perpendicular to the red longitudinal line).



EX1006, Fig. 3



EX1006, Fig. 15

Annotated Fig. 7 (below) also shows the symmetrical and diametrically opposed locations of the threads on the setscrew by showing diametrically opposed trailing ends of the double-lead thread on the top of the setscrew. A POSA would have understood and expected that each of the double-lead threads would have identical length and therefore understand that diametrically opposed thread ends are the result of diametrically opposed thread starts. The diametrically opposed locations of the threads on the receiver and of the threads on the setscrew define that the two threads start simultaneously.

[illegible]

EX1007, Fig. 7

61. A POSA would have further understood that for double start threads on the setscrew to engage with the symmetrical, diametrically opposed receiver threads, (1) the receiver threads would necessarily have to mirror each other, and (2) the start and end structures would necessarily be spread equidistant around their respective ends. This understanding would have been further reinforced by the conventional manner of making dual start threads, which includes using diametrically opposed thread starts and threads of equal lengths, as discussed above. *Supra*, ¶¶54-60. Further, diametrically opposed thread starts would have been the obvious choice when threading a dual start closure under the threads of two symmetrical, diametrically opposed receiver arms. Specifically, a POSA would have understood that each of the thread starts on the closure top would be designed to simultaneously thread under the corresponding threads at the edge of each diametrically opposed receiver arm. This can only be accomplished by diametrically opposing the thread starts on the closure top.

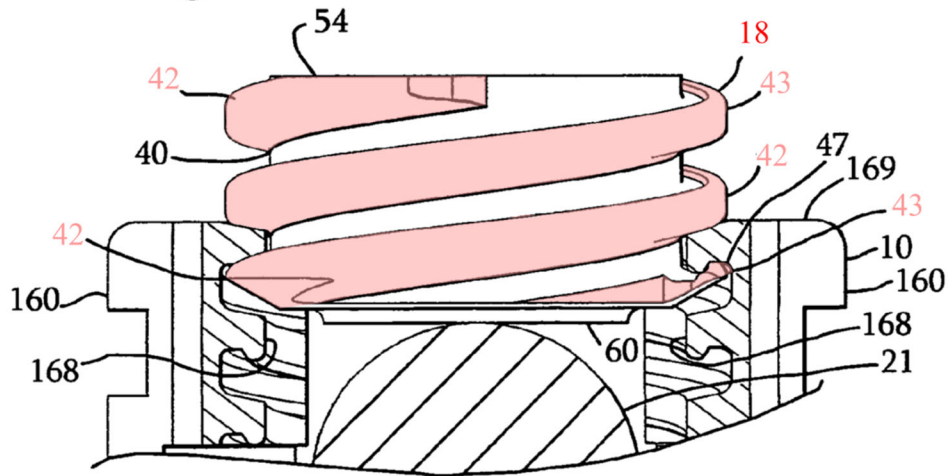
62. Thus, before January 10, 2012, a POSA would have been aware of multi-start threads (including diametrically opposed, simultaneously mating dual-start threads) as an available and advantageous design choice when designing closure tops, as multi-start threads provided easier starting, balanced rotational forces, and faster closure top insertion, which were important advantages in the field

of spinal implants because they reduce surgical time and reduce the chance of implant failure.

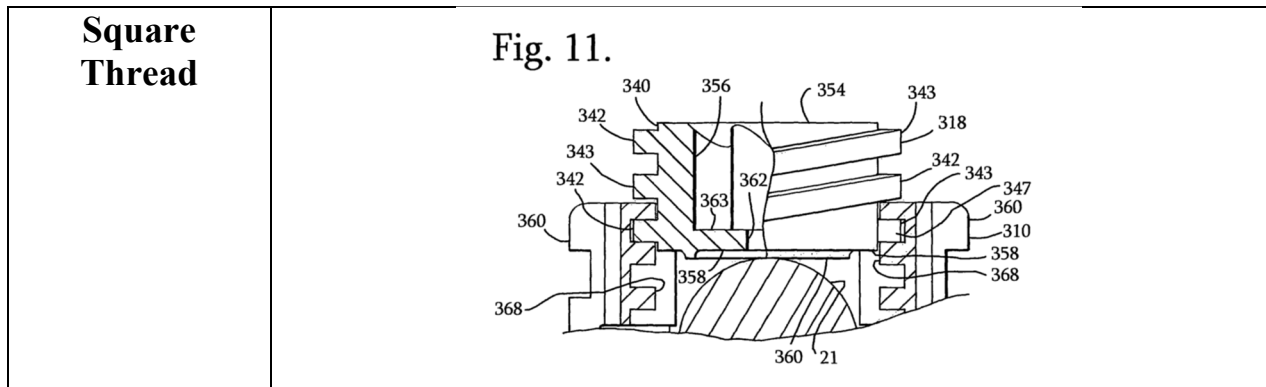
b. Closure Thread Types

63. As the '479 Patent admits, before January 10, 2012, “[*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.” EX1001, 1:53-1:59. The specification of the '479 Patent describes these “known closures.” In other words, these thread types were not invented by the inventor of the '479 Patent but were recognized as known thread types. The '479 Patent describes “flange forms,” stating that the “interlocking flange forms [are] described in greater detail in applicant’s U.S. Pat. No. 6,726,689” and incorporating that patent by reference. EX1001, 6:9-12; *see also id.* Abstract, 2:55-56, 5:45-47, 6:9-12, 6:24-32, 6:48-52, 7:10-13, 7:23-28, 10:11-15, 10:53-59, 10:64-11:1, 11:9-18, Figs. 1-7, 15-17 (describing flange forms); U.S. Pat. No. 6,726,689 (“Jackson ’689”) (EX1015) at Abstract, 1:6-18, 13:12-15, 13:41-16, 14:48-60, Figs. 6, 13. Annotated Fig. 3 in the '479 Patent, below, shows the known flange forms 42 and 43 on the closure 18:

Fig. 3.



64. The specification also describes and shows square threads, EX1001, Abstract, 1:53-59, 2:57-60, 6:12-23, 6:34-47, 8:57-9:10, Fig. 11; reverse-angle threads, *id.*, Abstract, 1:53-59, 2:57-60, 6:12-23, 6:34-47, 9:11-31, Fig. 12; v-threads, *id.*, Abstract, 1:53-59, 2:57-60, 5:4-6, 6:34-47, 9:32-52, Fig. 13; and buttress threads, *id.*, Abstract, 1:53-59, 2:57-60, 6:12-23, 6:34-47, 9:53-10:6, Fig. 14.

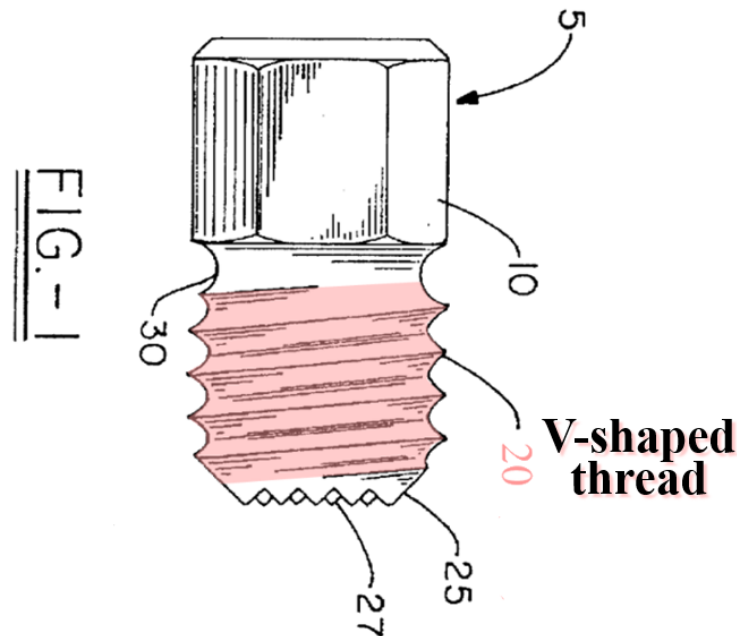


Reverse-Angle Thread	Fig. 12.
V-Thread	Fig. 13.
Buttress Thread	Fig. 14.

65. These thread types are also described in prior art, which confirms that the thread types described in the '479 Patent, and their advantages, would have been known to a POSA.

66. An example of a traditional V-shaped thread can be found in U.S. Patent No. 5,697,929 to Mellinger ("Mellinger '929") (EX1018) which is entitled

“Self-Limiting Set Screw for Use with Spinal Implant Systems” and which issued on December 16, 1997. EX1018. As shown in annotated Figure 1 below, Mellinger '929 discloses that the “thread configuration is a standard, V-shaped thread.” *Id.*, 2:60-61, Fig. 1.



67. While V-shaped threads were the oldest thread configuration, a number of alternative thread designs were also well known well-before the '479 Patent and provided known advantages for inhibiting splaying of the two arms of the receiver. For example, a reverse angle thread can be found in Morrison, which issued in 2001. EX1016. As shown below in annotated Figure 3, Morrison discloses a closure top with a reverse angle thread 46 where “the angle between a plane normal [54] to the longitudinal axis [43] and the rearward surface [52], or pressure angle, is negative.” *Id.*, 2:48-51; *see also id.*, 4:43-5:13, Fig. 3.

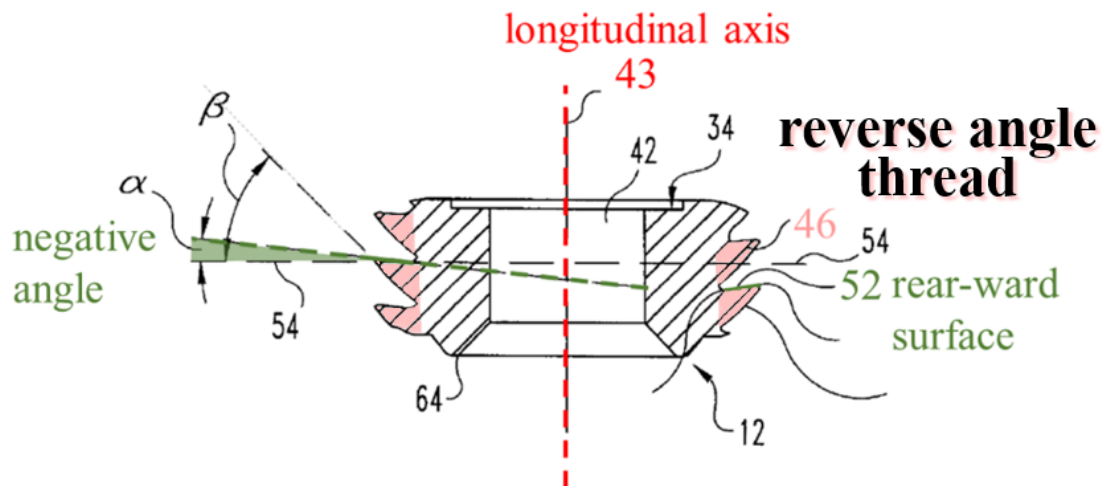
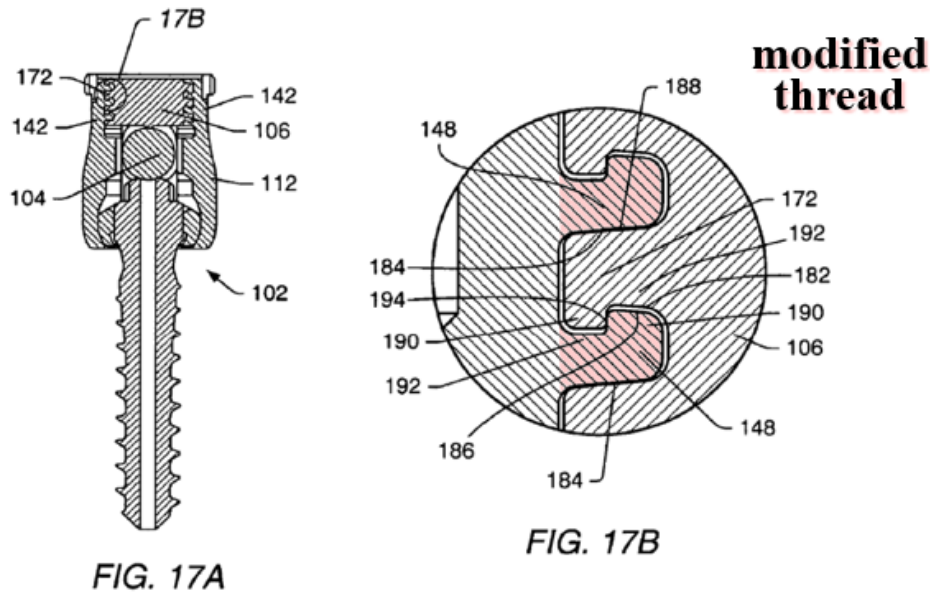


Fig. 3

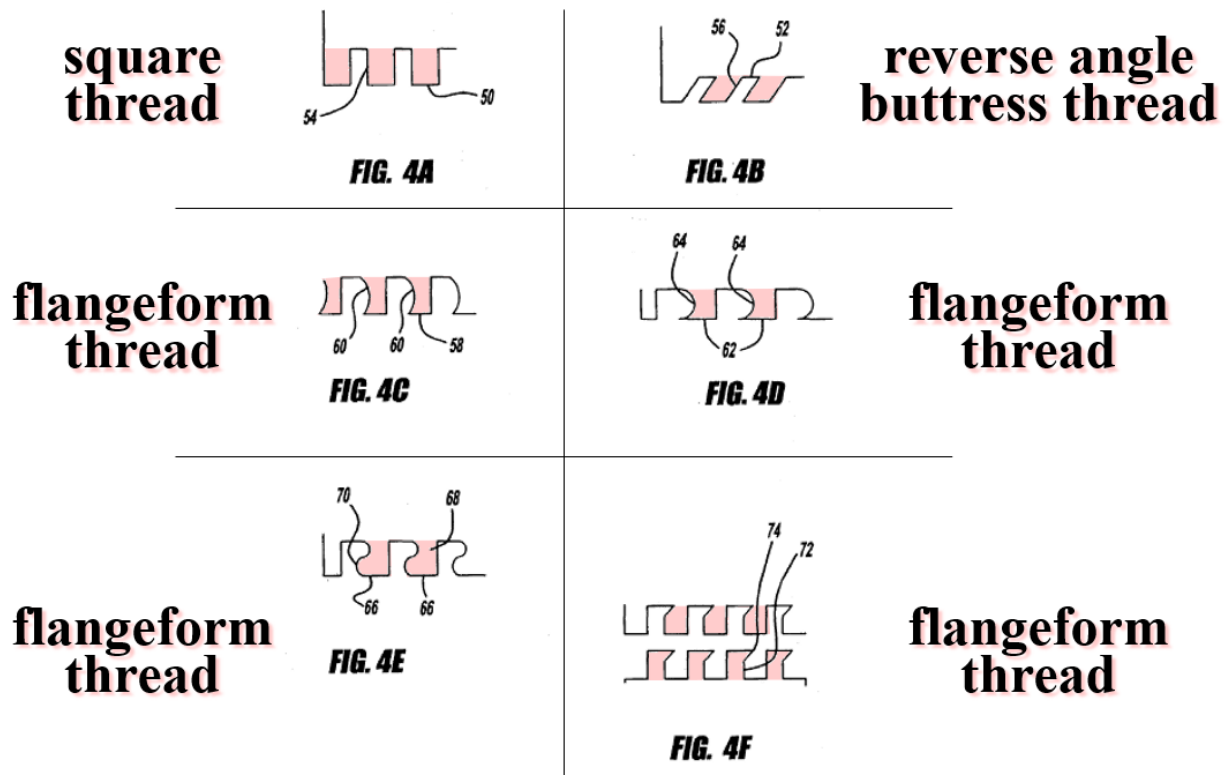
Specifically, Morrison teaches that the “pressure angle is between -1 and -10 degrees. In a currently more-preferred embodiment, the pressure angle is -5 degrees.” *Id.*, 2:53-56. In such a configuration, “splaying of the medical device is prevented.” *Id.*, 2:60-62.

68. Alternatively, helical flange threads forms were also well known, an example of which can be found in U.S. Patent No. 7,250,052 to Landry (“Landry”) (EX1019), which issued in 2007. Landry discloses various “modified threads” for use on a closure top. EX1019, 17:22-36. As shown in Figure 17A and annotated Figure 17B below, these modified threads have “[r]aised portions 190 and recessed portions 192 ... on male distal surface 182 and female proximal surface 186. Cooperating surfaces 194 of modified threads 172 and 148 may contact or be proximate to one another during use.” *Id.*, 17:38-41. “Engagement of cooperating surfaces 194 *may inhibit spreading of arms 142 away from each other.*” *Id.* 17:45-47.



EX1019, Figs. 17A, 17B. Landry further acknowledges several other well-known thread type options, stating “[c]losure member 106 may couple to collar 112 by a variety of systems including, but not limited to, standard threads, modified threads, reverse angle threads, buttress threads, or helical flanges. A buttress thread on a closure member may include a rearward-facing surface that is substantially perpendicular to the axis of the closure member.” *Id.*, 17:12-18.

69. As shown in annotated Figures 4A-4F below, U.S. Patent Publication No. 2004/0162560 to Raynor (“Raynor”) (EX1021) also discusses a number of alternative thread types for spinal implant set screws, including square threads (Fig. 4A), reverse angle buttress threads (Fig. 4B), and a variety of flange form threads that provide a “gripping function” (Figs. 4C-F). EX1021, ¶¶[0028]-[0029].



70. Jackson himself acknowledged that all of these alternative thread types were well-known in the prior art in his own prior art publications. *See, e.g.*, U.S. Patent No. 6,726,687 to Jackson (EX1023), 5:67-6:9 (“[T]he closure 106 has a generally cylindrical shaped body 135 that has a threaded radially outward surface 140 that has a thread thereon that is sized, shaped and positioned to threadedly mate with threads of the arm threaded surfaces 126 and 127, as seen in FIG. 10. The thread can be a *conventional V-thread*, a *buttress thread*, a *reverse angle thread* or other threads related to reverse angle threads in that they exert forces to draw or pull the arms 121 and 122 toward one another rather than cause them to splay or open at the top.”); EX1009, ¶[0092] (“[N]ear the bottom 36 of each of the end guides 9 on inner surfaces of the side walls 32 and 33, is a helical 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, as also described below.”); *id.*, ¶[0103] (“Near 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 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.”); *see also id.*, ¶¶[0089], [0098]. Thus, each of these known thread types had known advantages, and a POSA would have been readily able to choose between them for any given application.

2. Other Aspects of Spinal Implant Design

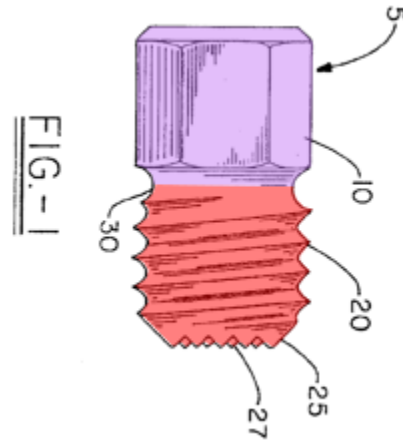
71. Before January 10, 2012, various design options for spinal implants were widely known and available in order to allow a POSA to design implants, taking into consideration the overall size of the implants and the needs of the procedure and the patient. Here, I will specifically address the advantages of design options related to the use of break-off closure tops, the use of break-off receiver arm extensions, and the use of attachable/detachable guide tools.

a. Break-Off Closure Tops

72. Before January 10, 2012, multiple structures for engaging and torquing a closure top were well known. Of course, inset recesses were known for engaging screwdriver heads of various shapes and sizes, but it was also a well-known option to have an external driving structure equivalent to the head of a bolt. One known advantage of an external drive structure is that such a structure could be built to breakoff at a predetermined torque, thereby ensuring that the closure top would be tightened to the desired level, but not over torqued, when it was installed. *See* EX1018, 2:34-39; EX1016, 4:4-17. Another known advantage of a break-off head in a spinal implant was that it allowed the use of a low profile device that would have increased patient safety. EX1018, 1:37-40 (“[I]t is also an object to provide a design which is as small as possible to provide *minimal disruption* to the biological environment.”); *see also id.* at 3:15-19 (“[T]he necked area 30 is intended to shear evenly, i.e., in a way which will prevent an uneven break which could inhibit the insertion of a removal tool into the set screw or leave a jagged surface which could cause irritation to the patient.”).

