

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ROGER P. JACKSON
Patent Owner

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

Inter Partes Review No. IPR 2023-01432

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. 10,898,233 (“the ’233 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 ’233 Patent, (2) the general knowledge a person of ordinary skill in the part (“a POSA”) had at the effective filing date of the ’233 Patent (which I have been asked to assume is January 10, 2012), (3) the meaning a POSA would ascribe to the claims of the ’233 Patent, (4) the scope and content of the prior art references, and (5) whether any of the Challenged Claims of the ’233 Patent, as of its effective filing date, would have been 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 '233 Patent are obvious. As explained further below, the '233 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 of a set screw to capture a rod in a U-shaped receiver was well known in the prior art, as the '233 Patent admits. The '233 Patent purports to improve on prior art closure tops by using a dual-start thread, rather than a single-start thread, to mate the closure top to the receiver. But dual-start threads were a well-known design choice and had previously been used in the context of closure tops for polyaxial pedicle screws. In the prosecution of the '233 Patent, dual-start thread claims were rejected as being unpatentable in view of U.S. Patent Application Publication No. 2005/0277928 to Boschert. From my review of the prosecution history of the '233 Patent, the claims of the patent appear to have been allowed based on (1) the use of a curvate, as opposed to flat, tool attachment groove near the top of the receiver and (2) the use of truncated thread starts with curvate leading faces. But both of these features, and their benefits, were well known in the prior art, including on prior art polyaxial pedicle screw systems. The additional features claimed in the '233 Patent, including various thread types, various grooves and gripping features for instrument attachment, breakoff receiver arm extensions, and top loaded inserts,

were all conventional features readily available to a POSA when designing a pedicle screw system. The '233 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 '233 Patent provides no inventive contribution and all of the Challenged Claims are obvious in view of the prior art.

4. U.S. Patent Application Publication No. 2005/0267477 to Jackson ("the '477 Publication") (EX1005) discloses closures that can be used with known U-shaped spinal bone screw receivers to capture a rod. The closures disclosed in the '477 Publication include many of the claimed features, including a thread with a curvate leading face. The '477 Publication expressly teaches that "it [is] foreseen that the closure 1 may be used in conjunction with any type of medical implant having an open or closed head." *Id.*, ¶0027. Therefore, a POSA would naturally combine the teachings of the '477 Publication regarding closures with known medical implants having an open head, such as the open head polyaxial bone screw of U.S. Patent 7,857,834 ("Boschert") (EX1006) or U.S. Patent Application Publication No. 2010/0312287 ("the '287 Publication") (EX1007). The '477 Publication was not cited or discussed during prosecution of the '233 Patent.

5. Boschert, which published in 2005 as U.S. Patent Application Publication No. 2005/0277928 and issued in December 28, 2010, discloses a

polyaxial bone screw with a U-shaped receiver and teaches that dual-start threads offer a benefit over single-start threads when used on a closure top. 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 also expressly invites modifications to its closure, 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. Therefore, a POSA would naturally combine the teachings of Boschert regarding the benefit of using dual start threads to mate a closure with a receivers, with known closures (i.e., set screws), such as those disclosed in the ’477 Publication. The resulting combination would use the dual start threads of Boschert, each with the curvate leading face of the ’477 Publication. Boschert’s teaching of dual-start threads was the basis for a rejection during prosecution of the ’233 Patent and prompted claim amendments before the claims were allowed. As discussed further throughout this declaration, the features added via amendment were disclosed in the ’477 Publication and the ’287 Publication, which were not discussed during prosecution.

6. The ’287 Publication is one of several prior art references that describe a variety of instrument attachment features for gripping and manipulation on the external surfaces of polyaxial pedicle screws. *See* EX1007. The ’287 Publication discloses a polyaxial bone screw with a U-shaped receiver that includes curvate tool

attachment grooves on the outer side surfaces of the receiver. *Id.*, ¶¶ [0078], [0152]. The '287 Publication expressly states that its receiver can be used with a variety of known closures, stating that “the closure structure 30 can be any of a variety of different types of closure structures for use in conjunction with the present invention with suitable mating structure on the upstanding arms 152 of the receiver 20.” *Id.*, ¶¶ [0086], [0156]. Therefore, a POSA would naturally combine the teachings of the '287 Publication regarding receivers with curvate tool grooves, with known closures, such as those disclosed in the '477 Publication. Together with Boschert's teaching regarding the benefits of using dual start threads, the resulting combination would use the receiver of the '287 Publication (with its tool grooves), together with the closure of the '477 Publication (with its curvate leading thread face) modified to use the dual start threads as taught by Boschert. The '287 Publication was not cited or discussed during prosecution of the '233 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 the '287 Publication, to facilitate implantation of a rod and to accommodate severe spinal deformities. Johnson is cited on the face of the '233 Patent but was not discussed during prosecution of the

'233 Patent, either alone or in combination with the other references discussed herein.

8. The prior art combinations discussed herein were never discussed in any rejection during prosecution of the '233 Patent. Instead, the Challenged Claims were allowed on the basis of conventional prior art receiver and closure top features without the benefit of the full set of prior art, and combinations thereof, that are discussed herein. In my opinion, the curvate leading thread face taught by the '477 Publication in combination with the dual-start threads taught by Boschert and the tool attachment grooves taught by the '287 Publication, rendered obvious Claims 1-7, 13, 15-18, and 20 of the '233 Patent. Such a combination would have included every feature claimed in the '233 Patent with the exception of conventional breakoff receiver arm extensions described in Claim 14. Claim 14 was also obvious because breakoff receiver arm extensions were a conventional design option, as disclosed by Johnson.

9. Furthermore, nothing in the teaching of the '233 Patent describes any benefit from any particular combination of the claimed features. And in my opinion, there is little that is synergistic or even related between the decision of whether and where to place tool attachment grooves on the outside of the receiver; the particular type of thread form used in the closure top; the use of a single or double start for the closure top threads; the shape of the leading face of the closure top threads; or the

addition of break-off extensions to the receiver arms. Therefore, in my opinion, each of the Challenged Claims of the '233 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, or 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 threadforms 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 threadform 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 rebent (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. Early in my consulting, as adjunct faculty I 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.

20. My opinions are also informed by my own knowledge and experience as a POSA in the pertinent field.

V. APPLICABLE LEGAL STANDARDS

21. 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

22. 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

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.

proven by a preponderance of the evidence, which I understand to mean “more likely than not.”

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 '233 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 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 am not aware of any evidence of invention of the claimed subject matter by Dr. Roger Jackson (the named inventor of the '233 Patent) before January 10, 2012.

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 am not aware of any evidence of invention of the claimed subject matter by Dr. Roger Jackson (the named inventor of the '233 Patent) before January 10, 2012.

26. 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.

27. 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.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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

35. I understand that to date no court has construed the claim terms of the '233 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 '233 Patent are based on the ordinary and customary meaning of the claim terms in the context of the entire '233 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

36. It is my opinion that the relevant field of the invention of the '233 Patent is spinal implants and threaded connections.

37. 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.

38. I understand that Dr. Roger Jackson, the named inventor of the '233 Patent, received his bachelor's 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.

39. 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.

40. Based on my experience and my review of the relevant prior art, it is my opinion that technology for threaded connections for spinal implants, 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 '233 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.

41. 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,

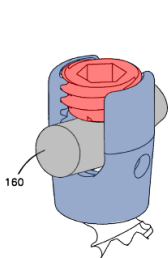
2012, covered a range of educational backgrounds and experience. Most workers in this field had at least a bachelor's degree in mechanical engineering, biomedical engineering, materials science, or an equivalent discipline, but some, including myself, had terminal degrees. Those working in this the field also had a range of experience within the field, from newly hired engineers and 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.

42. 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. As of January 10, 2012, I met this definition of a POSA. All of the opinions expressed in this declaration are offered from the perspective of a POSA, as defined above, as of January 10, 2012.

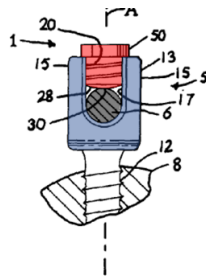
B. Knowledge of a Person of Ordinary Skill in the Art

43. 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.

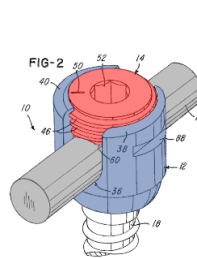
44. As the '233 Patent concedes, at least as of January 10, 2012, “[b]one anchors, such as bone screws and hooks,” were well-known. EX1001, 1:31-34. Known bone anchors included polyaxial bone screw assemblies. *Id.*, 1:48-52; *see also* EX1006, 4:44-47, 5:2-11, Figs. 4, 9, 7, 17; EX1005, ¶¶[0018], [0025]-[0027], [0039], Figs. 5-6; U.S. Patent Application Publication No. 2011/0152947 (“Kirschman”) (EX1033), ¶¶[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 (**red**), and rod (**grey**):



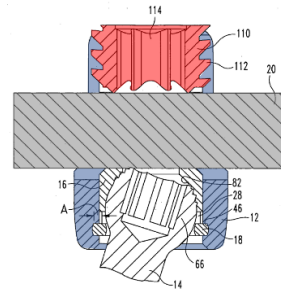
EX1006, Fig. 7



EX1005, Fig. 6

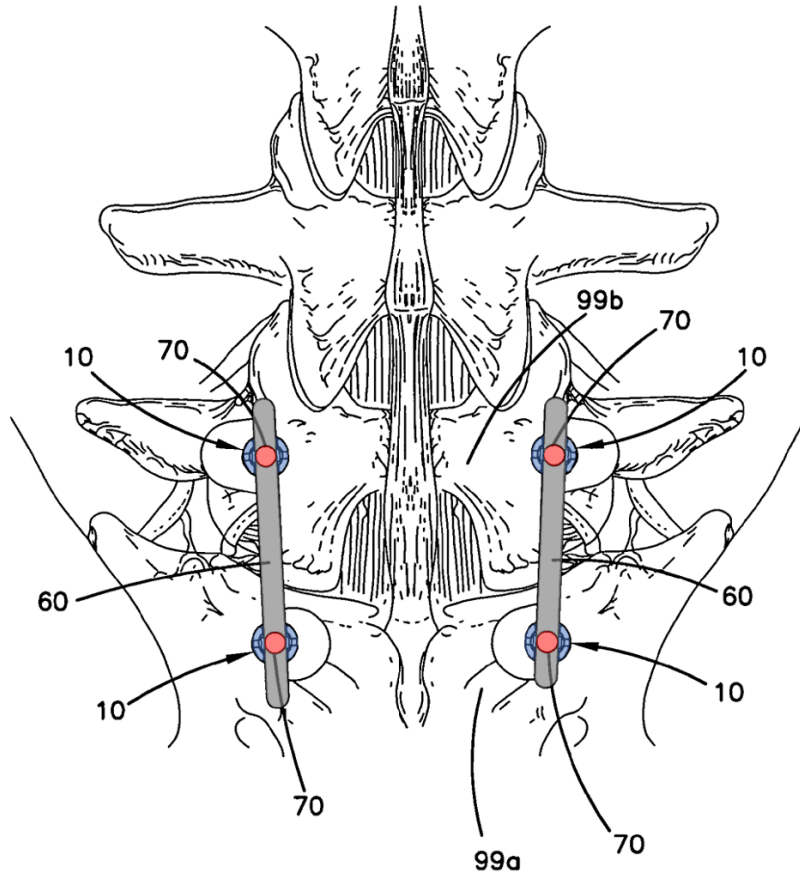


EX1033, Fig. 2



EX1008, Fig. 7

45. In addition, at least as of January 10, 2012, using a rod with bone screws for “providing vertebral support” was a “common mechanism.” EX1001, 1:34-37. It was also known that, “[a]lthough both closed-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.*, 1:38-45. Fig. 2 of Boschert, annotated below, shows how open-ended anchors (i.e. receivers) (**blue**) and set screws (i.e. closures) (**red**) can be used together with a longitudinal rod (**grey**) to correct and/or stabilize spinal deformities.

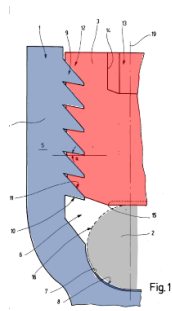


EX1006, Fig. 2.

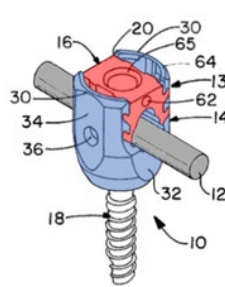
46. “Typical open-ended bone screws include a threaded shank with a head or receiver having a pair of parallel projecting branches or arms which form a yoke with a U-shaped slot or channel to receive a rod or other longitudinal connecting member.” EX1001, 1:53-57; *see also* EX1006, Abstract, 4:13-28, 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 member² after the rod or other longitudinal connecting member is placed in the channel.” EX1001, 1:60-64. 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.*, 1:64-2:2; *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, 2:31-33, 3:48-51, 3:64-4:61, 5:14-28, Figs. 1, 3-6C; U.S. Patent No. 6,302,888 (EX1017), Abstract, 1:63-65, 2:10-22, 4:38-60, 5:53-56, Figs. 1-2, 5-7, 9-10. In addition to those shown above, sample depictions of representative prior art receiver (**blue**) and closure (**red**) constructs with a longitudinal rod (**gray**) are shown below, along with their publication dates:

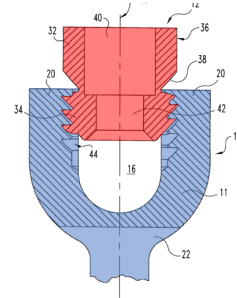
² Closure members have been referred to with a variety of terms in the prior art, including closure, closure top, closure plug, plug, set screw, and the like.



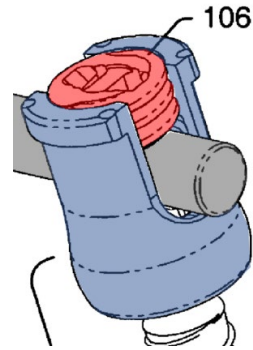
1999
EX1012, Fig.1



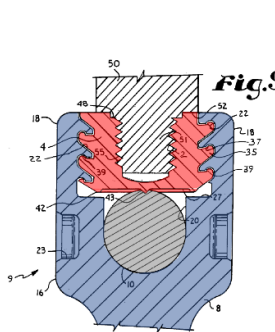
2001
EX1017, Fig. 1



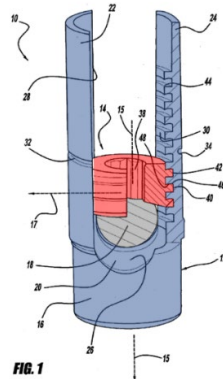
2001
EX1016, Fig. 1



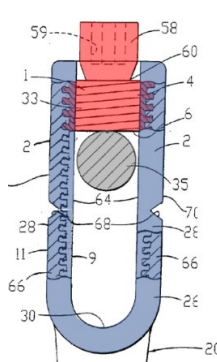
2004
EX1019, Fig. 1



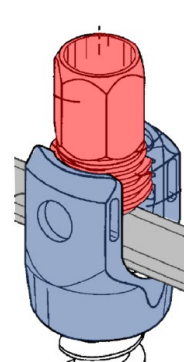
2004
EX1013, Fig. 9



2004
EX1021, Fig. 1



2006
EX1023 Fig. 1



2011
EX1022, Fig. 1

47. Thus, before January 10, 2012, the general environment of a polyaxial bone screw assembly, including open-ended receivers with a pair of spaced arms forming a channel, longitudinal connecting members such as rods, and closures 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.

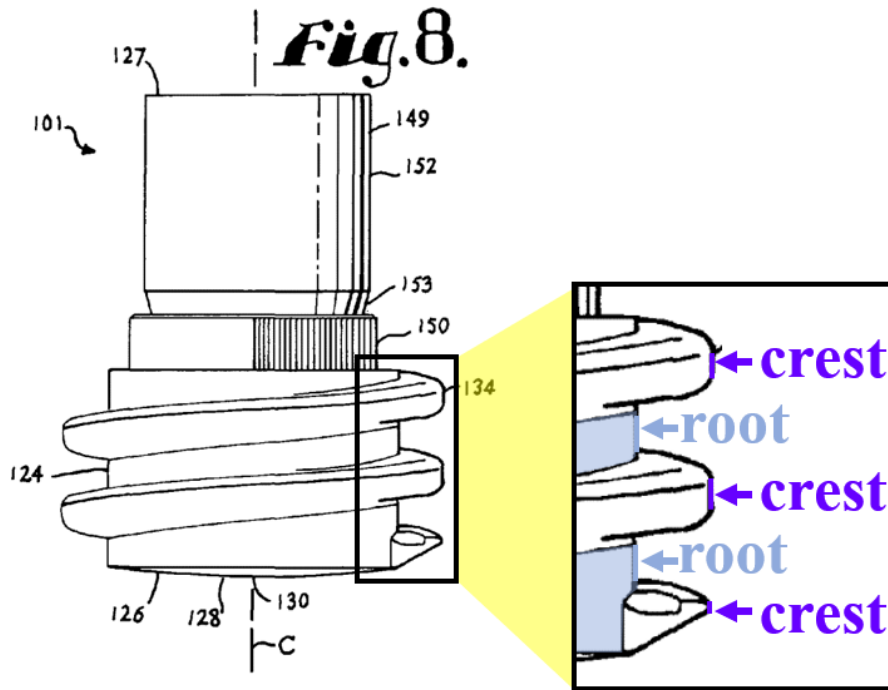
1. Threaded Connectors

48. 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 screw.

49. 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 threadform, the number of the threads and location and shape 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.” EX1031 (“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.*

50. The '477 Publication describes the root and crest of a thread form. EX1005, ¶[0031]. As shown in the annotated and enlarged Figure 8, below, the root is defined as the surface of the thread which joins the flanks of adjacent thread forms 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, which were important advantages in the field of spinal implants at least because they reduce surgical time and reduce the chance of implant failure.

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 ("the '001 Patent") (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, 2:50-54. The '001 Patent disclosed that "the superiority" of the multi-start threads is that they "prevent differential strain rates caused by the sudden one-sided 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.*, 2:54-56; *see also Id.*, 4:28-39, Fig. 4 (showing diametrically opposed thread starts). Accordingly, the '001 Patent

teaches that multi-start threads with thread starts equidistant around the 360-degree circumference of a fastener was 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 = $360 / \text{Number of starts}$."⁴ *Id.* Accordingly, for a dual 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

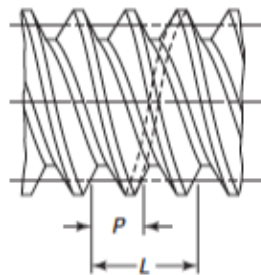
⁴ Emphases and text coloring in quotations added unless specified throughout.

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 refer to the same general concept.

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." EX1014 at 6. 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 threads were well known well before 2012, as evidenced by their description in the ASME 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." EX1031 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). 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

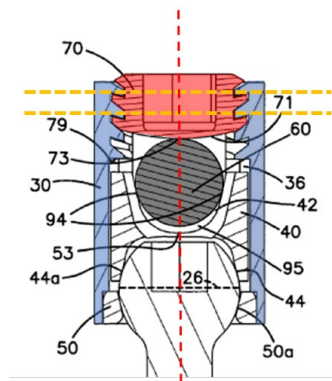
Id. at 9.

58. Before January 10, 2012, it was known that this multi-start threading could be used in spinal implants. For example, U.S. Patent No. 6,010,502 to Bagby (“Bagby”) (EX1026), 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.” EX1026, 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.*, 13:35-41. Thus, Bagby reinforces that dual-start threads use start structures that are diametrically opposed and offer advantages over a single start.

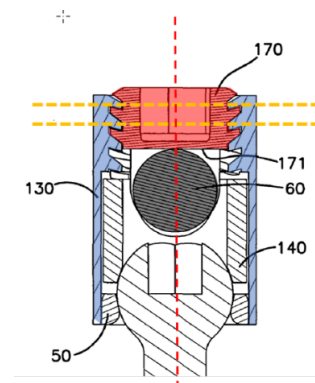
59. Moreover, before January 10, 2012, it was known that multi-start threads were beneficial, for the reasons discussed below, in the specific context of a set screw that needs to hold a rod in place in polyaxial spinal pedicle screw and rod spinal implants, the same as described by Jackson in the ’233 Patent. For example, Boschert disclosed a medical device comprising a receiver with a top portion that defines a pocket, or saddle (i.e., a channel), 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

(i.e., a closure). 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, 4:48-50. Boschert further disclosed that the threads of the setscrew 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 recognize that Boschert discloses diametrically opposed 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 thread leads are 180 apart (as illustrated by the yellow horizontal lines that are perpendicular to the red longitudinal line).

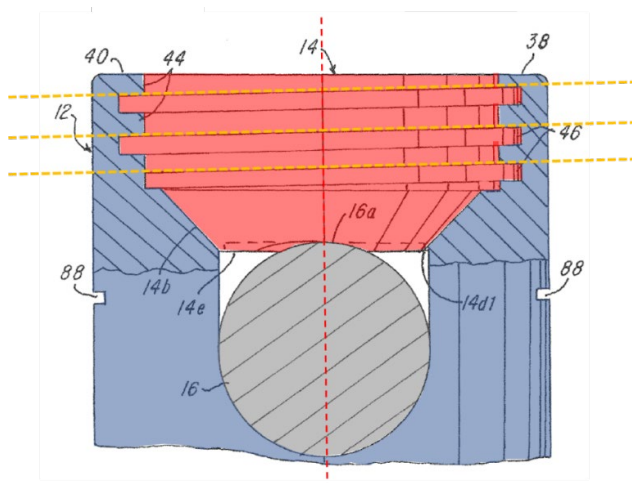


EX1006, Fig. 3



EX1006, Fig. 15

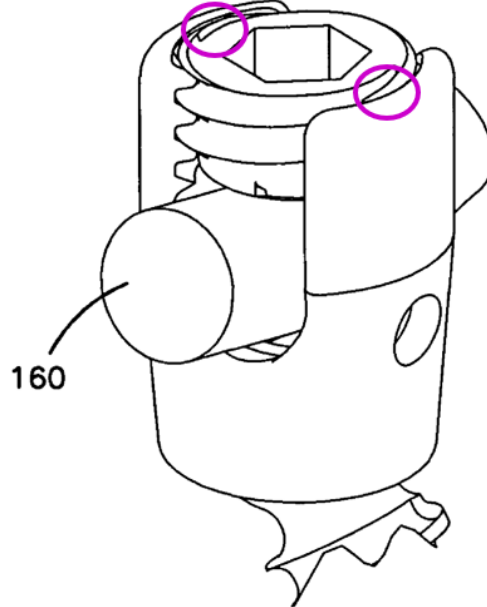
This is compared to the receiver (or, more generally, the corresponding thread) of a single-start closure top, with threads on each arm of the receiver that are not symmetrical or diametrically opposed, as shown below in Kirschman (as illustrated by the yellow lines that are not perpendicular to the red longitudinal line).



EX1033, Fig. 7

61. Finally, a POSA would recognize that Boschert discloses diametrically opposed starts because, as annotated Fig. 7 shows, at the top of the closure top the trailing ends of Boschert's 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 would have understood that diametrically opposed thread ends are the result of diametrically opposed thread starts.

thread end



EX1006, Fig. 7

Therefore, in my opinion, Boschert discloses 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 the two arms of the receiver.

62. A POSA would further have understood that for double start threads on the set screw (i.e., closure) 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 equidistance around their respective ends. This understanding is 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* ¶¶54-61. 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.

63. Thus, before January 10, 2012, a POSA would have been aware of multi-start threads (including diametrically opposed 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. Truncated Threads and Leading Face Shapes

64. Before January 10, 2012, it was known that truncating thread starts, rather than letting them taper out to a sharp leading edge, had certain advantages. Simple graphics depicting these two options are provided below.



Tapered Start



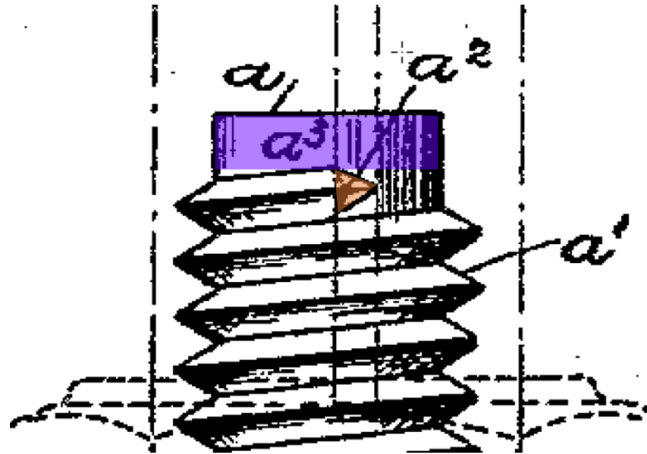
Truncated Start

By truncating a thread start a POSA was able to avoid very thin portions of the tapered thread, which are sharp and could cut a surgeon's glove, could be easily damaged, and could lead to cross threading. Truncating the thread was generally accomplished by removing a portion of the initially existing thread, which could leave an exposed protruding portion of the shank below the thread start. This had known advantages of facilitating alignment and starting of the threading. And by shaping the leading face of the thread, for example by adding a curvate shape, thread alignment and starting was even further facilitated.

65. U.S. Patent No. 447,775 to Higbee ("Higbee") (EX1015), entitled "Screw bolt and nut," issued in 1891 and disclosed a thread-start cut that is known today as the Higbee cut. Higbee noted that an issue in prior-art thread starts was that "[i]n threaded couplings of the kind described the thread is usually turned in or, on a cylindrical or annular part prepared to receive it, and at the end of said part the thread merges gradually in its face, which is usually in a plane at right angles to the center of the thread." EX1015, 1:20-26. "As a result of this mode of construction the end of the thread is for some distance very thin and by no means symmetrical to

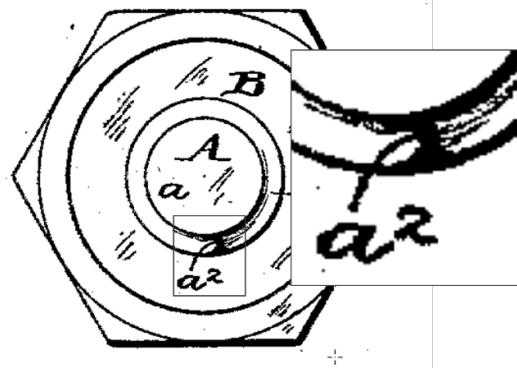
the center line of the thread” and, thus, threads “can be and frequently are put together wrongly, not only cramping and binding the parts but breaking and injuring the threads.” *Id.*, 1:26-34. To address this problem, Higbee disclosed “terminating the thread below the face-level of the cylinder or annulus on or in which it is formed, and forming the extreme end so that it will have a ***broad blunt face*** lying symmetrically on each side of the center line of the thread. By this construction the ends of the threads are made strong, stout, and of substantially the same cross-section as the thread itself, and the two parts of the union are fitted together with automatic precision, so that there is the ***least possible risk of jamming or breaking into the thread.***” *Id.*, 1:40-52.

66. Higbee disclosed that, in its figures, “A is the bolt, *a*, its end, *a'* its thread, and *a*² the thread end.” *Id.*, 2:67-68. As a result of removing the tailout section of the thread, Higbee noted that “the thread end *a*² or *b*² lies below the face or end *a* or *b* of the part in or on which it is formed.” *Id.*, 2:77-80. “By leaving the smooth extensions *a*³ or *b*³ as shown the nut and bolt or their equivalents are brought together and properly aligned before the thread ends engage, and thus an additional safeguard against misadjustment is provided.” *Id.*, 2:83-88. Cropped and annotated Figure 1 of Higbee shows the thread end *a*² (i.e., the start structure shown in orange) of thread *a'* and smooth extension *a*³ (shown in purple).



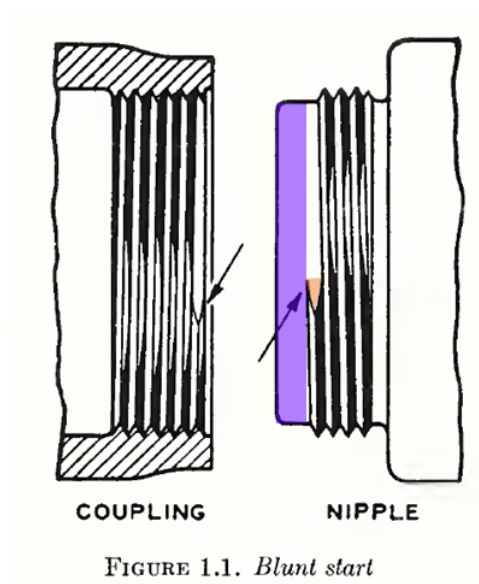
EX1015, Fig. 1 (cropped) [Higbee]

Further, Higbee disclosed that “[t]he exact form of the thread end is not very important so long as it is blunt and substantially symmetrical with respect to the center line of the thread” and “may be cut off on an oblique plane, as in Figs. 1, 2, 3, and 4, or cut off square, as in Fig. 5, or rounded, as in Fig. 6.” *Id.*, 2:88-94. The rounded thread end a^2 is shown in enlarged Figure 6 at right.



67. The Higbee cut, which is also known as a blunt start, blunt end thread, or truncated thread start, was well-known to a POSA before January 10, 2012. Indeed, Handbook H28 stated that “Blunt start” or “blunt end” “designates the removal of the incomplete thread at the end of the thread. This is a feature of threaded parts that are repeatedly assembled by hand, such as hose couplings and thread plug gages, to *prevent cutting of hands and crossing of threads*, and which

was formerly known as a *Higbee cut*.” EX1024 at 13. As shown in the annotated figure below, the Handbook H28 depicted the blunt start as follows (arrows pointing to the starts):

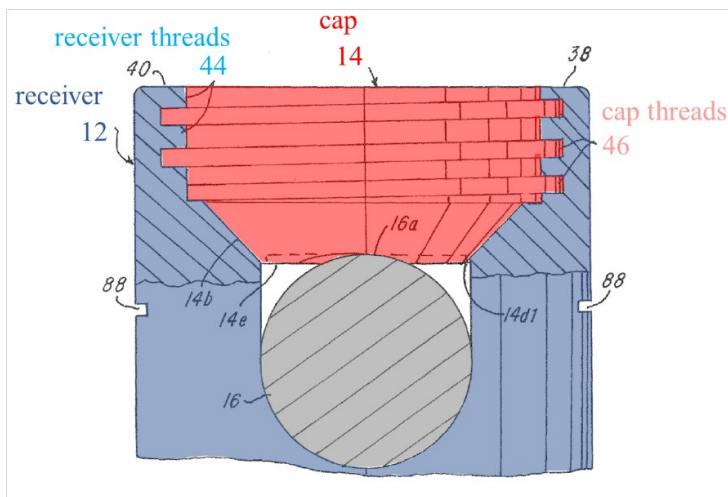


EX1024 at 13. This depiction also clearly shows the smooth extension of the nipple extending below the thread start structure to facilitate alignment, as was taught by Higbee.

68. Before January 10, 2012, truncated thread starts, including curvate leading surfaces, had also been applied to set screws in polyaxial pedicle screw and rod spinal implant systems similar to those of the '233 Patent by Jackson. For example, Kirschman, which was filed in December 2009 and published in June 2011, disclosed “[a]n implant having a receiver that is adapted to receive a polyaxial screw in the bore and either an internal or external cap.” EX1033, Abstract.

Kirschman disclosed that, while the “purpose of the threaded locking cap is to affix a spinal stabilizing element,” *id.*, ¶[0004], a cap “may be difficult to engage in the tulip or receiver” because “the thread start-point of both the male and female threads are difficult to identify in a surgical environment,” which is “exacerbated by the necessity to make thread dimensions very small in order to limit the size of the implant due to anatomical constraints,” *id.*, ¶[0006]. Thus, Kirschman identified a need for “a thread design that prevents cross threading of the small-pitch threads of the locking cap/tulip pair, achieves high connection strength immediately after initial thread engagement and offers improved tactile feedback of thread engagement to the surgeon.” *Id.*, ¶[0008].