73. Mellinger '929 is one example of a known breakoff top. *See* EX1018. As shown in annotated Figure 1 (right), Mellinger '929 disclosed a “set screw” (i.e. closure) that included a “necked area 30” that “joins the external torque head [shown in purple below] to the threaded screw portion [shown in red below] of the set

screw.” *Id.*, Abstract, Fig. 1. Mellinger ’929 further disclosed that the “necked portion has a cross-sectional thickness and strength to provide for shearing at a predetermined load limit, such as from about 54 to about 64 pounds per inch.” *Id.*, Abstract; *see also id.*, 1:5-8 (“The invention relates generally to set screws for use with spinal implant systems, and more particularly to a set screw having a head for the external application of torque which will shear at a predetermined load”); *id.*, 2:19-22 (“A set screw 5 in accordance with the invention is shown in FIG. 1 having a first externally threaded screw portion 20 and an axially aligned external torque or tightening head 10 joined to the screw portion 20 by a neck shearing area 30.”); *id.*, 2:34-39 (“The external torque head or tightening head 10 is dimensioned so as to transmit a predetermined torque level, i.e., more than about 45 or 50 inch-pounds and preferably 55 to 65 inch-pounds. The amount of torque which can be applied to the head prior to shearing will depend on the material as well as the cross-sectional area of the neck.”); *id.*, 3:6-15 (“In accordance with the invention, a torque-limiting area 30 is provided to limit the application of tightening torque in order to protect the threaded area 20. More specifically, the torque-limiting area 30 comprises a necked portion having a longitudinal length of about 0.03 to about 0.05 inch and having a groove or radiused



area which is designed to cause the torque applicator head 10 to shear at a predetermined load which is between 50 and 70 inch-pounds, preferably from 54 to 64 inch-pounds, in order to eliminate the need for a torque wrench to measure the tightening.”); *id.*, Figs.1, 4-5, cls. 1-2, 9-10, 12, 15-18.

74. Morrison issued on October 2, 2001, and also disclosed a closure member 12 that “includes a break-off section 32 [shown in purple at right] and a screw section 34 [shown in red at right].” EX1016, 3:64-67, Fig. 4. As shown in annotated Figure 4, Morrison disclosed that “closure member 12 is threadedly engaged with receiving member 11 to a point at which further

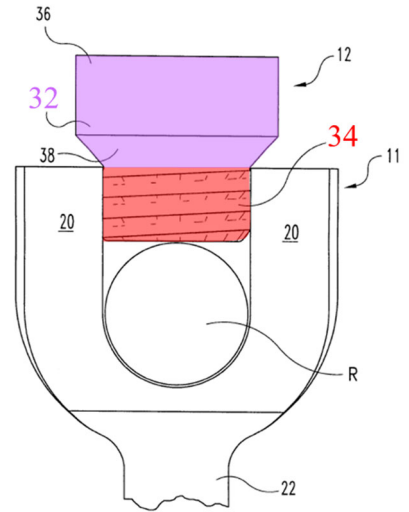
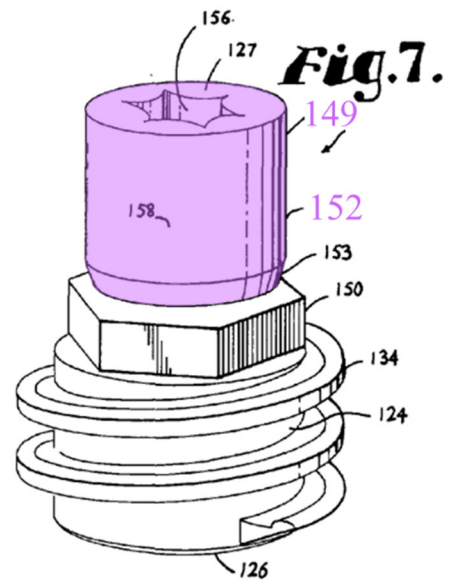


Fig. 4

threaded progression is impeded, as for example when the screw section 34 contacts an object within the channel 16, such as rod R seated against wall 24. As further torque is applied to break-off screw closure member 12, as with an [sic] hexagonal driving tool inserted into hole 40, eventually the stress on the neck portion 38 is great enough to cause the upper section 36 to **break off from** screw section 34 at neck portion 38.” *Id.*, 4:4-17; *see also id.*, 4:18-22, Figs. 1, 3-4, 5-6C, cls. 10, 14, 31.

75. The '477 Publication provides yet another example of a known breakoff top. Specifically, as shown in annotated Figure 7, the '477 Publication states that “closure 101 also includes a driving or installation break-off head 149 [shown in purple at right] and a removal head 150 that are coaxially attached to the body 124.” EX1005, ¶[0042]; *id.* Fig. 7. In addition,



the “driving head 149 is disposed on a break-off portion 152 that is secured to the body 124 at a breakaway region 153 adjacent the removal head 150 and is ***designed to break away from*** the remainder of the closure 101 subsequent to a predetermined torque being applied to the driving head.” *Id.*, ¶[0042]. The '477 Publication discloses that advantages of a breakoff closure top are a lower-profile closure and ensuring that a closure top would be tightened to the desired level, but not over torqued, when it was installed. *Id.*, ¶¶[0009], [0011], [0035].

76. Thus, before January 10, 2012, a POSA was aware of breakoff closure tops and the advantages they provided to ensure proper torque levels and reduce profile for patient safety.

77. The choice to use breakoff heads on setscrews or to use non-breakoff heads was independent of other aspects of the pedicle screw and rod system such as whether a single-, dual-, or multi-start thread is used; or what type of thread is used.

b. Designs for Facilitating Implantation of Spinal Implant Devices

78. Surgeons generally use the smallest incision consistent with the desired access. Especially in certain patients, such as obese patients, attempting to place a small spinal implant by hand deep into the patient through a minimal incision would not be advisable. Accordingly, as discussed further below in Sections VI.B.2.b.i. and ii., before January 10, 2012, there were multiple well-known designs for facilitating implantation of spinal implant devices from outside the patient's body through a small incision in the patient. For example, one could use a guide tool that was separate from the spinal implant. The guide tool could attach to the spinal implant for purposes of facilitating implantation of the spinal implant and then detach from the spinal implant after the implant was in the desired location. Often the guide tool would attach to the spinal implant by mating with a groove on the implant. As an alternative to the use of a separate guide tool, one could instead use a spinal implant with break-off extensions (often on the receiver portion of the spinal implant). The extensions could be used to facilitate implantation and then could be removed after implantation.

i. Attachable/Detachable Guide Tools

79. Before January 10, 2012, it was well-known that attachable and detachable guide tools could be used to facilitate implantation of spinal implant devices. For example, in cases of severe spinal deformity, longer tools may be needed to capture a rod (i.e., longitudinal connecting member) and to allow for a closure to be tightened from a longer distance. In addition, for minimally invasive surgical methods, the tools and devices used to implant the medical devices were needed to extend from the insertion location inside the patient to outside of the patient's body through small openings. To address these issues, attachable/detachable guide tools were developed well before January 10, 2012. These guide tools could allow a closure to be transferred from outside the patient's body into the patient's body, thereby moving the rod down until it is seated in the bottom of the U-shaped groove of the receiver. Once tightened, the guide tools are no longer needed, and the guide tool can be removed from the receiver and from the patient's body.

80. As early as 1985, U.S. Patent No. 4,545,374 to Jacobson ("Jacobson") (EX1030) described the use of a cannulated guide to "contact a predetermined position" in the spine and "conduct[] a surgical procedure on the spinal column by manipulating instruments through the cannula." EX1030, 2:24-30. Jacobson recognized the benefits of percutaneous methods of accessing the spine over long

incisions from cutting a channel into a patient's back to access the spine. *See id.*, 1:11-2:21.

81. U.S. Patent No. 7,862,595 to Foley ("Foley") (EX1031), which was filed in 2007 and issued in January 2011, similarly recognized that "[m]inimally invasive surgical techniques are particularly desirable in, for example, spinal . . . applications because of the need for access to locations deep within the body and the danger of damage to vital intervening tissues," and disclosed instruments to achieve the benefits of such minimally invasive techniques. EX1031, 1:20-2:2. For example, as shown in annotated Figure 4, Foley disclosed attachable/detachable cannulated tools with bone screws to pass a set screw into the receiver of the bone screw from outside of the patient. In particular, Foley disclosed anchor extension 30 (i.e., the guide tool), mounted to anchor 60 (i.e., the receiver) to insert set screw 76 (i.e., the closure). *Id.* Fig. 4. As disclosed in Foley, "yoke 68" of anchor 60 "is mountable to anchor extension 30." *Id.*, 7:34-48. The anchor extension is "held firmly" against "upper surfaces 73" of anchor arms 71 "by set screw 76, which is releasably coupled to yoke 68" and anchor extension 30's "inner sleeve 50." *Id.*, 8:27-36.

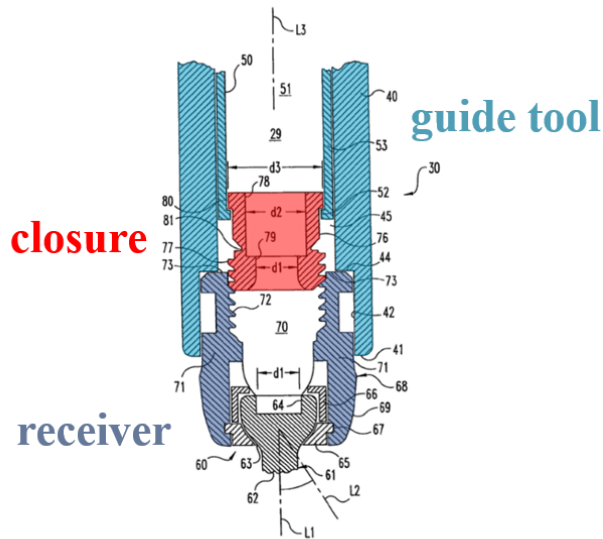


Fig. 4

Foley further disclosed that the set screw 76 is “driven downward to contact brace 90, 290.” *Id.*, 14:13-14. When the upper portion of set screw 76 is broken off, anchor extension 30 is “release[ed] . . . from anchor 60 . . . allowing removal of extensions 30, 230 from the subject.” *Id.*, 14:22-26.

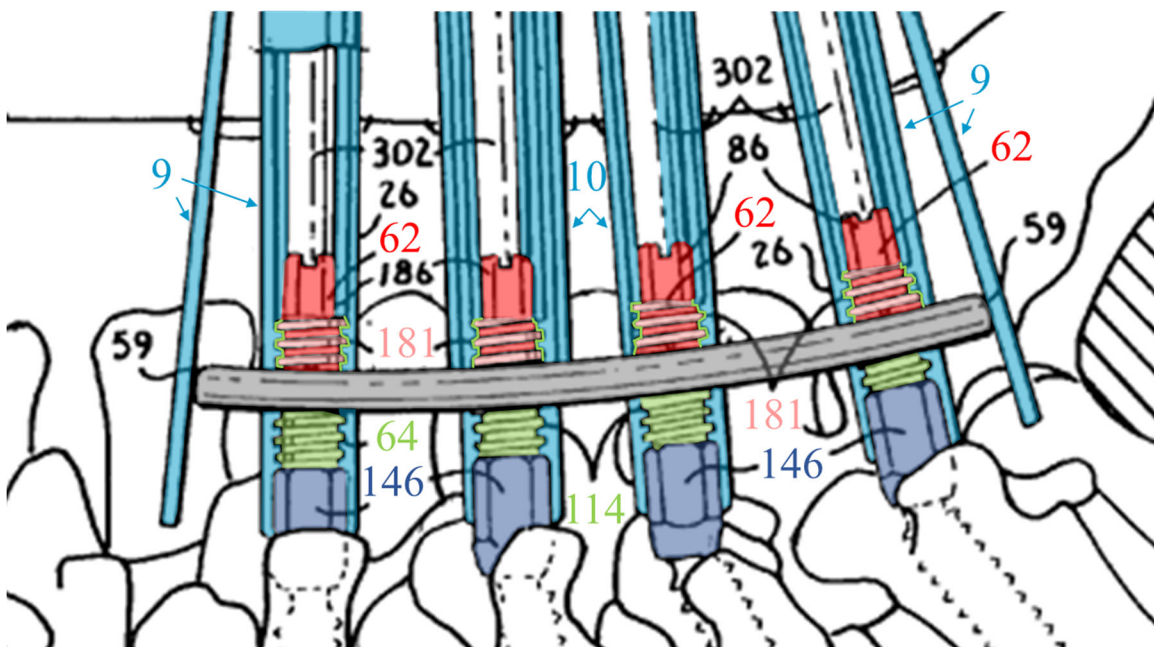
82. In 2006, the '391 Publication similarly disclosed an attachable/detachable guide tool set consisting of multiple guide tool assemblies, which “include[] an end guide tool 9 or an intermediate guide tool 10,” as part of a system “for percutaneously implanting spinal screws and for implanting a rod for spinal support and alignment, using minimally invasive techniques.” EX1009, ¶¶[0002], [0082]. “[N]ear 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.” *Id.*, ¶[0092]. 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 may be utilized such as helically wound flange forms, reverse angle threads, buttress threads, etc.” *Id.*, ¶[0103]. Again like the helically wound thread on the end guide tool, this thread on the intermediate guide tool “cooperates with the closure top 62.” *Id.*

83. 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.” *Id.*, ¶[0171]; *see also id.*, Fig. 42. “[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. *Id.*, ¶[0172]; *see also id.*, ¶[0120] (“In particular, the guide and advancement structures 64 and 114 on the respective tools 9 and 10 are located and positioned to align with the guide and

advancement structure 183 on the insides of the bone screw arms 150 and 151, as shown in FIG. 42 and pass the closure top 62 therebetween while allowing the closure top 62 to continue to rotate and to continuously apply force to the rod 8, so as to aid in seating the rod 8 in the bone screw head 146.”), Fig. 43. 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.” *Id.*, ¶[0173].

84. The guide tool and how it interacts with the closure and the receiver are show below in annotated and excerpted Figure 42, which illustrates “an intermediate stage of implanting a rod,” *id.*, ¶[0062]:



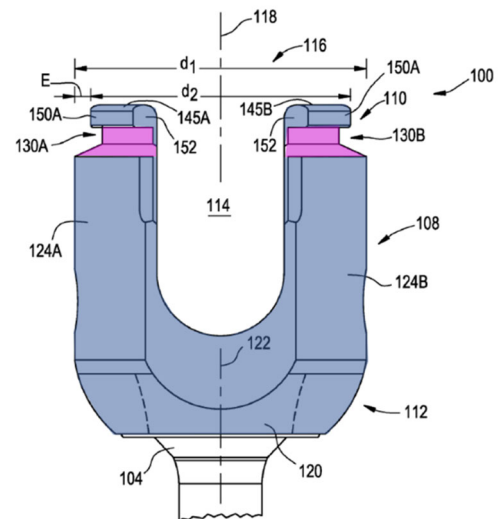
See id. Fig. 42; *see also id.*, ¶[0063], Fig. 43 (illustrating the rod fully installed in the bone screws).

85. As another example, U.S. Patent No. 7,854,751 to Sicvol (“Sicvol”) (EX1034), entitled “Percutaneous access devices and bone anchor assemblies,” published in March 2007 and issued on December 21, 2010, recognized that “the trend in spinal surgery has been moving toward providing minimally invasive devices and methods for implanting bone anchors and spinal fixation devices.” EX1034, 1:45-47. Thus, Sicvol disclosed “devices [that] permit the delivery and implanting of one or more bone anchors in a minimally invasive manner thereby limiting trauma to surrounding tissue,” and in particular, “bone anchors that facilitate the connection of instruments . . . to the bone anchor.” *Id.*, 1:54-64. Specifically, as shown in annotated Figure 6 (right), Sicvol

disclosed bone anchor assembly 100 with receiving member 108 that “include[s] at least one groove [(pink)] 130 that is configured to receive a portion of an instrument to **releasably connect** the instrument to the bone anchor assembly.” *Id.*, 9:31-34, Fig. 6; *see id.*, 8:22-10:15. These

“arcuate groove[s] 130 . . . extend about a portion or all of the circumference of the proximal end of each leg 124A, 124B. Each groove 130A, 130B may have size and

FIG. 6



shape that is complementary in size and shape to a projection provided on the instrument.” *Id.*, 9:40-49, Figs. 5&6; *see also id.*, Figs. 7, 11A-16, 20A-20D.

86. Thus, before January 10, 2012, attachable/detachable guide tools were well-known and a familiar element of spinal implants to a POSA.

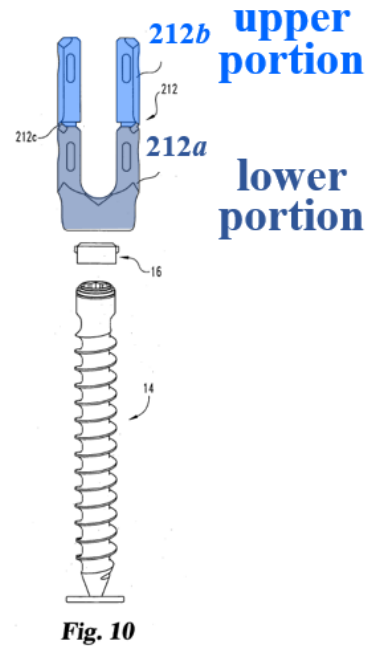
87. The decision to use or not use an attachable/detachable was independent of other aspects of the pedicle screw and rod system such as whether a particular thread type is used or whether a single or double thread start is used.

ii. Break-Off Receiver Arm Extensions

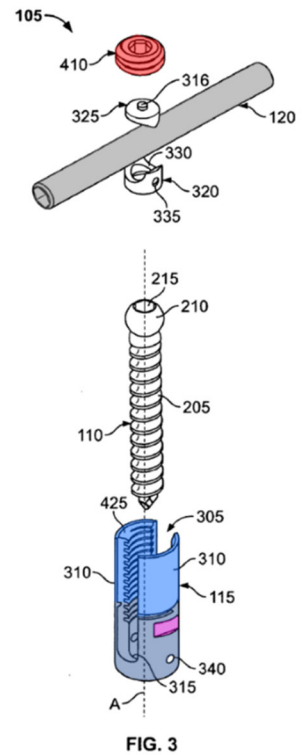
88. Before January 10, 2012, it was well-known that break-off extensions could be used in spinal implant devices, especially as an alternative to using a separate guide tool. As discussed above, during a spine surgery using the devices at issue, a rod is placed into the U-shaped receiver of a spine screw, and by tightening a closure top into that receiver, the closure top forces the rod down until it is fully seated at the bottom of the U-shaped slot in the receiver. In many cases, the typical height of the receiver arms is sufficient to accomplish this function. But in cases of severe spinal deformity, longer U-shaped arms may be needed to capture the rod and allow for a longer tightening distance of the closure top or to allow the surgeon to implant the fixation devices and rods from outside the patient’s body in minimally invasive operations. To address this issue, breakoff arm extensions were developed well before January 10, 2012. Breakoff arm extensions can serve a similar purpose

to attachable/detachable guide tools, without the need to separately attach the guide tool to the receiver head. These arms capture the rod between them and allow the closure top to be tightened along their length, thereby moving the rod down until it is seated in the bottom of the U-shaped groove. Once tightened, the longer arms are no longer needed, and the arm extensions can be broken off leaving the shortened lower-profile receiver, now containing both the rod and the closure top, to remain in the patient's body. Thus, unlike attachable/detachable guide tools, the breakoff arms cannot be re-attached once removed. As a result, POSA would have known the benefit of including breakoff arm extensions to allow for the efficiency of breakoff extensions during implantation, with the option to attach additional tools during implantation or later for later repair or removal. Some examples of these well-known break-off extensions in the prior art are discussed below.