69. In response to this need, Kirschman disclosed truncated thread starts on the closure. As shown in annotated Figure 7 below, Kirschman disclosed a receiver with first and second arcuate wall threads 42 and 44 that “cooperate to define the receiver threads for threadably receiving male cap threads 46 on the cap 14 [i.e., a closure] so that the cap 14 can be screwed onto the receiver 12 in order to lock the rod 16 in the rod-receiving channel 28 of the receiver 12.” *Id.*, ¶[0036].



The cap threads 46 and receiver threads also include leading edge portions 46a and 44a1 (i.e. the start structures), respectively, that are “truncated and adapted so that when these leading edge portions 44a1 and 46a are adjacent each other and initially pass each other when the cap 14 is mounted on the receiver 12, the leading edge portions 44a1 and 46a move relative to each other a drop down distance DD.” *Id.*, ¶[0038]. As shown below in annotated Figures 3 and 4, Kirschman shows the truncated, curved end of the cap thread, highlighted in orange below.

EX1033

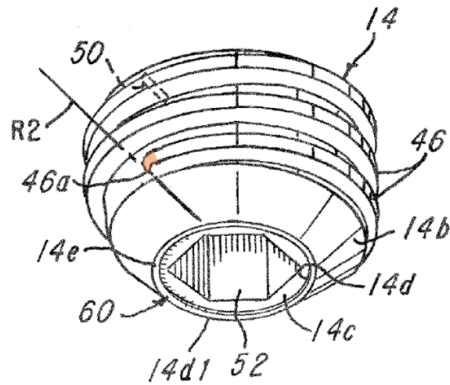


Fig. 3

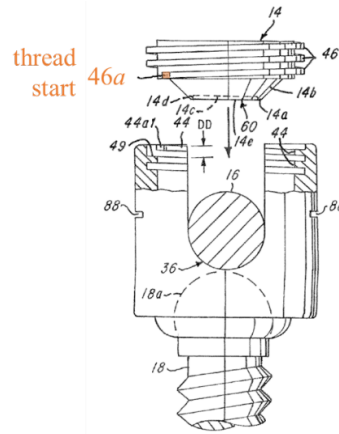
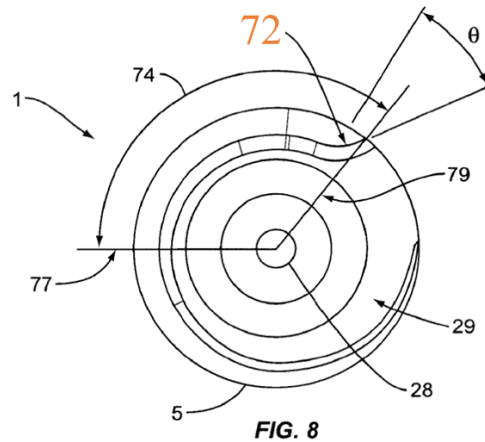


Fig. 4

As evidenced by Kirschman's identification of the 1891 patent to Higbee (U.S. Patent No. 447,775) (EX1015) as "first invent[ing]" "[u]tilizing blunt-tip threads for the prevention of cross threading," Kirschman acknowledges that truncated leads of threads was prior art. EX1033, ¶[0009].

70. Another example of prior art recognizing the advantage of truncated leading edge is Patent Application Pub No. US 2011/0106179 to Prevost et al. ("Prevost") (EX1022), entitled "Set screw having variable pitch thread for use with spinal implant systems," filed on October 30, 2009, and published on May 5, 2011. As shown in annotated Figure 8 below, Prevost disclosed that "[t]he external thread 5 not only has a variable pitch but also includes a *truncation cut 74 at the thread start 72*. Referring to FIG. 8, the external thread 5 includes a thread start 72 at the bottom end 29 of the set screw 1. Thread start 72, as used herein, means the location

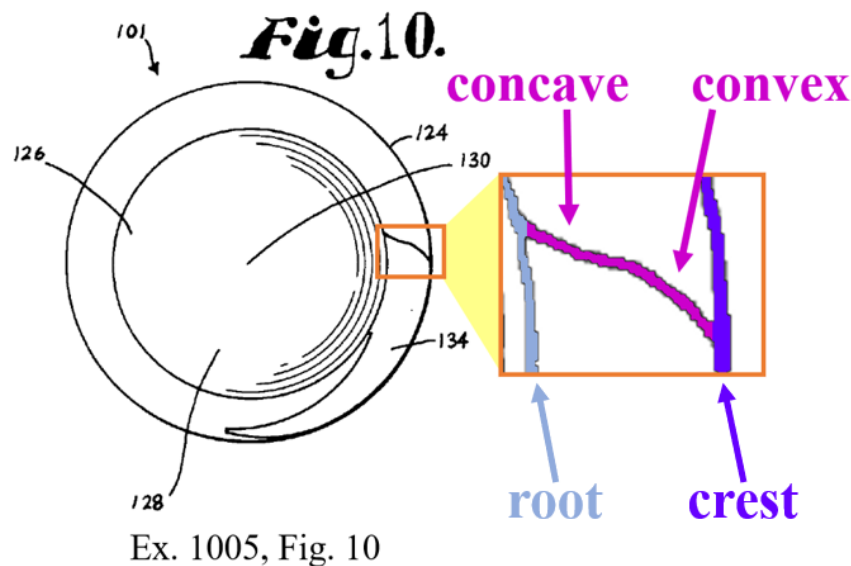
at the bottom end 29 of the set screw 1 where the external thread 5 begins. The thread start 72 has a truncation cut 74 *so the threading begins smoothly and consistently at the same location.*” EX1022, ¶[0031].



Id., Fig. 8. Prevost disclosed the advantages of the truncation of the leading edge of the screw thread and the curvate leading edge 72 shown on his Figure 8. *Id.*

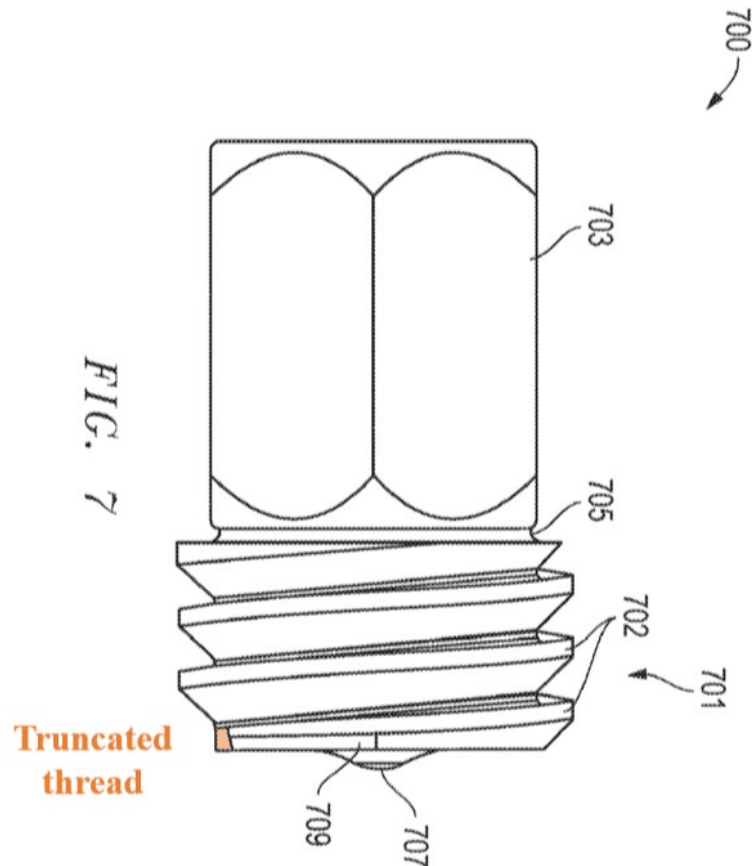
71. As another example, the '477 Publication, which published on December 1, 2005, discloses a “closure for use in conjunction with an open receiver of a medical implant for capturing and locking a rod member in the implant.” EX1005, Abstract. The '477 Publication disclosed two embodiments of its closure. For the first embodiment, the '477 Publication disclosed that the closure is cylindrical with a helically wound guide and advancement structure along the outside surface. *Id.*, ¶¶[0029]-[0030]; *see also id.*, Fig. 1. For the second embodiment, the '477 Publication incorporated most of the features from the first embodiment. *Id.*, ¶[0039]. The primary difference between the embodiments is the

shape of the closure break-off head. *Id.*, ¶¶[0033] (hexagonal), [0043] (cylindrical); *compare id.* Fig. 1, with *id.*, Fig. 7. As shown in the annotated figures below, the '477 Publication disclosed a start structure with a leading face that is truncated and includes a concave segment near the thread root and a convex segment near the thread crest. *Id.*, Figs. 7, 10.



72. As a further example, U.S. Patent Application Publication No. 2010/0137918 to Wilcox et al. (“Wilcox”) (EX1038), which published on June 3, 2010, discloses a “method of conducting a surgery” that “includes implanting an anchor into a bone” with an anchor that “comprises a screw coupled to a receiving portion that is configured to engage a rod” and a “set screw” to “coupl[e] the rod within the receiving portion.” EX1038, ¶[0010]. As shown below in annotated Figure 7, Wilcox discloses that its set screw has a threaded portion 701 that “includes

a Higby-style truncation 709 of the initial thread 702 which facilitates easier threading of the set screw 700 within the head portion 307. The Higby-style truncation 709 is manufactured such that the leading razor edge of the thread is removed.” *Id.*, ¶[0050].



Id., Fig. 7.

73. Thus, before January 10, 2012, a POSA was aware of truncated threads with a curvate leading face spaced above the bottom of the closure, and was further aware that such constructs provided advantages for facilitating thread alignment and

starting. Before January 10, 2012, double start threads, truncated Higbee type threads, and a curvate leading face for a thread were all available design choices for a POSA. By that time, a POSA would commonly know to select a double start thread for easier engagement in a surgical setting and to more rapidly screw the closure in place in the receiver, or a truncated thread for easier positioning with less possibility of thread damage on either single or double start closures. In addition, by that time, a POSA would commonly know to select a curvate leading face in order to present a less sharp surface for surgeon's gloves on either a single or a double start closure. Indeed, based on my experience as a POSA as of January 10, 2012, it is my opinion that a POSA would have understood that surgeons did not like sharp edges that could potentially cut their gloves and that a POSA would have understood that it was advantageous to avoid sharp corners.

c. Thread Manufacturing

74. Before January 10, 2012, a POSA would have understood several basic concepts regarding the thread manufacturing. As an initial matter, a POSA would have understood that a thread is a “ridge, usually of uniform section and produced by forming a groove in the form of a helix on the external or internal surface of a cylinder.” EX1024 at 10. A POSA would have also understood that a thread includes a crest is the “surface of the thread which joins the flanks of the thread and is farthest from the cylinder or cone from which the thread projects,” and a root is

the “surface of the thread which joins the flanks of adjacent thread forms and is identical with or immediately adjacent to the cylinder or cone from which the thread projects.” *Id.* at 12.

75. Before January 10, 2012, a POSA would have understood that there were alternative ways to manufacture threads, including thread cutting, thread milling, and thread rolling. Regardless of the specific method used, a POSA would have understood that the basic process for manufacturing a thread generally begins with a metal cylinder. To form a thread, a POSA would have understood that a tool or cutter machines grooves into the cylinder (either on the outside for a male component or on the inside of a hollow cylinder for a female component), based on desired thread parameters, to form ridges that comprise the thread. The result of this process would be the formation of a thread that continues to the bottom of the original cylinder. Due to the way that threads are created, the bottom threading would be relatively sharp and pointed.

76. As discussed above, before January 10, 2012, a POSA would have understood that there are distinct advantages to applying a further finish to threading after the initial cuts. Specifically, a POSA would have understood that a truncated cut of the threading would result in the ends of threads that are strong, stout, and have a reduced chance of jamming or breaking. EX1015, 1:40-52. ASME Standard B1.7-2006 also mentions Higbee in its definition of a “blunt start thread”

as “a thread with removal of the incomplete thread at the starting end (see Fig. 4). This is a feature of the threaded parts that are repeatedly assembled by hand, such as hose couplings and thread gages, to prevent cutting of hands and crossing of threads. Also known as Higbee cut or a convoluted thread.” EX1031 at 6.

77. To create such a blunt start thread, a POSA would have understood that an additional process would often need to be applied to the thread. *See* U.S. Patent Application Publication No. 2005/0286984 to Weise (EX1049), ¶¶[0033]-[0036]. In particular, a POSA would have understood that one process would have been to use a groove tool to essentially shave off the bottom of the thread so that the thread’s leading face is spaced above the bottom of the end of the metal cylinder resulting in a truncated thread, *id.*, ¶¶[0034]-[0036], as also shown below in the excerpt from Handbook H28.

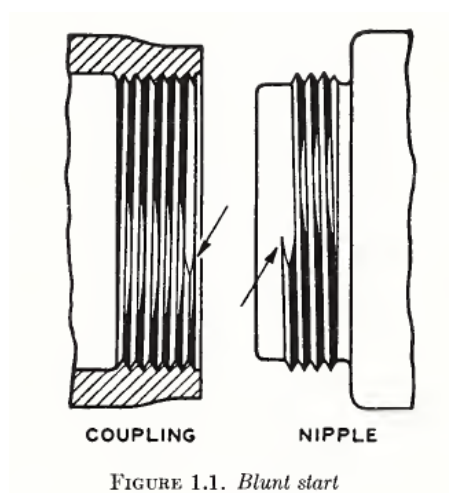


FIGURE 1.1. *Blunt start*

EX1024 at 13. Once the thread has been shaved to the appropriate depth, the tool would lift off from, or exit, the thread profile. A POSA would have further

understood that one such tool that would have been used to shave off the bottom of a thread would have been a tool with a circular end. A POSA would have understood that the result would have been a concave curvate surface on the leading face of the thread near the root of the thread. EX1049, ¶[0034]. Moreover, a sanding, grinding, or milling bit used to truncate the threads would have typically left a concave, curvate surface near the root of the thread. Depending on the tool's exit or its CNC programming, the leading face near the crest of the thread could advantageously be rounded to avoid sharp edges, resulting in a convex shape of the leading surface near the crest of the thread. *Id.*, ¶¶[0034]-[0036]. Alternatively, a post-forming process could have been used, such as tumbling or electropolishing. In these circumstances, the use of standard manufacturing practices (as I described above) typically resulted in a leading face of the thread that is both concave near the root and convex near the crest.

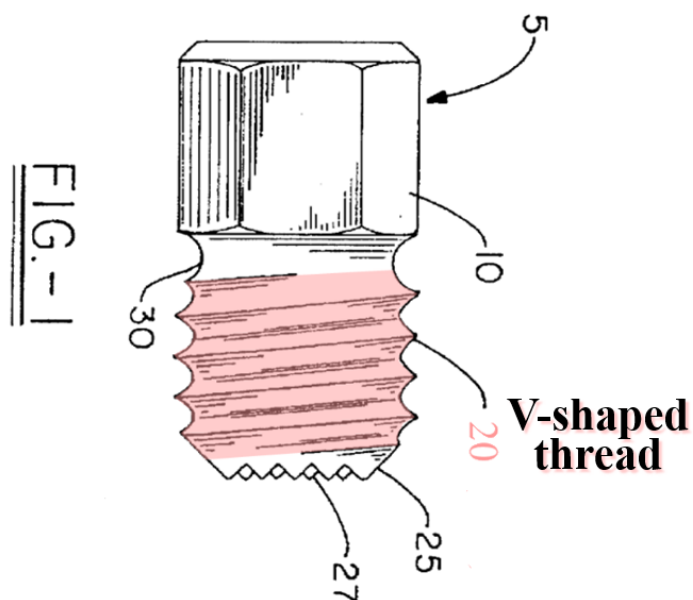
78. As discussed above, before January 10, 2012, a POSA would have understood the benefit of avoiding a thread leading face that is sharp or pointed. A POSA would also have understood that, if the groove tool exits the thread in such a way that the leading face is only concave, the result would be a sharp or pointed edge of the thread adjacent the crest of the thread. *See* EX1022, Fig. 8. As a result, before January 10, 2012, a POSA would have understood that a leading face that was only concave was not optimal. Instead, a POSA would have understood that a

leading face that was concave near the root and convex near the crest would avoid a sharp or pointed edge because the convex surface of the leading face would round off, or blunt, the sharpness adjacent the crest of the thread. Indeed, Higbee explains that a thread face can be rounded. EX1015, 1:88-94. Therefore, in my opinion, common manufacturing techniques and choices as of January 10, 2012, would have resulted in the obvious construction of a rounded, non-sharp, and convex start of the truncated thread and a rounded and concave ending of the thread start.

d. Closure Thread Types

79. As the '233 Patent admits, before January 10, 2012, “***known 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, 1:64-2:3.

80. An example of a traditional V-shaped thread can be found in the 1997 U.S. Patent No. 5,697,929 to Mellinger (“Mellinger ’929”) (EX1027). As shown in annotated Figure 1 below, Mellinger ’929 discloses that the “thread configuration is a ***standard, V-shaped thread***.” EX1027, 2:60-61.



81. While V-shaped threads were the oldest thread configuration, a number of alternative thread designs were also well known well-before the '233 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. 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; 4:43-5:13; Fig. 3.

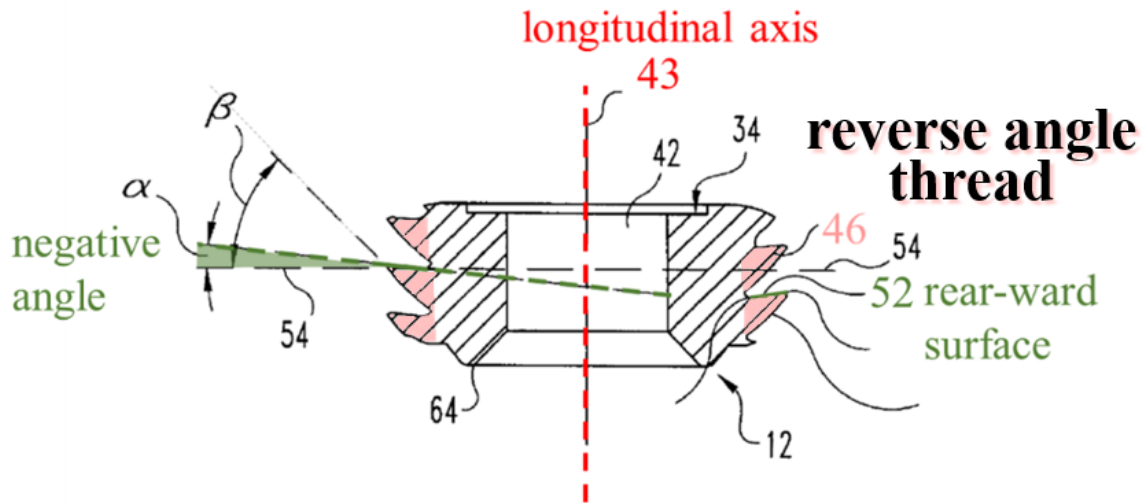
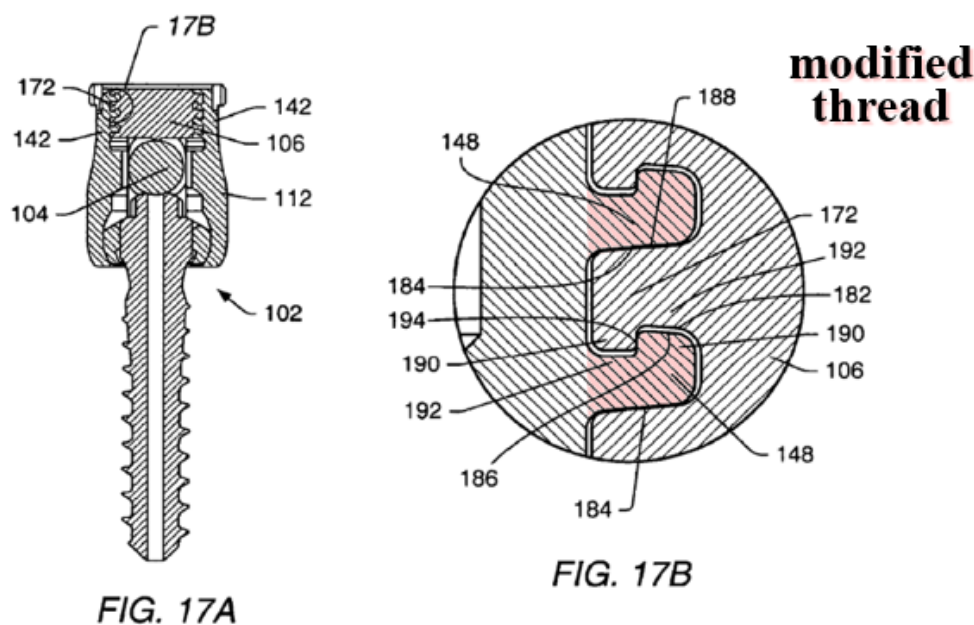


Fig. 3

Specifically, Morrison teaches that the “pressure angle is between -1 and -40 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.

82. Alternatively, helical flange threads forms were also well known, an example of which can be found in the 2007 U.S. Patent No. 7,250,052 to Landry. (“Landry”) (EX1019). 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

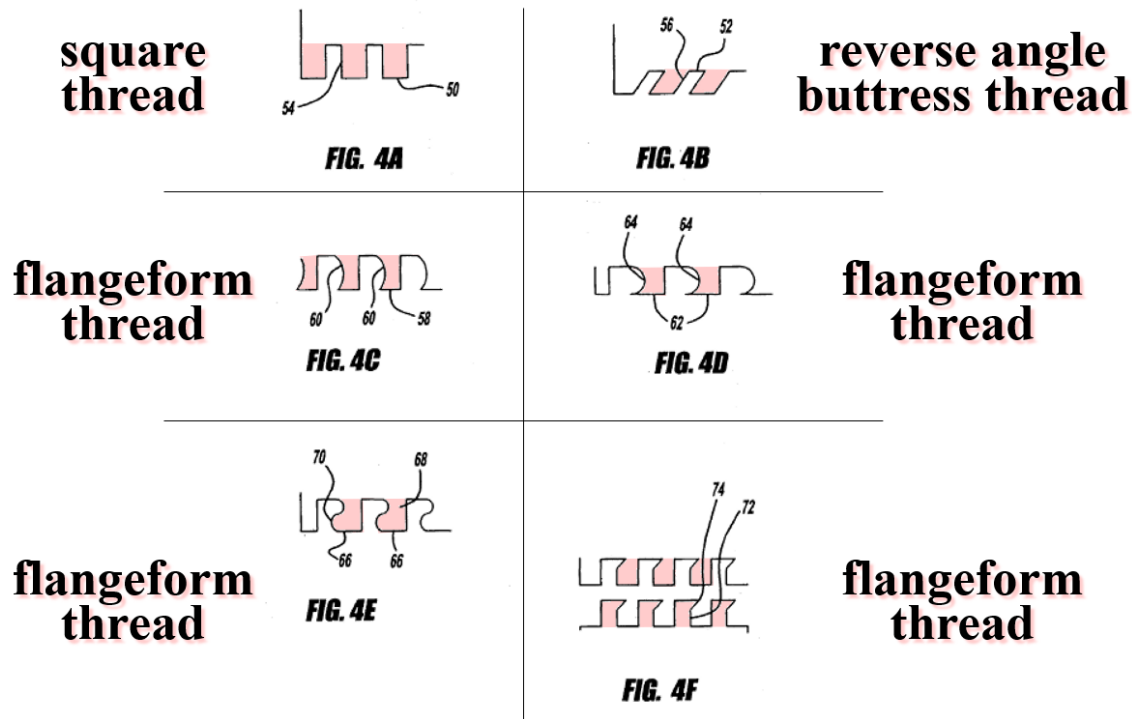
another during use.” *Id.*, 17:37-41. “Engagement of cooperating surfaces 194 may *inhibit spreading of arms 142 away from each other.*” *Id.* 17:45-47.



Id., Figs. 17A, 17B. Landry further acknowledges several other well-known threadform 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.

83. As shown in annotated Figures 4A-F below, U.S. Patent Publication No. 2004/0162560 to Raynor (“Raynor”) (EX1021) also discusses a number of alternative threadforms for spinal implant set screws, including square threads (Fig.

4A), reverse angle buttress threads (Fig. 4B), and a variety of flangeform threads that provide a “gripping function” (Figs. 4C-F). EX1021, ¶¶[0028]-[0029].



84. Jackson himself acknowledged that all of these alternative threadforms 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 (EX1028), 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.”); EX1007 (’287 Publication), ¶[0151] (“However, it is foreseen that the guide and advancement structure 162B could alternatively be *a buttress thread, a square thread, a reverse angle thread or other thread like or non-thread like helically wound advancement structures* for operably guiding under rotation and advancing the closure 30B downward between the arms 152B[.]”). 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

85. 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. In some instances, the development of minimally invasive, percutaneous, laparoscopic, endoscopic, or computer controlled surgical techniques would require the selection of different designs or features of implants. For example, the use of a guidewire for the implantation of screws in a minimally invasive surgery might demand that the system be cannulated with a hole through the center of a screw and set screw, which could affect selection of set screw features. Here, I will specifically address the advantages of known design options related to attachable guide tools and tool grooves, break-off receiver arm extensions, and top loaded inserts.

a. Designs for Facilitating Implantation of Spinal Implant Devices

86. 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.a.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 & Tool Grooves

87. 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.

88. These tools and devices could be detachably attached to grooves or apertures specifically shaped, sized, and located on the outside surfaces of the bone screw receiver to mate with the tool(s), whether during implantation or, if necessary, removal of the implants. It was well-known that tool attachment grooves or slots could be included on the arms of a receiver to allow for attachment of various tools to the receiver. As was well known before January 10, 2012, the shape, size, and location of a tool groove or aperture on the outside of a screw head correlates to the shape, size, and location of the corresponding guide tool. *E.g.*, EX1007, ¶[0152]

(“*[T]ool attachment receiving grooves or apertures may be configured in a variety of sizes and shapes, including radiused*, and be disposed at other locations on the arms 152B.”); U.S. Patent Application Publication No. 2006/0069391 (“the ’391 Publication”) (EX1020), ¶[0116] (“other suitable attachment structure[s] could be used, such as *sloped or tapered undercut surfaces* on the screw heads that overlap, mate and interlock with radially or linearly projecting structure[s] on or near the ends of the guide tools.”); EX1020, ¶[0180] (“[T]he apertures . . . may be configured to be of a variety of sizes and locations for attachment to the guide tool along any of the surfaces of the arms 444 and 445.”); U.S. Patent No. 7,854,751 to Sicvol (“Sicvol”) (EX1030), 9:47-49 (“Each groove 130A, 130B may have size and shape that is complementary in size and shape to a projection provided on the instrument.”). In other words, the tool grooves interact directly with the ends of the guide tools and must therefore be sized, shaped, and located to effectively capture the guide tool. For example, some guide tools have flexible arms that expand over the top of the receiver head and then snap into place below the top lip of the tool groove. Other guide tools rotate into the tool attachment grooves, which requires at least that the tool attachment groove be curvate. In this way, it was known that tool attachment grooves and apertures could take a variety of forms or shapes and could be located anywhere on the outside surfaces of the receiver as long as they could be effectively used with the corresponding guide tool. Some examples of these well-

known tool attachment structures and design elements in the prior art are discussed below.

89. As early as 1985, U.S. Patent No. 4,545,374 to Jacobson (“Jacobson”) (EX1046) 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.” EX1046, 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.

90. U.S. Patent No. 7,862,595 to Foley (“Foley”) (EX1040), 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. EX1040, 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.

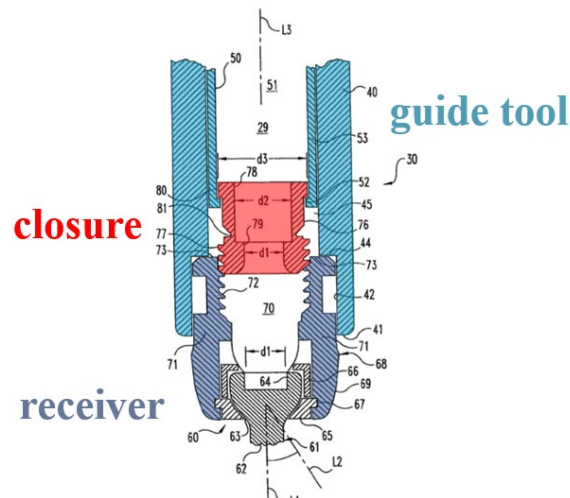
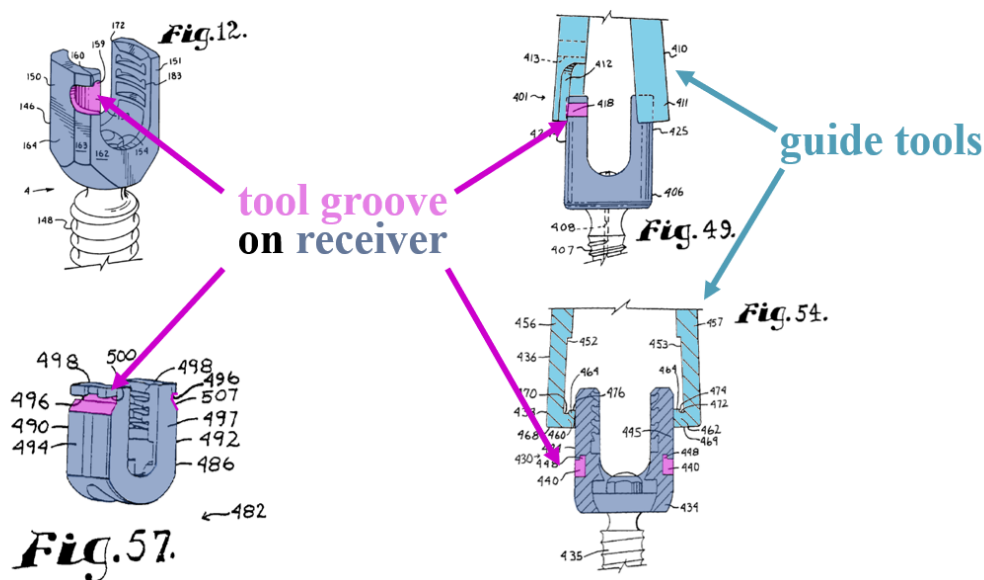


Fig. 4

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[d] . . . from anchor 60 . . . allowing removal of extensions 30, 230 from the subject.” *Id.*, 14:22-26.

91. In 2006, the '391 Publication disclosed a variety of tool grooves as part of a system “for percutaneously implanting spinal screws and for implanting a rod for spinal support and alignment, using minimally invasive techniques.” EX1020, ¶[0002]. The tool set disclosed in the '391 Publication includes implant and guide tools configured for releasable attachment to a spinal implant bone screw, hook, etc.

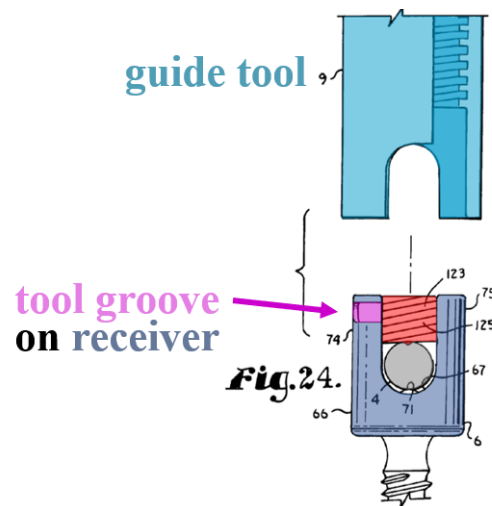
Id., ¶¶[0007], [0009]. The attachment structure on the bone screw for joining these tools to the bone screw can take any of a variety of forms, including “radial mating projections and receivers or grooves that allow the guide tool to be twisted on and twisted from the head of the bone screw.” *Id.*, ¶[0017]. In particular, as shown below in annotated Figures 12, 49, 54, and 57, the ’391 Publication disclosed four different tool grooves of different shapes and at different locations on each respective receiver, as shown and described in more detail below. *Id.*, Figs. 12, 49, 54, 57.