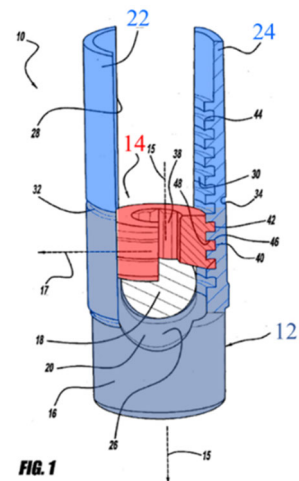
89. For example, Johnson discloses break-off extension receiver arms. In particular, as shown in the annotated Figure 10, a receiver member 212 “has a lower portion 212a and an upper portion 212b separated by a thinned section 212c.” EX1008, ¶[0051]. Johnson discloses that the “[t]hinned section 212 c” “separates upper portion 212b and lower portion 212a.” *Id.*, ¶[0054]. Johnson 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.*” *Id.*, ¶[0056]. Johnson discloses that, “[o]nce separated, *upper portion 212b may be removed* from the surgical site and discarded.” *Id.*



90. In 2007, U.S. Patent Application Publication No. 2007/0270813 to Garamszegi (“Garamszegi”) (EX1035) disclosed breakoff extension arms and a tool attachment groove. As shown in annotated Figure 3, Garamszegi disclosed a pedicle screw assembly that includes coupling element 115 (blue) configured to receive elongate rod 120 (gray). EX1035, ¶[0055]. “A pair of laterally-opposed, *upwardly extending projections 310*” are *attached to element 115*, and these projections have “internal, threaded surfaces” configured to mate with the outer threads on compression nut 410 (red). *Id.* ¶¶[0055]-[0056]. On the outside surface of the coupling element 115 is a tool attachment groove (purple). *Id.*, Fig. 3.

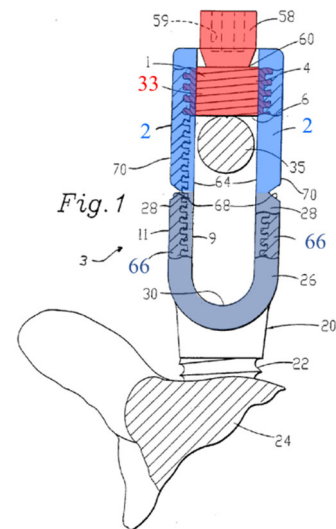


91. In 2004, Raynor similarly disclosed breakoff extension arms. As shown in the annotated Figure 1 at right, Raynor disclosed a medical device 10 that includes a rod receiving member 12 and a “locking member [(red)] in the form of a set screw generally indicated at 14.” EX1021, ¶[0019]. Raynor disclosed that its rod receiving member “can assume various specific forms,” including in which the rod receiving member 12 has “extended arms 22 and 24 [(blue)], each of the arms 22, 24 [(gray)] including an



indent or recess 32, 34 allowing for *easy breaking off of the extended portion of the arms 22, 24.*” *Id.*, ¶[0022].

92. As shown in annotated Figure 1, in 2006, U.S. Patent Application Publication No. 2006/0058794 to Jackson (“Jackson ’794”) (EX1037) also disclosed a bone screw 20 with “break-off extensions 2” that “are connected to the main portions 66 of the arms 28 [of the U-shaped open head 26] by reduced or otherwise weakened regions 68.” EX1037, ¶[0041]. Jackson ’749 further disclosed that “[t]he *extensions 2 can be broken off* or separated from the main portions 66 of the arms 28 by pivoting or bending the extensions 2 back and forth about the regions 68 while the main portions 66 are held in place, after the closure 33 has passed between the extensions 2,” “*resulting*” in a “*low-profile implanted structure.*” *Id.*; see also *id.* Abstract, ¶¶[0019]-[0020], [0027], [0040], Figs. 1-2, 6, cls. 1, 6, 10, 16.



93. Thus, breakoff arm extensions and their benefits were well-known to POSA before January 10, 2012.

94. The decision to use or not use breakoff arm extensions was independent of other aspects of the pedicle screw and rod system such as whether a particular thread type is used, or whether a single or double thread start is used.

VII. THE '479 PATENT

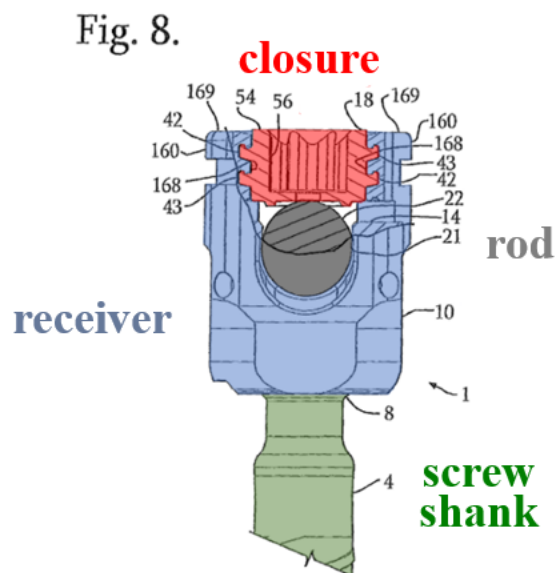
A. Overview

95. The '479 Patent is entitled “Multi-Start Closures for Open Implants” and names Roger P. Jackson as the inventor. EX1001 at 1. The '479 Patent issued on December 16, 2014. *Id.*

96. The '479 Patent claims priority to two provisional applications, the earliest of which was filed on January 10, 2012. *Id.*, 1:7-12. I therefore presume January 10, 2012, to be the effective filing date of the '479 Patent.

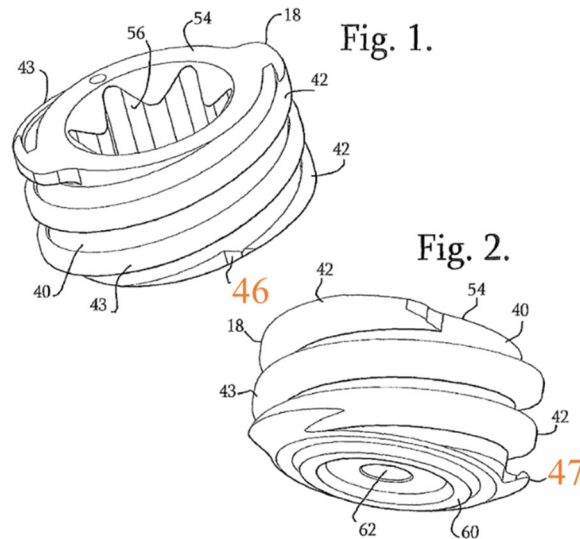
97. The '479 Patent appears to have been drafted under the incorrect understanding that using dual- or multi-start threads on a closure top was a new idea. The patent acknowledges that bone screws and closure tops were well known in the prior art, stating that “[b]one anchors, such as bone screws ... are utilized in many types of spinal surgery in order to secure various implants to vertebrae along the spinal column of the purpose of stabilizing and/or adjusting spinal alignment.” *Id.*, 1:21-24. The specification further states that “open-ended bone anchors are known,” *id.*, 1:28, and generally “include a threaded shank with a head or **receiver** having a pair of parallel projecting branches or arms which form a yoke with a U-shaped slot or **channel to receive a rod** or other longitudinal connecting member,” *id.*, 1:42-46. 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 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.*, 1:53-59. These known components are highlighted below in annotated Fig. 8.



98. The patent then identifies the problem to be 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 of the implant arms and the rotated until a portion of the structure is captured by mating guide and advancement structure on both arms of the implant, all the while the closure is being pressed down on the rod while other forces are pushing and pulling the rod back out of the implant.” *Id.*, 2:4-12. The specification proposes to solve this problem by using a “double-start closure ... having two helically wound

forms thereon, each form having a start structure for simultaneously engaging and 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.



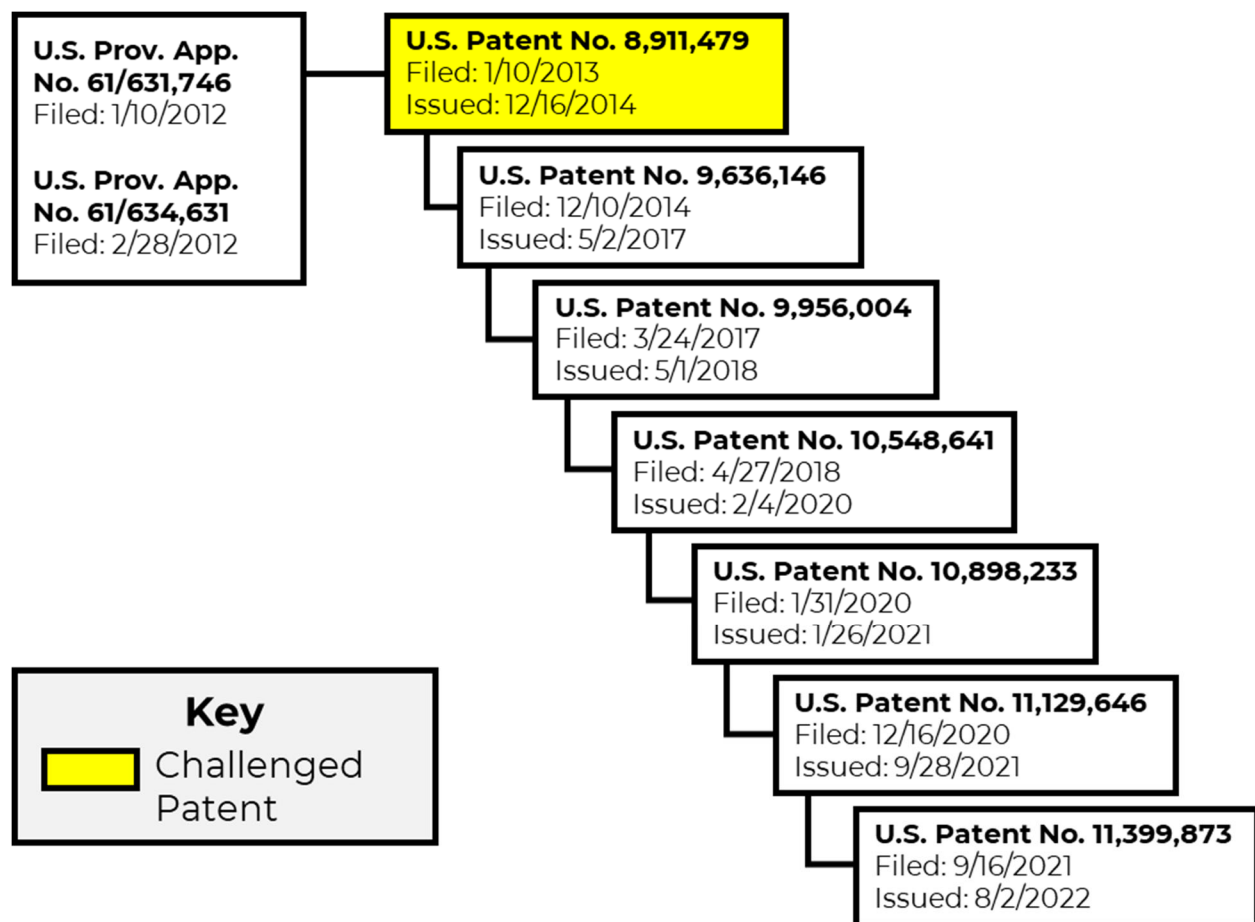
The specification also recognizes that any multi-start—that is, more than one—closure could also be used. *Id.*, 2:24-32 (“one or more helically wound guide and advancement features”), 2:40-41 (“The helically wound forms of the multi-start closure spiral around a cylindrical plug body thereof . . .”), 2:47-48 (“Multi-start closures of the invention may have two or more coarse or fine helical forms . . .”).

99. The independent claims of the ’479 Patent (Claims 1, 10, 18, and 21), as well as one dependent claim (Claim 19), are each directed at using dual- or multi-start threads on a closure top in an otherwise-known medical assembly comprising the closure top and a receiver with two spaced arms, each with a guide and advancement structure for mating with the multi-start closure. The dependent claims

add limitations of using various specific thread types on the closure top (Claims 2-6, 11-15, 20), break-off closure tops (Claims 7, 16), break-off receiver arm extensions (Claims 8, 17), or detachably attached guide tools (Claims 9, 22)—each of which were known in the prior art.

B. Prosecution History

100. The '479 Patent is the first in a patent family that claims priority to U.S. Provisional Application No. 61/634,361, filed on February 28, 2012, and U.S. Provisional Application No. 61/631,746, filed on January 10, 2012. The various patents that have issued as part of this family are illustrated in the chart below:



101. During prosecution of the '479 Patent, Applicant represented that “the situs of the invention is believed to be in the use of a pair of helical wound guide and advancement structures (threads or flangeforms) that provide a dual start.” EX1002 at 2013 (3.24.14 Amendment). The Examiner initially rejected the proposed claims as anticipated or rendered obvious by Hutchinson (U.S. Patent Application Publication No. 2009/0216280), *id.* at 2023-24 (4.23.14 Rejection). In response, Applicant pointed out that “[i]n Hutchinson, a single thread is disclosed, not two distinct helically wound forms.” *Id.* at 2097 (7.8.2014 Amendment). The Examiner then allowed the claims of the '479 Patent without having discussed any dual start prior art. *Id.* at 2103-09; *see also id.* at 2022-25 (rejection not addressing any dual start prior art).

102. While Boschert’s application, U.S. Patent Application No. 2005/0277928, was cited in an Information Disclosure Statement along with hundreds of other references, *id.* at 1128 (1.10.2013 IDS), the Examiner appears not to have discovered Boschert’s teaching (from either Boschert’s 2005 patent application or the resulting U.S. Patent No. 7,857,834, which issued on December 28, 2010) regarding dual-start threads until prosecution of the fifth patent in this family, U.S. Patent No. 10,898,233. The original proposed claim of the application of the '233 Patent required a tool groove at the top of the receiver in combination with a dual-start closure top. EX1036 at 25. The Examiner rejected these claims

over Garamszegi (U.S. Pub. No. 2008/0045953), which disclosed a tool groove on a conventional bone screw receiver, in view of Boschert, which disclosed a dual-start closure top. *Id.* at 64-69 (6.12.20 Rejection). In response to this rejection, 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.” *Id.* at 324 (9.1.2020 Amendment). Applicant then amended his claims to require curvate leading surfaces on each thread and distinguished Boschert on this basis. *Id.* at 345-46 (9.4.2020 Supplemental Amendment Remarks), *id.* 324-25 (9.1.2020 Claim Amendment). The Challenged Claims of the ’479 Patent do not include the same curvate leading face requirement that was used to distinguish Boschert.

103. Neither the ’477 Publication nor the ’391 Publication were cited during the prosecution of the ’479 Patent. Johnson was cited, but its teachings regarding breakoff arm extensions were not discussed by the Examiner, either alone or in combination with Boschert and the 477 Publication.

C. The Challenged Claims

104. The Challenged Claims of the ’479 Patent are Claims 1-22. The ’479 Patent includes four independent claims—1, 10, 18, and 21. These claims substantially overlap, but Claim 1 expressly requires two starts on the closure top,

while Claims 10, 18, and 21 require “at least two starts” and/or a “multi-start” closure.

105. I have focused on Claim 1 as representative. Claim 1 is set forth below in its entirety, with individual limitations broken out and enumerated. Claim 1⁶ recites:

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:

⁶ I have attached as an appendix to my declaration a claim listing of all Challenged Claims. Because many limitations of Claims 1, 10, 18, and 21, and their respective dependent claims, are common, I have assigned a unique identifier to each limitation found in the claims and I have attempted to group limitations based on the feature the limitation is directed at (group [A] relates to the closure, group [B] relates to the receiver, group [C] relates to the interaction between the receiver and the closure top. This claim listing, and my assignment of a unique identifier for each limitation, are intended solely for ease of reference. My opinions herein address each and every limitation of the Challenged Claims.

[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

[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

[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.

106. Claim 10 recites many of the same limitations as Claim 1 but claims “at least” two, rather than two, starts on the closure and specifies that each receiver arm has “an inwardly facing surface” with the discontinuous helically wound guide and advancement structures on them. Claim 10 in its entirety, states as follows:

[Preamble] A medical implant comprising:

[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

[A8] b) a closure structure having a cylindrical body and a second helically wound guide and advancement structure having at least two starts.

107. Claim 18 recites many of the same limitations as Claim 1 but claims a “multi-start” closure, rather than two starts, and specifies that the receiver arms have “inwardly facing surfaces” with the discontinuous helically wound guide and advancement forms on them. Claim 10 in its entirety, states as follows:

[Preamble] In a medical implant, the improvement comprising:

[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

[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.

108. Claim 21 recites many of the same limitations as Claim 1 but claims a “multi-start” closure with “at least two starts,” rather than two starts, and specifies that the receiver arms have “inwardly facing surfaces” with the discontinuous helically wound guide and advancement forms on them. Claim 21 is also specific to “a polyaxial bone anchor” and includes a “shank being pivotable with respect to the receiver prior to locking of a position.” Claim 21 in its entirety, states as follows:

[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:

[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.

109. Claim 2 depends from Claim 1 and adds the limitation: **[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.

110. Claim 3 depends from Claim 1 and adds the limitation: **[A3]** wherein the first and second helically wound forms are v-threads.

111. Claim 4 depends from Claim 1 and adds the limitation: **[A4]** wherein the first and second helically wound forms are square threads.

112. Claim 5 depends from Claim 1 and adds the limitation: **[A5]** wherein the first and second helically wound forms are reverse angle threads.

113. Claim 6 depends from Claim 1 and adds the limitation: **[A6]** wherein the first and second helically wound forms are buttress threads.

114. Claim 7 depends from Claim 1 and adds the limitation: **[A7]** wherein the closure member has a break-off head.

115. Claim 8 depends from Claim 1 and adds the limitation: **[B2]** wherein the receiver has break-off extensions.

116. Claim 9 depends from Claim 1 and adds the limitation: **[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.

117. Claim 11 depends from Claim 10 and adds the limitation: **[A2]** wherein the first and second helically wound guide and advancement structures are interlocking flange forms.

118. Claim 12 depends from Claim 10 and adds the limitation: **[A3]** wherein the second helically wound guide and advancement structure includes at least two v-threads.

119. Claim 13 depends from Claim 10 and adds the limitation: **[A4]** wherein the second helically wound guide and advancement structure includes at least two square threads.

120. Claim 14 depends from Claim 10 and adds the limitation: **[A5]** wherein the second helically wound guide and advancement structure includes at least two reverse angle threads.

121. Claim 15 depends from Claim 10 and adds the limitation: **[A6]** wherein the second helically wound guide and advancement structure includes at least two buttress threads.

122. Claim 16 depends from Claim 10 and adds the limitation: **[A7]** wherein the closure structure has a break-off head.

123. Claim 17 depends from Claim 10 and adds the limitation: **[B2]** wherein the receiver has break-off extensions.

124. Claim 19 depends from Claim 18 and adds the limitation: **[A10]** wherein the multi-start closure is a double-start closure.

125. Claim 20 depends from Claim 18 and adds the limitation: **[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.

126. Claim 22 depends from claim 21 and adds the limitation: **[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.

D. Opinions on Claim Construction

127. In view of the claim construction standards articulated above, it is my opinion that the claim terms should all be assigned their ordinary and customary meaning as they would have been understood by a POSA as of the priority date in view of the '479 Patent specification and prosecution history.

VIII. SCOPE AND CONTENT OF THE PRIOR ART REFERENCES

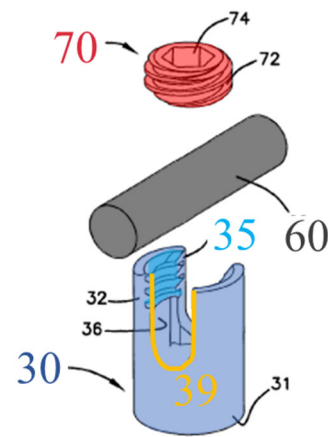
A. Overview of Boschert

128. Boschert, EX1006, published on December 15, 2005, more than 6 years before the earliest effective filing date of the '479 Patent. I understand Boschert therefore is prior art to the '479 Patent under 35 U.S.C. § 102(b). Boschert discloses an orthopedic fixation device for securing a rod to a bone for stabilization of the spine. EX1006, Abstract, 1:5-7. Therefore, and as described further below, in my opinion Boschert is in the same field of endeavor as, and is analogous art to, the '479 Patent. *Compare id.*, 4:26-28 (“The fixation device 10 further includes a fastener such as a setscrew 70 for clamping the rod 60 within the saddle 39 of the receiver 30.”), *with* EX1001, 1:14-18 (“The present invention is directed to structure for

joining together parts of a medical implant, in particular to closure mechanisms for use with open bone anchors in spinal surgery ...”).