92. As a further example, in 2007, U.S. Patent No. 7,160,300 to Jackson (“Jackson ’300”) (EX1041) disclosed similar apparatuses for “percutaneously implanting a rod for spinal support and alignment using minimally invasive techniques,” recognizing that was “desirable to develop apparatuses and techniques

that allow for the insertion of bone screws . . . with significantly reduced invasion into the body of the patient and with minimal incision size in the skin over the operational site.” EX1041, 1:6-32. Jackson ’300 disclosed using the tool groove to detachably affix the guide tool to the receiver in order to pass a closure into the receiver from outside the patient’s body. Specifically, as seen in annotated Figure 24 below, Jackson ’300 disclosed a “guide tool 9” with an attachment structure to be received in a groove, identified as “circumferentially located receiver 78” (i.e., the tool groove) on the outer surface of bone screw head 66 (i.e., the receiver) adjacent the top surface and extending to the front of screw head 66. *Id.*, 6:7-16.

Fig. 24.

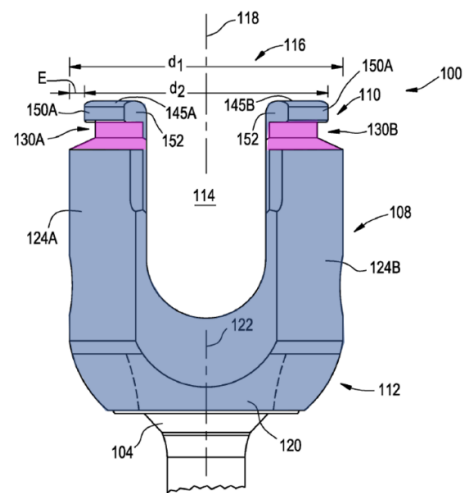


Jackson ’300 also notes that receiver 78 (i.e., the tool groove) can “be located anywhere on the bone screw head 66” (i.e., the receiver). *Id.*, 6:7-16; *see also id.*, Figs. 17, 18, 22.

93. As another example, Sicvol, 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.” EX1030, 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, Sicvol disclosed bone anchor assembly 100 with receiving member 108 that “include[s] at least one *groove*

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; *see id.*, 8:22-10:15. As shown in annotated Figure 6 (at right), 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 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.

FIG. 6



94. As another example, U.S. Patent Application Publication No. 2006/0036244 to Spitler (“Spitler”) (EX1032), entitled “Implant assembly and method for use in an internal structure stabilization system,” published on February 16, 2006 and, as shown in annotated Figure 15 (right), disclosed a stabilization assembly with head 1500 that included a “[r]educed area **1521a and 1521b** [that] form a groove with ledge 1501 acting as a stop” (shown at right). EX1032, ¶[0137], Figs. 15, 17. Spitler further disclosed that “[t]his **grove accepts an extension**, such as the extension shown in FIG. 30-32.” *Id.*; *see id.*, Figs. 1, 3, 11-14, 20, 22a-23, 30-32, 37.

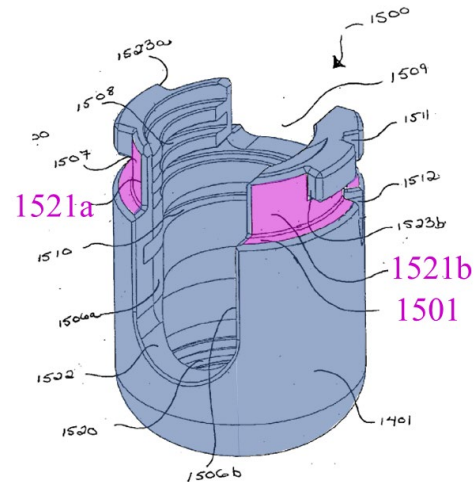
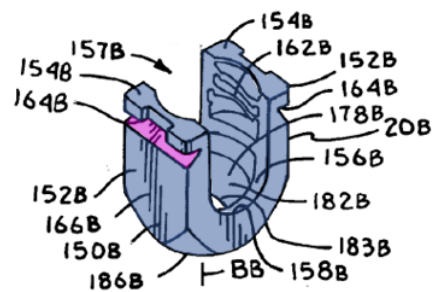


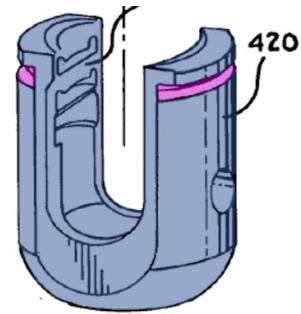
FIG.15

95. As a further example, the '287 Publication disclosed multiple embodiments of a dynamic fixation medical implant that includes a receiver with different grooves on the outside surfaces of the receiver arms. As shown in annotated Figure 37 below, as to the first tool attachment embodiment in the '287 Publication, “[e]ach of the arms 152B includes a **V-shaped-like under-cut tool engagement groove 164B** formed on a substantially planar outer surface 166B



thereof which may be used for holding the receiver 20B with a holding tool (not shown) having projections that are received within the grooves 164B during implantation of the shank body 16B into the vertebra.” *Id.*, ¶[0152], Fig. 37; *see also id.*, ¶[0078]. The ’287 Publication disclosed that “tool attachment receiving grooves or apertures may be configured in a variety of sizes and shapes, including radiused, and be disposed at other locations on the arms 152B.” *Id.*, ¶[0152]; *see also id.*, Figs. 5-9, 14-17, 32-34, 37, 39.

96. The other embodiment is receiver 420, which is “identical or substantially similar” to receiver 20 (and receiver 20B). *Id.*, ¶[0097]. As to the shape, as shown in cropped and annotated Figure 22 (right), the outer side surfaces of receiver 420 are substantially cylindrical, the tool grooves on each arm are radiused. *Id.*, Fig. 22.



97. As seen in the examples above, various design choices were available to a POSA as to how to design and locate a tool attachment groove or aperture on the outside of a bone screw receiver head, and these design choices were dictated by the shape and function of a corresponding guide tool.

98. Thus, before January 10, 2012, tool grooves on the arms of receiver heads were well-known and a familiar element of spinal implants to a POSA.

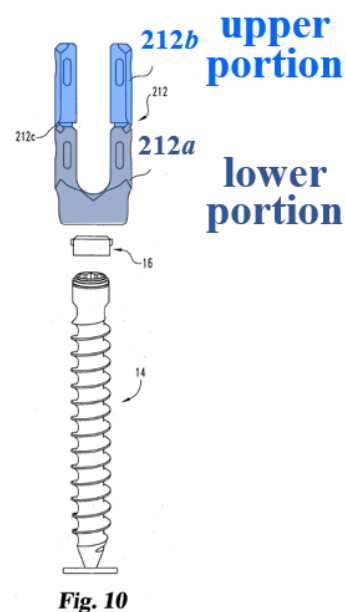
99. The decision to use or not use a tool groove, how to configure the tool groove, and where to place it on the outside of the receiver, was independent of other aspects of the pedicle screw and rod system such as whether the leading edge of a thread is truncated or whether a single or double thread start is used.

ii. Break-Off Receiver Arm Extensions

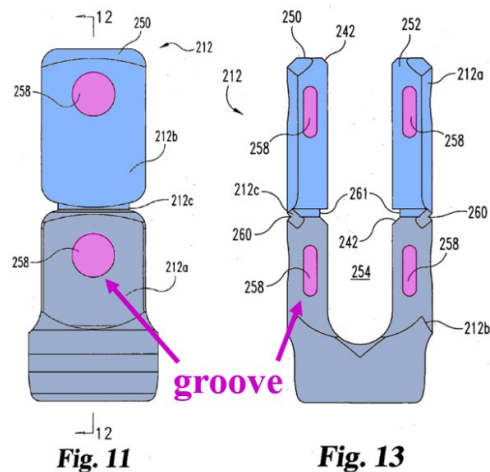
100. Before January 10, 2012, it was well-known that break-off extensions could be used in spinal implant devices, sometimes an alternative to using a separate guide tool. As discussed above, during a spine surgery using the devices at issue, a rod is placed into the U-shaped receiver of a spine screw, 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. Unlike attachable/detachable guide tools, the breakoff arms cannot be re-attached once removed. As a result, POSA would have known of the benefit of including both breakoff arm extensions and a tool groove(s) 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.

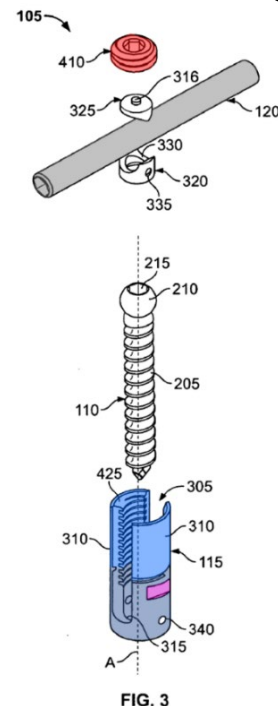
101. For example, in 2007, Johnson disclosed break-off extension receiver arms. In particular, as shown in the annotated Figure 10, a receiver member 212 “has a lower portion 212a and an upper portion 212b separated by a thinned section 212c.” EX1008, ¶[0051]. Johnson disclosed that the “[t]hinned section 212 c” “separates upper portion 212b and lower portion 212a.” *Id.*, ¶[0054]. Johnson disclosed that, “[o]nce the compression member is tightened against elongated member 220 to lock the assembly to the surgeon’s satisfaction, *upper portion 212b may be cut or sheared*



off or otherwise removed from lower portion 212a.” Id., ¶[0056]. Johnson disclosed that, “[o]nce separated, *upper portion 212b may be removed* from the surgical site and discarded.” *Id.* As further shown in annotated Figures 11 and 13 (right), Johnson disclosed tool attachment grooves “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].

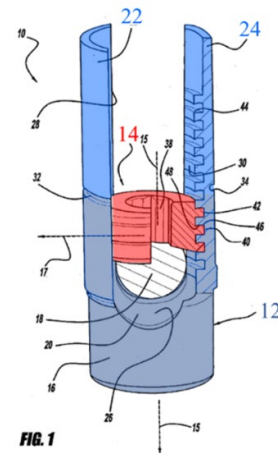


102. U.S. Patent Application Publication No. 2007/0270813 to Garamszegi (“Garamszegi ’813”) also disclosed breakoff extension arms and a tool attachment groove. As shown in annotated Figure 3, Garamszegi ’813 disclosed a pedicle screw assembly that includes coupling element 115 (blue) configured to receive 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

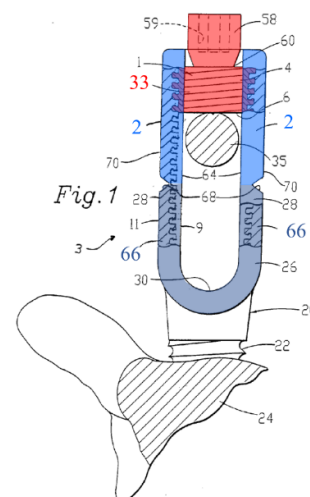


on compression nut 410 (red). *Id.* ¶¶[0055]-[0056]. On the outside surface of the coupling element 115 is a tool attachment groove (purple).

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



104. As shown in annotated Figure 1, U.S. Patent Application Publication No. 2006/0058794 to Jackson (“Jackson ’794”) (EX1023) 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.” EX1023, ¶[0041]. Jackson ’794 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



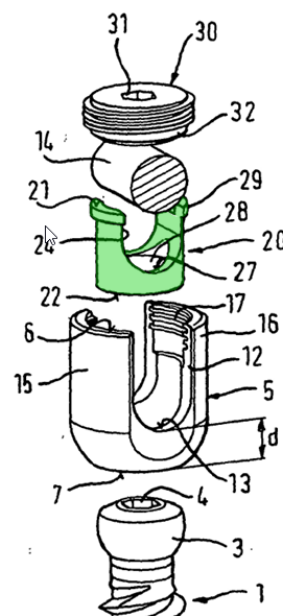
main portions 66 are held in place, after the closure 33 has passed between the extensions 2,” “**resulting**” in a “**low-profile implanted structure.**” *Id.*; see also *id.*, Abstract, ¶¶[0019]-[0020], [0027], [0040], Figs. 1-2, 6, cls. 1, 6, 10, 16.

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

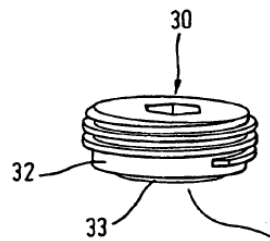
106. The decision to use or not use breakoff arm extensions was independent of other aspects of the pedicle screw and rod system such as whether a reverse angle thread is used, whether the leading edge of a thread is truncated, or whether a single or double thread start is used.

b. Top-Loaded Inserts

107. Before January 10, 2012, it was well-known that a variety of inserts could be added to a bone screw assembly in order to support a longitudinal connecting member, such as a rod, within the bone screw assembly and to fix the position of the receiver head in relation to the screw shank. An insert could be any structure placed between the longitudinal connecting member and the screw shank head. Such a structure was often referred to as an insert but could also be referred to as, *inter alia*, a seat, a pressure element, a saddle, or a spacer. An example depiction of the relationship between a rod (14), screw shank



head (3), receiver head (5), and insert (20, **green**) is shown above in the excerpted, annotated figure from the 2007 European Patent No. 1,743,584 to Matthis et al. (“Matthis”) (EX1034). As shown in the excerpted Figure 6 below, Matthis also disclosed a set screw with a truncated thread start that is located above the flat bottom of the set screw.



EX1034, Fig. 6.

108. While the specific shapes and sizes of the inserts may vary, inserts were most commonly shaped so as to have top and bottom surfaces that correspond to the surfaces of the longitudinal connecting member and the screw shank head of the bone anchor assembly. For instance, for a cylindrically shaped longitudinal connecting member (e.g., a rod), the top side of the insert would often have a U-shaped channel to accommodate the bottom side of a cylindrical rod. For a partially spherical screw shank head (e.g., as commonly used in a polyaxial bone screw assembly), the bottom side of the insert would often have a concave surface to accommodate the screw shank head.

109. It was well-known that including such an insert as an intermediary structure between the connecting member and screw shank in the bone anchor

assembly would more evenly distribute the forces applied between those components. For instance, the U-shaped channel of an insert provides additional points of contact with—and, therefore, more evenly distributed support for—the longitudinal connecting member as compared to an assembly in which the connecting member sits directly atop the spherical screw shank head. Likewise, the concave bottom side of an insert provides additional points of contact with the spherical screw shank head, thereby more evenly applying any downward force onto the screw shank head as compared to an assembly in which the connecting member sits directly atop the spherical screw shank head.

110. Indeed, it was well-known that the application of downward force onto a screw shank head was an important function of the insert component in a bone screw assembly. This downward force served multiple purposes. First, the downward force would prevent the bone screw shank from moving upward within the receiver. Additionally, the downward force would, in some instances, press the screw shank head downwards onto a seating surface of the receiver and, in doing so, create friction between the surfaces of the screw shank head and receiver. Using downward force to create this friction was particularly important for bone screw assemblies allowing for rotational articulation of the bone shank relative to the receiver head (e.g., a “polyaxial” bone screw assembly) because the downward force

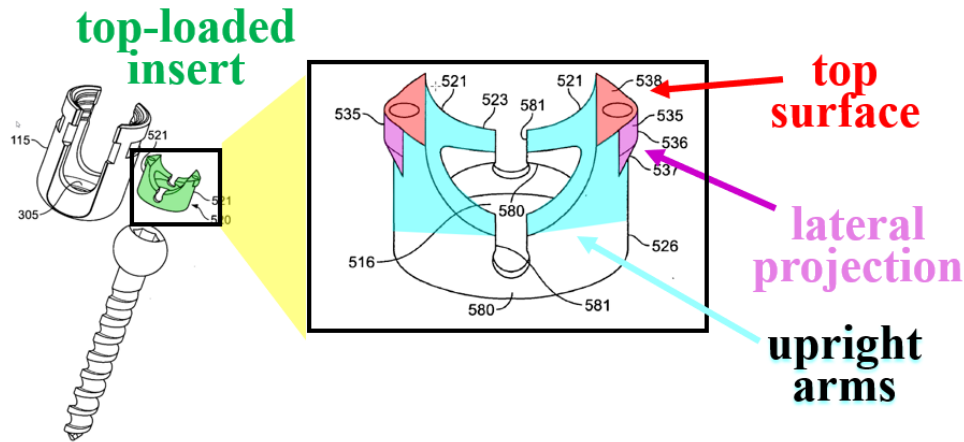
would be sufficient to fix the shank head within the receiver at a particular angle of articulation.

111. It was further known that application of downward force could be accomplished in multiple ways. There were at least two categories of inserts capable of applying downward force in this manner. First, there were inserts that applied downward force upon the placement of a closure or set screw within the receiver. For these inserts, placement of the closure within the receiver caused contact between the bottom of the closure and the top of the inserts, thereby transferring downward force through the insert onto the screw shank head. Second, there were inserts that applied downward force upon placement of the insert within the receiver, even prior to placement of the closure. For these inserts, the downward force was typically created due to some form of compression of the insert between a surface of the receiver and the screw shank head, thereby creating a downward application of force onto the screw shank head.

112. More specifically, inserts with upstanding arms that included lateral protrusions at the top of said arms were well-known before January 10, 2012. In the first category, the lateral protrusions at the top of the upright arms would provide a surface to facilitate contact between the closure and the insert. In the second category, the protrusions would not directly contact the closure but would instead allow the insert to be positioned underneath a downward-facing surface of the

receiver to prevent upward movement of the insert within the receiver. As a result, POSA would have known the benefit of including an insert with lateral protrusions to intermediate between a longitudinal connecting member and a screw shank and, in some cases, to transfer downward locking forces onto the screw shank head. Some examples of these well-known inserts in the prior art are discussed below.

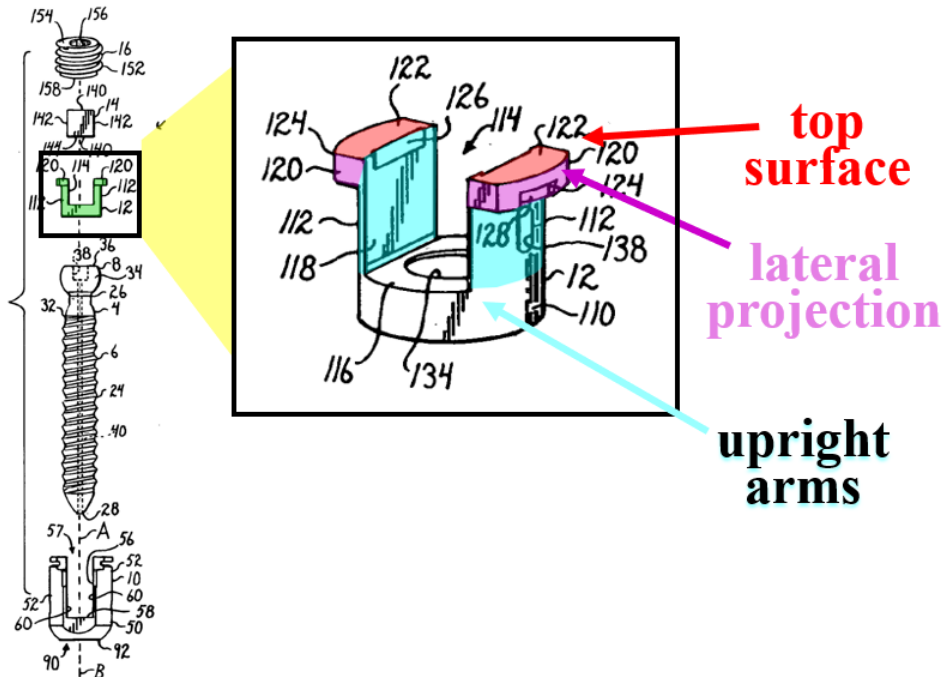
113. For example, as shown below in annotated Figures 9 and 10D, Garamszegi '813 discloses a “bottom saddle 520” (i.e., the insert) with “opposed walls 521” (i.e., upright arms) that “tilt toward one another in response to compression forces” and “spring back to their original or resting parallel orientation in the absence of compression forces.” EX1035, ¶[0077]. The “[o]uter surfaces of the opposed walls 521 include opposing *projections 535 that extend laterally* from the walls 521.” *Id.* ¶[0078]. The “projections 535 have a flat or horizontal proximal surface 538,” which “prevents the saddle 520 from sliding out of the coupling element 115 in the proximal direction.” *Id.* ¶[0079]. Upon insertion into the coupling element 115, the opposing projections 535 of the saddle 520 “line up with” and “pop into” corresponding “cavities” formed in the coupling element 115. Placement of the saddle in this manner creates a force sufficient to “maintain[] the saddle 520 in frictional engagement with the head portion 210 of the fixation element 110 to prevent relative movement between the fixation element 110 and the coupling element 115[.]” *Id.* ¶[0087].



Id., Figs. 9, 10D.

114. As shown below in annotated Figures 1 and 2, U.S. Patent Application Publication No. 2008/0319490 to Jackson (EX1036) discloses a “compression or pressure *insert* 12” with a “pair of *upstanding arms*” that “form a generally squared-off U-shaped, open, through channel 114.” EX1036, ¶[0044]. “The arms 112 disposed on either side of the channel 114 each include a top *flanged portion* 120, each portion 120 including a *top planar surface* 122[.]” *Id.* To lock the assembly the “closure member 16 is rotated,” which causes the bottom surface of the closure member to “press[] against the surfaces 12[2]” of the pressure insert, “pushing the insert 1[2] downwardly onto the shank upper portion 8 that in turn presses against the receiver surface 84, locking the shank 4 with respect to the receiver 10 in a desired angular or articulated position.” *Id.*, ¶[0049].

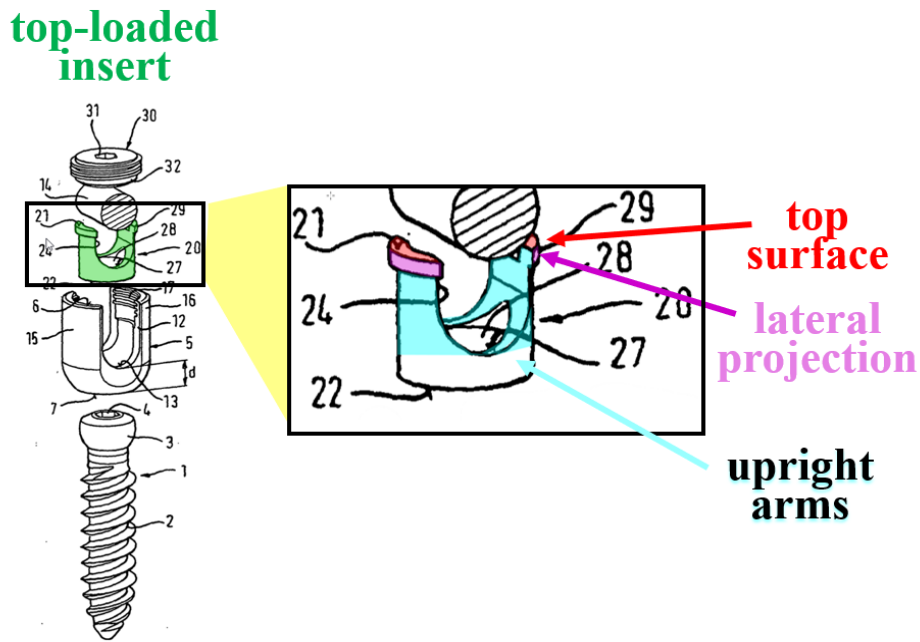
top-loaded insert



EX1036, Figs. 1, 2.

115. As shown below in annotated Figure 1, Matthis similarly discloses a “pressure element 20” (i.e., the insert) with a “substantially cylindrical construction” and a “U-shaped recess 24.” EX1034, ¶[0022]. The pressure element includes “legs 25, 26” (i.e., upright arms) that “project over the rod when the rod rests on the bottom 27 of the U-shaped recess 24.” *Id.*, ¶[0022]. “By means of the U-shaped recess 24 the open legs 25, 26 of the pressure element 20 are formed ending towards the first end 21.” *Id.* “[T]he pressure element 20 comprises adjacent to its first end 21 a **circumferential projection** 29 at said legs 25, 26[.]” *Id.*, ¶[0024]. When a nut is screwed into the assembly, the nut “abuts against the upper end of the legs 25, 26 of

the pressure element and exerts a downward force on the pressure element 20, which presses onto the screw head 3 to lock the screw in its final polyaxial position in the receiving part 5.” *Id.*, ¶[0037].



EX1034, Fig. 1.

116. Thus, inserts and their benefits were well-known to POSA before January 10, 2012.

117. The decision to use or not use an insert, and the design of that insert, was independent of other aspects of the pedicle screw and rod system such as whether the leading edge of the thread is truncated and curved, whether a single or double thread start is used, or whether the outside of the receiver arms includes a tool groove or aperture.

VII. THE '233 PATENT

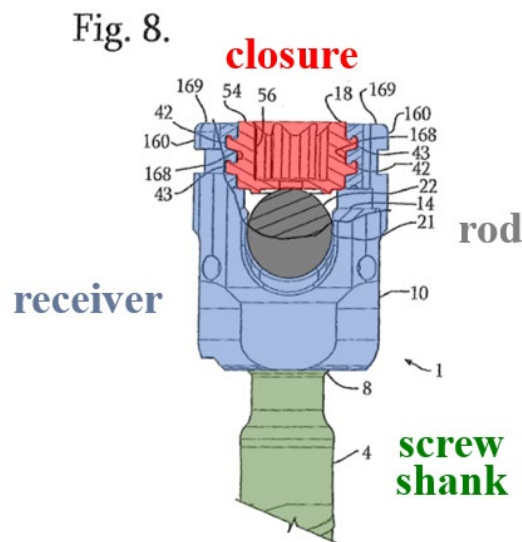
A. Overview

118. The '233 Patent is entitled “Medical Implant Receivers Having Dual Lead in Closure Mating Thread Forms and Curvate Extending Instrument Engaging Grooves” and names Roger P. Jackson as the inventor. EX1001 at 1. The '233 Patent issued on January 26, 2021. *Id.*

119. The '233 Patent claims priority to two provisional applications, the earliest of which was filed on January 10, 2012. *Id.*, 1:10-22. I therefore presume January 10, 2012, to be the effective filing date of the '233 Patent.

120. The '233 Patent appears to have been drafted under the assumption that using dual-start threads on a closure 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 for the purpose of stabilizing and/or adjusting spinal alignment.” *Id.*, 1:31-34. The specification further states that “open-ended bone anchors are known,” *id.*, 1:38-39, 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.*, 1:53-57. This U-shaped channel is “closed by a closure member after the rod or other longitudinal connecting

member is placed in the channel.” *Id.*, 1:60-64. 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.*, 1:63-2:3. These known components are highlighted and annotated below in Fig. 8. *Id.*, Fig. 8.



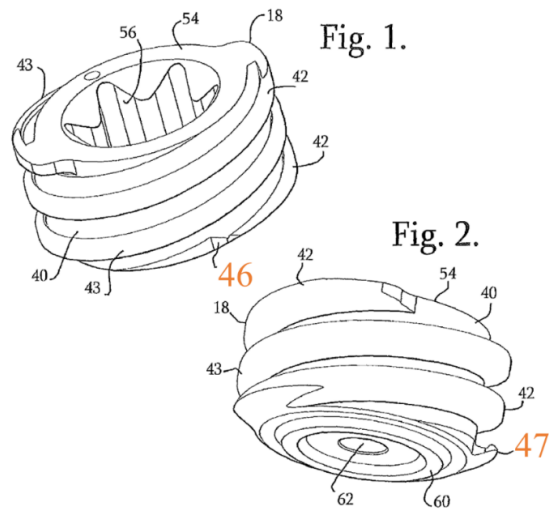
121. The patent then identifies the problem to be addressed as follows: “when the closure is a cylindrical plug having a single start helically wound guide and advancement structure, such structure must be aligned with mating structure on one of the implant arms and then rotated until a portion of the structure is captured by mating guide and advancement structure on both arms of the implant, all the while the closure is being pressed down on the rod while other forces are pushing and pulling the rod back out of the implant.” *Id.*, 2:17-25. The specification proposed

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 a mating helical form on a respective open implant arm.” *Id.*, 2:46-49.

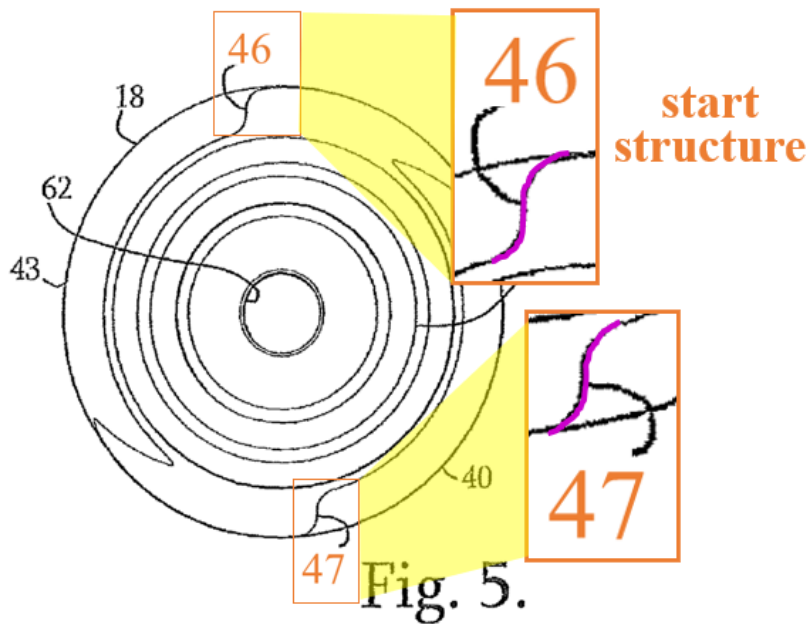
122. In my opinion, the '233 Patent does not describe any inventive significance to the leading face of the closure thread. The entirety of the textual description of the leading faces is as follows:

Each of the start structures 46 and 47 includes a leading face having at least one curvate surface. The at least one curvate surface includes at least one radius of curvature. In one embodiment, the at least one curvate surface is both concave and convex.

Id., 9:38-42. Nothing is taught of whether a leading curved surface or a double curved leading surface at the start of the thread face would be more advantageous than any other thread start configuration. There is no further discussion in the text of the disclosure. Figures 1 and 2 show these start structures 46 and 47, consisting of truncated thread starts as was well-known in the prior art, but the curvature of the leading faces cannot be observed and is not described in the corresponding text.



The only figure showing the curves of the leading faces is Figure 5, as enlarged and annotated below.



123. The specification also does not prescribe any inventive significance to the addition of a tool groove on the receiver. The attachment of detachable tools to

the receiver is not identified as a problem to be addressed, but rather as a design choice available, which does not change the double-start closure or the corresponding receiver threads. *See Id.*, 3:18-25. In fact, the '233 Patent describes a variety of grooves and apertures, *id.*, 12:19-13:9, “some or all of” which could be used for a variety of purposes, *id.*, 13:9-25, and which “may be configured in a variety of shapes and sizes and be disposed at other locations on the receiver arm 160 outer surfaces 176,” *id.*, 13:21-25.