129. Boschert discloses a medical device comprising a receiver with a top portion that defines a pocket, or saddle, for receiving a rod, a bone fastener (such as a bone screw), a seat structure, a retainer (such as a retaining ring), and a setscrew. EX1006, 4:13-28. The head of the bone screw and the seat structure are bottom-loaded into the receiver and secured by the retainer to the bottom end of the receiver. *Id.*, 4:22-26. The set screw is threaded into the saddle, forcing the rod to seat against the top of the seat structure. *Id.*, 4:26-28, 48-50. The bone screws have a polyaxial configuration. *Id.*, 4:44-47, 5:5-11.

130. 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). *Id.*, 6:20-24, Fig. 1. The 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. *Id.*, 6:24-48; *see also id.*, 7:12-15.

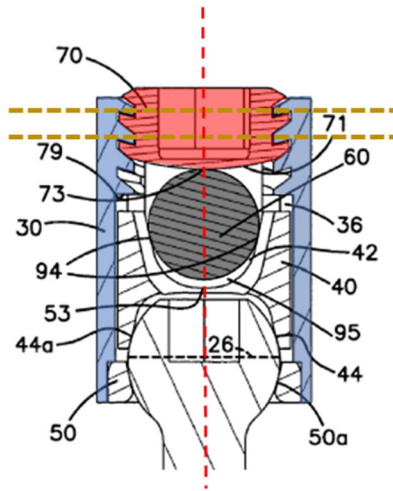


Ex. 1006, Fig. 1

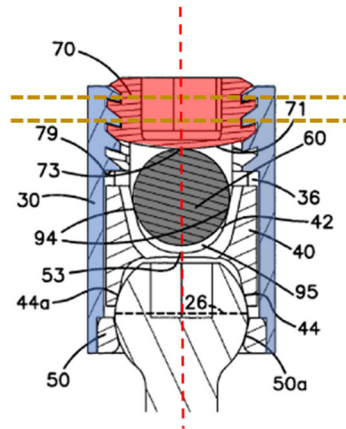
Boschert further discloses that the threads of the set screw can be designed to have a “double lead to allow the setscrew 70 to start more easily than with a single lead.”

Id., 7:21-23. Relatedly, as shown below in annotated Figure 3, Boschert discloses interior threads on the receiver that are mirrored along the longitudinal axis (**red**), thereby providing for simultaneously receiving the double leads of the closure top.

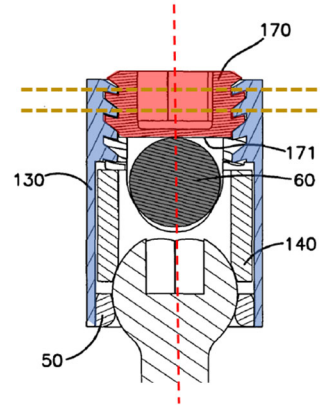
Id., Fig. 3.



131. A POSA would recognize that Boschert contemplates and discloses diametrically opposed starts to its dual lead threads. Specifically, Figs. 3 and 15 both show that the threads on either side of the receiver are symmetrically and diametrically opposed to each other across the longitudinal axis (shown in **red**) as illustrated by the lines perpendicular to the longitudinal axis (**yellow**).



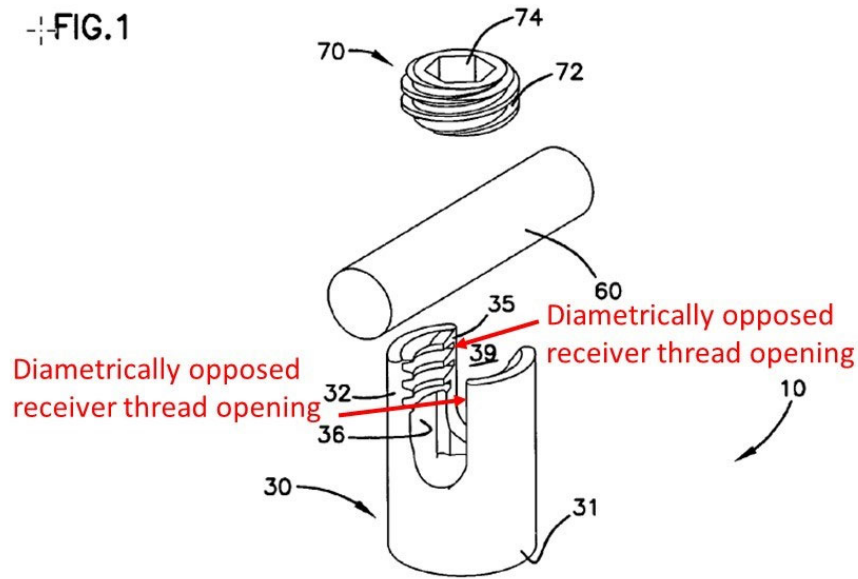
EX1006, Fig. 3



EX1006, Fig. 15

132. A POSA would have understood that for double start threads on the setscrew to engage with these receiver threads, (1) the receiver threads would necessarily have to mirror each other, and (2) the start structures would necessarily be spread equidistant around the starting end. This understanding would have been further reinforced by the conventional manner of making dual start threads, which includes using diametrically opposed thread starts as discussed above. EX1014 at 3; EX1026, 13:35-41. Further, diametrically opposed thread starts would have been the obvious choice when threading a dual start closure under the threads on two diametrically opposed receiver arms. Specifically, a POSA would have understood that each of the thread starts on the closure top would be designed to simultaneously thread under the corresponding threads at the edge of each diametrically opposed receiver arm, as illustrated in Fig. 1 below.

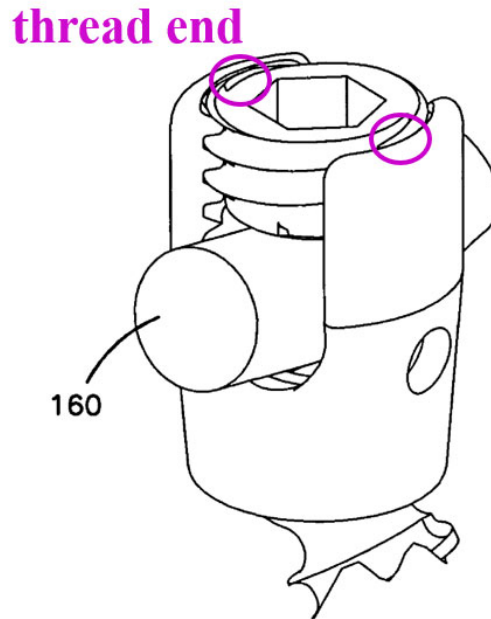
FIG. 1



EX1006, Fig. 1

This can only be accomplished by diametrically opposing the thread starts on the closure top.

133. My opinion that Boschert discloses simultaneous mating of thread starts is also supported by Fig. 7. As annotated below, Fig. 7 shows, at the top of the closure top, that the trailing ends of the double lead thread are diametrically opposed. A POSA would have understood and expected that each of the double lead threads would have the identical length, and therefore understand that diametrically opposed thread ends are the result of diametrically opposed thread starts.



EX1006, Fig. 7

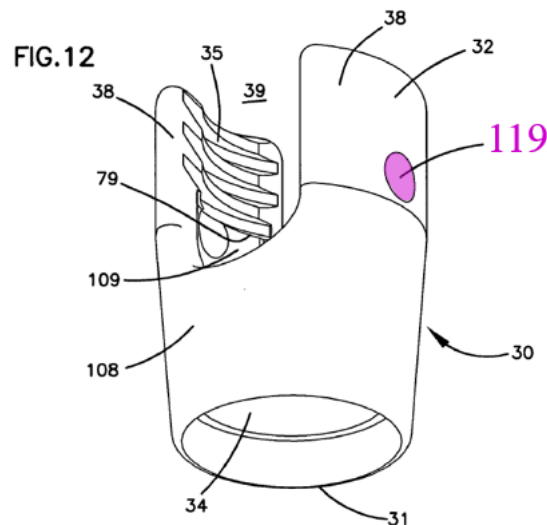
The diametrically opposed locations of the threads on the receiver and of the threads on the setscrew define that the two threads start simultaneously.

134. Therefore, in my opinion, Boschert discloses, both expressly and inherently, and renders obvious a first start structure disposed at a diametrically opposite location on the set screw from a second start structure such that, in use, each of the thread starts would simultaneously engage one of the two arms of the receiver.

135. 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.” *Id.*, 7:58-62. Therefore, in my opinion, 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.

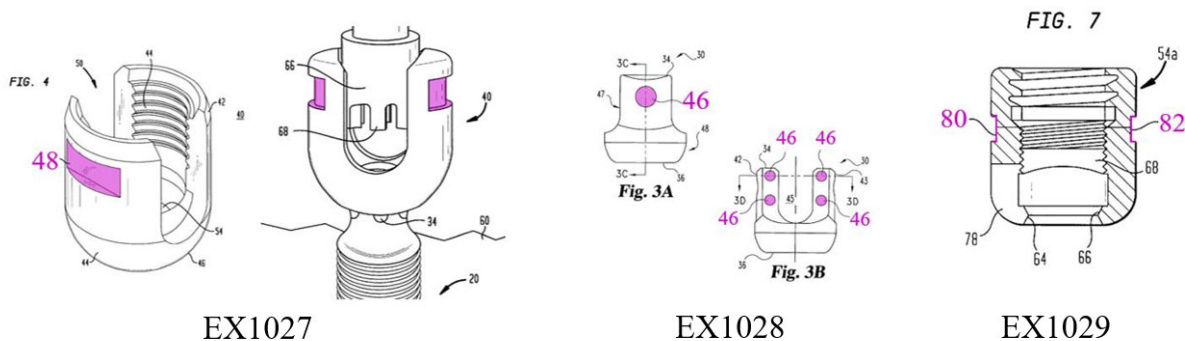
136. Boschert also expressly contemplates the use of “grasping features” on the outside surface of the receiver. Specifically, Boschert states that “[a]s illustrated in FIG. 12, the receiver 30 may also include grasping features 119 on the outer surface 108 that would accommodate instrumentation to facilitate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



EX1006, Fig. 12

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.



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

B. Overview of the '477 Publication

137. The '477 Publication, EX1005, was published on December 1, 2005, more than 6 years before the earliest effective filing date of the '479 Patent. I understand the '477 Publication is therefore prior art to the '479 Patent under 35 U.S.C. § 102(b). The '477 Publication discloses a medical implant assembly that uses a closure to capture and lock a rod in a spinal implant. EX1005, ¶¶[0007], [0026]-[0029], [0039]-[0041]. Therefore, in my opinion the '477 Publication is in

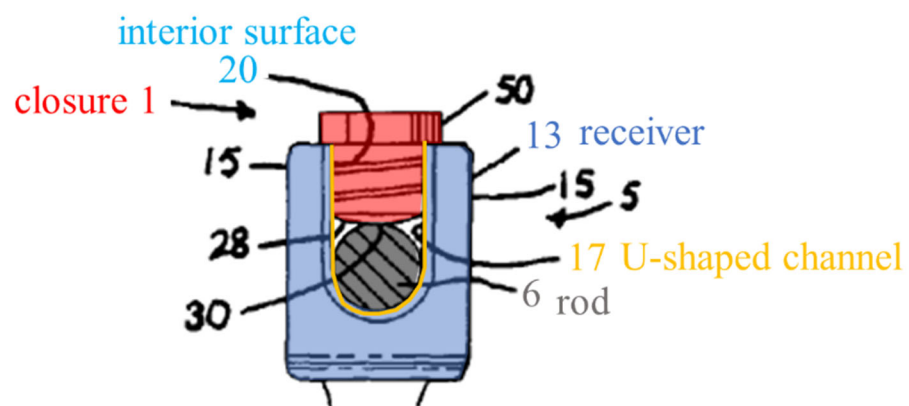
the same field of endeavor as, and is analogous art to, the '479 Patent. *Compare id.* ¶¶[0007] (“A closure and locking member is provided for a medical implant . . . used in a spinal implant system for providing support or reconstruction to the spine, such as a transverse connector. A typical implant for use with a closure of the invention includes a receiver having a pair of spaced arms with an open channel located therebetween.”), *with* EX1001 at 1:16-20 (“The present invention is directed to structure for joining together parts of a medical implant, in particular to closure mechanisms for use with open bone anchors in spinal surgery...”); *see also* EX1005, ¶¶[0026]-[0029], [0039]-[0041].

138. 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. *Id.*, ¶¶[0007], [0026]-[0038], Figs. 1-6. The inner surface 20 of each arm has a partial helically wound guide and advancement structure that mates with a similar

structure on a closure 1 when the closure is rotated.

Id., ¶¶[0007], [0029], Fig. 5. The

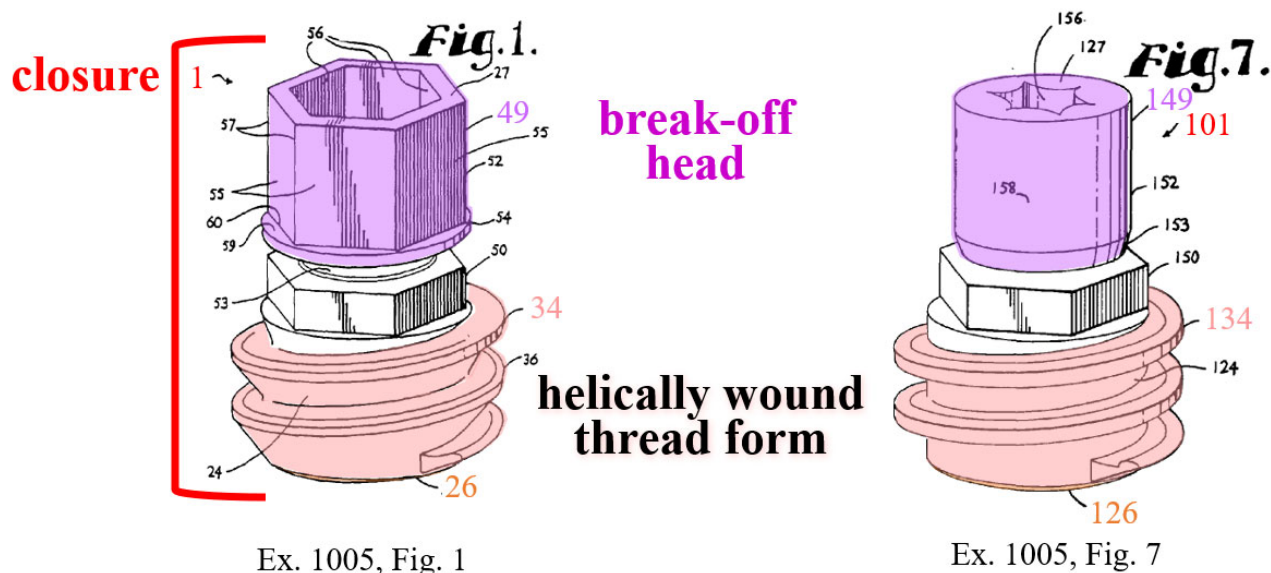
'477 Publication



Ex. 1005, Fig. 6

discloses that the guide and advancement structure could be any one of a variety of different thread types, including a reverse angle thread. *Id.*, ¶[0030].

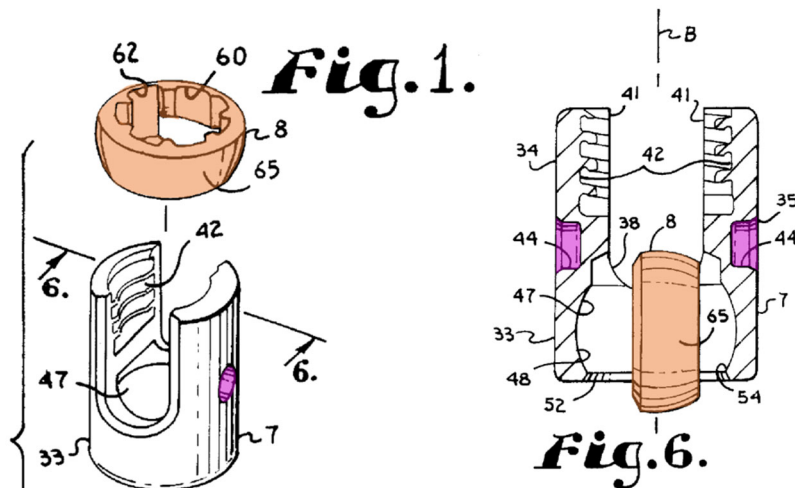
139. The '477 Publication discloses two preferred embodiments of the closure as shown and annotated below.



140. In the first embodiment, the '477 Publication discloses that the body 24 of closure 1 is cylindrical and has a central axis of rotation. *Id.*, ¶[0029], Fig. 1. 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. *Id.*, ¶[0030]; *see also, e.g., id.*, Fig. 1. 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.” *Id.*, ¶[0032]; *see also id.* ¶¶[0033], [0043], Figs. 1, 7.

141. The second embodiment of the closure 101 in the '477 Publication teaches many of the same elements as the first embodiment. *See id.*, ¶[0039] (incorporating by reference the description of the first embodiment into the second embodiment); *see also id.*, ¶[0038]-[0045]. The primary difference between the embodiments is the shape of the closure break-off heads 49 and 149. *Id.*, ¶[0033] (hexagonal), ¶[0043] (cylindrical); *compare id.* Fig. 1, with *id.* Fig. 7. The '477 Publication teaches that the closure 101 is cylindrical and has a central axis of rotation. *Id.*, ¶[0040], Figs. 7, 8. 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. *Id.*, ¶[0041]; *see also, e.g., id.*, Fig. 7, 8.

142. The '477 Publication further incorporates by reference U.S. Pat. No. 6,716,214 (“the '214 Patent”), which issued in 2004. *Id.*, ¶[0027]. 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. Ex. 1013, Figs. 1, 6. 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.” Ex. *Id.*, 7:2-4, Figs. 1, 6.



143. 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.*, ¶[0007] (“A closure and locking member is provided for a medical implant. The implant may be a bone screw, hook, or other open or closed element used in a spinal implant system for providing support or reconstruction to the spine, such as a transverse connector. A typical implant for use with a closure of the invention includes a receiver having a pair of spaced arms with an open channel located therebetween.”); *id.*, Abstract (“A closure for use in conjunction with an open receiver of a medical implant ... ”); *id.*, ¶[0025] (“[T]he closure 1 is shown utilized to close a top of a polyaxial medical implant bone screw, generally 5[.]”).

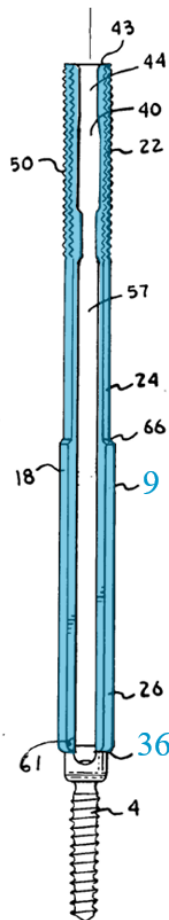
C. Overview of the '391 Publication

144. The '391 Publication, EX1009, was published on March 30, 2006, which is more than three years before the earliest effective filing date of the '479 Patent. I understand that the '391 Publication is therefore prior art to the '479 Patent under 35 U.S.C. § 102(b). The '391 Publication discloses attachable/detachable guide tools that could be used to transfer a closure top from the guide tool into the receiver head via corresponding discontinuous helically wound threads on the guide tool and on the receiver head.

145. 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.” EX1009, Abstract. Therefore, in my opinion the '391 Publication is in the same field of endeavor as, and is analogous art to, the '479 Patent. *Compare Id.*, ¶[0007] (“A tool assembly and a set of tools according to the invention is provided for percutaneously implanting bone screws and an associated spinal rod in a patient.”), *with* EX1001 at 1:14-18.

146. As shown in excerpted and annotated Figure 1 below, 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*

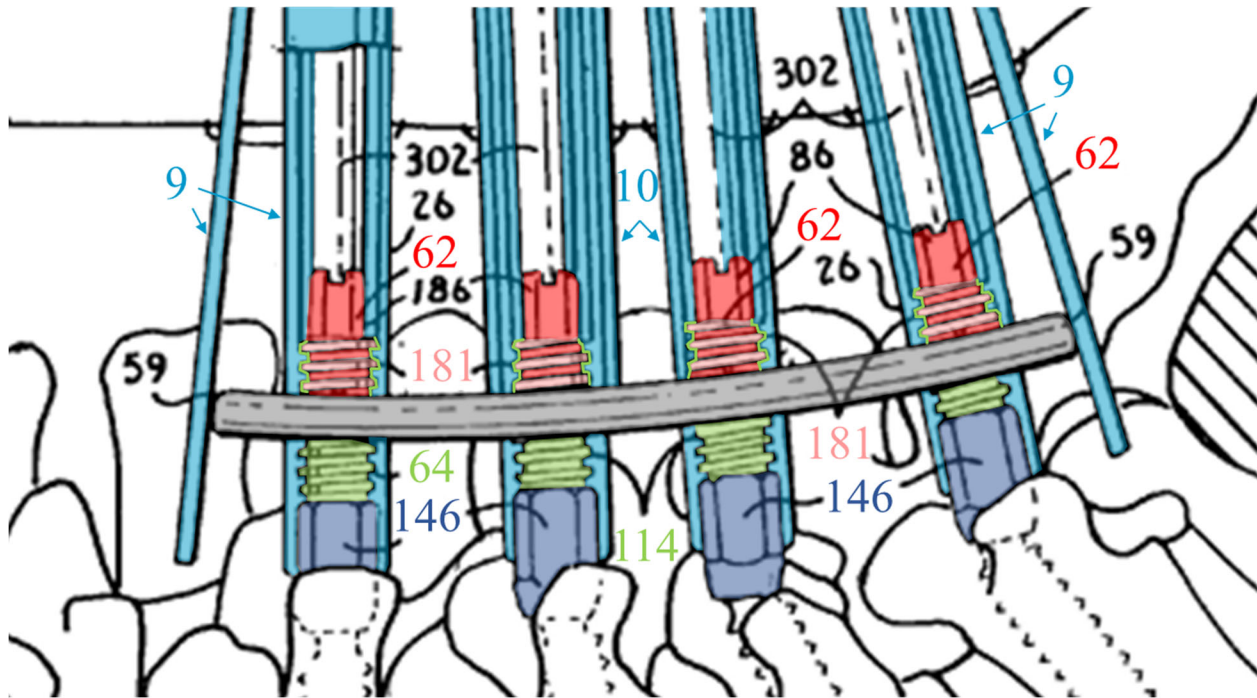
techniques.” EX1009, ¶¶[0002], [0082], Fig. 1. The bottom interior surfaces of the guide tools include projections for interacting with grasping features on the exterior surfaces of the receiver. *Id.*, ¶¶[0105]-[0116]. Also “near the bottom 36 of each of the end guides 9 on inner surfaces of the side 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.” *Id.*, ¶¶[0092], [0103]; *see also id.*, Fig. 9.



Id., Fig. 1.

147. 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.” *Id.*, ¶[0171]; *see also id.* Fig. 42. “[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. *Id.*, ¶[0172]; *see also id.*, ¶[0120] (“In particular, the guide and advancement structures 64 and 114 on the respective tools 9 and 10 are located and positioned to align with the guide and advancement structure 183 on the insides of the bone screw arms 150 and 151, as shown in FIG. 42 and pass the closure top 62 therebetween while allowing the closure top 62 to continue to rotate and to continuously apply force to the rod 8, so as to aid in seating the rod 8 in the bone screw head 146.”), Fig. 43. 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.” *Id.*, ¶[0173].

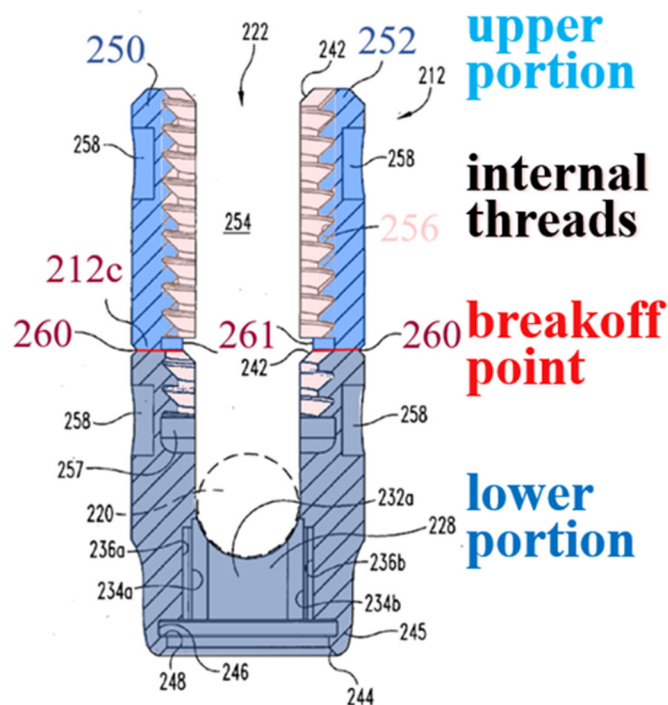
148. The guide tool (shown in **light blue** below) and how it interacts with the closure (**red**) and the receiver (**blue**) are shown below in annotated and excerpted Figure 42, which illustrates “an intermediate stage of implanting a rod,” *id.*, ¶[0062]:



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

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

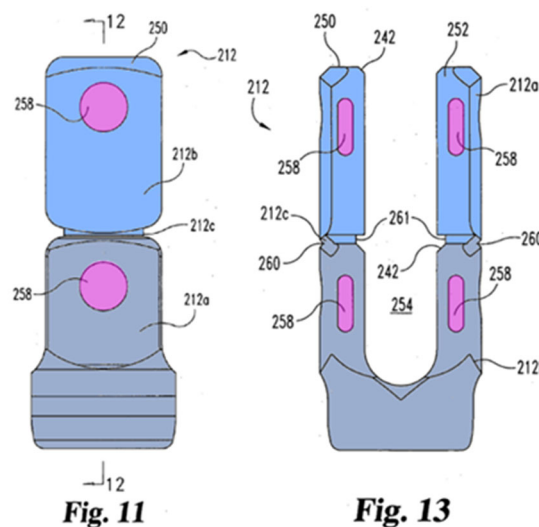
member 212, and a portion of each branch 250, 252 forms at least a part of upper portion 212b of receiver member 212.” *Id.*, ¶[0052]. Johnson discloses that “internal threads 256 are formed in branches 250, 252 through substantially the entire length of upper portion 212b and into lower portion 212a.” *Id.* Johnson discloses that the threads 256 “can be a reverse angle thread.” *Id.* Johnson further discloses that the “[t]hreads 256 may [be] configured so that they are essentially continuous from upper portion 212b to lower portion 212a” so that a compression member “can be inserted into upper portion 212b and moved down to lower portion 212a.” *Id.*, ¶[0053].



152. Johnson 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.” Id., ¶[0056]. Johnson discloses that, “[o]nce separated, upper portion 212b may be removed from the surgical site and discarded.” *Id.*

153. As further shown in Figures 11 and 13, Johnson discloses tool attachment grooves 258 (purple) “which allow the surgeon to grip receiver member 212 (on either or-both of portions 212a, 212b) with an appropriate forceps, wrench or other gripping or turning tool.” *Id.*



¶¶[0052]-[0053], Figs. 11, 13. 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.” *Id.*, ¶[0055]. Johnson discloses that a compression member is then “thread into threads 256, forcing elongated member 220 further down in channel 254” so that the “elongated member 220 is forced all the way through upper portion 212*b*, into lower portion 212*a*, and against a crown member and/or anchor member in chamber 228.” *Id.*

IX. MOTIVATION TO COMBINE

A. Motivation to Combine Boschert and the '477 Publication

154. In my opinion, it would have been obvious to a POSA to combine the teachings of Boschert with the various thread types and breakoff closure top of the '477 Publication before the priority date of the '479 Patent.

155. As set forth above, Boschert is in the exact same field as the '479 Patent—the design of polyaxial pedicle screw and rod implant systems to treat spinal column disorders. *Supra* Section VIII.A. Boschert teaches a polyaxial pedicle screw including a U-shaped receiver for capturing a rod once its opening has been closed with a setscrew. EX1006, 6:20-24, Fig. 1. Boschert further teaches advantages provided by certain features of closure tops (setscrews) used with polyaxial pedicle screws. In particular, Boschert disclose that it would be advantageous to design closure tops with a double lead in order “to start more easily than with a single lead,” *id.*, 7:21-23, and discloses symmetrical threads on the receiver to mate simultaneously with the double-lead threads on the setscrew, *id.*, Figs. 3 & 15. Boschert also expressly contemplates potential modifications to its disclosed closure top, 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.” *Id.*, 7:58-62.

156. The '477 Publication is also in the exact same field as the '479 Patent, as set forth above. *Supra* Section VIII.B. The '477 Publication teaches closure tops for use with conventional bone screw receivers, stating, “A closure and locking member is provided for a medical implant. The implant may be a bone screw, hook, or other open or closed element used in a spinal implant system for providing support or reconstruction to the spine, such as a transverse connector. A typical implant for use with a closure of the invention includes a receiver having a pair of spaced arms with an open channel located therebetween.” EX1005, ¶[0007]; *see also id.*, Abstract (“A closure for use in conjunction with an open receiver of a medical implant...”), ¶[0025] (“the closure 1 is shown utilized to close a top of a polyaxial medical implant bone screw, generally 5.”), ¶[0027] (“[I]t is foreseen that the closure 1 may be used in conjunction with any type of medical implant having an open or closed head.”). Like Boschert, the '477 Publication specifically teaches using its claimed closure top with a polyaxial bone screw with a U-shaped receiver. *Id.*, ¶[0025], Figs. 5, 6; EX1006, 6:24-48, 7:12-15. Therefore, in my opinion, 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. The closure of the '477 Publication includes a breakoff top or head for a lower-profile closure and for tightening the closure top 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].

157. As explained further below, 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. 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 closure tops. A POSA would have been motivated to use the dual-start threads of Boschert in combination with the thread types discussed in the '477 Publication. Further, in making this combination, a POSA would have been motivated to use a breakoff closure top as taught in the '477 Publication.

1. Motivation to Use Known Thread Types

158. In my opinion, 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. As set forth above, 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. *Supra* Section VI.B.1.b. 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]. 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* Section VI.B.1.a. Therefore, a 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; *supra* Section VI.B.1.b, as well as retaining Boschert’s dual starts and their the known benefits, including starting more easily, as disclosed in Boschert, and balancing rotation forces and speeding insertion, as was well-known in the art, *supra* Section VI.B.1.a.; EX1026, 13:35-41; EX1014 at 4.

159. 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. *Supra* Section VI.B.1.b. 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 closure tops. *Id.*

2. Motivation to Use Known a Breakoff Head

160. 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 '477 Publication's express invitations to use its closure top in combination with known receivers, such as those set forth in Boschert. EX1005, ¶¶[0007], [0025], [0027]. In addition, a POSA would have understood, including from the '477 Publication's teachings, that breakoff heads such as those disclosed in the '477 Publication have known advantages, including resulting in a lower-profile closure (after the breakoff head is removed) and the ability to break off the closure head at a predetermined torque, thereby ensuring that the closure top would be tightened to the desired level, but not over torqued, when it was installed. *Id.*, ¶¶[0009], [0011], [0035]; *supra* Section VI.B.2.a. A POSA would have also been motivated to so modify Boschert to take advantage of these benefits, including ensuring that the closure top would be tightened to the desired level, but not over torqued, when it was installed; increasing patient safety due to use of a low-profile device; and increasing ease of correct torquing by eliminating the need for a torque wrench to measure the tightening. EX1018, 1:37-40, 2:34-39, 3:6-19; EX1016, 4:4-17; *supra* Section VI.B.2.a.

161. A POSA would have had an expectation of success with this combination, at least because breakoff closure tops, and techniques for manufacturing them, were well known in the art, readily available, and had been used in multi-axial pedicle screws. *Supra* Section VI.B.2.a. 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 closure tops. *Id.*

B. Motivation to Combine the '391 Publication with Boschert

162. In my opinion, a POSA implementing the closure top 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. 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.

163. 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, Abstract; *supra* Section VIII.C. As in Boschert, the bone screw of the '391 Publication has a U-shaped open receiver that captures a rod when a closure top is threaded into it. EX1009, ¶¶[0116], [0118], Figs. 12, 46. 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. *Supra*, Section VIII.C. 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, 6:15-19. 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. 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. *See supra* Section VIII.C. Therefore, in my opinion, 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* Section VI.B.2.b.i.

164. 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. *Id.* Such a combination of

familiar elements using known methods would yield predictable results, as it was well known to a POSA before the priority date of the '479 Patent that guide tools provided these advantages and could be successfully used with polyaxial bone screw receivers. *Id.*

165. Moreover, a POSA would have been motivated to combine the teachings of the '391 Publication with 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.*

C. Motivation to Combine Johnson with Boschert.

166. In my opinion, a POSA implementing the closure top 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. 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.

167. Like Boschert, Johnson is directed to a polyaxial pedicle screw implant that receives a rod member. EX1008, Abstract; *supra* Section VIII.D. As in Boschert, the bone screw of Johnson has a U-shaped open receiver that captures a rod when a closure top is threaded into it. *Supra* Section VIII.D. In my opinion, 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, *id.*, and as was otherwise known in the art, *supra* Section VI.B.2.b.ii.

168. For example, Johnson teaches that break-off extension arms provide the benefit of simplifying the introduction of an elongate member or rod. Johnson discloses that, “[w]hen the surgeon wishes to insert an elongated member 220 into receiver member 212, he or she need not bend it or use a special reducing tool to insert it into the lower end of a receiving channel. Rather, he or she places a portion of the elongated member 220 into channel 254 in upper portion 212*b* of receiver member 212.” EX1008, ¶[0055]. Johnson discloses that a compression member is then “thread into threads 256, forcing elongated member 220 further down in channel 254” so that the “elongated member 220 is forced all the way through upper portion 212 *b*, into lower portion 212 *a*, and against a crown member and/or anchor member in chamber 228.” *Id.* Johnson also discloses that “[o]nce separated, upper portion 212*b* may be removed from the surgical site and discarded.” *Id.*, ¶[0056]. 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. *Supra*, Section VI.B.2.b.ii.

169. 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 and had been successfully used in medical implant devices. *Id.* 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.*

170. 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.*

X. SPECIFIC OPINIONS RELATING TO GROUNDS FOR UNPATENTABILITY.

A. Ground 1: Claims 1, 5, 10, 14, and 18–21 Are Anticipated or Rendered Obvious by Boschert

1. Claim 1

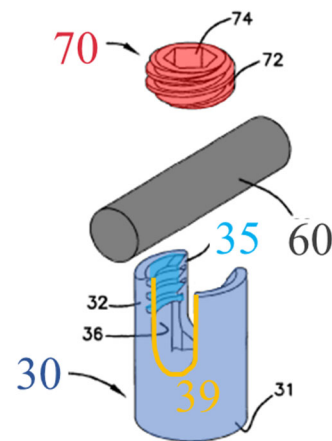
- a. 1[Preamble]: “In a medical implant having a substantially cylindrical closure member and a receiver member having first and second spaced arms forming an open channel, the closure member having**

an axis of rotation for closing the open channel, the improvement comprising:

171. To the extent the preamble is limiting, in my opinion, Boschert discloses this limitation. Boschert is titled “Spinal Fixation Implant Assembly” and expressly discloses a medical implant. EX1006, Abstract (“An orthopedic fixation device for securing a rod to a bone is provided.”), 1:34-37 (“The present invention generally involves a technique commonly referred to as spinal fixation whereby surgical implants are used for fusing together and/or mechanically immobilizing vertebrae of the spine.”), 4:13-16 (“an orthopedic fixation device 10”).

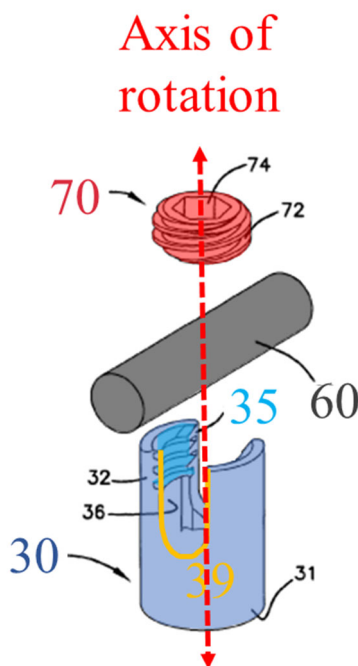
172. Boschert expressly discloses a receiver member having first and second spaced arms forming an open channel. Specifically, as shown in annotated Figure 1, Boschert discloses “a receiver 30 having a top portion 32 defining a saddle 39 (i.e., a pocket) [yellow] for receiving a rod 60 [gray].”

EX1006, 4:16-18, Figs. 1, 3, 4, 7, 12, 14, 15. The 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.” *Id.* 6:11-23, Figs. 1, 3, 4, 7, 12, 14, 15.

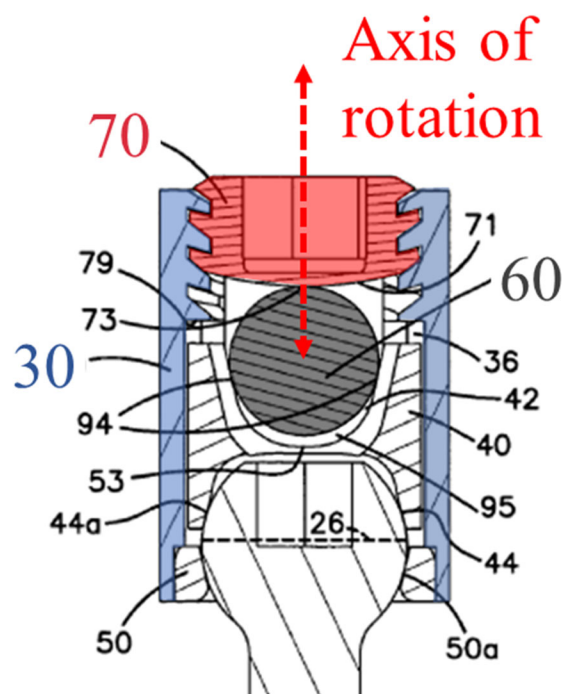


173. Boschert also expressly discloses an implant with a substantially cylindrical closure member having an axis of rotation for closing the open channel.

Specifically, Boschert discloses a substantially cylindrical “fastener such as a setscrew 70 [red] for clamping the rod 60 within the saddle 39 of the receiver 30.” *Id.*, 4:26-28, Figs. 1, 2, 3, 4, 7, 12, 14, 15. The disclosed “setscrews 70 are threaded into the saddle 39 thereby forcing the rods 60 to seat against the top sides of the seat structures 40.” *Id.*, 4:47-50; *see also id.* 6:20-28; Figs. 1, 3, 4, 7, 15. Boschert also discloses that the set screw has an axis of rotation by describing that “the setscrews 70 are threaded into the saddle 39,” as shown in annotated Figures 1 and 3 below. *Id.*, 4:48-49, Figs. 1, 3. A POSA would have understood that, by threading set screw into the saddle, Boschert disclosed an axis of rotation, as shown in annotated Figures 1 and 3 below.



EX1006, Fig. 1

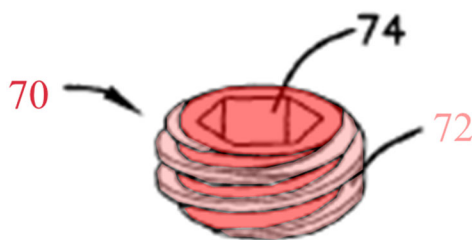


EX1006, Fig. 3

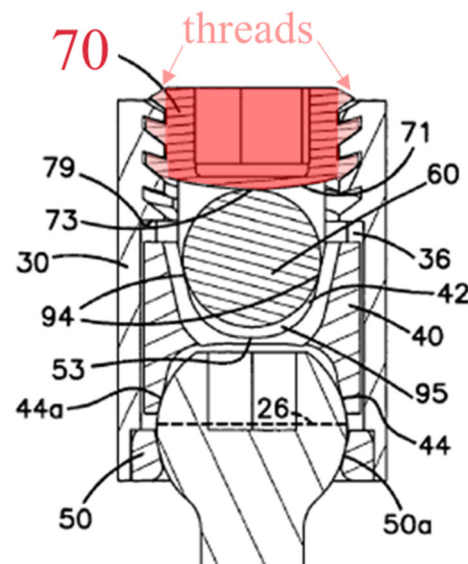
174. In my opinion, based on the above disclosures, Boschert discloses this limitation.