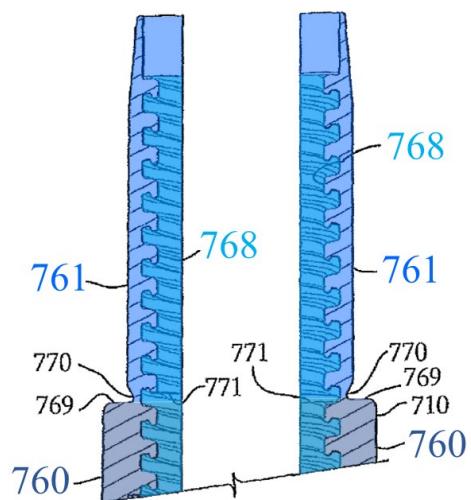
124. For example, the '233 Patent describes that the arms 160 of the receiver include both vertical and horizontal grooves. The arms “include an opposed pair of vertically extending outer grooves, generally 174,” *id.*, 12:19-23, Figs. 18-25, as well as a horizontal “tool receiving and engaging groove 189,” both shown in annotated Figure 19 below, *id.*, 13:7-9, Fig. 19. As seen in annotated Figure 19, the vertical groove intersects the horizontal groove, and both grooves are located adjacent the top surface 169 of the arms. *Id.* Fig. 19.

top
surface



**vertical
groove**

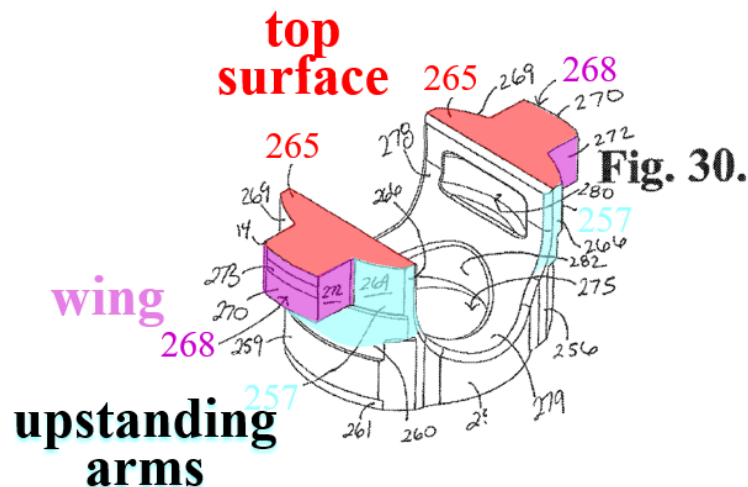
Fig. 15.



Patent discloses that “open receiver 710” is “substantially similar to the receiver 10” with “the exception that the receiver 710 includes opposed arms 760, each having an *integral upstanding break-off extension 761*.” *Id.*, 23:60-64, Fig. 15. The receiver arms and extensions each have “an *inner helically wound guide and advancement structure 768* that is sized and shaped to mate with” the closure top threads 42 and 43 of closure top 18. *Id.*, 23:64-24:1. The break-off extensions 761 are “initially integral” and then “broken off by a user after the closure 18 has been rotatably advanced . . . into the channel located between the receiver arms 760.” *Id.*, 24:1-6.

127. Finally, the specification does not prescribe any inventive significance to the addition of an insert or compression member into the receiver. The use of a compression insert to secure the rod within the channel of the receiver is not identified as a problem to be addressed, but rather as a design choice available, and which does not change the double-start closure top or the corresponding receiver threads, or the use of grooves on the outer surfaces. *Id.*, 7:33-36: *see generally id.*, 2:37-3:36. The '233 Patent discloses “locking compression insert 14” which “is sized and shaped to be received by and down-loaded into the receiver 10 at the upper opening 166.” *Id.*, 15:36-39, Figs. 18, 30-36; *see generally id.*, 15:36-17:63.

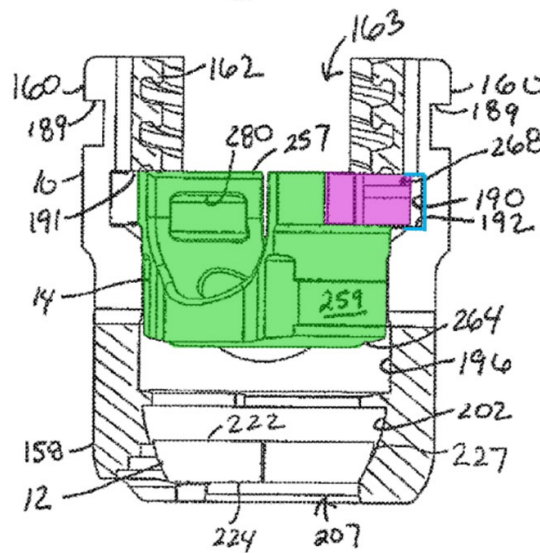
128. Specifically, as shown in annotated Figure 30, insert 14 has “body 256” which is “integral with a pair of upstanding arms 257,” *id.*, 16:1-2, each of which “includes an outwardly extending wing, generally 268,” *id.*, 16:28-29, Fig. 30. The insert also includes “substantially planar arm top surfaces 265,” *id.* 16:21-22, which “also extends along the respective wing 268,” *id.*, 16:32-34.



129. As seen in annotated Figures 18 and 38 below, the insert 14 (**green**) is down- or top-loaded into the receiver (**blue**). *Id.*, 17:49-56, Figs. 18, 38; *see also id.*, 19:17-37.

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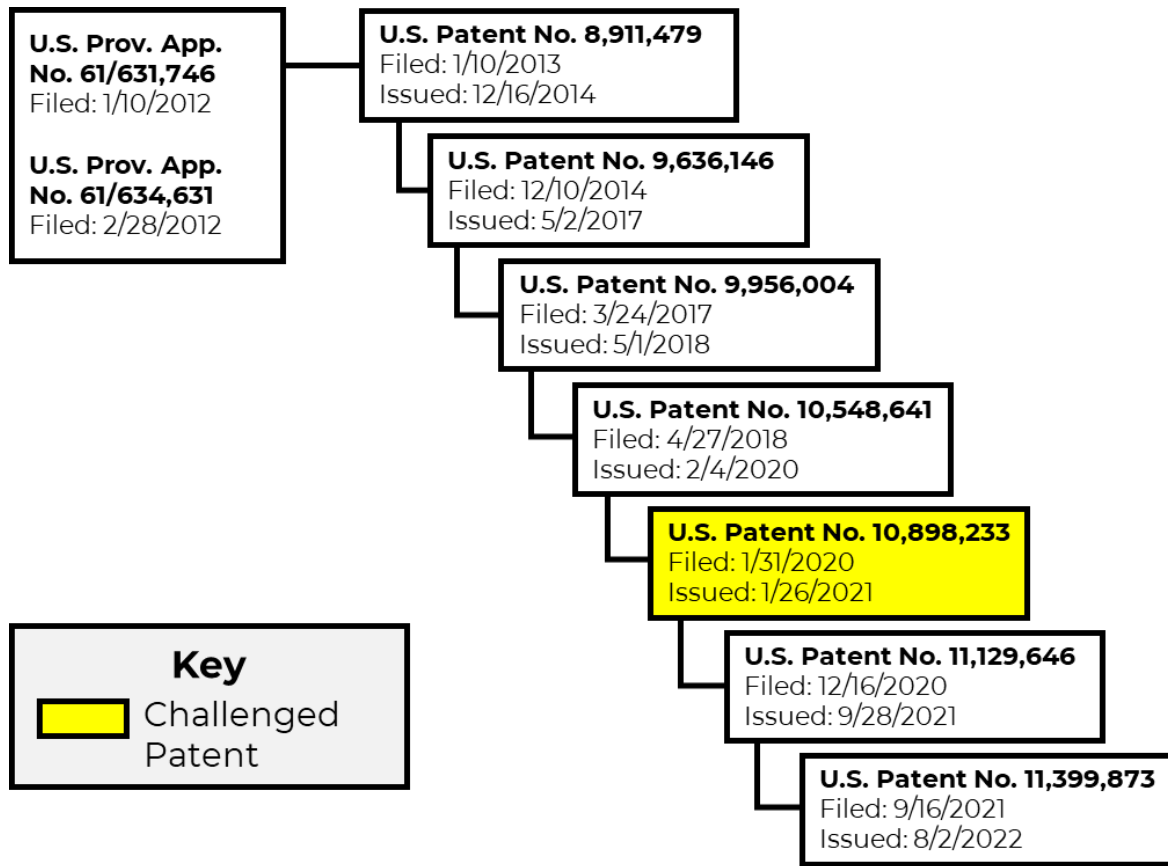
Fig. 39.



131. The rod is inserted into the bone screw assembly, followed by a closure structure “until a selected pressure is reached at which point the rod 21 engages the U-shaped seating surface 278 of the compression insert 14, further pressing the insert spherical surface 284 against the shank spherical surface 144, pressing the shank upper portion 8 and attached retainer 12 into locked frictional engagement with the receiver 10.” *Id.*, 21:1-13, Figs. 48, 49.

B. Prosecution History

132. The '233 Patent is part of 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:



133. The as-filed claims of the application for the '233 Patent added a tool groove at the top of the receiver in addition to a dual start closure. These claims were rejected over Garamszegi (U.S. Pub. No. 2008/0045953) (“Garamszegi ’953”) (EX1037), which disclosed a tool groove on a conventional bone screw receiver, in view of Boschert, which disclosed a dual start closure top. EX1002 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 [i.e. closure] can be designed with a double lead to allow the setscrew 70 to start easier than one with a single lead.*” *Id.* 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). Applicant also distinguished Garamszegi '953, stating that its figures “unambiguously show a *flat groove*, but *not a ‘curvate extending groove.’*” *Id.* at 324 (9.1.2020 Amendment). The amended claims were allowed without further rejection. *Id.* at 351-55 (9.17.2020 Allowance).

134. In my opinion, the '233 Patent was allowed based on arguments that the Applicant made during prosecution (e.g., about the scope and content of the prior art) that are inconsistent with my understanding of the relevant prior art, as well as with the prior art evidence presented herein.

C. The Challenged Claims

135. The Challenged Claims of the '233 Patent are Claims 1-7 and 13-20. The '233 Patent includes only one independent claim, Claim 1. Claim 1⁶ in its entirety, is reproduced below.

⁶ I have attached as an appendix to my declaration a claim listing of all Challenged Claims. I have assigned a unique alphanumeric identifier to each limitation, which is intended solely for ease of reference. In the identifier, the letter assigned to the limitation (e.g., [A], [B], [C]) corresponds to the claimed feature to which that limitation relates. Specifically, [A] limitations relate to the claimed receiver

A medical implant assembly comprising:

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

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

[B1] the channel adapted to receive a longitudinal connecting member,

[C] the channel configured to be closed with a closure having an axis of rotation;

[A1] a first interior surface of the first arm opposite the outer side face surface thereof; a second interior surface of the second arm opposite the outer side face surface thereof;

generally, [B] limitations relate to the channel formed by the arms of the claimed receiver, [C] limitations relate to the claimed closure, [D] limitations relate to the outer side face surfaces of the receiver arms, [E] limitations relate to breakoff extensions for the receiver arms, and [F] limitations relate to inserts. My opinions herein address each and every limitation of the Challenged Claims.

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

[A2] a second discontinuously helically wound structure on the second interior surface of the second arm,

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

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

[C4] the closure configured to be rotationally advanced within the channel until the bottom surface engages and locks the longitudinal connecting member within the channel; and

[D] the first and second arm outer side face surfaces each having a curvate extending groove configured to be engaged by an instrument, each groove extending

horizontally to at least one of the front or back outer face surface of each arm and being located adjacent the top side surface on each arm, wherein an entirety of each groove is configured to be located above a top surface of the longitudinal connecting member when the longitudinal connecting member is received and locked in the channel by the closure.

136. Claim 2 depends from Claim 1 and adds the limitation: **[D1]** wherein each groove includes an outer facing surface.

137. Claim 3 depends from Claim 2 and adds the limitation: **[D2]** wherein the outer facing surfaces of the grooves extend in a direction parallel to the longitudinal axis.

138. Claim 4 depends from Claim 1 and adds the limitation: **[D3]** wherein each groove includes a downward facing surface.

139. Claim 5 depends from Claim 4 and adds the limitation: **[D4]** wherein the downward facing surfaces of the grooves are planar.

140. Claim 6 depends from Claim 5 and adds the limitation: **[D5]** wherein each downward facing surface of the grooves are parallel with one another.

141. Claim 7 depends from Claim 1 and adds the limitation: **[D6]** wherein each groove includes an upward facing surface.

142. Claim 13 depends from Claim 1 and adds the limitation: **[C5]** wherein the first and second discontinuously helically wound structure comprises one of a reverse angle thread, a square thread, a buttress thread, or a helical flange form.

143. Claim 14 depends from Claim 1 and adds the limitation: **[E]** wherein the first and second arm each has a breakoff extension.

144. Claim 15 depends from Claim 1 and adds the limitation: **[D7]** wherein each outer side face surface has an outward facing planar surface.

145. Claim 16 depends from Claim 15 and adds the limitation: **[D8]** wherein the outward facing planar surface on each arm is recessed and parallel with respect to the longitudinal axis of the receiver and to each other.

146. Claim 17 depends from Claim 1 and adds the limitation: **[F]** further including an insert configured to be top loaded into the receiver, the insert having first and second opposed upright arms with top surfaces and lateral protrusions with top surfaces contiguous with the top surfaces on the upright arms of the insert.

147. Claim 18 depends from Claim 1 and adds the limitation: **[F1]** wherein the receiver includes a central bore having a recess into which an insert is configured to be at least partially positioned by being down loaded into the receiver through the channel.

148. Claim 19 depends from Claims 1 and 18 and adds the limitation: [F2] “wherein the insert is a retainer configured to engage a head of a bone attachment shank.”

149. Claim 20 depends from Claim 1 and adds the limitation: [C6] wherein each of the leading faces on the first and the second start structures has a concave surface adjacent a root and a convex surface adjacent a crest of the respective first and second continuously helically wound structures.

D. Opinions on Claim Construction

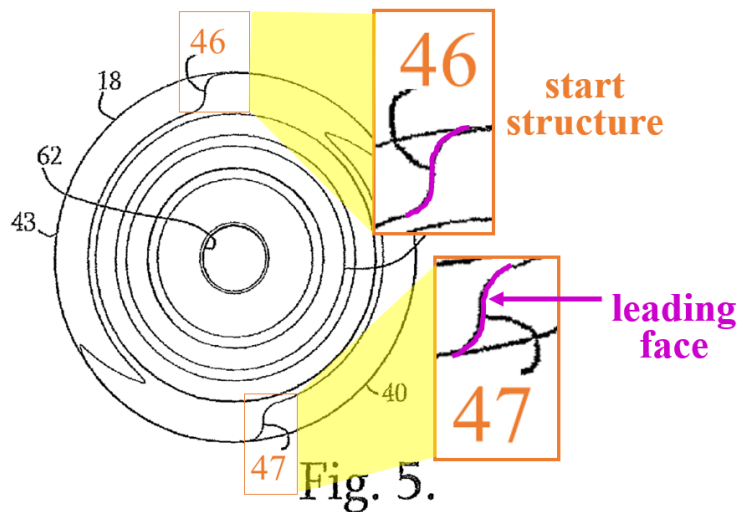
150. In view of the claim construction standards articulated above, it is my opinion that the claim terms should all be assigned their ordinary and customary meaning as they would have been understood by a POSA as of the priority date in view of the '233 Patent specification and prosecution history. In the paragraphs that follow, I opine on the ordinary and customary meaning of select terms that are not used or explained in the specification and relate those terms to the disclosed embodiments of the '233 Patent.

1. **“the [first/second] start structure having a leading face with a concave surface portion and a convex surface portion” (claim 1); “each of the leading faces on the first and the second start structures has a concave surface adjacent a root and a convex surface adjacent a crest of the respective first and second continuously helically wound structures” (Claim 20)**

151. The claimed “leading face” is never specifically identified by reference number in the ’233 Patent. The entirety of the written description on this feature states:

Each of the start structures 46 and 47 includes a leading face having at least one curvate surface. The at least one curvate surface includes at least one radius of curvature. In one embodiment, the at least one curvate surface is both concave and convex.

EX1001, 9:38-42. Start structures 46 and 47 are shown in Figure 5, enlarged and annotated below, which is the only figure that shows the described concave and convex surfaces on the leading face.

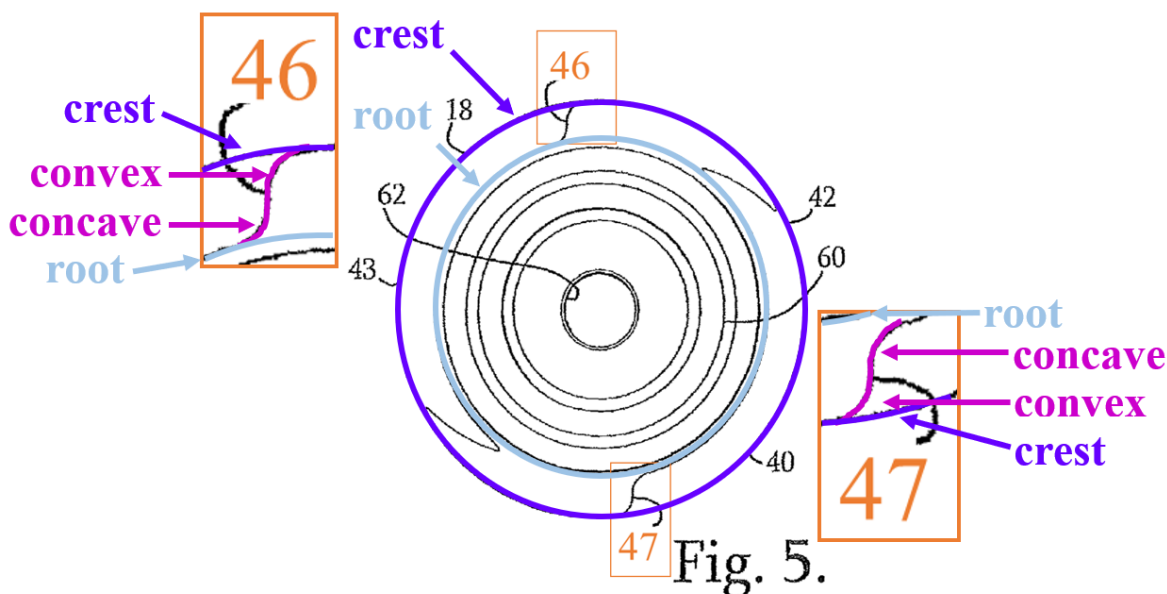


152. From this disclosure, and consistent with the plain meaning, in my opinion a POSA would have understood that a “start structure” is the beginning of a thread and the “leading face” is the forward most surface of the thread in the direction the thread is to be rotated.

153. A “thread” is defined as a ridge in the form of a helix on the external or internal surface of a cylinder. EX1024 at 10. The “crest” of the thread is defined the surface of the thread which joins the flanks of the thread and is farthest from the cylindrical body from which the thread projects. EX1014 at 4. The “root” is defined as the surface of a thread which joins the flanks of the adjacent thread forms and is immediately adjacent to the cylindrical body from which the thread projects. *Id.* at 5.

154. Based on these plain meanings, a POSA would have understood that, when the closure top is viewed from the bottom, the root has a smaller circumference

and is located adjacent the concave (inwardly curving) portion of the leading face, while the crest has a larger circumference and is located at the perimeter of the thread near the convex (outwardly curving) portion of the leading face. The approximate location of the root and crest are illustrated below with reference to Fig. 5.



EX1001, Fig. 5

I've also labeled the concave and convex portions of the leading face, showing that they are adjacent to the root and the crest respectively.

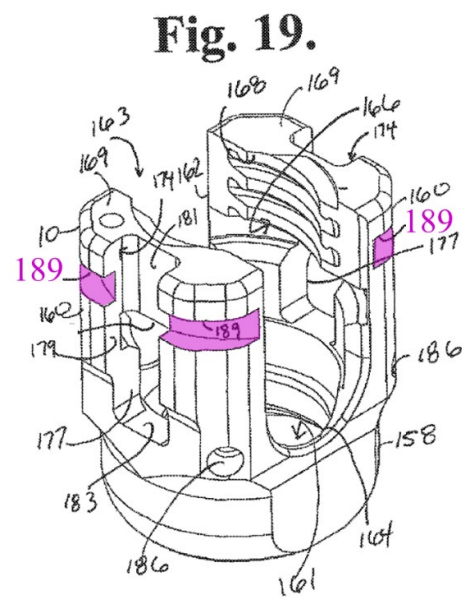
2. “a curvate extending groove” (Claim 1)

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

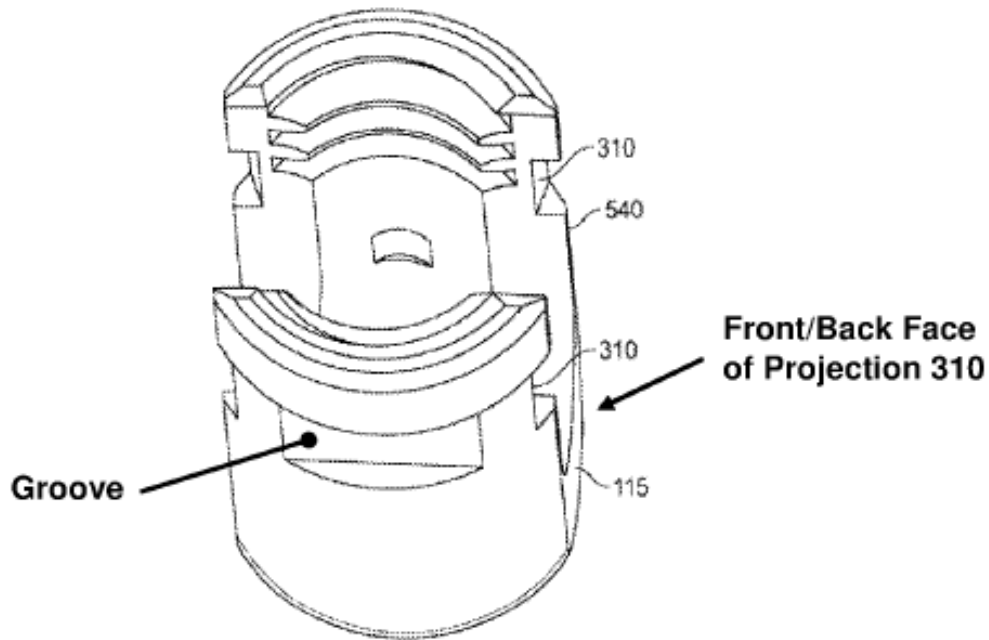
156. The word “curvate” is generally defined as an adjective meaning “curved.” EX1039 at 3-4. A “curve” is generally defined as a surface that deviates from the straightness or planarity in a smooth, continuous fashion. EX1029 at 6. I have seen nothing in the specification or prosecution history of the ’233 Patent that requires any departure from this plain and ordinary meaning.

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

158. The plain meaning is also consistent with distinctions made during prosecution of the ’233 Patent to overcome rejections related to the shape of the curvate groove. The claims had been rejected over Garamszegi ’953 (EX1037).



EX1002 at 61-70. The disclosed receiver head from Garamszegi '953 is shown in Figure 11 below, with annotations added by Applicant during prosecution.



EX1002 at 345. In distinguishing Garamszegi '953, Applicant stated: “The Office alleges that Garamszegi discloses a curvate extending groove . . . Figures 4 and 9 alone do not clearly show the contour of the groove. However, figures 2, 3, and 11 unambiguously show a *flat* groove, but not a ‘curvate extending groove,’ as recited in independent claim 1.” *Id.*

159. Therefore, in my opinion, a POSA reading the claims of the '233 Patent in view of the specification and prosecution history would have understood the claim

language “curvate extending groove” to refer to a groove that is not straight or flat but that deviates from straightness in a continuous fashion (i.e., a radiused groove).

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

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

161. The ’233 Patent discloses a closure top that includes one or more helically wound guide and advancement features that each have a start surface, with “each start structure simultaneously engaging and being captured” by the spaced arms of the open implant upon initial rotation of the closure top. EX1001, 2:37-45; *see also id.*, 3:9-14 (describing a multi-start closure embodiment with a pair of opposed arms each “having guide and advancement structure for simultaneous mating engagement with a start of the helically wound multi-start closure”). The ’233 Patent further discloses that, “when the closure structure 18 is rotated into the receiver 10 between receiver arms 160, each having a guide and advancement structure 168, the start 46 engages mating guide and advancement structure 168 on one arm 160 and the start 47 simultaneously engages guide and advancement structure 168 on the opposing arm 160, both forms 42 and 43 being simultaneously captured by the mating forms 168 on the opposed arms 160.” *Id.*, 9:19-27. The ’233

Patent discloses that, “unlike single start advancement structures, the helical forms 168 on the opposing arm surfaces 166 that are configured to mate with the dual start closure top 18 are reverse or flipped images of one another, the structures 168 on each arm 160 being aligned with respect to the receiver axis B, so that each closure structure start and are simultaneously engaged and captured at each arm 160 at the same time.” *Id.*, 12:10:17; *see also id.*, 22:57-65, 23:11-19, 23:32-39, 23:52-59, 24:51-56.

162. Claim 1 recites that “a rotation of the closure about the axis of rotation between the first arm and the second arm configured to cause a simultaneous mating of the first start structure under the first discontinuously helically wound structure and the second start structure with the second discontinuously helically wound structure due to a diametrically timed positioning of the first and second start structures on the closure.” *Id.*, 25:43-50. In my opinion, a POSA, having read the specification of the ’233 Patent, would have understood that “simultaneous mating” meant that the first and second start engaged the first and second discontinuously helically wound structures at the same time. In my opinion, a POSA, having read the specification of the ’233 Patent, would have understood that “diametrically timed positioning” meant that the first and second starts were positioned on the closure top in such a way that permits simultaneous mating with the first and second discontinuously helically wound structures. In other words, a POSA would have

understood that “diametrically timed positioning” meant that the first and second starts were positioned 180 degrees apart on the closure top. This understanding is also confirmed by the ’233 Patent itself, which shows the same symmetrical threads on the receiver. *E.g., id.*, Figs. 3, 8, 9, 11-15.

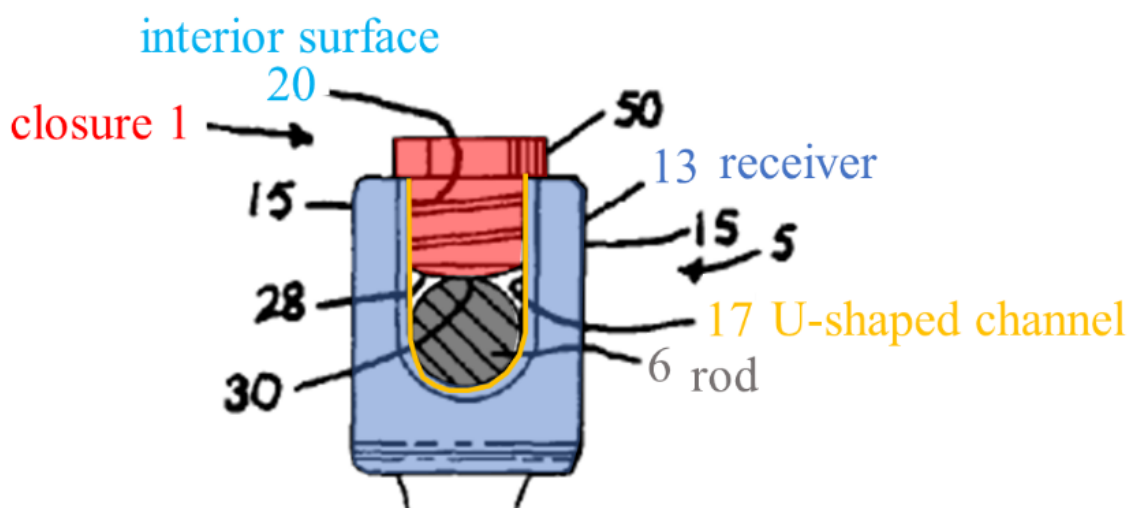
VIII. SCOPE AND CONTENT OF THE PRIOR ART REFERENCES

A. Overview of the ’477 Publication

163. The ’477 Publication, EX1005, was published on December 1, 2005, more than 6 years before the earliest effective filing date of the ’233 Patent. I understand the ’477 Publication is therefore prior art to the ’233 Patent under 35 U.S.C. § 102(b). The ’477 Publication discloses a closure for use with a generic medical implant assembly to capture and lock a rod in the spinal implant. EX1005, ¶¶[0007], [0026]-[0029], [0039]-[0041]. Therefore, in my opinion the ’477 Publication is in the same field of endeavor as, and is analogous art to, the ’233 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, 1:26-30 (“The present invention is directed to structure for joining together parts of a medical implant, in

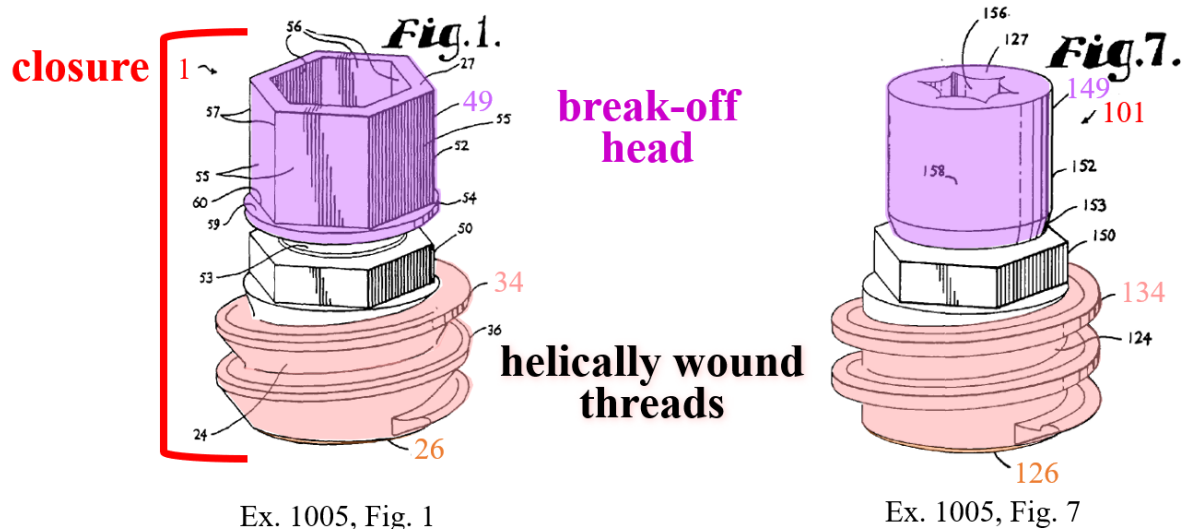
particular to closure mechanisms for use with open bone anchors in spinal surgery”); *see also* EX1005, ¶¶[0026]-[0029], [0039]-[0041].

164. As an exemplary medical implant, the '477 Publication discloses a polyaxial screw that includes a receiver 13 with a pair of upstanding arms 15 forming a U-shaped channel 17 for receiving a rod 6. EX1005, ¶¶[0007], [0026]-[0038], Figs. 1-6. 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 discloses that the guide and advancement structure could be any one of a variety of different thread forms, including a reverse angle thread. *Id.*, ¶[0030].



Ex. 1005, Fig. 6

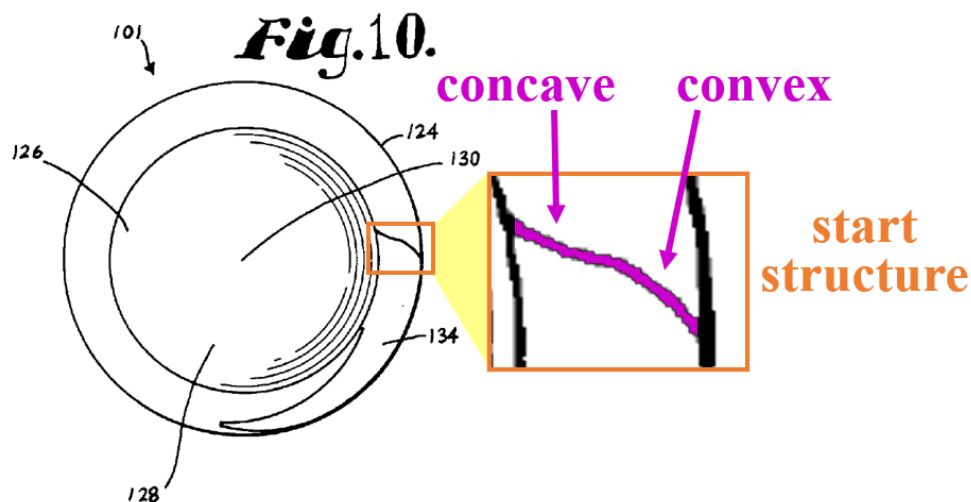
165. The '477 Publication discloses two preferred embodiments of the closure as shown and annotated below.