- 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”

175. In my opinion, Boschert discloses this limitation. Boschert expressly discloses first and second helically wound forms located on the closure member. Specifically, Boschert discloses that a setscrew 70 is “threaded into the saddle 39” by exterior threads 72. EX1006, 6:20-28. Annotated Fig. 1 and Annotated Fig. 3 (in profile) below show that the exterior threads 72 of the setscrew 70 spiral around the cylindrical body of the closure top and thus are helically wound:

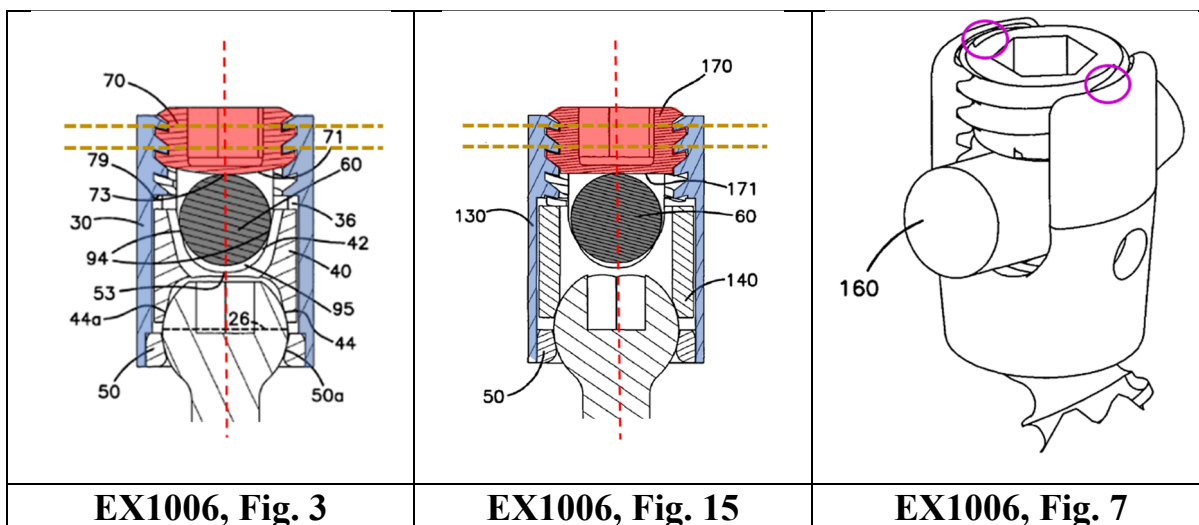


EX1006, Fig. 1



EX1006, Fig. 3

176. Boschert also expressly discloses first and second helically wound forms, or double threads, on the closure top. 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.” *Id.*, 7:21-23. This is consistent with a POSA’s understanding of the known benefits of multi-start threads. *See supra* Section VI.B.1.a. Boschert also expressly discloses first and second helically wound forms on the closure by showing in figures 3 and 15, excerpted and annotated below, parallel threads on each side of a closure viewed in profile, each of which are a separate thread. And figure 7, annotated below, shows two thread ends (circled in purple). A POSA would have understood and expected that each of the double-start threads would have the identical length, and therefore understand that diametrically opposed thread ends (below in purple) are the result of diametrically opposed thread starts.

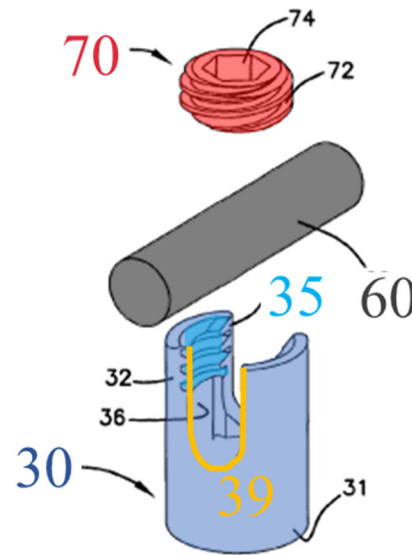


177. In my opinion, Boschert also necessarily discloses that each thread on the double-thread closure would have a start, because any thread must have a start and an end. *Supra* Section VI.B.1. Thus a POSA would have understood that for a closure with two threads, each thread must have a start.

178. In my opinion, based on the above disclosures, Boschert discloses this limitation.

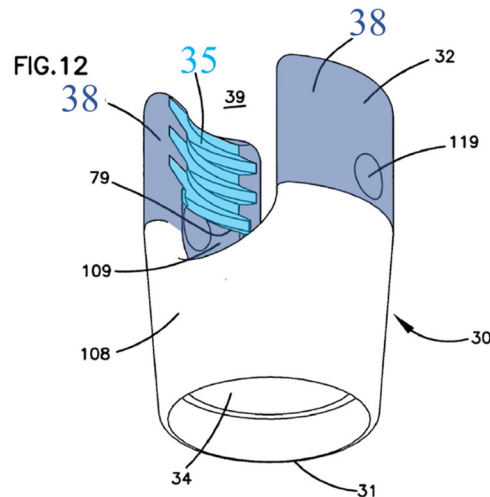
- c. **1[B1]: “b) a first discontinuous helically wound structure on the receiver first arm and a second discontinuous helically wound structure on the receiver second arm and**

179. In my opinion, Boschert discloses this limitation. 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. Specifically, Boschert discloses a receiver 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 Ex. 1006, Fig. 1 threads 35 that mate with corresponding exterior threads 72 of the setscrew 70 to allow the setscrew 70 to be threaded into the saddle 39 to lock the rod 60 and screw in place.” EX1006, 6:11-28, Figs. 1, 3, 4, 12, 14, 15. The threads are helically

wound. *Id.*, Figs. 1 and 3. Moreover, as shown in annotated Figure 1 above and in Figure 12 below, because the threads on the receiver are interrupted by a channel, Boschert discloses discontinuously helically wound threads.



A POSA would have therefore understood that Boschert discloses discontinuous helically wound structures on each receiver leg.

180. In my opinion, based on the above disclosures, Boschert discloses this limitation.

- 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.”**

181. In my opinion, Boschert discloses this limitation. Boschert expressly teaches double threads on the closure top, or set screw, and specifically that a

“double lead [] allow[s] the setscrew 70 to start more easily than with a single lead.”

EX1006, 7:21-23.

182. In my opinion, Boschert discloses to a POSA that the start structures of the disclosed double threads would simultaneously mate with the interior threads on the receiver legs. Specifically, as seen in annotated Figures 3 and 15, below, Boschert shows both that the threads on either side of the **receiver 30** are symmetrically and diametrically opposed to each other across the longitudinal axis and that the threads on either side of the **closure 70** are symmetrically and diametrically opposed to other across the longitudinal axis, as demonstrated by the horizontally parallel threads (**yellow lines**) on each side of the receiver and closure. EX1006, Figs. 3, 15. This positioning of the receiver threads and the closure threads results in simultaneous starting and mating of the two closure thread starts with the two receiver threads.

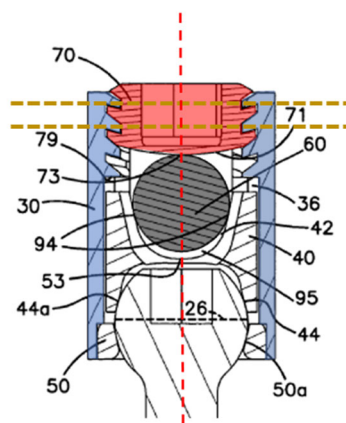


Fig. 3

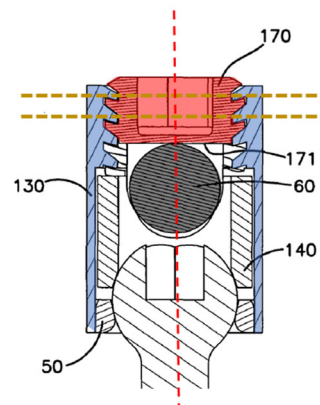
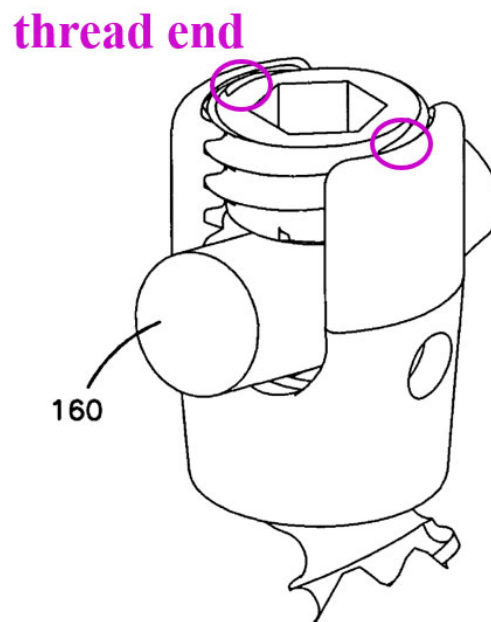


Fig. 15

183. Boschert's disclosure of diametrically opposed thread starts is also supported by Figure 7. As annotated below, Figure 7 shows, at the top of the closure top, that the **trailing ends** of the double lead thread are diametrically opposed. A POSA would have understood and expected that each of the double-start threads would have the identical length, and therefore understand that diametrically opposed **thread ends** are the result of diametrically opposed thread starts.



184. Further, based on the knowledge of a POSA of the conventional manner of making double start threads before January 10, 2012, a POSA would have understood Boschert to have disclosed diametrically opposed thread starts. *See supra* Section VI.B.1.a; 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. 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. This, 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. This understanding is also confirmed by the ’479 Patent itself, which shows the same symmetrical threads on the receiver. *E.g.*, EX1001 Figs. 3, 8, 9, 11-15.

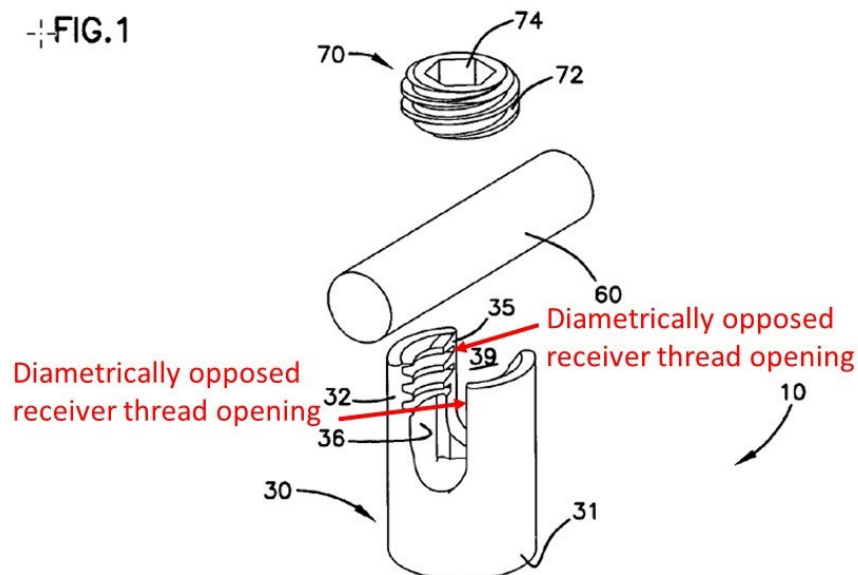
185. Based on Boschert’s disclosures of diametrically opposed thread starts and of symmetrically and diametrically opposed receiver threads across the longitudinal axis, a POSA would have understood that Boschert expressly disclosed simultaneous mating of the first start with the arm first helically 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. In particular, Boschert expressly disclosed the “double lead” and receiver structure required to facilitate simultaneous mating of the double starts. Boschert further refers to the benefits of this simultaneous threading: “*a double lead* to allow the setscrew 70 to start more easily than with a single lead.” EX1006, 7:21-23. In my opinion, to achieve Boschert’s disclosed benefit of a double lead in view of

Boschert's disclosed receiver member's structure, a POSA would have understood that Boschert also disclosed 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.

186. To the extent that Boschert does not expressly disclose 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, Boschert necessarily discloses this element. 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 starting end, and (3) this positioning would result in simultaneous mating of each receiver thread start with the first and second receiver thread. This understanding would have been further reinforced by the conventional manner of making dual start threads, which includes using diametrically opposed thread starts as discussed above. EX1014 at 3; EX1026, 13:35-41; *supra* Section VI.B.1.a.

187. To the extent that Boschert does not expressly or inherently disclose 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, in my opinion, it would have been obvious to a POSA before the priority date of the '479 Patent to use closure double-thread starts that mate simultaneously with a first and second receiver arm in Boschert. Specifically, a POSA would have understood that the thread starts on the closure top would be designed to be diametrically opposed to each other and that each of the corresponding threads at the edge of the opposed receiver arms would also be diametrically opposed, as illustrated in Fig. 1 below.

EX1006, Fig. 1.



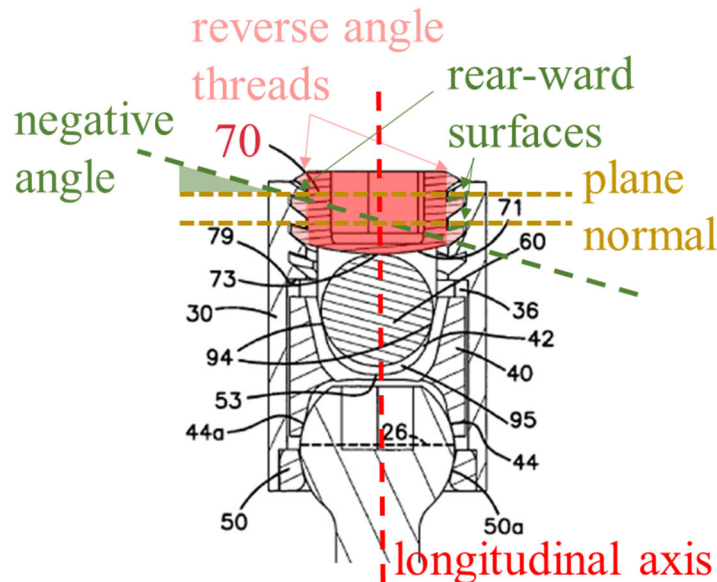
This design configuration can only result in each of the thread starts on the closure top simultaneously mating with the receiver threading. Furthermore, of all the examples that I have seen of double-start threads in a wide variety of applications, I have never seen an example where the two thread starts are not located diametrically opposite each other. *Supra* Section VI.B.1.a. Indeed, use of diametrically opposed starts is the standard way to manufacture dual start threads, and such a configuration would not facilitate threading if the starts did not simultaneously mate with the receiving threads. *Id.* For all of these reasons, in my opinion, Boschert discloses and renders obvious 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. In my opinion, based on the above disclosures, Boschert discloses or renders obvious this limitation.

188. Accordingly, in my opinion Boschert anticipates and/or renders obvious every element of Claim 1.

2. Claim 5

189. All of the limitations of Claim 5 are recited in Claim 1, except Claim 5 further recites: [A5] “wherein the first and second helically wound forms are reverse angle threads.” In my opinion Boschert discloses, or at least renders obvious, this claim.

190. Boschert expressly discloses first and second helically wound forms on the closure member that are reverse angle threads. The threads disclosed in Figures 3, 4, and 15 of Boschert are reverse-angle threads for a closure. EX1006, Figs. 3, 4, 15. In particular, as shown in annotated Figure 3, because the angle between a plane normal to the longitudinal axis and rearward surface, or pressure angle, is negative, a POSA would have understood that Boschert expressly disclosed reverse angle threads on its closure. *See supra* ¶67 (discussing Morrison).



Ex. 1006, Fig. 3

191. Further, a POSA would have understood that it would be advantageous to use a variety of helically wound guide and advancement structures, including a reverse-angle threads, on a closure and that such structures were well known in the mechanical arts 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; *supra* Section VI.B.1.b. The '479 Patent itself admits that “[k]nown closures include . . . a variety of single start helically wound guide and advancement structures including, for example, thread forms having . . . reverse-angle . . . thread forms” EX1001, 1:53-2:4. In my opinion, based on the above disclosures, 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. *See supra* Section VI.B.1.a.

192. Accordingly, in my opinion Boschert anticipates and/or renders obvious every element of Claim 5.

3. Claim 10

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

193. To the extent the preamble is limiting, in my opinion Boschert discloses this limitation. In my opinion, Boschert discloses, or renders obvious, this limitation for the reasons set forth above with respect to Limitation 1[Preamble], which claims “a medical implant.” *See supra* Section X.A.1.a. Boschert moreover discloses this limitation because Boschert is titled “Spinal Fixation Implant Assembly” and discloses a spinal fixation technique “whereby surgical implants are used for fusing together and/or mechanically immobilizing vertebrae of the spine.” EX1006, 1:34-37.

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”

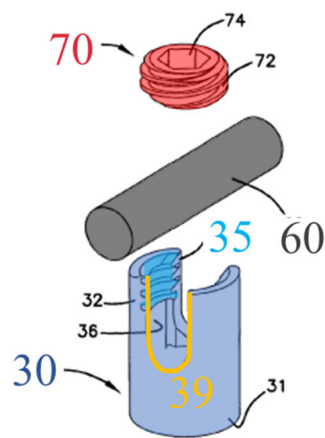
194. In my opinion, Boschert discloses this limitation. While worded slightly differently, this limitation recites the same requirements of the receiver as Limitations 1[Preamble] and 1[B1], except the limitation specifies a receiver having “a body,” adds that the channel is “for receiving a longitudinal connecting member,” and specifies that the arms have “inwardly facing surface[s]” with the discontinuously helically wound guide and advancement structure. In my opinion, a POSA would have understood that a “guide and advancement structure” was

substantially identical to a “helically wound structure.” In my opinion, Boschert discloses this limitation for the reasons set forth above and as further discussed below. *See supra* Sections X.A.1.a, X.A.1.c.

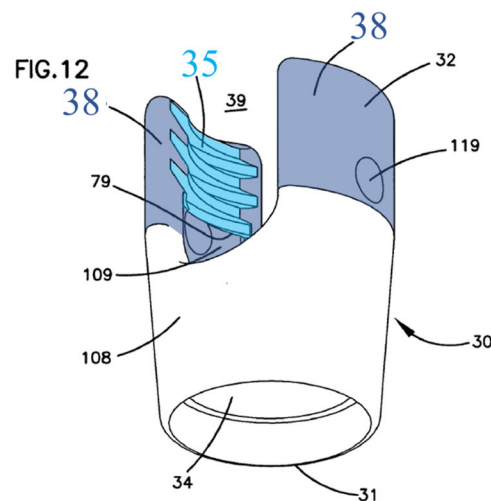
195. As discussed above, Boschert discloses a receiver having a pair of upstanding spaced arms that form a channel. *Supra* Section IX.A; *see also* EX1006, 4:16-18, 6:11-28, Figs. 1, 3, 4, 7, 12, 14, 15. The receiver 30 in Boschert further has a body at “a bottom portion 31.” *Id.*, 4:16-19 (“The fixation device 10 includes a receiver 30 having a top portion 32 defining a saddle 39 (i.e., a pocket) for receiving a rod 60, and a bottom portion 31 adapted for receiving a head 23 of a bone fastener such as a bone screw 20.”). Therefore, Boschert explicitly discloses a receiver having a body and a pair of upstanding spaced arms forming a channel.

196. Moreover, Boschert explicitly discloses “a receiver 30 having a top portion 32 defining a saddle 39 (i.e., a pocket) for receiving a rod 60.” *Id.*, 4:16-18. A POSA would have understood that the rod 60 was a longitudinal connecting member that was received in Boschert’s channel. As shown in annotated Figures 1 and 12 below, 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. The legs 38 also preferably 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.” EX1006, 6:11-28, Figs. 1, 12. Thus, Boschert also discloses that each of its receiver arms (legs 38) has an inwardly facing surface (i.e., the inwardly facing surfaces of legs 38) with a first discontinuous helically wound guide and advancement structure (**light blue**) located thereon.



Ex. 1006, Fig. 1



197. In my opinion, based on the above disclosures, Boschert discloses this limitation.

- 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.”**

198. In my opinion, Boschert discloses this limitation. While worded slightly differently, this limitation recites the same requirements of the closure as Limitations 1[Preamble] and 1[A1], describing the helically wound guide and

advancement structure on the closure as having “at least two starts” instead of “a first start” and “a second start,” as in Claim 1. For the reasons discussed above, *supra* Sections X.A.1.a, X.A.1.b, Boschert discloses a closure structure having a cylindrical body and a second helically wound guide and advancement structure. *See* EX1006, 4:26-28, 4:47-50, Figs. 1, 2, 3, 4, 7, 12, 14, 15. For the reasons discussed above, *supra* Section X.A.1.b, Boschert discloses a closure structure having a second helically wound guide and advancement structure. *See* EX1006, 6:20-28, Figs. 1, 3. Moreover, for the reasons discussed above, *supra*, Section X.A.1.b, in my opinion, Boschert discloses two starts and so thereby also discloses a closure with at least two starts. *See* EX1006, 7:21-23, Figs. 3, 7, 15. Further, in my opinion, a POSA would have understood that where two starts can be used, any multi-start screw can be used, as the conventional principles for threads with more than one start were the same whether the thread had two, three, or more starts. *Supra* Section VI.B.1.a; EX1014 at 3.