166. In the first embodiment, the '477 Publication discloses that the 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 forms, including a reverse angle thread. *Id.*, ¶[0030]; *see also, e.g., id.*, Fig. 1.

167. 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

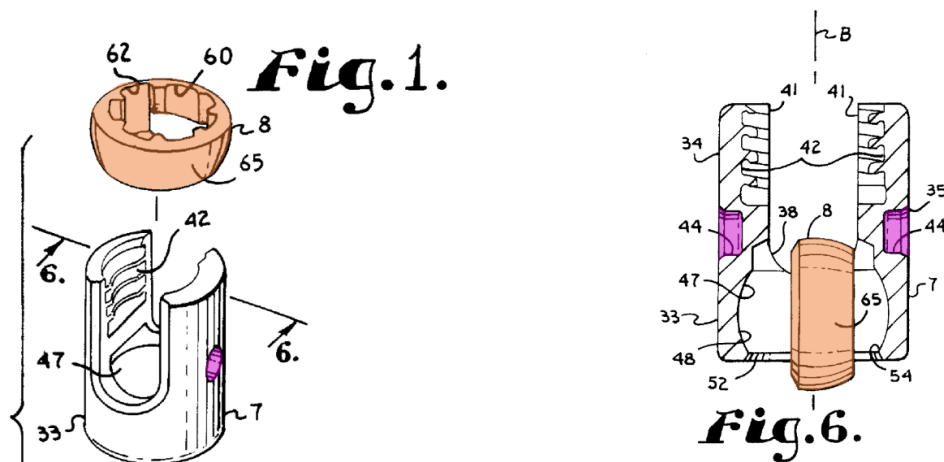
and advancement structure 134 along the outside, which could be one of a variety of thread forms, including a reverse angle thread. *Id.*, ¶[0041]; *see also, e.g., id.*, Figs. 7, 8. In addition, as shown in annotated and enlarged Figure 10 below, the second embodiment teaches that the leading face of the start structure is formed in an s-curve, with both concave and convex curves. *Id.*, Fig. 10 (bottom plan view).



Ex. 1005, Fig. 10

168. The '477 Publication further incorporates by reference U.S. Pat. No. 6,716,214 (“the '214 Patent”) (EX1042). EX1005, ¶[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. EX1042, 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.” *Id.*, 7:2-4, Figs. 1, 6. The '214 Patent further discloses

the use of additional fixation system elements top-loaded into the receiver for engaging with the shank and receiver, such as retainer ring 8 (**orange**). *Id.*, Fig. 1.



169. 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* ¶[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.”); Abstract (“A closure for use in conjunction with an open receiver of a medical implant...”; ¶[0025] (“[T]he closure

1 is shown utilized to close a top of a polyaxial medical implant bone screw, generally 5”).

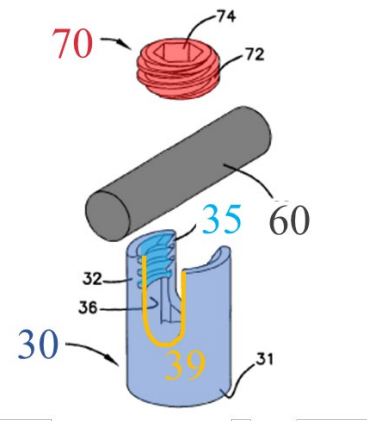
B. Overview of Boschert

170. Boschert, EX1006, published on December 15, 2005, more than 6 years before the earliest effective filing date of the ’233 Patent. I understand Boschert therefore is prior art to the ’233 Patent under 35 U.S.C. § 102(b). Boschert discloses an orthopedic fixation device for securing a rod to a bone for stabilization of the spine. EX1006, Abstract, 1:5-7. Therefore, in my opinion Boschert is in the same field of endeavor as, and is analogous art to, the ’233 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, 1:26-30 (“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 . . .”).

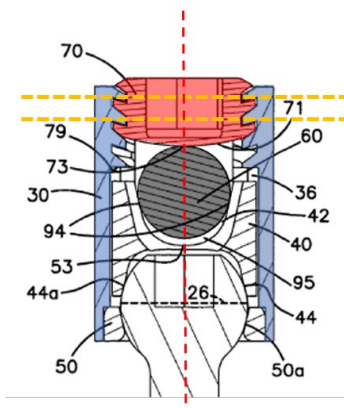
171. Boschert discloses a medical device comprising a receiver with a top portion that defines a pocket, or saddle, for receiving a rod, a bone fastener (such as a bone screw), a seat structure, a retainer (such as a retaining ring), and a setscrew (i.e., a closure). EX1006, 4:13-28. The head of the 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, 4:48-50. The bone screws have a polyaxial configuration. *Id.*, 4:44-47, 5:5-11.

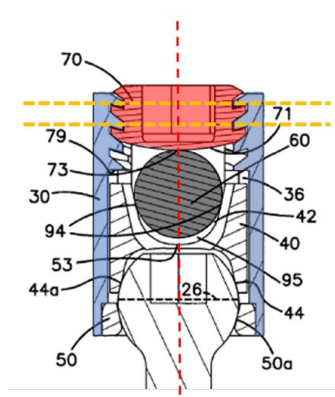
172. Boschert discloses a receiver 30 (blue) with two upwardly extending legs defining the saddle 39 (yellow) (i.e. the channel) which is U-shaped for receiving the rod 60 (gray). *Id.*, 6:20-24, Fig. 1. The legs have interior threads (light blue) that mate with corresponding exterior threads on the 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.*, 6:25-48; *see also id.*, 7:12-15. Ex. 1006, Fig. 1



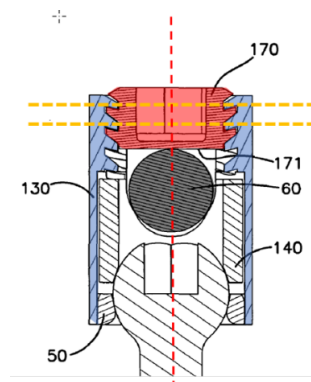
Boschert further discloses that the threads of the set screw can be designed to have a “double lead to allow the setscrew 70 to start more easily than with a single lead.” *Id.*, 7:21-23. Relatedly, as shown below in annotated Figure 3, Boschert discloses that interior threads on the receiver that are mirrored along the longitudinal axis (red), thereby providing for simultaneously receiving the double leads of the closure top. *Id.*, Fig. 3.



173. 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**).



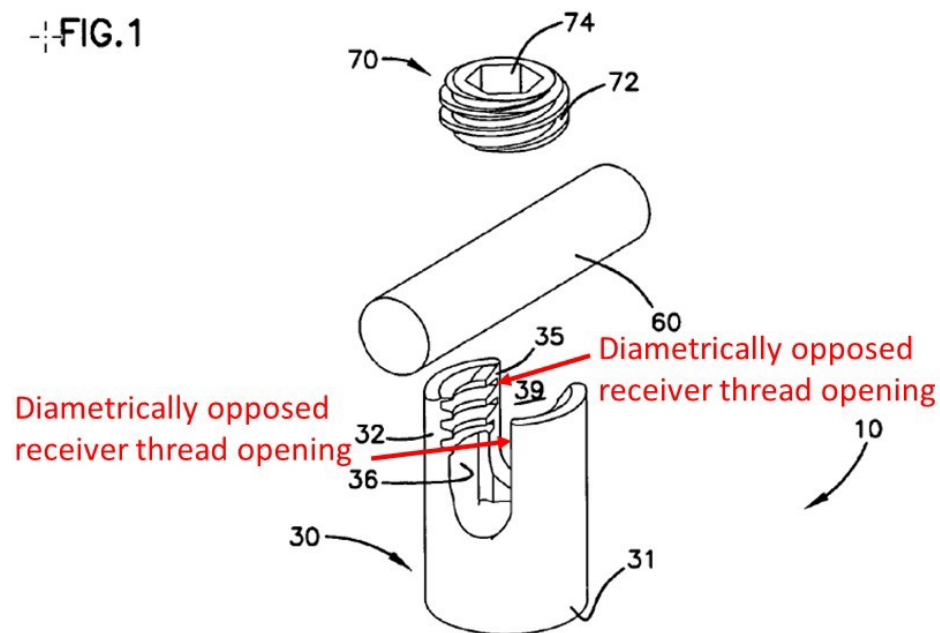
EX1006, Fig. 3



EX1006, Fig. 15

174. 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 is further

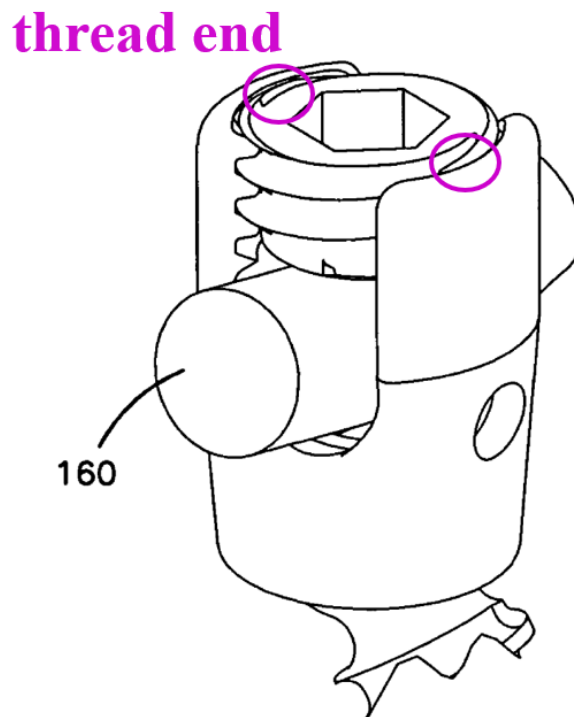
reinforced by the conventional manner of making dual start threads, which includes using diametrically opposed thread starts as discussed above. EX1014 at 3; EX1026, 13:35-41. Further, diametrically opposed thread starts would have been the obvious choice when threading a dual start closure under the 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.



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

175. My opinion that Boschert discloses diametrically opposed thread starts is also supported by Fig. 7. As annotated below, Fig. 7 shows, at the top of the

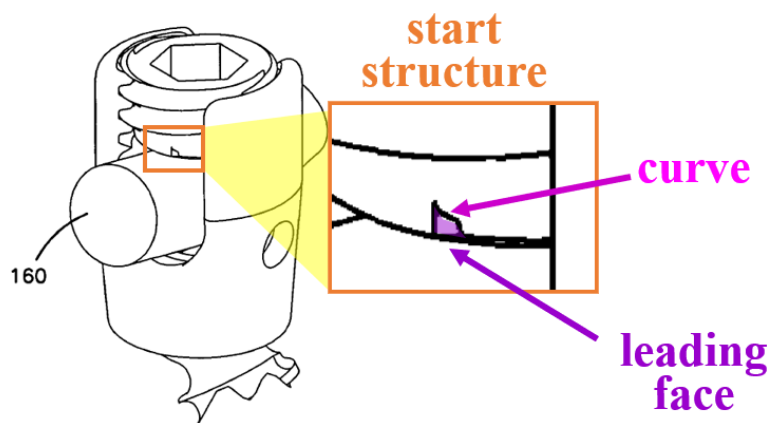
closure, that the trailing ends of the double lead thread are diametrically opposed. A POSA would have understood and expected that each of the double lead threads would have the identical length, and therefore would have understood that diametrically opposed thread ends are the result of diametrically opposed thread starts.



EX1006, Fig. 7

176. 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.

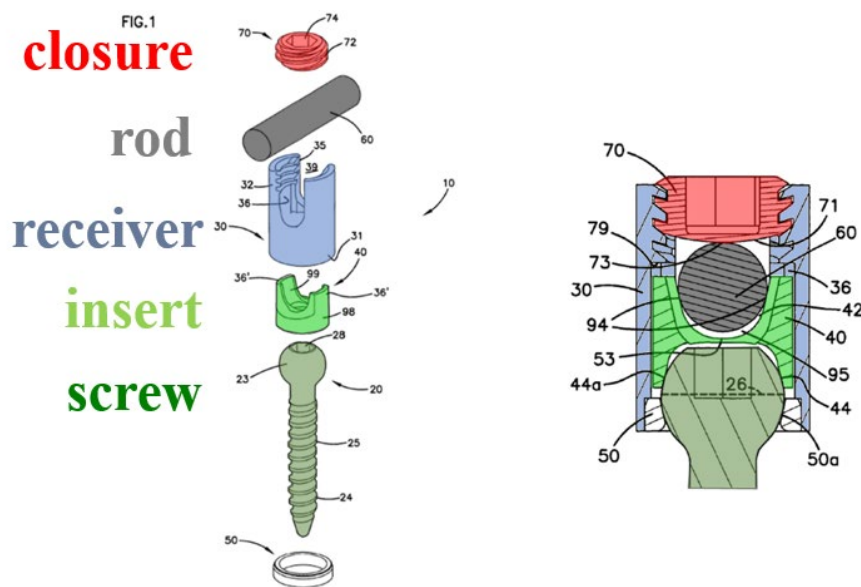
177. Boschert also suggests the use of truncated thread starts with curvate leading faces on each of its double lead threads. Specifically, Fig. 7, as annotated below, appears to show one of the two diametrically opposed thread starts, and appears to show at least a portion of that start as having a curvate S-shaped leading face.



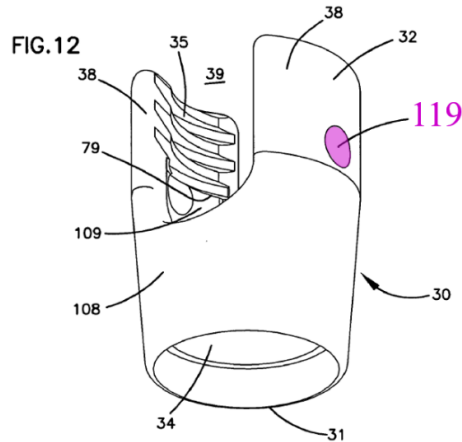
EX1006, Fig. 7

178. Boschert expressly contemplates potential modifications to its closure, stating that “[t]he embodiments of the locking arrangements disclosed herein (e.g., the set screw 70[]) are merely examples of types of locking arrangements that can be used. The locking arrangements can include any mechanism adapted to provide an axial locking force on the rod 60.” EX1006, 7:58-62. Therefore, in my opinion, a POSA would naturally look to other prior art that discloses known closure tops for use with the receiver of Boschert, such as the closure tops of the ’477 Publication.

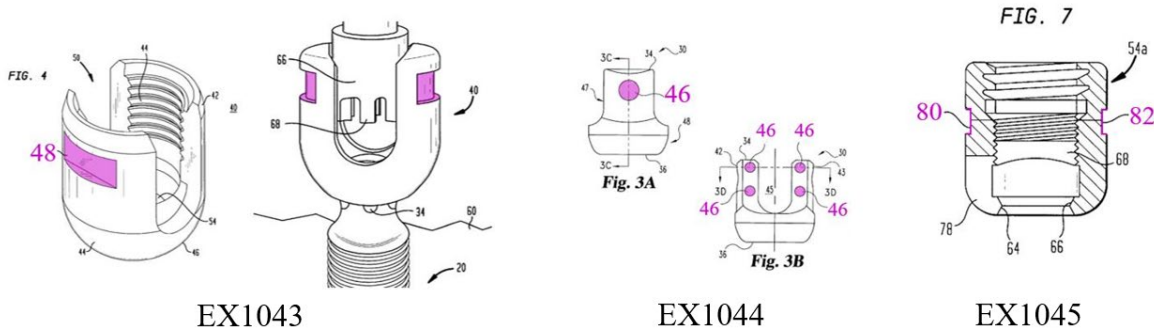
179. Boschert discloses a “seat structure 40” (i.e., the insert) that is loaded into the receiver “between the rod 60 and the head 23 of the screw 20.” *Id.*, 4:20-22, Fig. 1. Tightening of the set screw 70 (i.e., the closure) in the receiver “forces the seat structures 40 downwardly within the receivers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



180. Finally, Boschert 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.



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 (EX1043) (grooves 48, Figs 4, 8 at left); 6,280,442 (EX1044) (indentations or holes 46, Figs. 3A, 3B at middle), and 6,074,391 (EX1045) (slots 80 and 82, Fig. 7 at right) pictured below. EX1006, 1:55-60.

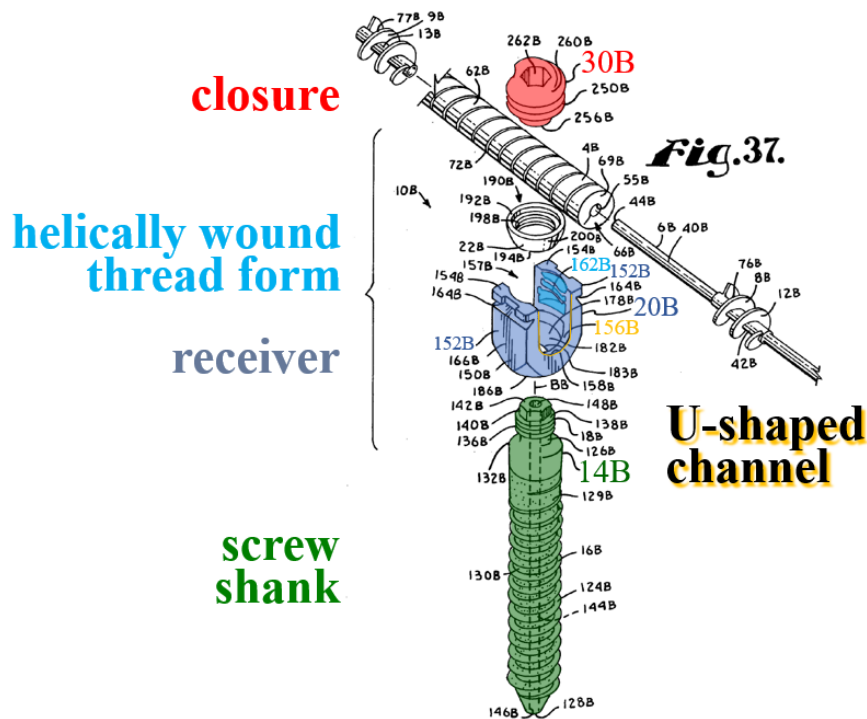


From these disclosures, a POSA would have understood that the type of grasping feature was not material to Boschert and that any known grasping feature could be used.

C. Overview of the '287 Publication

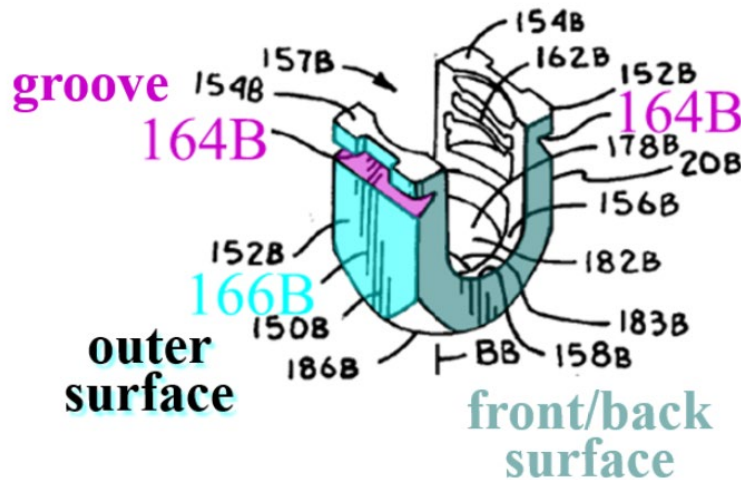
181. The '287 Publication, EX1007, was published on December 9, 2010, more than one year before the earliest effective filing date of the '233 Patent. I understand the '287 Publication is therefore prior art to the '233 Patent under 35 U.S.C. § 102(b). The '287 Publication discloses a medical implant assembly that uses a closure to capture and lock a longitudinal connecting member, such as a rod, in a spinal implant. EX1007, ¶¶[0002], [0132]-[0158]. Therefore, in my opinion the '287 Publication is in the same field of endeavor as, and is analogous art to, the '233 Patent. *Compare id.*, ¶¶[0133]-[0134] (“The dynamic connecting member assembly 1B cooperates with at least a pair of polyaxial bone screw assemblies according to the invention. . . . FIGS. 37 and 39 further show a closure structure 30B of the invention for capturing the longitudinal connecting member assembly 1B within the receiver 20B.”), *with* EX1001, 1:26-30 (“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]. The '287 Publication’s Summary of the Invention starts with “Polyaxial bone screw assemblies according to the invention ...” and polyaxial bone screw assemblies are the focus of the '233 Patent, further demonstrating that the two patents are in the same field of endeavor.

182. The '287 Publication is primarily concerned with “dynamic fixation” that involve using a flexible longitudinal connecting member in place of a stiff rod. In discussing such a dynamic fixation system, the '287 Publication describes various conventional bone screws receivers that include tool grooves for temporarily attaching various tools during the surgical procedure. In particular, the '287 Publication discloses a polyaxial screw assembly that includes a receiver 20B with a pair of upstanding arms 152B forming a U-shaped channel 156B for receiving a longitudinal connecting member assembly. EX1007, ¶¶[0133]-[0134], [0150], Figs. 37-39. The inner surface of each arm has a partial (i.e., discontinuous) helically wound guide and advancement structure 162B that mates with a similar structure on a closure 30B when the closure is rotated. *Id.*, ¶¶[0151], [0156], Figs. 37&39. The '287 Publication discloses that the guide and advancement structure could be any one of a variety of different thread forms, including a reverse angle thread. *Id.*, ¶[0156].



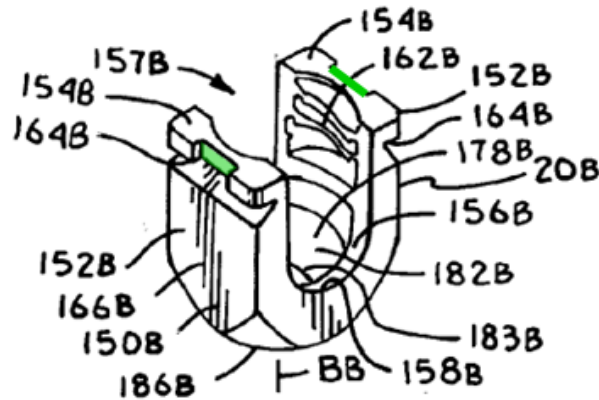
183. The '287 Publication discloses multiple preferred embodiments, each with one of two interchangeable receiver shapes. *Id.*, ¶[0115]. The first receiver outer shape has “substantially planar outer surface 166B” and front/back surfaces, as shown in cropped and annotated Figure 37 below. *Id.*, ¶[0152], Fig. 37 (receiver 20B); *see also id.*, ¶[0078], Figs. 5, 14 (receiver 20). On receiver 20B (or receiver 20), “[e]ach of the arms 152B includes a V-shaped-like undercut tool engagement groove 164B formed on a [the] substantially planar outer surface 166B thereof which may be used for holding the receiver 20B with a holding tool (not shown) having projections that are received within the grooves 164B” *Id.*, ¶[0152]; *see also id.*, ¶[0078]. As shown in cropped and annotated Figure 37, below, this groove

extends to, and intersects with, the front/back surface of receiver 20B. *Id.*, Fig. 37; *see also id.*, Figs. 5, 14.

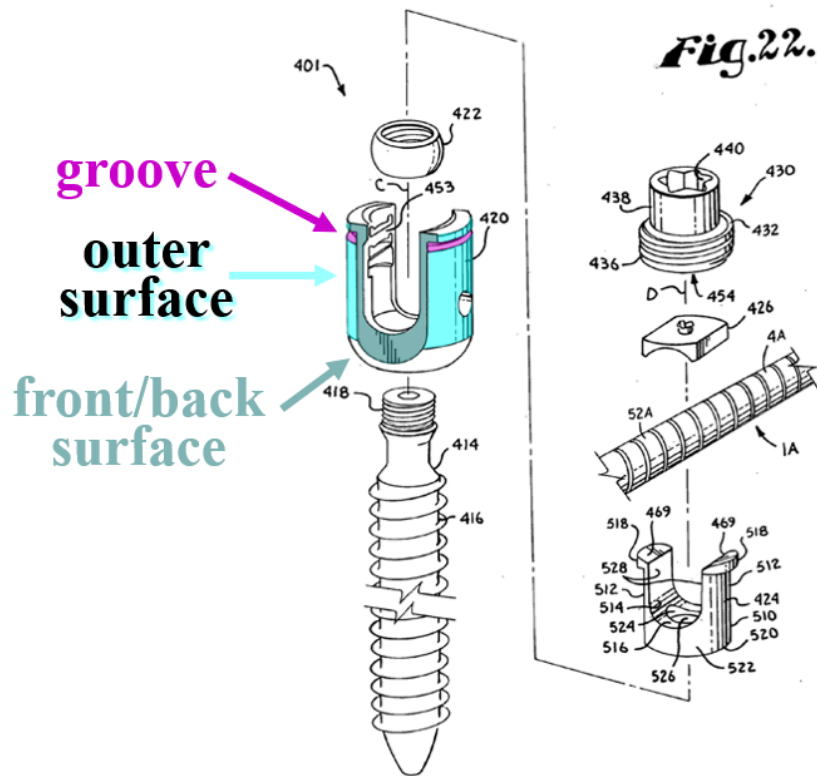


The '287 Publication further discloses that it “is foreseen that tool attachment receiving grooves or apertures may be configured in a variety of sizes and shapes, ***including radiused***, and be disposed at other locations on the arms 152B.” *Id.*, ¶[0152]; *see id.*, ¶[0078]. A POSA would have understood that a “radiused” tool groove means that the groove is curved around the longitudinal axis of the receiver (i.e., it has a radius in that direction). Such a radiused, i.e., curvate, groove has a known advantage of allowing a tool with corresponding projections to be inserted over the front and back surfaces of the receiver and then rotated 90 degrees to fit the projections on the tool into the radiused tool groove on the sides of the receiver as explained above. *See supra* Section VI.B.2.a.i.

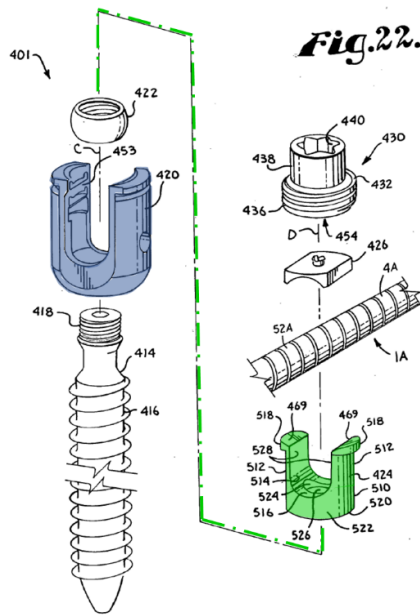
184. In addition to the horizontal v-cut groove, the outer surface of the receiver includes an additional vertical recessed groove (green) into the top edge of the v-cut groove, as shown in cropped and annotated Figure 37 below. *Id.*, Fig. 37.



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



186. This embodiment further includes a compression insert 424 that is top-loaded into the receiver. *Id.*, ¶[0126], Fig. 22. As seen in Figure 22 below, the insert 424 has lateral projections at the top of two upwardly extending arms. *Id.*, ¶[0126], Fig. 22.



The insert is sized and shaped to receive the longitudinal connecting member between the upwardly extending arms and, on the bottom, to frictionally engage and mate with the shank and retaining structures. *Id.*, ¶[0126]. The '287 Publication also expressly discloses a “*retaining and articulating structure 22*” in “fixed frictional contact with the receiver 20, so as to substantially attach and orient [the implant] . . . relative to the vertebra 28.” *Id.*, ¶[0063]; *see also* ¶¶[0098], [0126]. The described engagement between retaining insert 22 and the head of a bone attachment shank is depicted in illustrative Figures 17 and 14 below:

variety of different types of closure structures for use in conjunction with the present invention with suitable mating structure on the upstanding arms 152 of the receiver 20.” *Id.*, ¶¶[0086], [0156]. Therefore, a POSA would naturally combine the teachings of the ’287 Publication regarding receivers with tool grooves, with known closures, such as those disclosed in the ’477 Publication.

188. The stated objectives of the inventions disclosed in the ’287 Publication include “to provide a lightweight, reduced volume, low profile assembly . . . [and] to provide apparatus and methods that are easy to use.” *Id.*, ¶[0014].

D. Overview of Johnson

189. Johnson was published on April 19, 2007, which is more than three years before the earliest effective filing date of the ’233 Patent. I understand Johnson is therefore prior art to the ’233 Patent under 35 U.S.C. § 102(b). Johnson discloses a “medical implant device [including] a receiver member for receiving an elongated member, a crown member, an anchor member and a retaining member.” EX1008, Abstract. Therefore, in my opinion Johnson is in the same field of endeavor as, and is analogous art to, the ’233 Patent. *Compare id.*, ¶[0001], with EX1001,1:26-30.

190. As shown in the annotated Figure 10 to the right, Johnson discloses a receiver member 212 that “has a lower portion 212a and an upper portion 212b separated by a thinned section 212c.” EX1008, ¶[0051]. As shown in Figure 12 below, the receiver member includes a “pair of upright branches 250, 252 between which opening 222 extends,” wherein “[a] portion of each branch 250, 252 forms at least a part of lower portion 212a of receiver

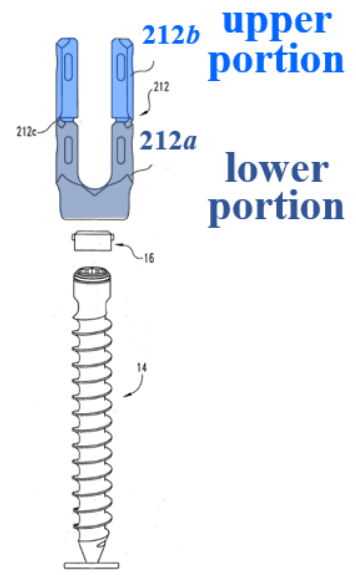
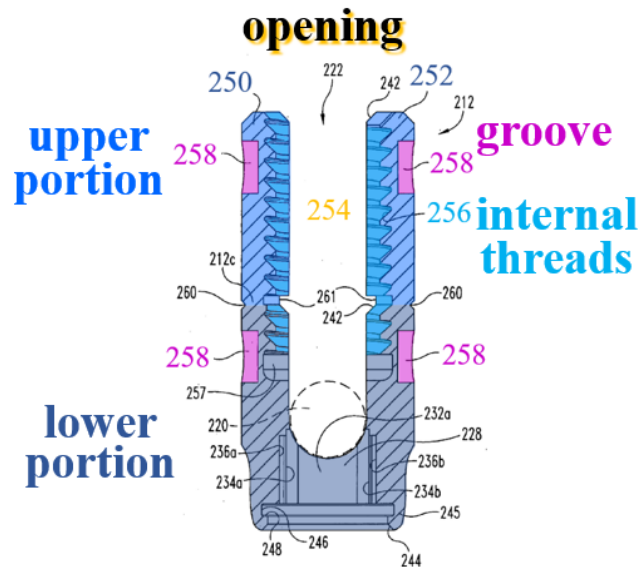


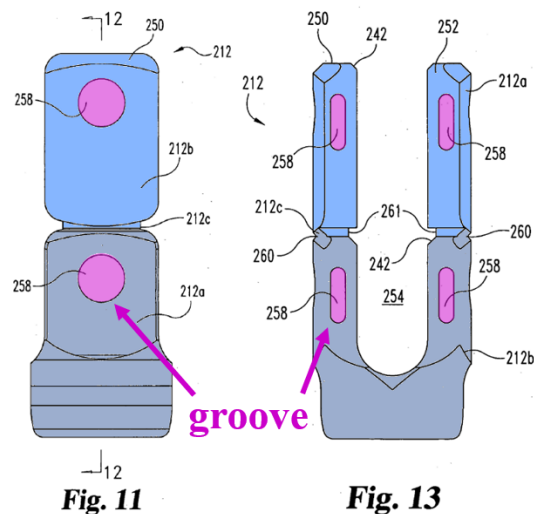
Fig. 10

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].



191. 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.*

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



gripping or turning tool.” *Id.*, ¶¶[0052]-[0053], Figs. 11, 13.

193. 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 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 “threaded into threads 256, forcing elongated member 220 further down in channel 254” so that the “elongated member 220 is forced all the way through upper portion 212*b*, into lower portion 212*a*, and against a crown member and/or anchor member in chamber 228.” *Id.*

IX. MOTIVATION TO COMBINE

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

194. In my opinion, it would have been obvious to a POSA before the priority date of the ’233 Patent to (i) combine the closure of the ’477 Publication with the receiver and inserts of the ’287 Publication and (ii) to modify the closure and receiver to have the double lead thread of Boschert.

195. The ’477 Publication is in the exact same field as the ’233 Patent, as set forth above. *Supra* Section VIII.A. The ’477 Publication teaches closures that could be used with any conventional bone screw receivers, stating, “A closure and locking

member is provided for a medical implant. The implant may be a bone screw, hook, or other open or closed element 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.”). The generic “medical implant” shown for use with the claimed closure of the ’477 Publication, as in the ’287 Publication, is a polyaxial bone screw with a U-shaped receiver. *Id.*, ¶[0025], Figs. 5, 6; *see also supra* Sections VIII.A. VIII.C. 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 the ’287 Publication. The closure of the ’477 Publication includes threading of various disclosed types with a curvate leading face for mating with the arms of the receiver.

196. The ’287 Publication is also in the exact same field as the ’233 Patent, as set forth above. *Supra* Section VIII.C. And, like the ’477 Publication, the ’287 Publication discloses a medical implant assembly that uses a closure to capture and

lock a longitudinal connecting member, such as a rod, in the U-shaped receiver of a spinal bone screw. EX1007, ¶¶[0002], [0132]-[0158]. The '287 Publication discloses multiple preferred embodiments, each with one of two interchangeable receiver shapes. *Id.*, ¶[0115]. When describing these various interchangeable receivers, the '287 Publication teaches that a well-known tool attachment grooves could be beneficially placed on the outer surface of the receiver. *Id.*, ¶[0152], Fig. 31, Fig. 37. The '287 Publication teaches that these grooves are “used for holding the receiver [] with a holding tool . . . having projections that are received within the grooves [] during implantation of the shank body [] into the vertebra. The grooves [] may also cooperate with a holding tool during bone screw assembly and during subsequent installation of the connecting member [] and closure [].” *Id.*, ¶[0152]. The '287 Publication further teaches well-known inserts placed within the receiver to facilitate capturing the rod and fixing the position of the shaft. *Id.*, ¶[0126]. The '287 Publication expressly contemplates that its bone screws can be used with other known closures, stating that “the closure structure 30 can be any of a variety of different types of closure structures for use in conjunction with the present invention with suitable mating structure on the upstanding arms 152 of the receiver 20.” *Id.*, ¶¶[0086], [0156].

197. Boschert is also in the exact same field as the '233 Patent —the design of polyaxial pedicle screw and rod implant systems to treat spinal column disorders.

Supra Section VIII.B. Boschert teaches a polyaxial pedicle screw including a U-shaped receiver for capturing a rod once its opening has been closed with a setscrew. Boschert further teaches that closures (setscrews) could be designed with a double, or multi-start, lead in order “to start more easily than with a single lead,” EX1006, 7:21-23, and discloses symmetrical threads on the receiver to mate simultaneously with the double-lead threads on the setscrew, *id.*, Figs. 3, 15. Boschert also expressly contemplates potential modifications to its disclosed closure, stating that “[t]he embodiments of the locking arrangements disclosed herein (e.g., the set screw 70[]) are merely examples of types of locking arrangements that can be used. The locking arrangements can include any mechanism adapted to provide an axial locking force on the rod 60.” *Id.*, 7:58-62.

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

1. Motivation to Use The '477 Publication Closure with the '287 Publication Receiver and Inserts.

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

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

201. Second, the '287 Publication discloses receivers with known tool-engaging grooves on the exterior surfaces of the receiver's upright arms. A POSA would have known that there were multiple well-known designs for facilitating implantation of spinal implant devices, including using a guide tool that attaches to—and detaches from—the spinal implant. *See supra* Sections VI.B.2.a, VI.B.2.a.i. A POSA would have understood that the use of such tools would have many

advantages including facilitating implantation of the receiver, enabling correction of the receiver after implantation, and maintaining the small size of the fixation device to permit minimally invasive techniques. *See supra* Section VI.B.2.a.i.

202. With this knowledge, a POSA would have recognized that it would be possible to realize the benefits of attachable/detachable guide tools to facilitate implantation by combining the closure of the '477 Publication with the receiver disclosed in the '287 Publication, which includes tool attachment grooves on the outer surfaces of the receiver.

203. Third, the '287 Publication discloses known inserts designed to be top-loaded into its receivers. *See supra* Sections VI.B.2.b, VIII.C. As set forth above, a POSA would have known that top-loaded receiver inserts could be added to a bone screw assembly in order to support the longitudinal connecting member, such as a rod, within the bone screw assembly and to fix the position of the receiver head in relation to the screw shank. *See supra* Section VI.B.2.b. A POSA would have further understood that using such inserts would provide several advantages, including by evenly distributing forces between the rod and the bone screw and by providing a downward force onto the head of the bone screw to lock the screw into a particular angular orientation with respect to the receiver (e.g., in the case of a polyaxial screw assembly). *See supra* Section VI.B.2.b.

204. With this knowledge, a POSA would have recognized that it would be possible to realize the benefits of such inserts by combining the closure of the '477 Publication with the receiver disclosed in the '287 Publication, which is configured to cooperate with a top-loaded insert to aid in securing a bone screw and rod within the receiver.

205. A POSA would have expected success with combining the '477 Publication's closure with the '287 Publication's receiver and insert because it merely involves the combination of familiar elements using known methods to yield predictable results. Specifically, it was well-known to a POSA before the priority date of the '233 Patent that guide tools provided the above-described advantages and could be successfully used in medical implant devices. *Supra* Section VI.B.2.a.i. Likewise, it was well-known to a POSA before the priority date of the '233 Patent that top-loaded inserts provided additional advantages and could be successfully used to separate a bone screw and a longitudinal connecting rod in an open-headed receiver assembly. A POSA would have had a reasonable expectation of success in making such a combination because it would merely require machining the respective closure and receiver structures to have compatible engagement structures, while otherwise leaving the components unchanged. *Supra* Section VI.B.2.b.

2. Motivation to Use Boschert's Dual Threads.

206. As set forth above, both the '477 Publication and the '287 Publication teach that closures should include threading (of various disclosed types) for mating with the arms of the receiver. *See supra* Sections VIII.A, VIII.C. The '477 Publication also teaches a closure thread with a leading thread face that includes a concave surface near the root and a convex surface near the crest. *See supra* Section VIII.A. As set forth above, a POSA would have been familiar with these various thread forms and their known advantages, including reducing outwardly directed forces that could cause splaying of the receiver arms. *See supra* Section VI.B.1.d. Also as set forth above, a POSA would have been familiar with truncated thread starts, such as the curvate leading face of the '477 Publication, and their advantages for easing thread insertion, reducing thread deformation, and eliminating sharp edges. *See* Section VI.B.1.b, VI.B.1.c.

207. Boschert teaches that it would be advantageous to design a closure with a double lead in order “to start more easily than with a single lead” when loaded into the top of an open receiver, EX1006, 7:21-23. Thus, a POSA would have been motivated to modify the '477 Publication/'287 Publication combination with the double lead thread disclosed in Boschert, given, at the very least, the POSA's understanding that such a change would result in more reliable threading of the fastener into the receiver, as was expressly taught by Boschert.

208. A POSA would also have been motivated to so modify the '477 Publication/'287 Publication combination to take advantage of known benefits of double-lead threads of balancing insertion forces, Bagby, EX1026, 13:35-41, and increasing insertion speed, Machinery's Handbook, EX1014 at 6. *See supra* Section VI.B.1.a. In making this combination, a POSA would also have retained the truncated thread starts of the '477 Publication with their curvate leading faces, in order to obtain their known advantages for further easing thread insertion, reduce thread deformation, and reducing sharp edges. *Supra* Sections VI.B.1.b, VI.B.1.c. The resulting closure would thus have dual-lead threads, each with a curvate leading face, that simultaneously mate with matching threads on the receiver. And, as I discussed above, *supra* Section VI.B.1.c, simply removing any sharp edge of the starting thread face would also result in a rounded or at least one curvate leading face.

209. Such a combination of familiar elements using known methods would yield predictable results, as it was well known to a POSA before the priority date of the '233 Patent that double lead threads provided these advantages and could be successfully used in closures. *Supra* Section VI.B.1.a. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for machining double lead threads were well known and

readily available and already in use in multi-axial pedicle screws. *Supra* Section VI.B.1.a.

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

210. In my opinion, it would have also been obvious to a POSA to combine the teachings of the '477 Publication, the '287 Publication, and Boschert with Johnson before the priority date of the '233 Patent. This would result in the closure of the '477 Publication with a receiver of the '287 Publication, together with Boschert's dual-start threads, together with the addition of break-off extensions for the receiver's arms.

211. Like the '477 Publication, the '287 Publication, and Boschert, Johnson is directed to a medical implant device that receives a longitudinal connecting member, such as a rod. EX1008, Abstract; *supra* Section VIII.D. Johnson additionally teaches that using break-off extension arms in such medical implants provides the benefit of simplifying the introduction of an elongate member or rod. Johnson discloses that, “[w]hen the surgeon wishes to insert an elongated member 220 into receiver member 212, he or she need not bend it or use a special reducing tool to insert it into the lower end of a receiving channel. Rather, he or she places a portion of the elongated member 220 into channel 254 in upper portion 212 b of receiver member 212.” *Id.*, ¶[0055]. Johnson discloses that a compression member is then “threaded into threads 256, forcing elongated member 220 further down in

channel 254” so that the “elongated member 220 is forced all the way through upper portion 212*b*, into lower portion 212*a*, and against a crown member and/or anchor member in chamber 228.” *Id.* Johnson also discloses that “[o]nce separated, upper portion 212*b* may be removed from the surgical site and discarded.” *Id.*, ¶[0056].

212. As set forth above, a POSA would have known that in certain situations (e.g., in the case of a severe spinal deformity or when the surgeon wishes to perform a minimally invasive operation), longer U-shaped arms of the receiver can be used to capture a longitudinal connecting rod and allow for a longer tightening distance of the closure. *See supra* Section VI.B.2.a.ii. A POSA would have known that break-off arm extensions were developed before the priority date of the ’233 Patent to address this issue by enabling the receiver to capture the rod between them and allow the closure top to be tightened along their length before being broken off from the receiver and leaving a low-profile receiver in the patient’s body. *See supra* Section VI.B.2.a.ii. A POSA would have known the benefit of including both break-off arm extensions and a tool groove(s) on a receiver to allow for the efficiency of break-off extensions during implantation, with the option to attach additional tools during implantation or later for later repair or removal. *See supra* Section VI.B.2.a.ii.

213. With this knowledge, a POSA would have recognized that it would be possible to realize these benefits in the open-ended receiver assembly by adding

break-off receiver extensions to the top of the '287 Publication's receiver arms, as taught in Johnson.

214. A POSA would have expected success with this combination because it merely involves the combination of familiar elements using known methods to yield predictable results, as it was well-known to a POSA before the priority date of the '233 Patent that break-off extension arms provided these advantages and could be successfully used in medical implant devices (and were indeed being used in scoliosis surgeries at that time). *See supra* Section VI.B.2.a.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. *See supra* Section VI.B.2.a.ii.

215. Moreover, a POSA would have been motivated to combine the teachings of Johnson with the '287 Publication, the '477 Publication, and Boschert based on the demands known to the medical device design community for medical devices with low profiles and that minimize the difficulty of use. *See Supra* Section VI.B.2.a.ii.

X. SPECIFIC OPINIONS RELATING TO GROUNDS FOR UNPATENTABILITY.

A. Ground 1: Claims 1-7, 13 and 15-20 Are Obvious in View of the '477 Publication, the '287 Publication, and Boschert.

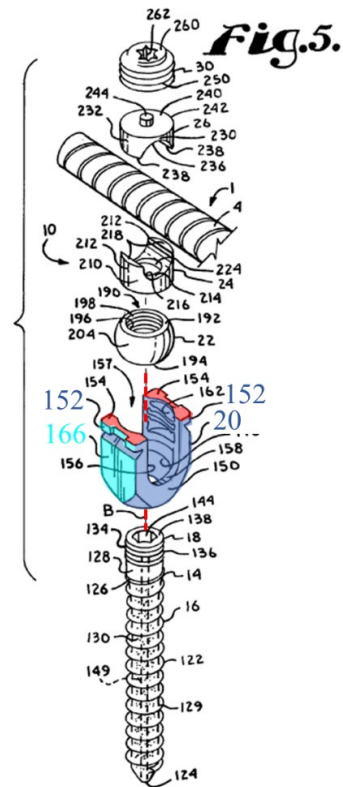
1. Claim 1

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

216. To the extent the preamble is considered limiting, in my opinion the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. The '477 Publication is titled “Removeable Medical Implant Closure” and discloses “a closure and/or locking member for use in conjunction with medical implants.” EX1005, ¶[0002]. The '287 Publication discloses a medical implant assembly that uses a closure to capture and lock a longitudinal connecting member, such as a rod, in a spinal implant. EX1007, ¶¶[0002], [0132]-[0158]. Boschert discloses an orthopedic fixation device for securing a rod to a bone for stabilization of the spine. EX1006, Abstract, 1:5-7; 4:26-28 (“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.”).

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

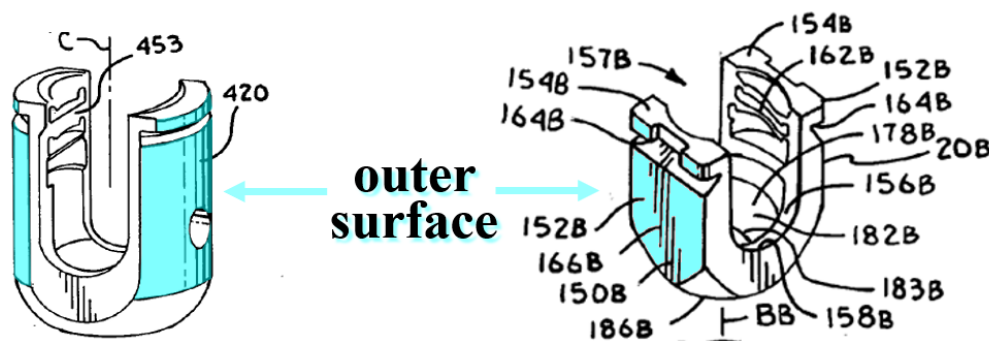
217. In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. The '287 Publication discloses a receiver with a pair of arms that each have outer side face surfaces. Specifically, as seen in annotated Figure 5 (right), the '287 Publication discloses that “receiver 20 includes . . . a pair of opposed upstanding arms 152” (blue) extending in the same direction as the longitudinal axis and each with a top surface 154 (red) and outer side surfaces 166 (light blue). EX1007, ¶¶[0076], [0078], Fig. 5; *see also id.*, ¶[0150], Fig. 37.



218. A POSA may understand the term “face” used in this limitation to sometimes refer to a planar surface, but in my opinion, that is not how the term is being used in this limitation, including because “face” is also used to describe the leading face of the start structure, which is curvate. In my opinion, a POSA would have understood “outer side face surface” to simply refer to the outer surface. Nevertheless, if “face” is construed to require planar outer side surfaces on the

receiver, it is my opinion that the claims would still be obvious in view of the '287 Publication.

219. A POSA would have recognized that the '287 Publication's outer side surfaces as disclosing this limitation regardless of whether the outer side surfaces are required to be planar or non-planar because the '287 Publication describes planar and non-planar faces as being interchangeable. In particular, in addition to the above-described embodiment with planar outer sides, the '287 Publication also discloses receiver 420, which as shown in the embodiment of Figures 22, 31-35, includes opposed upstanding arms extending in the same direction as the longitudinal axis and with a top side surfaces and outer side surfaces. Illustrative depictions of these two embodiments are shown side by side in the cropped and annotated figures below:



220. Despite receiver 20 having planar outer side surfaces and receiver 420 having non-planar outer side surfaces, the '287 Publication states that the receivers are “identical or substantially similar to” one another. *Id.*, ¶[0115]. Accordingly, a

POSA would have understood that either planar outer side surfaces or non-planar outer side surfaces would satisfy this limitation.

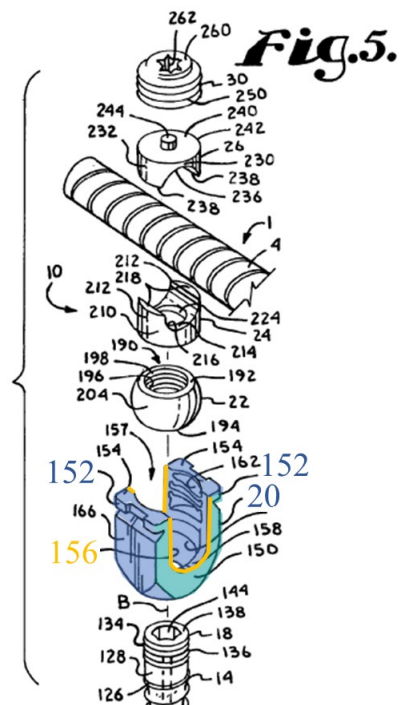
221. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1.

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

222. In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation.

223. As discussed above, the '287 Publication discloses a receiver with a pair of arms that have front and back outer face surfaces. As shown in annotated Figure 5, the '287 Publication discloses that the “*arms 152 form a U-shaped cradle* [i.e. a channel in **yellow**] and define a U-shaped channel 156 between the arms

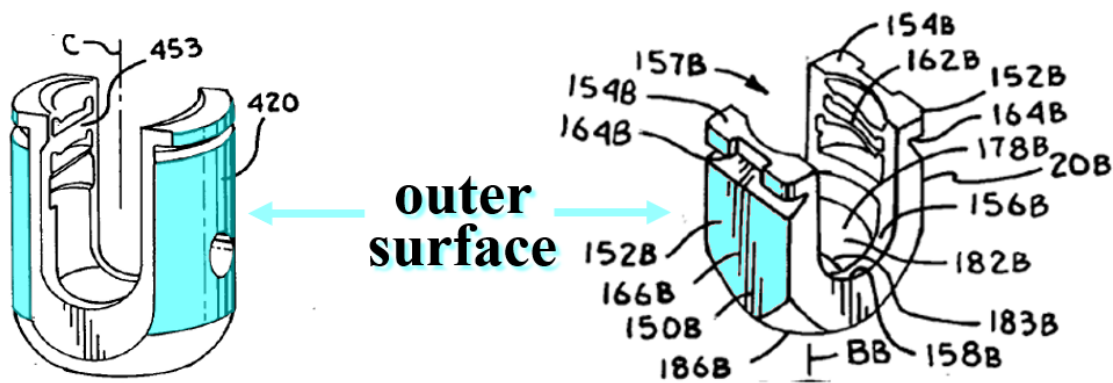
152,” *id.*, ¶[0076], Fig. 5; *see also id.*, ¶[0150], Fig. 37, which opens between the front outer face surface, which is immediately adjacent the channel, and opens



through the side opposite the front outer face surface, which a POSA would have understood to be the back outer face surface adjacent the channel. *Id.*, Fig. 5.

224. A POSA may understand the term “face” used in this limitation to sometimes refer to a planar surface, but in my opinion, that is not how the term is being used in this limitation, including because “face” is also used to describe the leading face of the start structure, which is curvate. In my opinion, a POSA would have understood “outer side face surface” to simply refer to the outer surface. Nevertheless, if “face” is construed to require planar outer side surfaces on the receiver, it is my opinion that the claims would still be obvious in view of the ’287 Publication.

225. A POSA would have recognized that the ’287 Publication’s outer side surfaces as disclosing this limitation regardless of whether the outer side surfaces are required to be planar or non-planar because the ’287 Publication describes planar and non-planar faces as being interchangeable. In particular, in addition to the above-described embodiment with planar outer sides, the ’287 Publication also discloses receiver 420, which as shown in the embodiment of Figures 22, 31-35, includes opposed upstanding arms extending in the same direction as the longitudinal axis and with a top side surfaces and outer side surfaces. Illustrative depictions of these two embodiments are shown side by side in the cropped and annotated figures below:



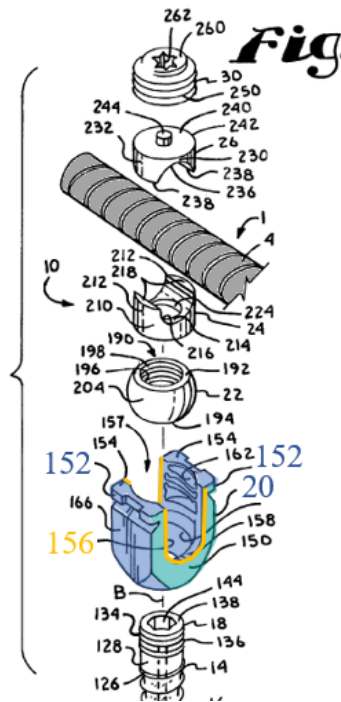
226. Despite receiver 20 having planar outer side surfaces and receiver 420 having non-planar outer side surfaces, the '287 Publication states that the receivers are “identical or substantially similar to” one another. *Id.*, ¶[0115]. Accordingly, a POSA would have understood that either planar front/back surfaces or non-planar front/back surfaces would satisfy this limitation.

227. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1.

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

228. In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation.

229. The '287 Publication expressly discloses that a longitudinal connecting member (**gray**) is received within the channel of the receiver, as shown in annotated Figure 5 shown below, *id.*, Fig. 5.



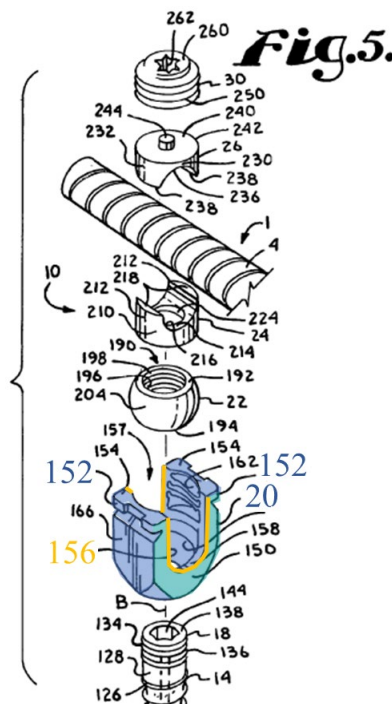
230. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1.

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

231. In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert and includes this limitation. The '477 Publication discloses a “closure for use in conjunction with an open receiver of a medical implant

for capturing and locking a rod in the implant.” EX1005, Abstract, ¶[0002], Fig. 6. The ’477 Publication states that “closures are externally threaded and are screwed into mating threads on the interior surfaces of the implant arms.” *Id.*, ¶[0005]. The ’477 Publication also discloses “closure 1 . . . has . . . *a central axis of rotation B.*” *Id.*, ¶¶[0029], [0040], Fig. 6.

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



EX1007, Fig. 5; *See supra* Sections IX.A, IX.A.1.

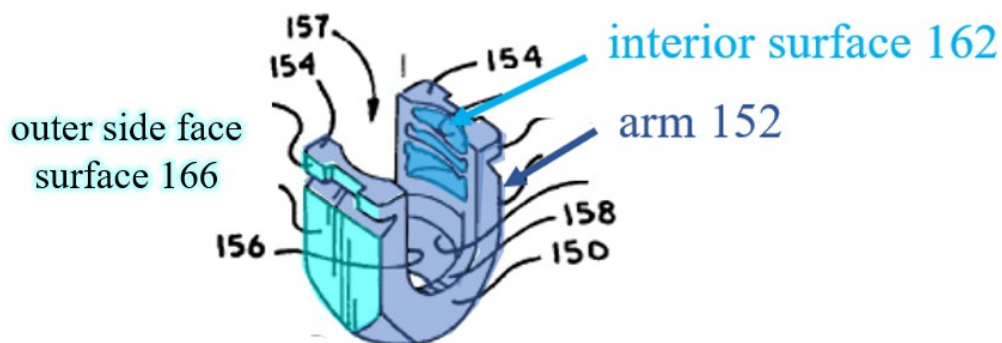
233. In the resulting combination, the closure of the '477 Publication would function in the same manner as described in the '477 Publication and would engage mating threads on the interior surfaces of receiver arms to close the channel created by those arms. However, instead of performing this function in conjunction with the open receiver of the '477 Publication, the closure would perform this function in conjunction with the receiver (and channel) of the '287 Publication. Indeed, as discussed in greater detail in the following section, the '287 Publication discloses that its receiver includes interior structures “*configured to mate under rotation with*” a closure such that the closure is “advanced into the U-shaped channel 156[.]” which reinforces the compatibility of the proposed combination, as well as the combination’s disclosure of this limitation. EX1007, ¶[0077].

234. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1.

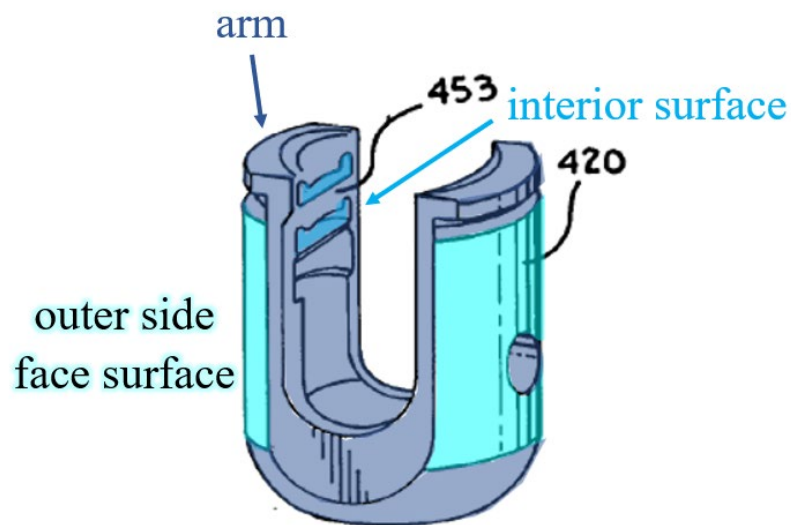
- f. **1[A1] “a first interior surface of the first arm opposite the outer side face surface thereof; a second interior surface of the second arm opposite the outer side face surface thereof; a first discontinuously helically wound structure on the first interior surface of the first arm,”**

235. In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. The '287 Publication discloses that “[e]ach of the arms 152” of the receiver “has an *interior surface* that defines an

inner cylindrical profile and *includes a partial helically wound guide and advancement structure 162.*” EX1007, ¶[0077]. The guide and advancement structure 162 is “configured to mate under rotation with a similar structure on the closure member 30,” such that the closure “is advanced into the U-shaped channel 156.” *Id.* As shown below in excerpted and annotated Figures 5 and 22, the guide and advancement structure is opposite the outer side faces of the receiver arms. Moreover, as also shown below in the excerpted and annotated Figures 5 and 22, because the threads on the receiver are interrupted by a channel, the ’287 Publication discloses discontinuously helically wound structure.



EX1007, Fig. 5

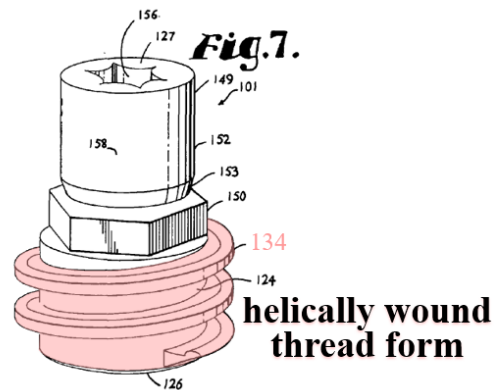


EX1007, Fig. 22

236. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1.

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

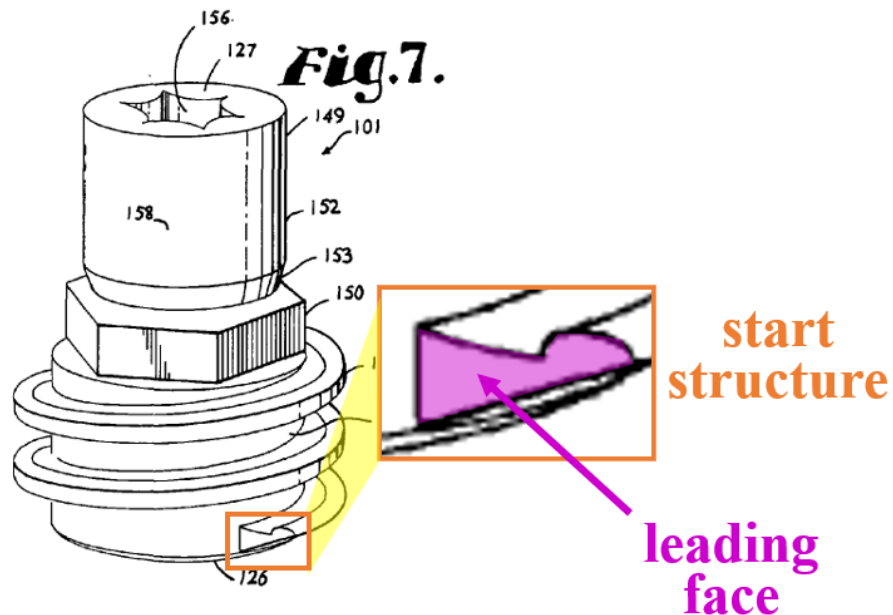
237. In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. The '477 Publication expressly discloses a first continuously helically wound thread form disposed on the closure. In particular, the '477 Publication discloses that “[l]ocated on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



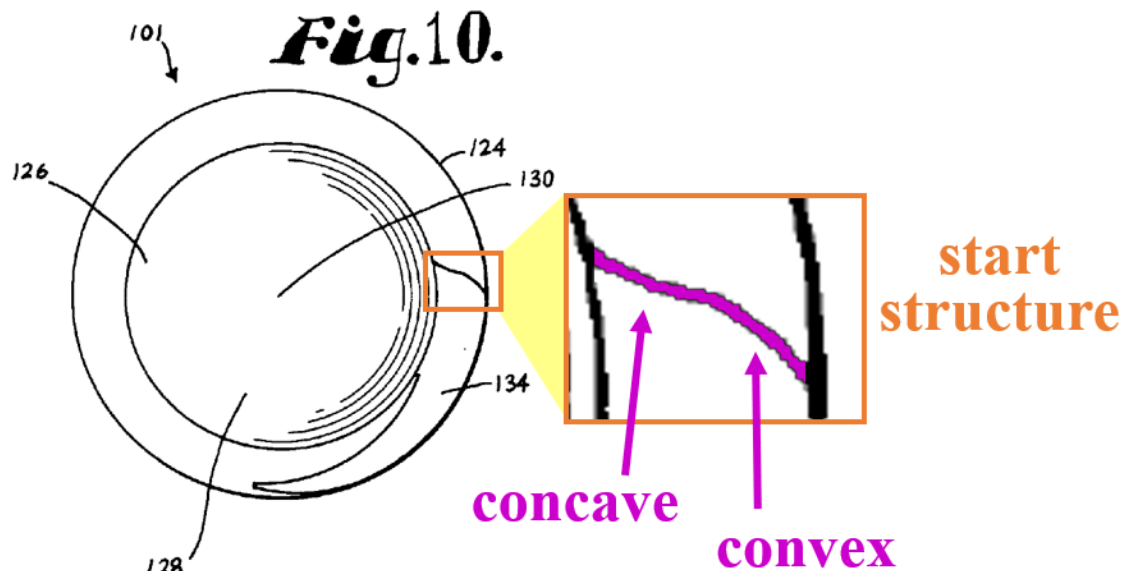
Figs. 7, 8.