199. In my opinion, based on the above disclosures, Boschert discloses this limitation.

200. Accordingly, in my opinion Boschert anticipates every element of Claim 10.

4. Claim 14

201. All of the limitations of Claim 14 are recited in Claim 10, except Claim 14 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 requirements 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. Boschert discloses a dual-start closure, which is a closure with at least two starts. EX1006, 7:21-23, Figs. 3, 7, 15. In my opinion, Boschert discloses this limitation for the reasons set forth above. *See supra* Section X.A.2. Accordingly, as set forth above, in my opinion, Boschert anticipates and/or renders obvious every element of Claim 14.

5. Claim 18

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

202. To the extent the preamble is limiting, in my opinion, Boschert discloses this limitation for the reasons set forth above with respect to the preamble of Claim 10, which claims “a medical implant.” *See supra* Section X.A.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”

203. While worded slightly differently, this limitation recites the same requirements of the receiver as limitations 1[Preamble], 1[B1], and 10[B3]. As I

discussed above, *supra* Sections X.A.1.a, X.A.1.c, X.A.3.b, Boschert discloses an open receiver member with spaced arms having inwardly facing surfaces, each with a helically wound guide and advancement form located thereon. *See* EX1006, 4:16-18, 6:11-28, Figs. 1, 3, 4, 7, 12, 14, 15. In my opinion, Boschert discloses, or renders obvious, this limitation for the reasons set forth above. *See supra* Sections X.A.1.a, X.A.1.c, X.A.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.”

204. In my opinion, Boschert discloses this limitation. While worded slightly differently, this limitation recites the same requirements of the closure as Limitations 1[Preamble], 1[A1], and 10[A8], describing the helically wound guide and advancement structure on the closure as “multi-start” instead of as having “a first start” and “a second start,” as in Claim 1, or “at least two starts,” as in Claim 10. This limitation also adds that the closure is “rotatably mounted on the receiver member at the spaced arm inwardly facing surfaces.”

205. Regarding the limitation that the closure is “rotatably mounted on the receiver member at the spaced arm inwardly facing surfaces,” Boschert discloses this limitation. Specifically, Boschert explicitly discloses that “setscrews 70 are threaded into the saddles 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; *id.*, Figs. 1, 3, 4,

7, 15. In my opinion, a POSA would have understood that a setscrew that is threaded into a receiver member, as disclosed by Boschert, was a closure that is rotatably mounted on the receiver member at the spaced arm inwardly facing surfaces.

206. Regarding the further limitation that the closure member is a multi-start closure member, for the reasons discussed above, in my opinion, Boschert discloses two starts and so thereby also discloses a multi-start closure member. *See supra* Sections X.A.1.a, X.A.1.b, X.A.3.c. Indeed, a POSA would have understood that a multi-start closure member was simply a closure with two or more starts. *See* EX1024 at 10; EX1022 at 8. Further, a POSA would have understood that where two starts can be used, any multi-start screw can be used, as the conventional principles for threads with more than one start were the same whether the thread had two, three, or more starts. EX1014 at 3.

207. In my opinion, based on the above disclosures, Boschert discloses this limitation.

208. Accordingly, in my opinion, Boschert anticipates every element of Claim 18.

6. Claim 19

209. All of the limitations of Claim 19 are recited in Claim 18, except Claim 19 further recites: [A10] “wherein the multi-start closure is a double-start closure.” While worded slightly differently, this limitation recites the same requirements of

the closure as limitation 1[A1], which recites a closure member with two helically wound forms, the first having a first start and the second having a second start—in other words, “a double-start closure.” In my opinion, Boschert discloses this limitation for the reasons set forth above. *See supra* Section X.A.1.b. Accordingly, as set forth above, in my opinion, Boschert anticipates every element of Claim 19.

7. Claim 20

210. All of the limitations of Claim 20 are recited in Claim 18, except Claim 20 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.” In my opinion Boschert discloses all the features recited in Claim 20.

211. This limitation recites the same start structure requirements as Claim 5 and Claim 14, which call for reverse angle threads, but does so in the context of a “multi-start” closure and adds further options for the type of thread. Use of only one form, however, is required, as the limitation states that each form must only be “one of” the listed options. In my opinion, Boschert discloses this limitation for the reasons set forth above. *See supra* Sections X.A.2, X.A.4.

212. This limitation further recites that “the form mat[es] with the first helically wound guide and advancement form.” While worded slightly differently,

this limitation recites the same requirements of the closure as Limitation 1[C], which requires that the threads on the closure mate with the threads on the receiver. *See supra* Section X.A.1.d.

213. Accordingly, as set forth above, in my opinion, Boschert anticipates every element of Claim 20.

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:”**

214. To the extent the preamble is limiting, in my opinion Boschert discloses this limitation. Boschert discloses an orthopedic fixation device 10 (i.e., polyaxial bone anchor) that includes a bone screw 20 (i.e., shank) with a polyaxial configuration, EX1006, 4:44-47, 5:5-11, used in a medical device that also has a receiver 30, *id.*, 4:13-28. “The *polyaxial* configuration of the *bone screws* 20 allow the receivers 30 to *pivot* relative to the bone screws 20 to facilitate inserting the rods 60 in the saddles 39 of the receivers 30.” *Id.*, 4:44-47; *see also id.*, 2:42-45 (“Another inventive aspect of the disclosure relates to orthopedic fixation systems that secure polyaxial anchors by providing substantially full rings of contact with the heads of the anchors regardless of the angular orientations of the anchors.”), 5:5-11 (“The spherical head 23 is shaped to allow a polyaxial freedom of movement for the screw

20. In this manner, the screw 20 can have a range of motion throughout a 360-degree pattern from a longitudinal axis of the receiver 30. Polyaxial freedom of movement of the screw 20 provides the surgeon with a wide range of placement angles, thereby facilitating the rod placement process.”), Fig. 4. Boschert further discloses that “[c]ontinued tightening of the setscrews 70” “caus[e] the heads 23 of the bone screws 20 to be clamped between the bottom sides of the seat structures 40 and the retainers 50, and also caus[e] the rods 60 to be clamped between the setscrews 70 and the top side of the seat structures 40” and that “the screw heads 23 are preferably clamped with sufficient force to prevent the screw heads 23 from pivoting relative to the receivers 30.” *Id.*, 4:50-60. Thus, Boschert discloses that its shank is pivotable with respect to the receiver prior to locking of a position of the shank with respect to the receiver.

215. Further, as the '479 Patent concedes, at least as of January 10, 2012, “[b]one anchors, such as bone screws and hooks,” were well-known. EX1001, 1:21-24. Known bone anchors included polyaxial bone screw assemblies. *Id.*, 1:37-40.

216. In my opinion, based on the above disclosures, Boschert discloses this limitation.

- 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.”

217. While worded slightly differently, this limitation recites the same requirements of the receiver 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. As I discussed above, *supra*, Section X.A.5.c, a POSA would have understood that a multi-start closure member was simply a closure with two or more starts. *See* EX1024 at 10; EX1022 at 8. In my opinion, Boschert discloses, or renders obvious, this limitation for the reasons set forth above. *See supra* Sections X.A.3.b, X.A.3.c, X.A.5.b, X.A.5.c.

218. Accordingly, in my opinion, Boschert anticipates, or renders obvious, every element of Claim 21.

B. Ground 2: Claims 2-4, 6, 7, 11-13, 15, and 16 Are Obvious Based on Boschert in View of the '477 Publication

219. As set forth above, it would have been obvious to a POSA to combine the thread type and breakoff top teachings of the '477 Publication with Boschert before the priority date of the '479 Patent. *Supra* Section IX.A. Like Boschert, the '477 Publication is directed to a medical implant device that receives a rod member. EX1005, Abstract. The '477 Publication recognizes that conventional bone screws are well known in the prior art and proposes (1) optional substitutions of various known thread types on the closure top and receiver arms, *id.* ¶[0030], (describing “a

helically wound reverse angle thread form 36” and stating that “other types of guide and advancement structure could be utilized[, f]or example, . . . some other type of structure such as a flange form may be effectively used”); *id.* ¶[0041] (describing “a helical interlocking form, such as that described in U.S. Pat. No. 6,726,689, incorporated by reference,” and stating that “other types of guide and advancement structures could be utilized with the closure 101 including, but not limited to, a buttress thread form, a reverse angle thread form, a square thread form or some other type of flange form”); and (2) a breakoff head on the closure top that could be added to a conventional system, *id.* ¶[0032] (“The closure 1 also includes a driving or installation break-off head 49 and a removal head 50 that are coaxially attached to the body 24. . . . The driving head 49 is disposed on a break-off portion 52 that is secured to the body 24 at a breakaway region 53 adjacent the removal head 50 and is designed to break away from the remainder of the closure 1 subsequent to a predetermined torque being applied to the driving head 49, such as 100 inch pounds, during installation of the closure 1 into the bone screw 5.”). In my opinion, a POSA would have been motivated to use the various types of known threads in an existing system and to add breakoff closure tops to an existing system at least based on the available options and benefits of various thread types and of breakoff closure tops as taught by the ’477 Publication.

220. Regarding different thread types, for example, the '477 Publication teaches that different threads could be used, as described above, and a POSA would have known that different thread types could provide different advantages, such as inhibiting splaying of the two arms of the receiver or provide gripping between the joined components. *See* EX1016, 2:60-62, EX1019, 17:45-47; EX1021, ¶¶[0028]-[0029], Figs. 4C-F.

221. Regarding breakoff closure tops, for example, the '477 Publication teaches that breakoff closure tops had advantages for correctly driving and torquing a closure and providing a comparatively lower profile closure and a top that breaks away before being over-torqued, which would have motivated a POSA to use these features in conjunction with Boschert. EX1005, ¶¶[0009], [0011], [0035].

222. A POSA would have expected success with each of these combinations because they are all combinations 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 (1) various forms could be used for threads, and provide various advantages, and could be successfully used in closure tops, *supra* Section VI.B.1.b; and (2) breakoff closure tops provided the above-described advantages and could be successfully use in closure tops, *supra* Section VI.B.2.a. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least

because the techniques for manufacturing these features were well known and readily available. *Supra* Sections VI.B.1.b, VI.B.2.a.

223. As set forth above, Boschert already anticipates or renders obvious all limitations of Challenged Claims 1, 5, 10, 14, and 18-21. Claims 2-4, 6, 7, 11-13, 15, and 16 add the additional element of a different thread types or of a breakoff closure top, but each of these different thread types and breakoff closure tops were well-known in the prior art, including as taught by the '477 Publication. Therefore, below I address why the additional elements of Claims 2-4, 6, 7, 11-13, 15, and 16 are rendered obvious by the '477 Publication. For all other limitations, my opinions expressed above (that these features were already disclosed and/or rendered obvious by the disclosures of Boschert) remain and are unaffected by the additional disclosures of the '477 Publication.

1. Claim 2

224. All of the limitations of Claim 2 are recited in Claim 1, except Claim 2 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.” In my opinion, Boschert in view of the '477 Publication renders this additional limitation obvious.

225. The '477 Publication expressly discloses that the guide and advancement structure on the cylindrical closure body could be “a flange form.”

EX1005 ¶[0030]; *see also id.* ¶[0041]. The '477 Publication also discloses an embodiment with “helical interlocking form, such as that described in U.S. Pat. No. 6,726,689, incorporated by reference herein.” *Id.* ¶[0041], Figs. 7, 8. That patent 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.

226. Further, the '477 Publication discloses that the receiver arms “each include radially inward or interior surfaces 20 that have a discontinuous guide and advancement structure *mateable with cooperating structure on the closure* 1,” and that the cylindrical closure body has “a guide and advancement structure 34 *mateable with the guide and advancement structure on the inner surfaces 20 of the arms* 15 of the bone screw receiver 13.” EX1005, ¶¶[0026], [0030]. A POSA would have understood that the '477 Publication therefore discloses helically wound forms on the closure, including a flange form, that are “mateable” or that interlock with the respective helically wound structures on the arms, which a POSA would have understood would also have been flange form in order to be mateable with the closure’s flange form.

227. In my opinion, based on the above disclosures, when combining the disclosures of the '477 Publication and Boschert, 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. In my opinion, 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 disclosed 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. *See supra* Section IX.A.1. Accordingly, Boschert in view of the '477 Publication renders obvious every element of Claim 2.

2. Claim 3

228. All of the limitations of Claim 3 are recited in Claim 1, except Claim 3 further recites: **[A3]** “wherein the first and second helically wound forms are v-

threads.” In my opinion, Boschert in view of the ’477 Publication renders this additional limitation obvious.

229. The ’477 Publication discloses a “helically wound reverse angle thread form 36” for the guide and advancement structure on the cylindrical closure body and further states, “It is foreseen that other types of guide and advancement structure could be utilized. For example, a buttress thread form, a square thread form or some other type of structure such as a flange form may be effectively used” EX1005, ¶[0030]; *see also id.*, ¶[0041]. A POSA would have known that a v-thread is another type of guide and advancement structure that could have been used. *See supra* ¶¶63-70. Specifically, the ’479 Patent itself admits that “[k]nown closures include . . . a variety of single start helically wound guide and advancement structures including, for example, thread forms having v-thread” forms. EX1001, 1:53-2:4.

230. In my opinion, based on the above disclosures, when combining the disclosures of ’the 477 Publication and Boschert, 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. In my opinion, 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. *See supra* Section IX.A.1. Accordingly, Boschert in view of the '477 Publication renders obvious every element of Claim 3.

3. Claim 4

231. All of the limitations of Claim 4 are recited in Claim 1, except Claim 4 further recites: [A4] “wherein the first and second helically wound forms are square threads.” In my opinion, Boschert in view of the '477 Publication renders this additional limitation obvious.

232. The '477 Publication expressly discloses that the guide and advancement structure on the cylindrical closure body could be “a *square thread* form.” EX1005 ¶[0030]; *see also id.*, ¶[0041]. The '479 Patent itself admits that “[k]nown closures include . . . a variety of single start helically wound guide and advancement structures including, for example, thread forms having . . . square thread forms” EX1001, 1:53-2:4.

233. In my opinion, based on the above disclosures, when combining the disclosures of '477 Publication and Boschert, 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. In my opinion, 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. *See supra* Section IX.A.1. Accordingly, Boschert in view of the '477 Publication renders obvious every element of Claim 4.

4. Claim 6

234. All of the limitations of Claim 6 are recited in Claim 1, except Claim further recites: [A6] “wherein the first and second helically wound forms are buttress threads.” In my opinion, Boschert in view of the ’477 Publication renders this additional limitation obvious.

235. The ’477 Publication expressly discloses that the guide and advancement structure on the cylindrical closure body could be “a *buttress thread* form.” EX1005 ¶[0030]; *see also id.*, ¶[0041]. The ’479 Patent itself admits that “[k]nown closures include . . . a variety of single start helically wound guide and advancement structures including, for example, thread forms having . . . buttress . . . thread forms” EX1001, 1:53-2:4.

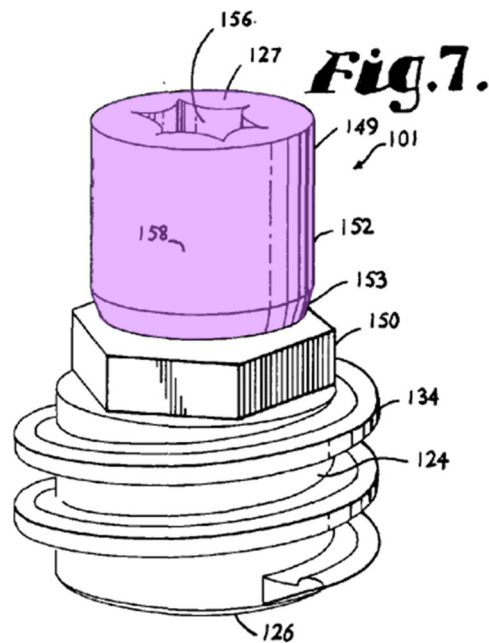
236. In my opinion, based on the above disclosures, when combining the disclosures of ’477 Publication and Boschert, it would have been obvious to a POSA to select from among any of the well-known thread types disclosed in the ’477 Publication, including a buttress thread for the first and second helically wound forms. In my opinion, 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. *See supra* Section IX.A.1. Accordingly, Boschert in view of the '477 Publication renders obvious every element of Claim 6.

5. Claim 7

237. All of the limitations of Claim 7 are recited in Claim 1, except Claim 7 further recites: [A7] “wherein the closure member has a break-off head.” In my opinion, Boschert in view of the '477 Publication renders this additional limitation obvious.

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



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

239. In my opinion, based on the above disclosures and in view of a POSA’s knowledge of break-off closures, a POSA implementing Boschert would have been motivated to use a closure that has 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. Moreover, in my opinion, a POSA would have been motivated to use a break-off head on the closure when combining the ’477 Publication and Boschert at least because (1) it would have been nothing more than the simple substitution of

one known element (non-break off closure) for another (a break-off closure) to obtain a predictable result (a lower-profile closure that could be tightened to a predetermined torque); (2) it would have been the mere application of a known technique (use of a break-off closure) to a known device (Boschert) to yield a predictable result (a lower-profile closure that could be tightened to a predetermined torque); and (3) there was a known design need for a lower-profile closure that could be tightened to a predetermined torque and a finite number of identified, predictable solutions (non break-off and break-off closures) that were known to a POSA and within their technical grasp. *See supra* Section IX.A.2. Accordingly, Boschert in view of the '477 Publication renders obvious every element of Claim 7.

6. Claim 11

240. All of the limitations of Claim 11 are recited in Claim 10, except Claim 11 further recites: [A2] “wherein the first and second helically wound guide and advancement structures are interlocking flange forms.” While worded slightly differently, this limitation recites the same requirements as limitations as 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. As I discussed above, *supra* Section X.A.3.c, Boschert discloses a dual-start closure, which is a closure with at least two starts. EX1006, 7:21-23, Figs. 3, 7, 15. As I also discussed above, *supra* Section X.B.1, the '477 Publication discloses an interlocking flange form as a helically wound guide

and advancement structure on the closure. EX1005, ¶¶[0030], [0041], Figs. 7, 8; EX1015, Abstract, 1:6-18, 13:12-155, 13:14-16, 14:48-60, Figs. 3, 13. As I also discussed above, *supra* Section X.B.1, a POSA implementing Boschert would have been motivated to use a flange form on the closure as disclosed by the '477 Publication. In my opinion, Boschert in view of the '477 Publication renders obvious every element of Claim 11 for the reasons set forth above. *See* Section X.B.1.

7. Claim 12

241. All of the limitations of Claim 12 are recited in Claim 10, except Claim 12 further recites: [A3] “wherein the second helically wound guide and advancement structure includes at least two v-threads.” This limitation recites the same start structure requirements as 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. As I discussed above, *supra* Section X.A.3.c, Boschert discloses a dual-start closure, which is a closure with at least two starts. EX1006, 7:21-23, Figs. 3, 7, 15. As I also discussed above, *supra* Section X.B.2, the '477 Publication explicitly encourages the use of “other types of guide and advancement structure[s],” EX1005, ¶¶[0030], [0041], and a POSA would have understood that a v-thread was one such type of guide and advancement structure. As I also discussed above, *supra* Section X.B.2, a POSA implementing Boschert would have been motivated to use a v-thread on the closure.

In my opinion, Boschert in view of the '477 Publication renders obvious every element of Claim 12 for the reasons set forth above. *See supra* Section X.B.2.

8. Claim 13

242. All of the limitations of Claim 13 are recited in Claim 10, except Claim 13 further recites: [A4] “wherein the second helically wound guide and advancement structure includes at least two square threads.” This limitation recites the same start structure requirements as 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. As I discussed above, *supra* Section X.A.3.c, Boschert discloses a dual-start closure, which is a closure with at least two starts. EX1006, 7:21-23, Figs. 3, 7, 15. As I also discussed above, *supra* Section X.B.3, the '477 Publication discloses a square thread as a helically wound guide and advancement structure on the closure. EX1005, ¶¶[0030], [0041]. As I also discussed above, *supra* Section X.B.3, a POSA implementing Boschert would have been motivated to use a square thread on the closure as taught by the '477 Publication. In my opinion, Boschert in view of the '477 Publication renders obvious every element of Claim 13 for the reasons set forth above. *See supra* Section X.B.3.