238. The '477 Publication also expressly discloses a first start structure of the first continuously helically wound thread form on the closure, the first start

structure having a concave surface portion and a convex surface portion. In particular, as shown in annotated and enlarged Figure 7 below, the '477 Publication discloses a start structure on the closure thread, the start structure having a leading face. *Id.*, Fig. 7; *see also id.*, Fig. 8.



In addition, as shown in the annotated Figure 10 below, the leading face of the start structure disclosed in the '477 Publication includes a partial concave surface portion and a convex surface portion. *Id.*, Fig. 10. A POSA would recognize this feature of Fig. 10 as the leading face of the thread, at least because it is the only feature shown that matches with leading face shown in Fig. 7.



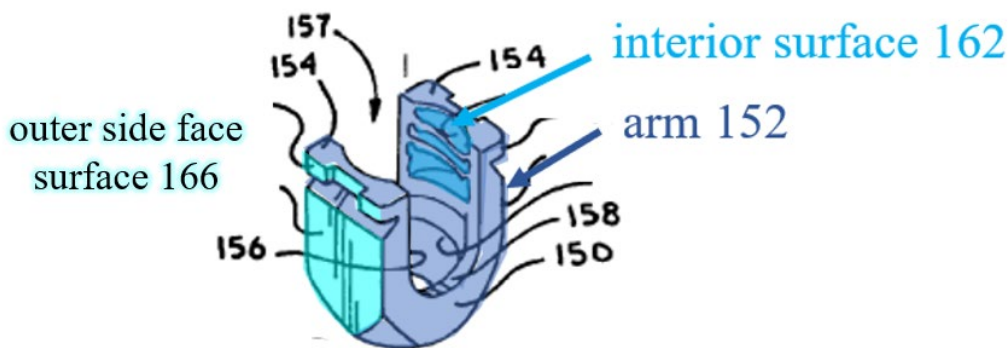
Ex. 1005, Fig. 10

239. The '287 Publication further expressly discloses that the first discontinuously helically wound structure on the receiver is configured to engage the first start structure on the closure. The '287 Publication discloses that “[e]ach of the arms 152” of the receiver “has an interior surface that defines an inner cylindrical profile and includes a partial helically wound guide and advancement structure 162.” EX1007, ¶[0077]. The guide and advancement structure 162 is “*configured to mate under rotation with a similar structure on the closure member 30,*” such that the closure “is advanced into the U-shaped channel 156.” *Id.* Based on these disclosures, a POSA would have understood that '287 Publication discloses that the first discontinuously helically structure on the interior of the receiver arms is configured to engage the first start structure on the '477 Publication's closure.

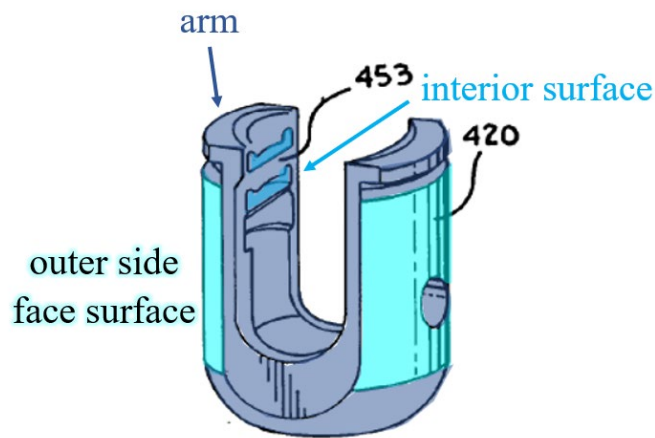
240. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1.

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

241. In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. As discussed above, the '287 Publication discloses that “[e]ach of the arms” of the receiver “includes a partial helically wound guide and advancement structure.” EX1007, ¶[0077]. The guide and advancement structure is opposite the outer side faces of the receiver arms, as shown in the annotated figures below.



EX1007, Fig. 5



EX1007, Fig. 22

242. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1.

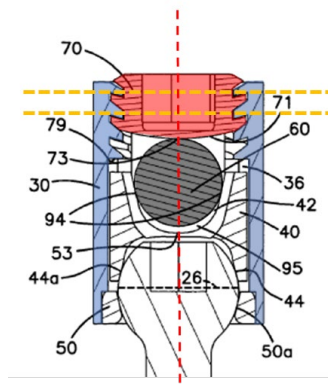
- i. **1[C2] “the second discontinuously helically wound structure configured to engage a second start structure of a second continuously helically wound thread form disposed on the closure, the second start structure having a leading face with a concave surface portion and a convex surface portion,**

243. In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. As discussed above, the '477 Publication teaches a first continuous helically wound structure on the closure with a start structure that has a leading face with a concave surface portion and a convex surface portion that is mateable with the arms of a receiver. *See supra* Sections VIII.A, X.A.1.g. Conversely, the '287 Publication discloses discontinuous helically

wound threads on the interior arms of a receiver for mating with the threads of a closure. *See supra* Sections VIII.C, X.A.1.g.

244. While the '477 Publication and the '287 Publication disclose only single-start threads, a POSA would have understood double-start threads to be expressly disclosed as advantageous in Boschert and would have been motivated to combine this teaching of Boschert with the '477 Publication and the '287 Publication as discussed in detail above. *Supra* Sections IX.A, IX.A.2.

245. Boschert teaches a second continuously helically wound structure on the closure with a start structure configured for engagement with the second discontinuously wound structure on the receiver second arm. *Supra* Section VIII.B. In particular, Boschert expressly discloses 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. Boschert also discloses a receiver 30 with discontinuous helically wound guide and advancement structures that are symmetrically and diametrically opposed to other across the longitudinal axis, as demonstrated by the horizontally parallel threads on each side of the receiver. *Id.*, Figs. 3, 15.



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

246. In my opinion, when the disclosures of the '477 Publication and the '287 Publication are combined with Boschert, a POSA would have kept the same leading face structure from the '477 Publication for use with the double-start threads and the symmetrically and diametrically opposed receiver threads taught by Boschert. *Supra* Sections IX.A, IX.A.2. Indeed, it was well known in the art that truncated thread starts with curvate leading faces, such as that disclosed in the '477 Publication, have advantages for removing sharp edges and reducing the risk of thread damage or cross threading. *Supra* Sections VI.B.1.b, VI.B.1.c. Therefore, the closure resulting from the combination of the disclosures of the '477 Publication, the '287 Publication, and Boschert would have used the curvate leading face of the

'477 Publication as the start structure on each of the two starts taught by Boschert and the receiver resulting from the combination would have used the discontinuous, symmetrical, and diametrically opposed threads taught by Boschert on the interior surface of the receiver arms in order to mate with the dual start threads of the modified closure for the reasons discussed above in discussed in detail above. *Supra* Section IX.A.

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

247. In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. As discussed above, the '477 Publication discloses a closure with an axis of rotation. *See supra* Sections VIII.A, X.A.1.e. The '477 Publication further discloses that its guide and advancement structure “acts cooperatively” to “allow the closure” to be “inserted into and rotated relative to the bone screw receiver” and to “guide and advance the closure” along the axis of rotation as the closure is “rotated clockwise.” EX1005, ¶[0030]. The receiver of the '287 Publication similarly discloses a receiver with internal threads on the arms of the receiver for mating with the threads of a closure. EX1007, Figs. 7, 9.

248. While the '477 Publication and the '287 Publication only disclose single start threads, Boschert discloses a receiver with two discontinuously helically wound thread forms for receiving a double start closure. *Supra* Section VIII.B. For example, Boschert discloses that the threads 72 can be designed with a “***double lead to allow the set screw 70 to start more easily than with a single lead.***” EX1006, 7:21-23. Boschert further discloses that the closure is “threaded into the saddles 39 [of the receiver] 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. As discussed above, *supra* Section VIII.B, Boschert discloses that a rotation of the closure about the axis of rotation between the first arm and the second arm causes simultaneous mating of the first start structure under the first discontinuously helically wound structure and the second start structure with the second discontinuously helically wound structure due to a diametrically timed positioning of the first and second start structures on the closure. *See* EX1006, Figs. 7, 15.

249. As I discussed above, *supra* Sections VIII.B, IX.A, X.A.1.f, a POSA would have understood that the thread forms on the receiver must mate with the thread forms on the closure, at least based on the express disclosures in the '477 Publication, the '287 Publication, and Boschert on mating thread forms, EX1005, ¶¶[0011], [0026], [0030], [0041], EX1006, 6:20-28; EX1007, Figs. 7, 9, and based on a POSA's knowledge of threaded connectors, *see supra* Section VI.B.1. Thus, in

my opinion, based on the above disclosures, a POSA would have understood that the closure of the '477 Publication when used with the receiver of the '287 Publication, as modified with the dual start threads of Boschert, would have resulted in a structure where a rotation of the closure about the axis of rotation causes mating of dual start threads of the closure with corresponding discontinuous threads on the receiver arms.

250. Further, in my opinion, Boschert discloses to a POSA that the start structures of the disclosed double starts on the closure have diametrically timed positioning and would simultaneously mate with the interior threads on the receiver arms because the receiver threads on each of the arms mirror each other. *Supra* Section VIII.B. Specifically, as seen in 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, as demonstrated by the horizontally parallel threads on each side of the receiver. 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.

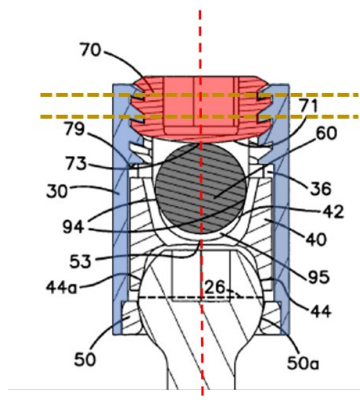


Fig. 3

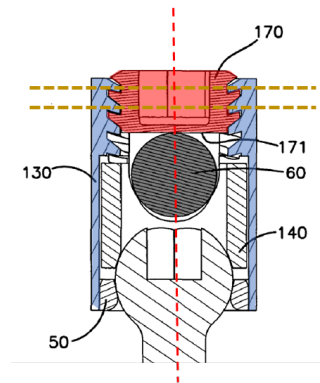
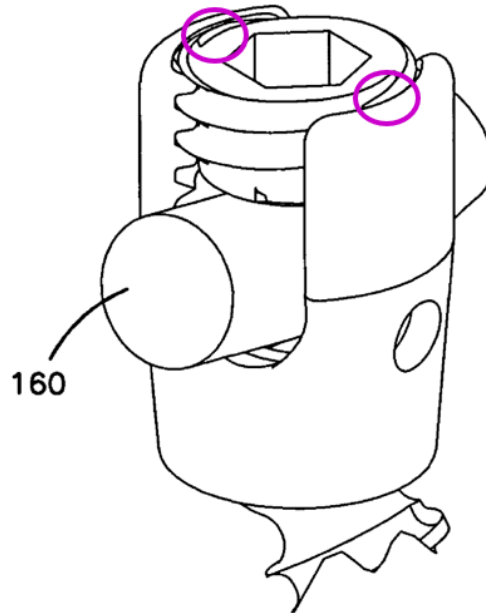


Fig. 15

251. Boschert's disclosure of diametrically timed 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 would have understood that diametrically opposed thread ends are the result of diametrically opposed thread starts.

thread end



252. Boschert's disclosure of diametrically timed thread starts is further supported by the knowledge of a POSA before the priority date of the '233 Patent of the conventional manner of making double start threads. *See supra* Section VI.B.1.a. Specifically, a POSA would know 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 dual lead as teaching two starts that has a cylindrical spacing angle 180° (*i.e.*, $360^\circ / 2$) and, thus, a first start structure that is disposed at a diametrically opposite location on the closure from the second start structure, which in turn results in simultaneous mating of one start structure on the closure with one receiver arm

and the other start structure on the closure with the other receiver arm. *Supra* Sections VI.B.1.a, VIII.B

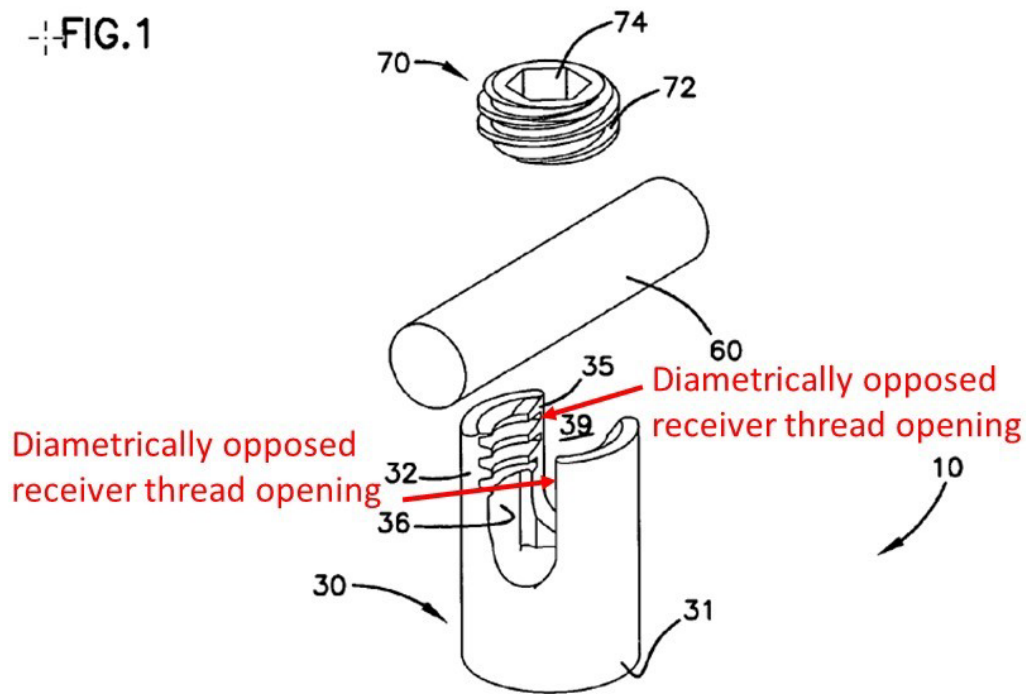
253. Based on Boschert's disclosures of diametrically timed thread starts and of symmetrically and diametrically timed receiver threads across the longitudinal axis, a POSA would have understood that Boschert expressly discloses simultaneous mating of the first start with the arm first helically wound structure and the second start with the arm second helically wound structure when the closure member is rotated between the first and second arms of the receiver member. In particular, Boschert expressly discloses 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; *supra* Sections VI.B.1.a, VIII.B.

254. 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 is 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* Sections VI.B.1.a, VIII.B.

255. To the extent that Boschert does not expressly or inherently disclose simultaneous advancement of the first and second start structure, in my opinion, it would have been obvious to a POSA before the priority date of the '233 Patent to use simultaneous advancement of the first and second start structure in the combination of the '477 Publication, '287 Publication and Boschert. Specifically, a POSA would have understood that the thread starts on the closure top would necessarily 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; *supra* Sections VI.B.1.a, VIII.B.

FIG. 1



This design configuration can only be accomplished by diametrically opposing the thread starts on the closure top. 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, 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.*

256. In my opinion, when the disclosures of the '477 Publication and '287 Publication are combined with Boschert, a POSA would have used the diametrically opposed double-start closure threads and the corresponding symmetrical receiver

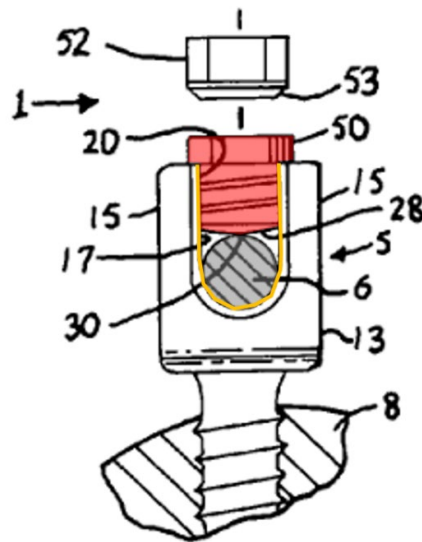
threads taught by Boschert for the benefits known and disclosed by Boschert. *Supra* Sections VIII.B, IX.A. Therefore, when the closure of the '477 Publication is combined with the receiver of the '287 Publication and Boschert's teachings regarding dual-start threads, the resulting combination would have resulted in a system wherein a rotation of the closure about the axis of rotation between the first arm and the second arm configured to cause a simultaneous mating of the first start structure under the first discontinuously helically wound structure and the second start structure with the second discontinuously helically wound structure due to a diametrically timed positioning of the first and second start structures on the closure.

- k. **1[C4] “the closure configured to be rotationally advanced within the channel until the bottom surface engages and locks the longitudinal connecting member within the channel; and”**

257. In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation.

258. The '477 Publication expressly discloses a “closure for use in conjunction with an open receiver of a medical implant *for capturing and locking a rod in the implant.*” EX1005, Abstract; *see also id.*, ¶[0002]. The '477 Publication further discloses that its guide and advancement structure “allow[s] the closure 1 to be inserted into and rotated relative to the bone screw receiver 13” to “guide and *advance the closure* 1 along the axis B as the closure 1 is *rotated clockwise.*” *Id.*, ¶¶[0030], [0039]. As shown in the excerpted, annotated Figure 5 below, after

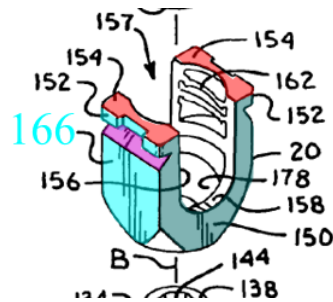
closure 1 is driven (i.e., rotatably advanced), closure 1 “*lock[s] the rod 6 in position relative to the bone screw*” and within the channel. *Id.*, ¶[0037], Fig. 5; *see also id.*, ¶¶[0018]-[0019], [0039], Fig. 6.



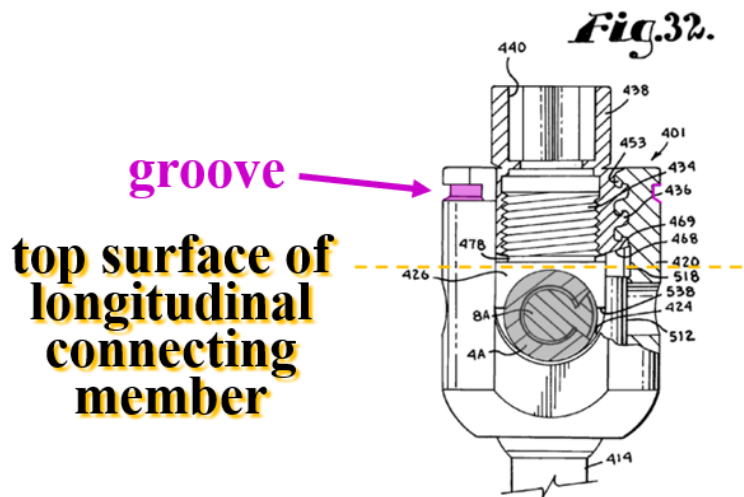
259. Thus, based on the above disclosures, the closure resulting from the combination of the disclosures of the '477 Publication, the '287 Publication, and Boschert would have included a closure rotationally advanceable within the channel until the bottom surface of the closure locks the longitudinal connecting member within the channel. *See supra* Section IX.A.1.

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

260. In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. As seen in annotated Figure 14, the '287 Publication discloses that “[e]ach of the arms 152 includes a V-shaped or undercut *tool engagement groove* 164



[purple] formed on a *substantially planar outer surface* 166 [light blue] thereof which may be used for holding the receiver 20 with a holding tool (not shown) having projections that are received within the grooves 164” EX1007, ¶[0078],



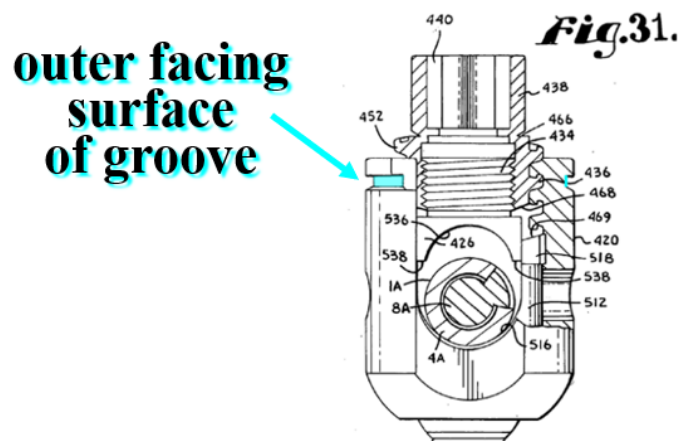
263. In my opinion, when the disclosures of the '477 Publication and Boschert are combined with the '287 Publication, a POSA would have used the receiver of the '287 Publication, including because the curvate extending groove on the outer side face surfaces of the receiver provides benefits known and disclosed by the '287 Publication as discussed above. *Supra* Section IX.A.1. Therefore, the receiver resulting from the combination of the disclosures of the '477 Publication, the '287 Publication, and Boschert would have included the curvate extending groove disclosed in the '287 Publication.

264. Accordingly, in my opinion the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 1.

2. Claim 2

265. All of the limitations of Claim 2 are recited in Claim 1, except Claim 2 further recites: [D1] “wherein each groove includes an outer facing surface.” In my

opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1. The '287 Publication discloses that its receiver may advantageously include groove 164B that “may be configured in a variety of sizes and shapes.” EX1007, ¶[0152]. In addition, as shown in annotated Figure 31 below, the '287 Publication expressly discloses a groove with an outer facing surface. *Id.*, Fig. 31.



266. A POSA would have been motivated to use the three-sided groove of this embodiment because the size and shape of the groove would have been a design choice dictated by the size and shape of the corresponding tool guide. Specifically, the '287 Publication states that groove 164B “may . . . cooperate with a holding tool during bone screw assembly” and “may be configured in a variety of sizes and shapes,” *Id.*, ¶[0152]. Thus, if the corresponding tool guide required a three-sided

groove that included an outer facing surface, a POSA would have been motivated to add that type of groove to the receiver head.

267. Accordingly, in my opinion the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 2.

3. Claim 3

268. All of the limitations of Claim 3 are recited in Claims 1 and 2, except Claim 3 further recites: [D2] “wherein the outer facing surfaces of the grooves extend in a direction parallel to the longitudinal axis.” In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1. The '287 Publication discloses that its receiver may advantageously include a tool groove with outer facing surfaces that extend in a direction parallel to the longitudinal axis. EX1007, Fig. 31.

**outer facing
surface
of groove**

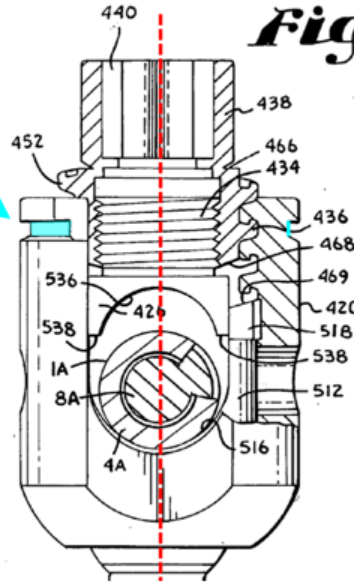
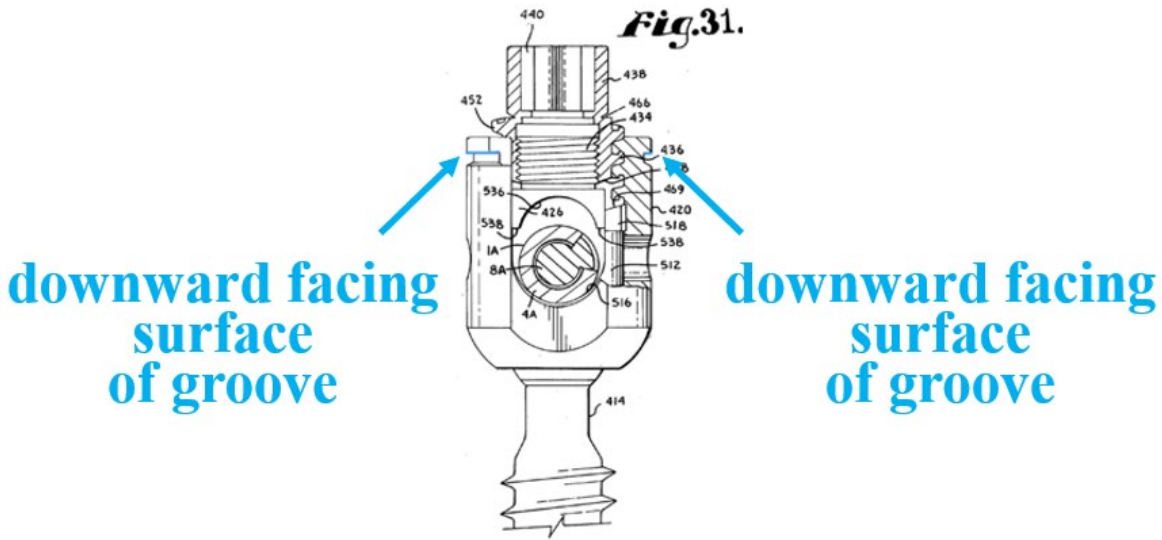


Fig.31.

269. Accordingly, in my opinion the combination of the '477 Publication, Boschert, and the '287 Publication renders obvious every element of Claim 3.

4. Claim 4

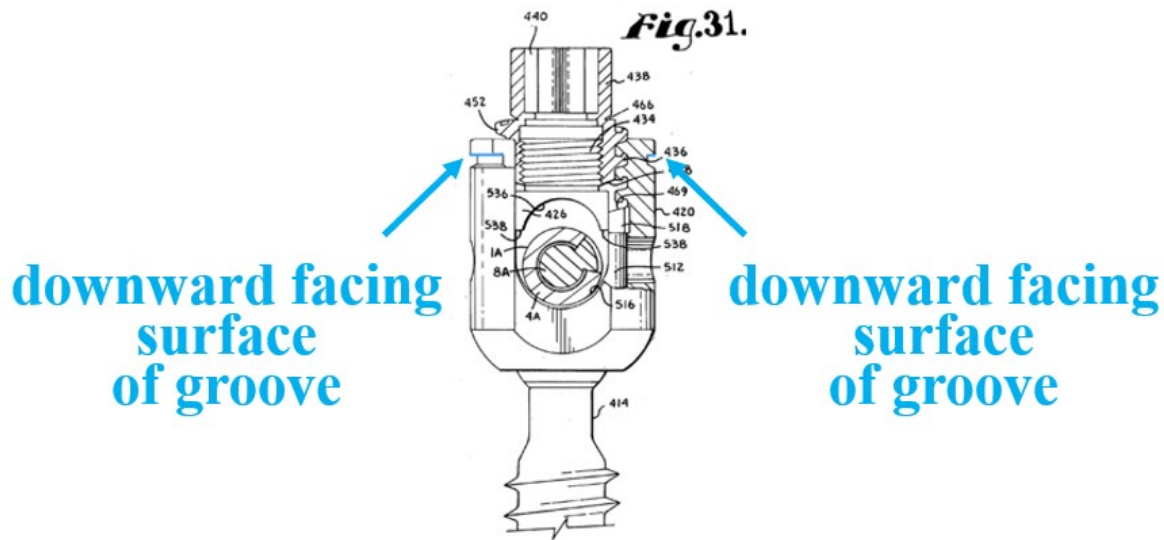
270. All of the limitations of Claim 4 are recited in Claim 1, except Claim 4 further recites: [D3] “wherein each groove includes a downward facing surface.” In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1. The '287 Publication discloses that its receiver may advantageously include a tool groove with downward facing surfaces. EX1007, Fig. 31.



271. Accordingly, in my opinion the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 4.

5. Claim 5

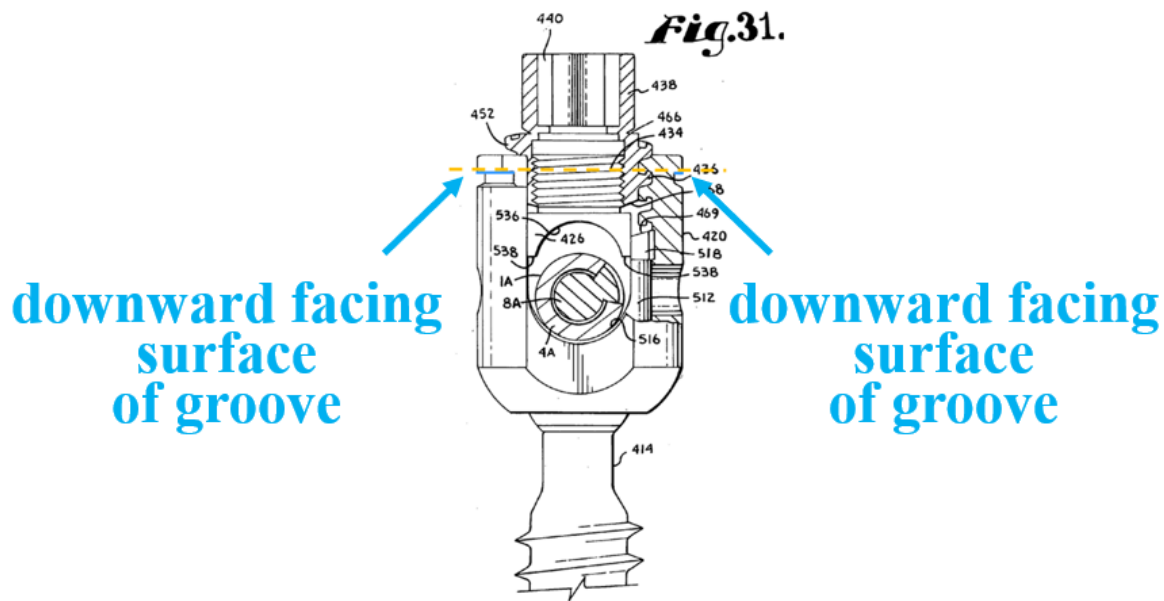
272. All of the limitations of Claim 5 are recited in Claims 1 and 4, except Claim 5 further recites: **[D4]** “wherein the downward facing surfaces of the grooves are planar.” In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1. The '287 Publication discloses that its receiver may advantageously include a tool groove with downward facing surfaces that are planar. EX1007, Fig. 31; *see supra* Section X.A.4.



273. Accordingly, in my opinion the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 5.

6. Claim 6

274. All of the limitations of Claim 6 are recited in Claim 1, except Claim 6 further recites: [D5] “wherein each downward facing surface of the grooves are parallel with one another.” In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1. The '287 Publication discloses that its receiver may advantageously include a tool grove where the planes of the downward facing surfaces are colinear and therefore, parallel to each other. *See* EX1007, Fig. 31.



275. Accordingly, in my opinion the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 6.

7. Claim 7

276. All of the limitations of Claim 7 are recited in Claim 1, except Claim 7 further recites: [D6] “wherein each groove includes an upward facing surface.” In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1. The '287 Publication discloses that its receiver may advantageously include a tool groove with upward facing surfaces. EX1007, Fig. 31.

279. The '477 Publication discloses that “[l]ocated on the cylindrical closure body 24 is a guide and advancement structure 34 mateable with the guide and advancement structure on the inner surfaces 20 of the arms 15 of the bone screw receiver 13.” EX1005, ¶¶[0030], [0039]. The '477 Publication teaches that the guide and advancement structure can be a “*reverse angle thread form*” and also that “other types of guide and advancement structure could be utilized,” including “a *buttress thread form, a square thread form or some other type* of structure such as a flange form[.]” *Id.*, ¶[0030]. For instance, Figure 7 shows that the guide and advancement structure can be a helical flange thread form. Alternatively, the '477 Publication discloses that the structure can be “a helically wound reverse angle thread form 36.” *Id.* As the '477 Publication explains, the guide and advancement structure helps the receiver to “resist[] splaying . . . as forces applied to the closure 1 are conveyed by the reverse angle thread form 36 during application of clockwise rotational torque into a downward axial force and inwardly directed radial force.” *Id.*

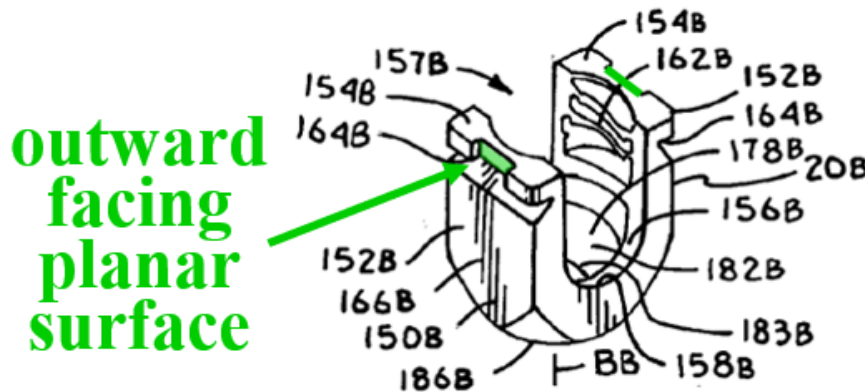
280. In the combination of the '477 Publication, the '287 Publication, and Boschert, a POSA would have looked to Boschert to add a second helically wound thread to the '477 Publication's closure, but would have otherwise retained the thread characteristics disclosed in the '477 Publication. *See supra* Section IX.A.2. In particular, the combination would retain the '477 Publication's helical flange or

reverse angle thread form, at least in part because of its splay-resistant benefits. *Supra* Section VI.B.1.d. Additionally, Boschert itself teaches reverse-angle threads, indicating that the retention of the '477 Publication's reverse-angle threading would not affect or prevent the combination with Boschert. EX1006, Fig. 15; *see also id.*, Figs. 3-4, 9-10 (single reverse angle thread on closure). The '287 Publication similarly teaches that a variety of thread types could be used to mate a closure to its disclosed receiver, including reverse angle threads. EX1007, ¶¶[0086], [0154], [0156].

281. Accordingly, in my opinion the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 13.

9. Claim 15

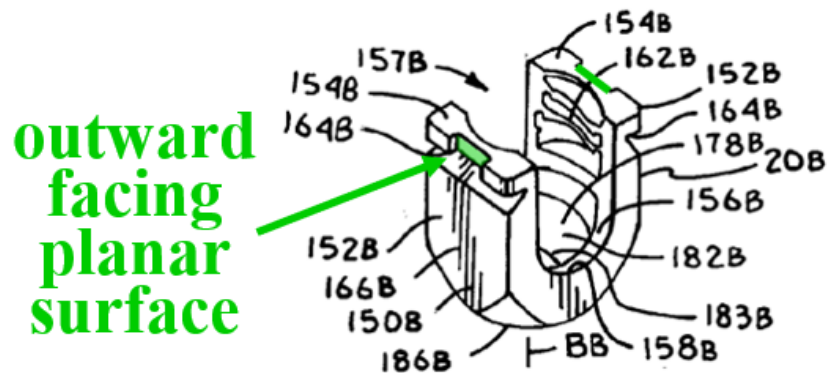
282. All of the limitations of Claim 15 are recited in Claim 1, except Claim 14 further recites: [D7] “wherein each outer side face surface has an outward facing planar surface.” In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1. The '287 Publication discloses that its receiver may advantageously include a recessed outward facing planar surface in the form of a vertical tool groove at the top of the outer side surfaces, as shown in Figure 37 below. EX1007, Fig. 37.



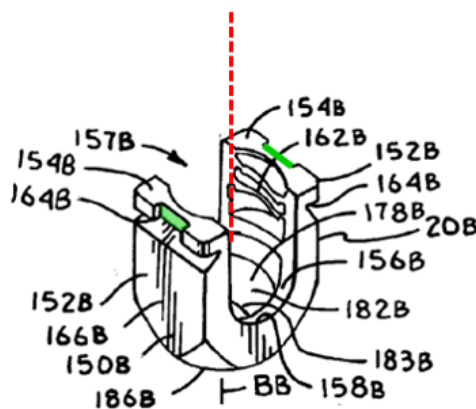
283. Accordingly, in my opinion the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 15.

10. Claim 16

284. All of the limitations of Claim 16 are recited in Claims 1 and 15, except Claim 16 further recites: [D8] “wherein the outward facing planar surface on each arm is recessed and parallel with respect to the longitudinal axis of the receiver and to each other.” In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. A POSA would have been motivated to look to the receiver of the '287 Publication for use with the closure of the '477 Publication for the reasons discussed above. *Supra* Sections IX.A, IX.A.1. The '287 Publication discloses that its receiver may advantageously include a recessed outward facing planar surface in the form of a vertical tool groove at the top of the outer side surfaces, as shown in cropped Figure 37 below. EX1007, Fig. 37.



As also seen in Figure 37 above, the recessed outward facing planar surfaces run parallel to the longitudinal axis and to each other. *Id.*



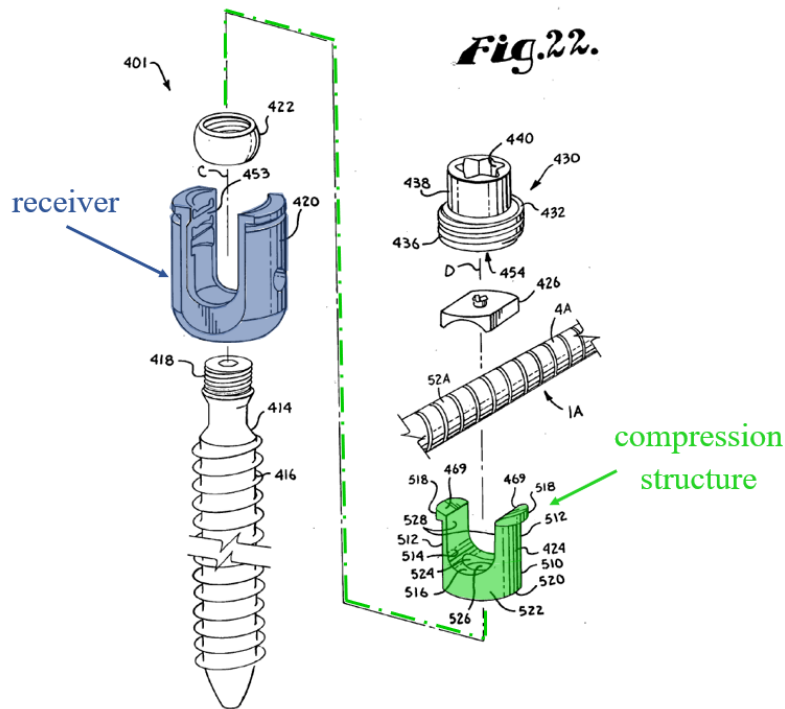
285. Accordingly, in my opinion the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 16.

11. Claim 17

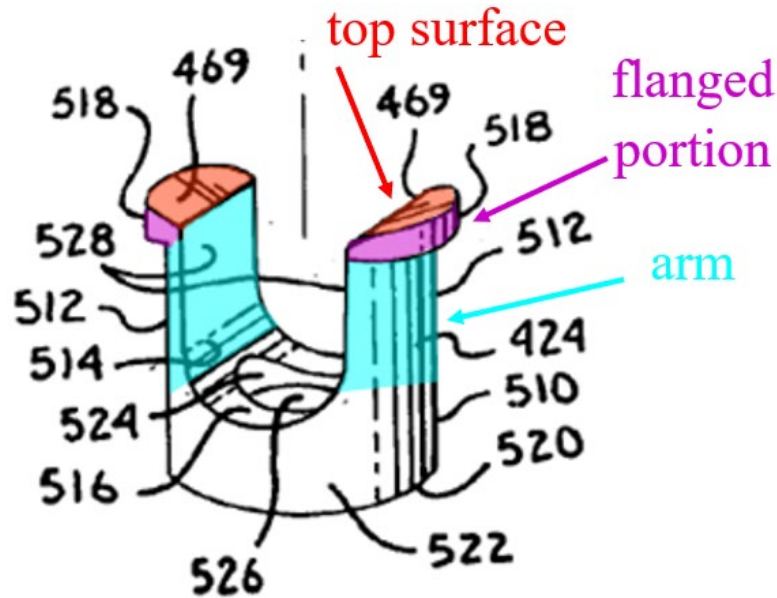
286. All of the limitations of Claim 17 are recited in Claim 1, except Claim 17 further recites: [F] “further including an insert configured to be top loaded into the receiver, the insert having first and second opposed upright arms with top surfaces and lateral protrusions with top surfaces contiguous with the top surfaces

on the upright arms of the insert.” In my opinion, the combination of the ’477 Publication, the ’287 Publication, and Boschert includes this limitation. As discussed above, *supra* Sections IX.A, IX.A.1, a POSA would have combined the closure of the ’477 Publication with the receiver of the ’287 Publication. In making this combination, a POSA would have had reason to utilize the ’287 Publication’s receiver and its corresponding top-loaded insert because, as discussed below, these two structures operate in combination to secure a bone screw and connecting rod in the receiver. Thus, in the above-described combination of the ’477 Publication, ’287 Publication, and Boschert, the resulting insert of the ’287 Publication would meet this limitation.

287. Specifically, the ’287 Publication expressly discloses an insert configured to be top loaded into the receiver, as shown for example in annotated Figure 22 below. EX1007, Fig. 22. The ’287 Publication further expressly states: “The cylindrical surface 522 has an outer diameter slightly smaller than a diameter between crests of the guide and advancement structure 453 of the receiver 420 ***allowing for top loading*** of the compression structure 424.” *Id.*, ¶[0126].



288. The '287 Publication also expressly discloses that the insert has first and second opposed upright arms with lateral protrusions and contiguous top surfaces. As seen in cropped and annotated Figure 22, insert 424 includes “arms 512 . . . [that] each include a top flanged portion 518, each portion 518 including the ramped or inclined surface 469[.]” *Id.*, ¶[0126], Fig. 22.



As seen in the above Figure 22, flanged portion 518 extends laterally beyond the limit of arms 512, and the top surface of each projection is co-extensive with the top surface 469 of the arms.

289. In my opinion, a POSA would have been motivated to use an insert such as that disclosed in the '287 Publication when combining the '477 Publication's closure with the '287 Publication's receiver because the user of such an insert was a known design choice with various benefits known to a POSA before the priority date for the '233 Patent. *Supra* Section VI.B.2.b. In particular, POSA would have known the benefits of using an insert as disclosed in the '287 Publication would have been consistent with the stated objectives of the '477 Publication, including because the insert would facilitate seating of the rod within the receiver and evenly distributing the pressure from the closure to the shank in order to fix the desired angle of the

shank. *See* Sections VI.B.2.b, IX.A.1. Given that the benefits of inserts with lateral protrusions were known in the art, a POSA would have been motivated to add such an insert because it would not change the double-start closure. *Supra* Sections VI.B.1.a, VI.B.2.b, IX.A; *see also* EX1007, ¶[0126], Fig. 31 (recesses for lateral protrusions located below discontinuously helically wound structures on receiver and apart from any grooves).

290. Accordingly, in my opinion the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 17.

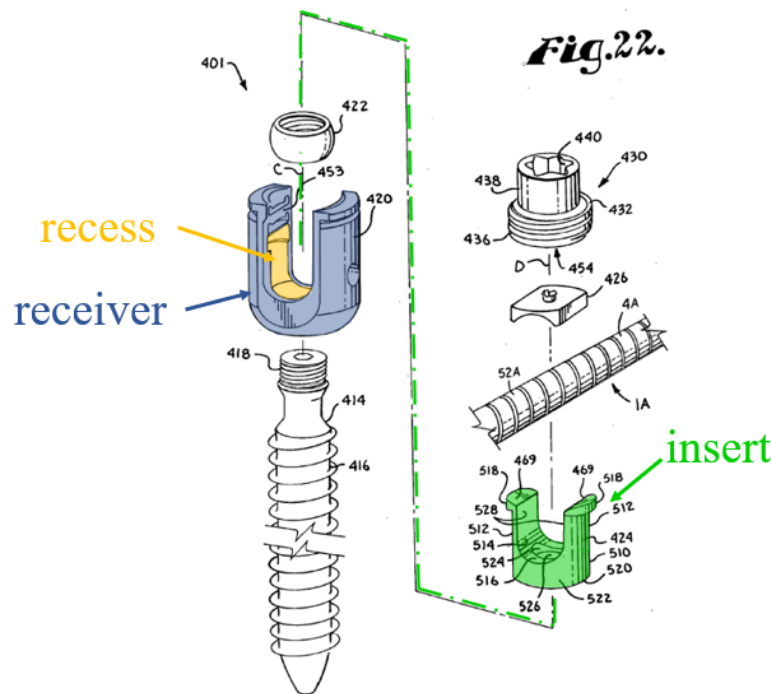
12. Claim 18

291. All of the limitations of Claim 18 are recited in Claim 1, except Claim 18 further recites: [F1] “wherein the receiver includes a central bore having a recess into which an insert is configured to be at least partially positioned by being downloaded into the receiver through the channel.” In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. As discussed above, *supra* Sections IX.A, IX.A.1, a POSA would have combined the closure of the '477 Publication with the receiver of the '287 Publication.

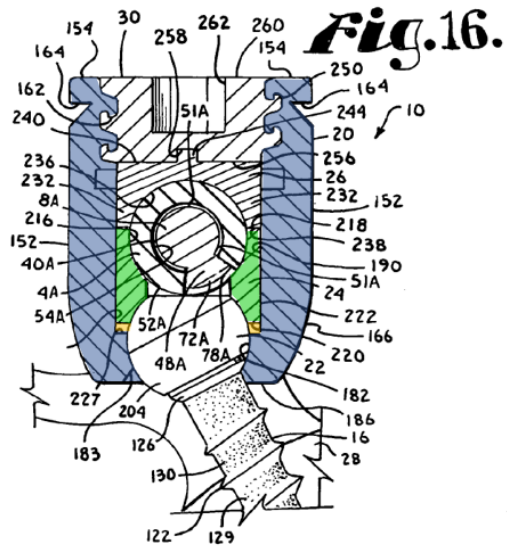
292. The '287 Publication expressly discloses a receiver with a central bore. Specifically, the '287 Publication discloses that “[c]ommunicating with the U-shaped channel 156 and located within the base 150 of the receiver 20 is a chamber or cavity 178 . . . , *the cavity 178 opening upwardly* into the U-shaped channel 156.

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

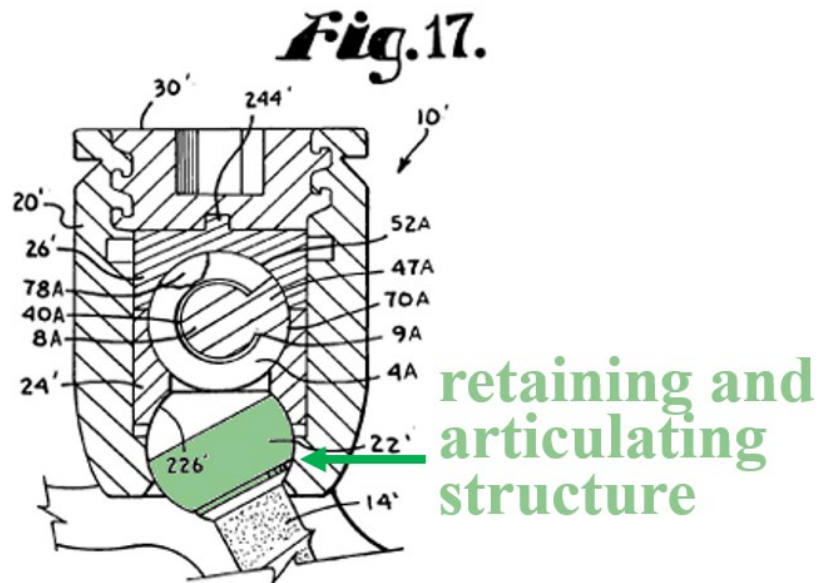
293. The '287 Publication also expressly discloses a recess into which two inserts are configured to be downloaded (or top-loaded) into the receiver. As shown for example in annotated Figure 22 below, insert 424 is downloaded into the receiver and into a recess in the receiver. *Id.* Fig. 22.



“[R]etaining and articulating structure 22 [or 422],” as shown below, is also downloaded through the channel into the central bore of the receiver. EX1007,



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

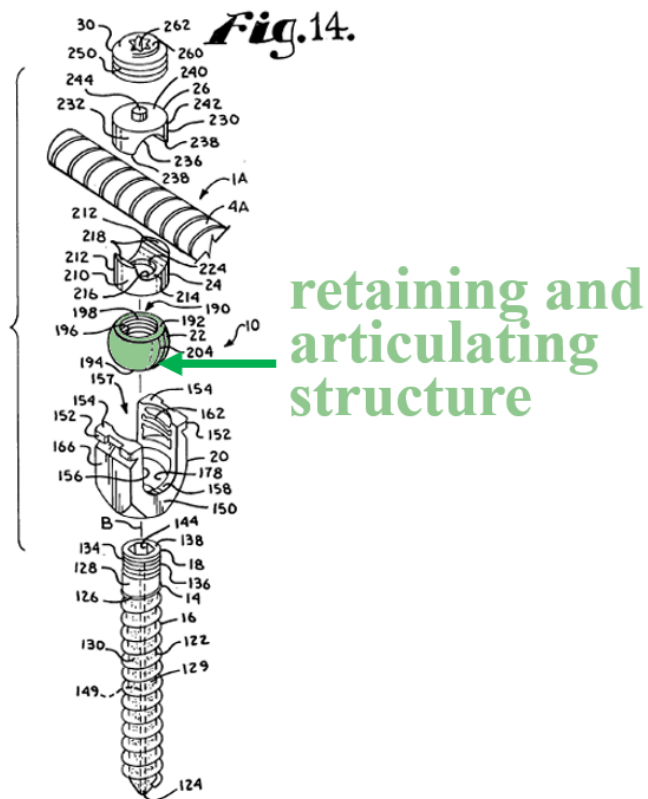
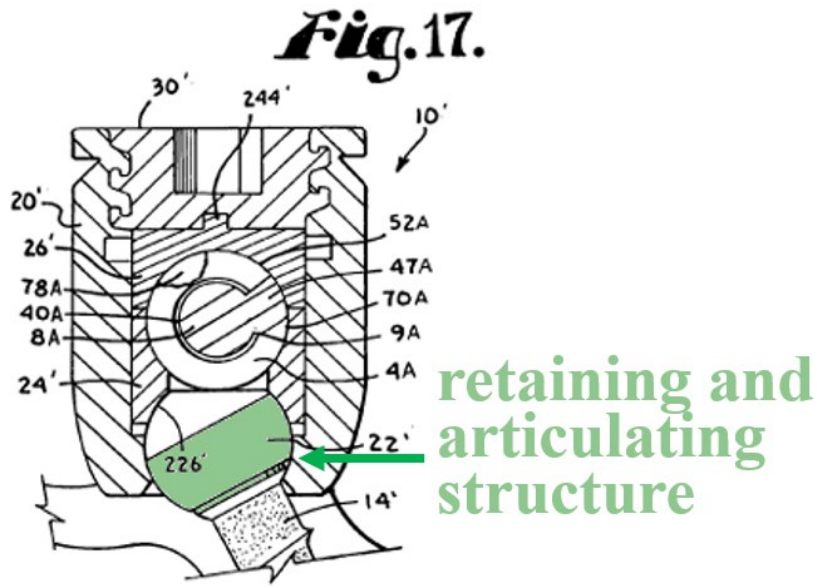


295. Accordingly, in my opinion the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 18.

13. Claim 19

296. All of the limitations of Claim 19 are recited in Claims 1 and 18, except Claim 19 further recites: [F2] “wherein the insert is a retainer configured to engage a head of a bone attachment shank.” In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. As discussed above, *supra* Sections IX.A, IX.A.1, a POSA would have combined the closure of the '477 Publication with the receiver of the '287 Publication.

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



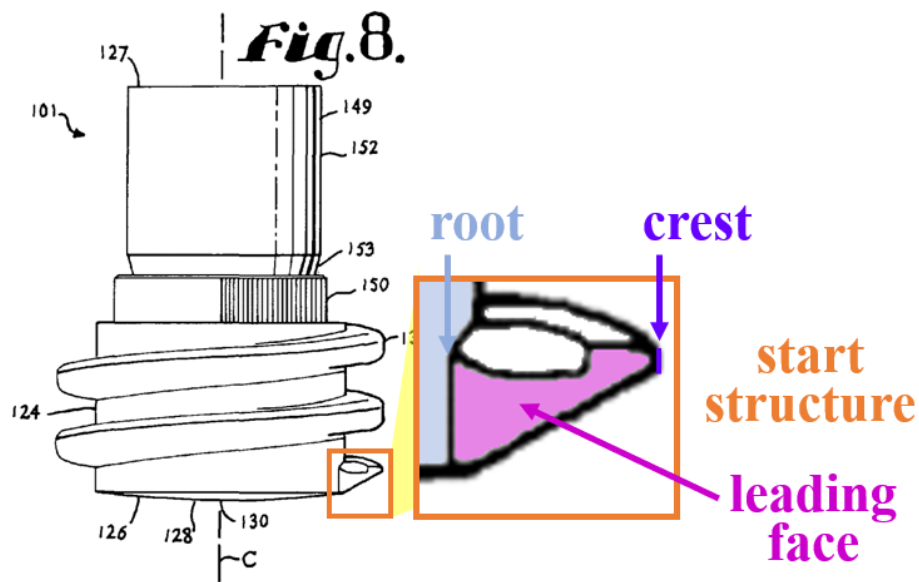
298. Thus, the '287 Publication discloses an insert that is a retainer configured to engage the head of the bone attachment shank. And, as discussed

above, *supra* Sections IX.A, IX.A.1, a POSA would combine the '477 Publication, '287 Publication, and Boschert to include the receiver and inserts of the '287 Publication, which, in the resulting combination, would engage the head of the bone attachment shank in the manner disclosed in the '287 Publication.

299. Accordingly, in my opinion the combination of the '287 Publication, '477 Publication, and Boschert renders obvious every element of Claim 19.

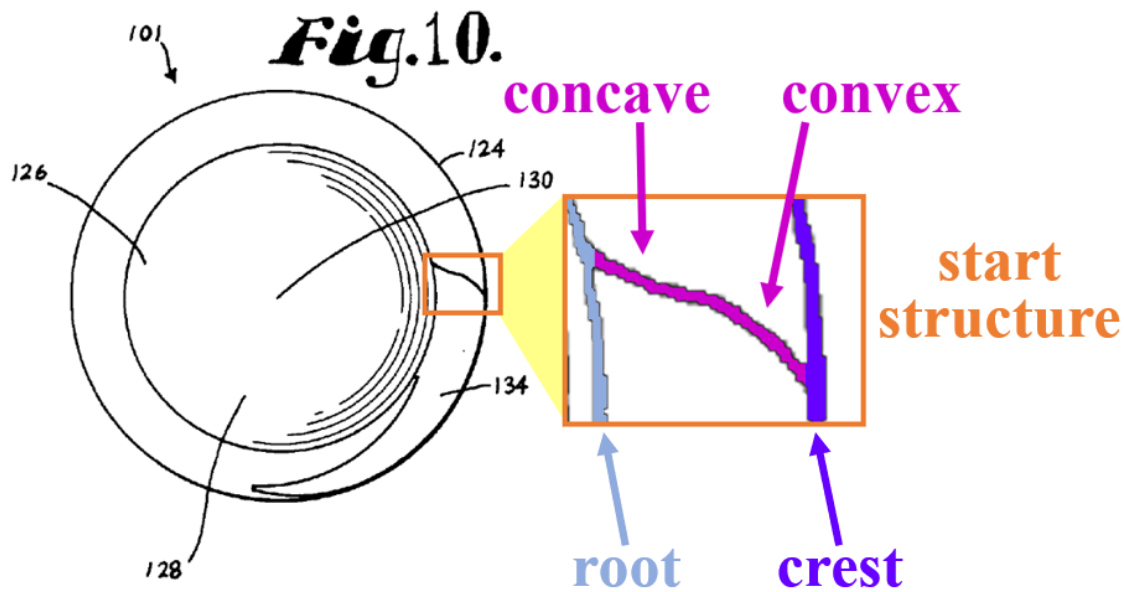
14. Claim 20

300. All of the limitations of Claim 20 are recited in Claim 1, except Claim 20 further recites: [C6] “wherein each of the leading faces on the first and the second start structures has a concave surface adjacent a root and a convex surface adjacent a crest of the respective first and second continuously helically wound structures.” In my opinion, the combination of the '477 Publication, the '287 Publication, and Boschert includes this limitation. As shown in annotated and enlarged Figure 8 below, the '477 Publication discloses a start structure on the closure thread having a leading face extending between a root and a crest of the continuously helically wound thread form. EX1005, Fig. 8; *see also id.*, Fig. 7.



Ex. 1005, Fig. 8

301. In addition, as shown in Figure 10, the leading face of the start structure disclosed in the '477 Publication includes a partial concave surface adjacent the root and a partial convex surface adjacent the crest. *Id.*, Fig. 10. A POSA would recognize this feature of Fig. 10 as the leading face of the thread, at least because it is the only feature shown that matches with leading face shown in Fig. 8 and extends continuously from the root to the crest.



Ex. 1005, Fig. 10

302. Boschert expressly teaches double threads on the closure top, or set screw, and specifically that a “double lead [] allow[s] the set screw 70 to start more easily than with a single lead.” EX1006, 7:21-23.

303. In my opinion, when the disclosures of the '477 Publication are combined with those of the '477 Publication and the '287 Publication, a POSA would have kept the same leading face structure from the '477 Publication for use with the double start threads and receiver threads taught by Boschert. *Supra* Sections IX.A, IX.A.2. Therefore, the closure top resulting from the combination of the disclosures of the '477 Publication, the '287 Publication, and Boschert would have used the curvate leading face of the '477 Publication as the start structure on each of the two starts taught by Boschert.

304. Accordingly, in my opinion the combination of the '477 Publication, the '287 Publication, and Boschert renders obvious every element of Claim 20.

B. Ground 2: Claim 14 Is Obvious in View of the '287 Publication, '477 Publication, Boschert, and Johnson.

305. The combination of the '287 Publication, the '477 Publication, and Boschert discloses most of the limitations of Claim 14, but does not expressly disclose the use of break-off extension arms. The Johnson reference does. As set forth above, *supra* Section IX.B, it also would have been obvious to a POSA to combine the teachings of Johnson with the '287 Publication before the priority date of the '233 Patent. Like the '287 Publication, the '477 Publication, and Boschert, Johnson is directed to a medical implant device that receives a rod member. EX1008, Abstract; *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 as taught by Johnson. *See supra* Section VI.B.2.a.ii

306. 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 “threaded into threads 256, forcing elongated member 220 further down in channel 254” so that the “elongated member 220 is forced all the way through upper portion 212*b*, into lower portion 212*a*, and against a crown member and/or anchor member in chamber 228[.]” *Id.* Johnson also discloses that “[o]nce separated, upper portion 212*b* may be removed from the surgical site and discarded.” *Id.*, ¶[0056]. Johnson further discloses tool attachment grooves 258 used in conjunction with the breakoff extensions “allow the surgeon to grip receiver member 212 (on either or both of portions 212*a*, 212*b*) with an appropriate forceps, wrench or other gripping or turning tool[.]” *Id.* ¶¶[0052]-[0053], Figs. 11, 13. Thus, based on these teachings, a POSA would have recognized the benefits of including break-off extension arms in an existing device with tool attachment grooves, including easier delivery of a rod while maintaining a low-profile device, and would have been motivated to use this feature in the ’287 Publication, the ’477 Publication and Boschert combination. *Supra* Section IX.B.

307. A POSA would have expected success with this combination because it merely involves the combination of familiar elements using known methods to yield predictable results, as it was well-known to a POSA before the priority date of the ’233 Patent that break-off extension arms provided these advantages and could be successfully used in medical implant devices with tool attachment grooves. *Supra* Section IX.B. 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. *Supra* Section VI.B.2.a.ii.

308. Moreover, a POSA would have been motivated to combine the teachings of Johnson with the '287 Publication, the '477 Publication, and Boschert based on the demands known to the medical device design community for medical devices with low profiles and that minimize the difficulty of use. *Supra* Section IX.B.

309. As set forth above, *supra* Section X.A, the '287 Publication, the '477 Publication and Boschert, render obvious every limitation of challenged claim 1. Claim 14 adds the additional element of breakoff arm extensions, but this additional element was well known in the prior art, including in Johnson. Therefore, below I address why the additional element of Claim 14 is rendered obvious by Johnson. For all other imitations, my opinions expressed above (that these features were already rendered obvious by the disclosures of the '287 Publication, the '477 Publication and Boschert) remain and are unaffected by the additional disclosures of Johnson.

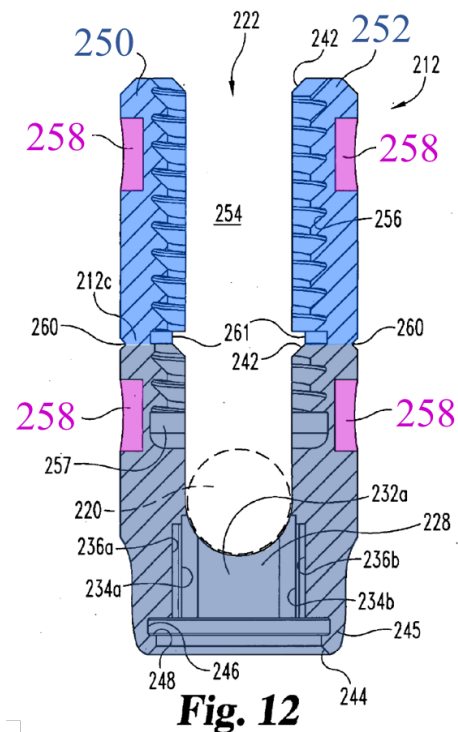
1. Claim 14

310. All of the limitations of Claim 14 are recited in Claim 1, except Claim 14 further recites: [E] “wherein the first and second arm each has a breakoff

extension.” In my opinion, the combination of the ’287 Publication, the ’477 Publication, Boschert, and Johnson includes this limitation.

311. In particular, as discussed above and as seen in Figure 12, Johnson discloses a first breakoff extension coupled to the first arm 250 and a second breakoff extension coupled to the second arm 252. EX1008, Figs. 10, 12.

312. In my opinion, based on the above disclosures, when combining the disclosures of the ’287 Publication, the ’477 Publication, Boschert, and Johnson a POSA would have included on each of the first and second arms a breakoff extension. *Supra* Section IX.B.



313. Accordingly, the ’287 Publication, the ’477 Publication, Boschert, and Johnson renders obvious every element of Claim 14.

XI. DISCUSSION OF SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

314. I am not aware of any evidence of secondary considerations that supports the non-obviousness of the Challenged Claims of the ’233 Patent. I am, however, aware of evidence of secondary considerations that support the obviousness of using a closure with dual start threads having diametrically opposed

starts to simultaneously engage mating threads of a bone screw receiver. For example, on January 4, 2017, Zimmer Spine filed '959 Application, entitled "Bone screw including a dual thread closure member." ("the '959 Application"). EX1018 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.

315. 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.

316. The examiner for the '959 Application rejected pending claim 2 as being unpatentable over Jackson '689 (EX1050) 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. EX1018 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.

317. 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 (EX1018 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 / Number of starts,” Zimmer Spine’s “previous argument[s] regarding simultaneous engagement can no longer be supported.” *Id.*

318. In my opinion, the prosecution of the ’959 Application, and its subsequent express abandonment, supports the ***obviousness*** of simultaneous mating dual start thread 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 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.

319. 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

320. 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.

321. 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.

322. 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.

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

Dated: September 20, 2023

Carl McMillin
Carl McMillin, PhD