9. Claim 15

243. All of the limitations of Claim 15 are recited in Claim 10, except Claim 15 further recites: [A6] “the second helically wound guide and advancement

structure includes at least two buttress threads.” This limitation recites the same start structure requirements as 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. As I discussed above, *supra* Section X.A.3.c, Boschert discloses a dual-start closure, which is a closure with at least two starts. EX1006, 7:21-23, Figs. 3, 7, 15. As I also discussed above, *supra* Section X.B.4, the ’477 Publication discloses a buttress thread as a helically wound guide and advancement structure on the closure. EX1005, ¶¶[0030], [0041]. As I also discussed above, *supra* Section X.B.4, a POSA implementing Boschert would have been motivated to use a square thread on the closure as taught by the ’477 Publication. In my opinion, Boschert in view of the ’477 Publication renders obvious every element of Claim 15 for the reasons set forth above. *See supra* Section X.B.4.

10. Claim 16

244. All of the limitations of Claim 16 are recited in Claim 10, except Claim 16 further recites: [A7] “wherein the closure structure has a break-off head.” This limitation recites the same start structure requirements as 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. As I discussed above, *supra* Section X.A.3.c, Boschert discloses a dual-start closure, which is a closure with at least two starts. EX1006, 7:21-23, Figs. 3, 7, 15. As I also discussed above, *supra* Section X.B.5, the ’477 Publication discloses

a closure that has a break-off head. EX1005, ¶¶[0039], [0042]-[0043], Figs. 5-8. As I also discussed above, *supra* Section X.B.5, a POSA implementing Boschert would have been motivated to use a closure that has a break-off head as disclosed in the '477 Publication. In my opinion, Boschert in view of the '477 Publication renders obvious every element of Claim 16 for the reasons set forth above. *See supra* Section X.B.5.

C. Ground 3: Claims 9 and 22 Are Obvious Based on Based on Boschert in View of the '391 Publication.

245. As set forth above, it also would have been obvious to a POSA to combine the teachings of the '391 Publication with Boschert before the priority date of the '479 Patent. *Supra* Section IX.B. Like Boschert, the '391 Publication is directed to a polyaxial bone screw with an open U-shaped receiver that receives a rod member and is closed with a closure top, and specifically to guide tools used with such receivers. EX1009, Abstract (teaching “[a] tool set for implanting bone screws in a human spine, followed by the implantation of a rod into the bone screws,” the tool set comprising “end guide tools” and “intermediate guide tools” that both “include an attachment structure for operably connecting the guide tool to a bone screw”). In my opinion, a POSA would have been motivated to add guide tools to an existing system at least based on the benefits of guide tools as taught by the '391 Publication. *See also supra* Section VI.B.2.i.

246. For example, the '391 Publication teaches that using attachable/detachable guide tools provides the benefits of minimal surgical invasion of the patient and ease of stabilizing, positioning, and securing implants. *Supra* Section VIII.C. Boschert also discloses “grasping features” that can “accommodate instrumentation to facilitate grasping, holding or manipulating of the receiver 30” during implantation. EX1006, 6:15-19. Boschert does not, however, disclose the details of the tools and instruments to be used with the disclosed receiver, and thereby invites a POSA to look to tools and instruments that were otherwise known in the art. Based on these teachings, a POSA would have recognized the benefits of using attachable/detachable guide tools with an existing device, including minimal surgical invasion of the patient and ease of stabilizing, positioning, and securing implants, and would have been motivated to use this feature with Boschert. *Supra* Section IX.B.

247. 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 guide tools provided these advantages and could be successfully used in medical implant devices. *Supra* Section VI.B.2.i. In addition, a POSA would have had a reasonable expectation of success in making such a combination,

at least because the techniques for machining guide tools were well known and readily available. *Id.*

248. Moreover, a POSA would have been motivated to combine the teachings of the '391 Publication with Boschert based on the demands known to the medical device design community for medical devices requiring minimal surgical invasion and that minimize the difficulty of use. *Id.*

249. As set forth above, Boschert anticipates and/or renders obvious every limitation of Challenged Claims 1, 5, 10, 14, and 18-21. *Supra* Section X.A. Claims 9 and 22 add the additional element of guide tools, but this additional element was well known in the prior art, including in the '391 Publication. Therefore, below I address why the additional element of Claims 9 and 22 is rendered obvious by the '391 Publication. For all other imitations, my opinions expressed above (that these features were already anticipated and/or rendered obvious by the disclosures of Boschert) remain and are unaffected by the additional disclosures of the '391 Publication.

1. Claim 9

250. All of the limitations of Claim 9 are recited in Claim 1, except Claim 9 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.” In my opinion, the obvious combination of Boschert and the ’391 Publication includes this limitation.

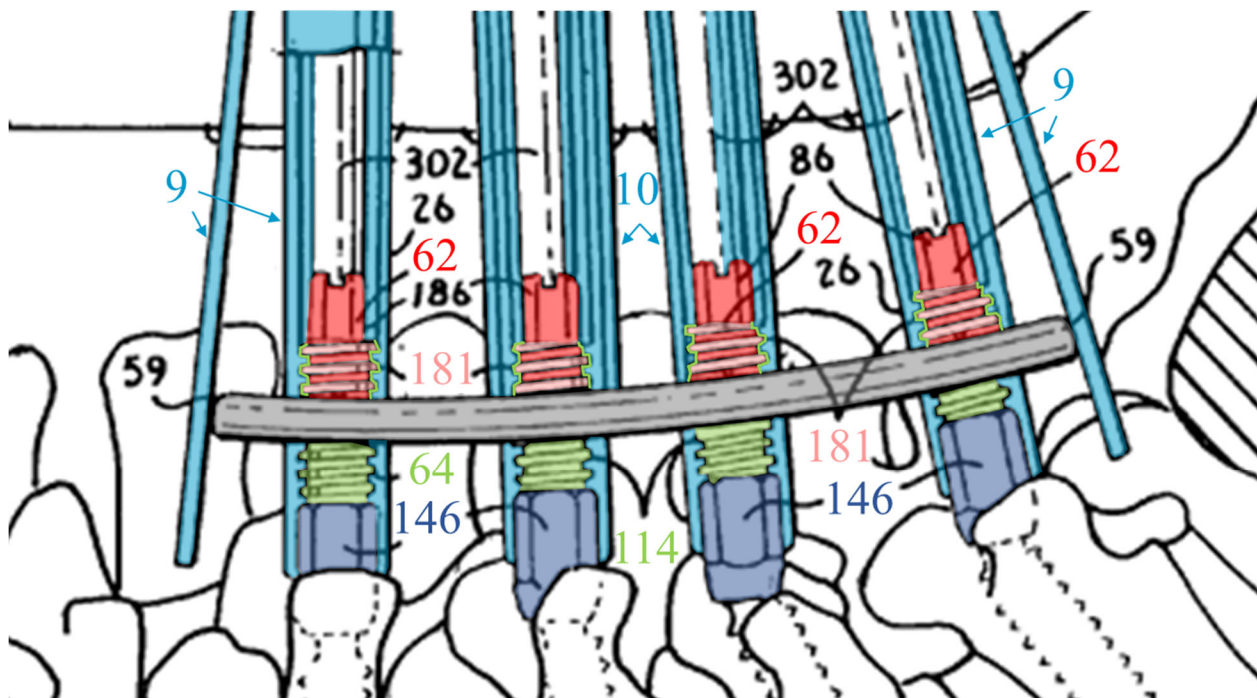
251. The ’391 Publication discloses a guide tool with arms detachably attached to the receiver with discontinuously wound structures on the guide tool arms and wherein simultaneous mating of the closure starts with the guide tool discontinuously wound structures occurs when the closure member is rotated between the guide tool arms and where the guide tool structures are sized and shaped to provide transfer of the closure between the guide tool and the bone screw assembly upon rotation of the closure.

252. In particular, the ’391 Publication discloses a “tool embodiment assembly 1” that “includes an intermediate guide tool 10.” EX1009, ¶[0082]. The ’391 Publication further discloses that, “to *attach* the bone screw head 146 to the guide tool 10, the guide tool 10 is rotated about its axis B such that legs 102 and 103 are lowered into place,” *id.*, ¶[0114], and, to “*disengage*” the guide tool 10 from the

bone screw 4, the guide tool 10 is “rotated counterclockwise from an attaching configuration,” *id.*, ¶[0115]. The guide tool mates with the bone screw receiver with pins on “implant engaging leg member 102 and 103.” *Id.*, ¶[0103]. 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.” *Id.*, ¶[0173].

253. The '391 Publication also expressly discloses third and fourth arms with discontinuous helically wound threads that transmit the closure top from the guide tool and into the receiver head upon rotation of the closure top. 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.” *Id.*, ¶¶[0092], [0103]. These threads cooperate with the closure top 62. *Id.*, ¶[0092] (“guide and advancement structure 64 ... to cooperate with equivalent or mateable structure ... on the closure top 62”), ¶[0103] (“The thread form 114 cooperates with the closure top 62 ...”). “[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” *Id.*, ¶[0171]; *see also id.* Fig. 42. “[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. *Id.*, ¶[0172]; *see also id.*, ¶[0120] (“In particular, the guide and advancement structures 64 and 114 on the respective tools 9 and 10 are located and positioned to align with the guide and advancement structure 183 on the insides of the bone screw arms 150 and 151, as shown in FIG. 42 and pass the closure top 62 therebetween while allowing the closure top 62 to continue to rotate and to continuously apply force to the rod 8, so as to aid in seating the rod 8 in the bone screw head 146.”), Fig. 42.



254. In my opinion, just as 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, such simultaneous mating would also result from use of

Boschert's double-start closure top with a guide tool designed to pass the double-start closure top from the guide tool to the receiver head. *See supra* Section X.A.1.d. 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]. 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 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." *Id.*, ¶[0103]. 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.

255. In my opinion, 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. In my opinion, 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. *Supra* Section IX.B.

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

2. Claim 22

257. All of the limitations of Claim 22 are recited in Claim 21, except Claim 22 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.” While worded slightly differently, this limitation recites the same requirements of the receiver as Claim 9, except Claim 22 recites that “each arm having helically wound guide and advancement structure thereon in synchronized relationship with the receiver helically wound guide and advancement forms.” In my opinion, this limitation is not substantively different than Claim 9’s requirements. As I discussed above, *supra* Section X.C.1, the ’391 Publication discloses a guide tool with two arms that each have helically wound threads (i.e., helically wound guide and advancement structures). EX1009, ¶¶[0092], [0103]. The ’391 Publication also discloses that the guide tool’s helically wound guide and advancement structures “are located and positioned to align with the guide and advancement structure 183 on the insides of the bone screw arms 150 and 151” and “pass the closure top 62 therebetween while allowing the closure top 62 to continue to rotate and to continuously apply force to the rod 8, so as to aid in seating the rod 8 in the bone screw head 146.” *Id.*, ¶[0120]; *see also id.*, ¶[0172], Fig. 42. Thus, in my opinion, 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. As I discussed

above, *supra* Section IX.B, a POSA implementing Boschert would have been motivated to use a guide tool as disclosed by the '391 Publication. In my opinion, Boschert in view of the '391 Publication renders this limitation for the reasons set forth above. *See* *supra* Section X.C.1. Accordingly, in my opinion, Boschert in view of the '391 Publication renders obvious every element of Claim 22.

D. Ground 4: Claims 8 and 17 Are Obvious Based on Boschert in View of Johnson.

258. As set forth above, it also would have been obvious to a POSA to combine the teachings of Johnson with Boschert before the priority date of the '479 Patent. *Supra* Section IX.C. Like Boschert, Johnson is directed to a polyaxial bone screw with an open U-shaped receiver that receives a rod member and is subsequently closed with a closure top. EX1008, Abstract. In my opinion, a POSA would have been motivated to add break-off extension arms to an existing bone screw receiver at least based on the benefits of break-off extensions as taught by Johnson. *Supra* Section IX.C.

259. For example, Johnson teaches that break-off extension arms provide the benefit of simplifying the introduction of an elongate member or rod. Johnson discloses that, “[w]hen the surgeon wishes to insert an elongated member 220 into receiver member 212, he or she need not bend it or use a special reducing tool to insert it into the lower end of a receiving channel. Rather, he or she places a portion of the elongated member 220 into channel 254 in upper portion 212*b* of receiver

member 212.” EX1008, ¶[0055]. Johnson discloses that a compression member is then “thread into threads 256, forcing elongated member 220 further down in channel 254” so that the “elongated member 220 is forced all the way through upper portion 212*b*, into lower portion 212 *a*, and against a crown member and/or anchor member in chamber 228.” *Id.* Johnson also discloses that “[o]nce separated, upper portion 212*b* may be removed from the surgical site and discarded.” *Id.*, ¶[0056]. 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 (i.e., the “elongated member” in Johnson) while maintaining a low-profile device, and would have been motivated to use this feature in the receiver of Boschert.

260. 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. *Supra* Section VI.B.2.ii. 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.* Moreover, a POSA would have been motivated to combine the teachings of Johnson with Boschert

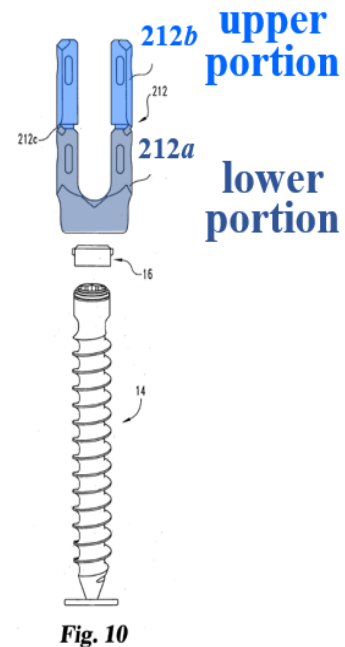
based on the demands known to the medical device design community for medical devices with low profiles and that minimize the difficulty of use. *Id.*

261. As set forth above, *supra* Section X.A, Boschert anticipates or renders obvious every limitation of Challenged Claims 1, 5, 10, 14, and 18-21. Claims 8 and 17 add the additional element of breakoff arm extensions, but this additional element was well known in the prior art, including as taught by Johnson. Therefore, below I address why the additional elements of claims 8 and 17 are rendered obvious by Johnson. For all other imitations, my opinions expressed above (that these features were already anticipated and/or rendered obvious by the disclosures of Boschert) remain and are unaffected by the additional disclosures of Johnson.

1. Claim 8

262. All of the limitations of Claim 8 are recited in Claim 1, except Claim 8 further recites: [B2] “wherein the receiver has break-off extensions.” In my opinion, Johnson renders this additional limitation obvious when its disclosures are considered in view of Boschert.

263. Johnson discloses a receiver member with breakoff extensions. In particular, as shown in annotated Fig. 10, Johnson discloses receiver member 212 that “has a lower portion 212a and an upper portion 212b separated by a thinned section 212c.” EX1008, ¶[0051], Fig. 10.



264. 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.” *Id.*, ¶[0056].

265. In my opinion, based on the above disclosures, a POSA implementing Boschert would have been motivated to use breakoff extensions as disclosed by Johnson on the receiver of Boschert. In my opinion, 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. *Supra* Section IX.C.

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

2. Claim 17

267. All of the limitations of Claim 17 are recited in Claim 10, except Claim 17 further recites: [B2] “wherein the receiver has break-off extensions.” The limitation added by Claim 17 recites the same requirements as Claim 8. In my opinion, Boschert in view of Johnson renders obvious this limitation for the reasons set forth above. *See supra* Section X.D.1. Accordingly, in my opinion, Boschert in view of Johnson renders obvious every element of Claim 17.

XI. DISCUSSION OF SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

268. I am not aware of any evidence of secondary considerations that supports the non-obviousness of the Challenged Claims of the '479 Patent.

269. I am, however, aware of evidence of secondary considerations that rebuts the non-obviousness of the Challenged Claims of the '479 Patent. For example, on January 4, 2017, Zimmer Spine filed U.S. Patent Application No. 15/397,959 (“the '959 Application”), entitled “Bone screw including a dual thread closure member.” EX1032 at 1. The '959 Application claimed priority to Provisional Application No. 61/601,809, which was filed on February 22, 2012, and was a continuation of Patent Application No. 13/771,442, which was filed on February 20, 2013. *Id.* at 3, 8.

270. On June 25, 2018, then-pending claim 2 of the '959 Application recited:

2. A vertebral fastener comprising:

a housing and a bone engaging shaft extending from the housing, the housing including a first leg and a second leg extending from a base portion of the housing and define a channel between the first leg and the second leg for receiving a connecting member therethrough, the bone engaging shaft having a distal region and a proximal region, wherein a first helical thread extends across the distal region and the proximal region, wherein a second helical thread extends across the proximal region and is located between adjacent windings of the first helical thread, and

a closure member configured to threadably engage the first and second legs of the housing;

wherein the closure member includes a first thread and a second thread intertwined with the first thread, the first thread having a start proximate a lower surface of the closure member and the second thread having a start proximate the lower surface of the closure member, and wherein the closure member is configured such that the start of the first thread of the closure member threadably initiates threaded engagement with the first leg of the housing substantially simultaneously as the start of the second thread initiates threaded engagement with the second leg of the housing.

Id. at 39.

271. The examiner for the '959 Application rejected pending claim 2 as being unpatentable over U.S. 6,726,689 to Jackson ("Jackson '689, EX1015) in view of U.S. Patent No. 5,520,688 to Lin ("Lin") and in view of U.S. Patent Application Publication No. 2007/0233122 to Denis. EX1032 at 57-63 (2018-11-05 Final Rejection). While the examiner found that Jackson '689 disclosed several limitations of pending claim 2, the examiner found that Jackson '689 did not disclose

a first thread and a second thread intertwined with the first thread. *Id.* at 58. The examiner, however, found that Lin disclosed a first thread and a second thread intertwined with the first thread. The examiner also found that Lin disclosed substantially simultaneous engagement of the first and second thread because Lin disclosed that its threads were 180 degrees apart from each other. *Id.* at 58-60. The examiner further found that it would have been obvious to modify Jackson '689 in view of Lin "in order to reinforce the fixation." *Id.* at 60.

272. Zimmer Spine expressly abandoned the '959 Application. Zimmer Spine stated that it had "become aware of prior art impacting the patentability of the claims pending in this application." Abandonment at 1 (EX1032 at 70). In particular, Zimmer Spine stated that it had become "aware of Oberg's Machinery Handbook, 28th Edition, which is a reference book that discusses conventional thread forms for use in a variety of applications" and that the Machinery Handbook "includes disclosure explaining how to produce a screw with multi-start threads on a CNC machine." *Id.* at 71. Zimmer Spine stated that, in view of the Machinery Handbook's disclosure that "[i]n order to achieve proper distribution of each start around the cylinder each thread has to start at an equal angle, determined by the following calculation: Thread cylindrical spacing = $360 / \text{Number of starts}$," Zimmer Spine's "previous arguments regarding simultaneous engagement can no longer be supported." *Id.*

273. In my opinion, the prosecution of the '959 Application, and its subsequent express abandonment, supports the *obviousness* of the Challenged Claims of the '479 Patent that recite simultaneous mating of the dual start features. This evidence has a clear nexus to the claimed inventions of the Challenged Claims because it relates to medical implants, specifically pedicle bone screws, and in particular ones with dual thread closures. This evidence demonstrates that the claimed invention of the '479 Patent was the product only of ordinary mechanical or engineering skill. This evidence also undercuts any suggestion that there was praise by others for the claimed invention because Zimmer abandoned the technology after discovering prior art relating to routine machining skills and techniques.

274. I reserve the right to respond to any evidence or assertions of alleged secondary considerations if it is presented at a later date.

XII. CONCLUSION

275. In signing this declaration, I recognize that the declaration may be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will cooperate to the best of my ability to appear for cross-examination within the United States during the time allotted for cross-examination.

276. I reserve the right to supplement my opinions in the future to respond to any arguments that the Patent Owner raises and to take into account new information as it becomes available to me.

277. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

278. I declare under penalty of perjury that the foregoing is true and correct.

Dated: September 20, 2023

Carl McMillin
Dr. Carl McMillin